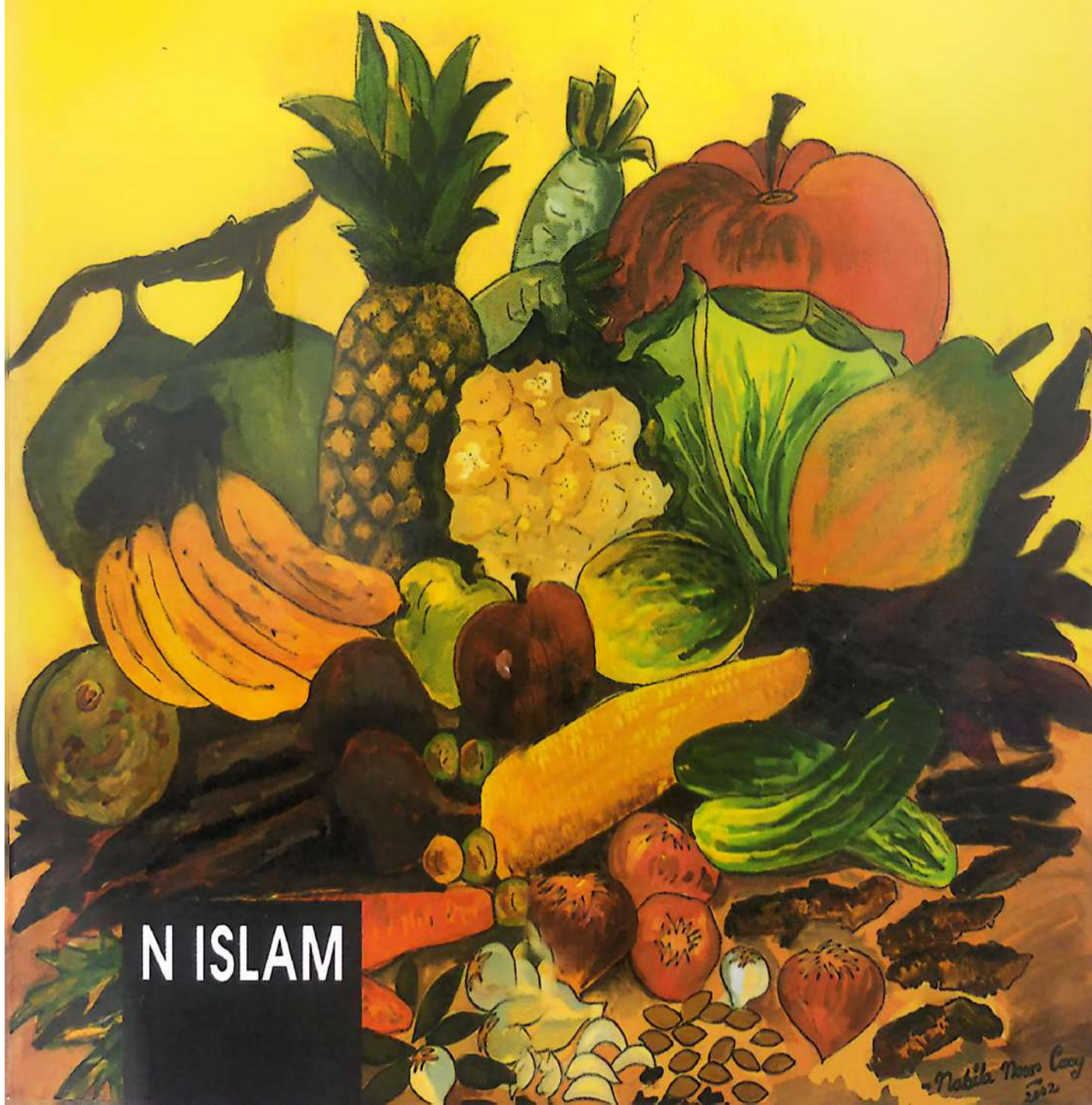


CAM

Some Thoughts & Reflections on

COMPLEMENTARY & ALTERNATIVE MEDICINE



N ISLAM

C A M

Some Thoughts & Reflections on
**COMPLEMENTARY & ALTERNATIVE
MEDICINE**

N Islam, IDA

DSc, MB, TDD, FCPS, FCCP,
FRCPE, FRCP, FCGP, FAS

National Professor of Bangladesh
&
Founder Vice Chancellor
University of Science & Technology Chittagong
(USTC)

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Dedication



Hakim Mohammed Said

The Torch-bearer of Unani System of
Medicine in India, Pakistan & Bangladesh

Foreword

The problems and prospects of traditional medicine in Bangladesh are not unique to that country. Rather the situation there could be considered as representing the prevailing conditions in many countries of our South-East Asia Region.

WHO's definition of Health states: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".

If we analyse this definition, we realize that our thoughts must go beyond the application of modern medicine only. It is after all a difficult task to be in a state of complete physical, mental and social well-being. To achieve this we have to take necessary measures not only to cure sickness and disease but also to prevent it. In order to attain this objective we must widen our perspective. It is true that if we don't have enough resources to buy two square meals a day, we are not healthy, as our mental well-being is bound to be affected by hunger. Imagine a situation where one cannot buy even an ordinary toy for a child who is crying for it. In such a situation, can both the adult and child remain healthy? This may sound too philosophical but need thinking.

Let us now have a look at a different situation. Perhaps all of us are aware of the fact that a good number of population who live in the rural villages in our region, never get an opportunity to even see a medically-qualified doctor before their death. In the context of the prevailing economic condition of countries in our region, we need to think of ways in which we can make alternative/ traditional medicine more accessible to the ordinary village populations. Traditional medicines deserve serious consideration due to our common economic, social and cultural backgrounds. Of course this does not mean that we have to pursue a non-scientific approach. Rather we need to seriously consider ways of scientifically utilizing the full potential of traditional medicine.

The health problems of our region need to be assessed from the management, economic, social science and scientific angles. An overall knowledge of the health problem is essential. After all, health is a broad issue and cannot be dealt with exclusively by medically qualified professionals only.

We have to accept that in many countries of our Region, medical education is divorced from other branches of the teaching curricula in universities. The medical curriculum most often allows very little exposure to life outside of the medical-related subjects.

It is often noted that even very intelligent people, before starting to perform any work, analyse the situation, try to understand the surroundings, even carry out research, and discuss the subject involved with their friends and well-wishers. But unfortunately, they fail to act timely. Therefore, we have to think very seriously whether with regard to traditional medicine, we are delaying the timely scientific intervention which is needed most urgently.

Scientific criticism is most welcome in the field of traditional medicine. But time has come when we have to think whether we are giving too much attention to critics. Oscar Wilde said, "A critic is the one who knows the price of everything and the value of nothing".

We have to work whole-heartedly to establish the due position of traditional medicine. Let us not forget that half-hearted effort does not produce half result, it produces no result. We must translate our thoughts into actions. John Hancock Field once said, "All worthwhile men have good thoughts, good ideas and good intentions, but precious few of them ever translate those into action",

Without losing any more time, let us start our work in right earnest in the field of traditional medicine. We have no more time to waste. Rather, we must remember what Cardinal John Henry Newman said: "Nothing would get done at all if a man waited until he could do something so well that no one could find fault with it".

To many people traditional medicine is not based on reason, but based on age-old values. These values influence the heart, while intellectual education only influences the head. Unfortunately, most medical personnel of today are trained only to act as per the calling of their heads, by suppressing the calling of their hearts. This, indeed, is very dangerous. Because it is the moral and ethical values which are ultimately of paramount importance for all health professionals.

In the turn of the 21st century we can't afford to ignore the role of CAM which has established its status today scientific, social, ethical and moral consideration. It must be considered complementary and not competitive. National Professor of Bangladesh Dr. Nurul Islam is the pioneer in understanding the strength of Complementary and Alternative Medicine today and the logic behind its use in Bangladesh context. I feel confident that this publication shall be a valuable guide for move in the right direction for Complementary and Alternative Medicine. WHO has a commitment for this system of medicine and I feel happy to be associated with such a publication.

Poonam K. Singh
DRD, WHO, SEARO

Preface

In this compilation I have liberally included articles published elsewhere notably among which is the special issue of the Journal of American Medical Association (JAMA) November, 1998.

We have applied for permission to the individual author and the publisher of the journal and hopefully await their permission because of the pressure from the press for the forthcoming ICTAM Conference in Germany, we have not waited anymore and optimistically have gone ahead with the publication with a free mind as the scientific truths should always be available to the scientists and researchers, nevertheless we gratefully acknowledge the contribution of JAMA, November, 1998 towards CAM in this specialization.

WHO, SEAR has encouraged me more than my expectation in this publication. I express my sincere gratitude to Ms. Poonam K. Singh, Deputy regional Director & Director Programme Management, WHO, SEAR for her acceptance to write a Foreword for the book which has enhanced the value of this publication.

To all authors who have Contributed articles, I cannot adequately offer my grateful thanks and say that their contributions are, in fact, more valuable than my compilation.

Finally, Hassan Kawser, Asst. Professor, Faculty of Pharmaceutical Sciences, USTC now a PHD student in Dhaka University has done this tedious job successfully. Scattered here and there, proof reading and compiling to this publication. I record my thanks and appreciation for him even though he had enough of scolding and warring during his performance. He never desired an appreciation, though he profoundly deserves.

N Islam

National Professor of Bangladesh &
Founder Vice Chancellor, USTC

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Introcution

Medicine in my childhood was different from what it is today. My mother had an attack of remittant fever lasting for more than 5 days. My relative doctor diagnosed it as a case typhoid. Chloramphenicol was then available only in capsule form for oral administration. Laboratory facilities were not available in the rural areas where my mother lived. Diagnosis had to be made on clinical grounds, careful history and thorough physical examination.

I arrived two days later and agreed with the diagnosis and the treatment advised. But the problem was to administer medicine as my mother was then in a typhoid state with low muttering delirium. Suddenly it occurred to me that I could administer the contents of the capsules through a Ryles tube. I opened the capsule and administered it through the Ryles tube with milk with the help of a syringe. The usual dosages were administered this way. Within 48 hours or so her temperature came down. Delirium stopped and she recognised me which she could not earlier. Subsequently medicine could be given by mouth and we did so.

Over the years the situation has completely changed. Chloramphenicol can now be administered perorally. Alternative medicines are also available. Clinical suspicion can now be confirmed by laboratory investigations which are available not far from the rural areas. People who could not afford Allopathic or modern medicine used to take Unani or Ayurvedic medicine and very rarely Homeopathic medicine.

There was no qualified medical doctors in the village. I was, in fact, the first one to be admitted in the MBBS course where many people would come to see me during holidays with admiration. The situation is now completely changed. Number of doctors have increased, medicines are now available. Almost every drug can now be administered in more than one way. People in the rural areas could not dream of seeing or visiting a medical graduate of modern medicine. They were not available. Treatment was in the hands of semi-qualified or half qualified traditional healers, Unani, Ayurvedic or homeopathic practitioners.

Prevailing diseases demanded need for doctors. Consequently various forms of practitioners evolved. Some started prescribing out of experience gained from their ancestors, others from little learning as apprentice from semi-qualified or qualified doctors, others were practitioners of Unani or Ayurvedic system of medicine and some were homeopathic

practitioners. In fact, the contribution of this group of practitioners could by no means be underestimated.

It is in this way people used to derive benefit of treatment. Some used traditional or herbal medicine, others used Unani-Ayurvedic medicine and others homeopathic medicine.

System of education in these disciplines did not exist, Government did not have any patronage - financial or otherwise for any one of these. As a result, semi-government, non government institutions grew up for economic reason. Homeopathy gained popularity and field of practice.

Many diseases are self limiting and do not require treatment. Some of the fevers are viral origin and last for a short period. Homeopathy in this field gained popularity for a cure, which was, in fact, natural. Because of the low cost of medicine, easy administration and availability also it gained popularity for no side effect in the paediatric group of patients.

While this system of treatment gradually developed, modern medicine was creating a gap between the doctors and patients. Advances in medicine created a gap in the physician-patient relationship and interaction by necessary and more often unnecessary investigation.

In fact, doctors started devoting more time for investigation than for interaction between patient and themselves. Whereas the alternative system of medicine did not suffer this loss.

Even in the developed world where these systems are not recognised for reimbursement for National Health Service, people utilised this system out of their own expenses. Of late revolutionary changes have taken place. Traditional medicine is now recognised by the WHO and a section has been devoted to traditional medicine.

In the USA, National Institute of Health has developed a section on Alternative medicine with an annual grant of USD 50 million. The treatments are now recognised and receive insurance coverage.

All these have not been done overnight. Rigid regulation in the US Health system demanded careful scrutiny and cautiously proceeded in which the system survived to comparative study, research and original publication in reputed recognised indexed journal. To quote Romer Markston, Director, NIH, USA "The advancement of science-based medicine has a downside: science-based speciality medicine has become less personal and more costly. And, cost-containment efforts pay for procedures done, rather than time spent with patients. For these and other reasons, patients seek to augment the benefits of modern

conventional medicine with CAM.

The initial striking evidence of the widespread use of CAM in the USA was reported by David Eisenberg and colleagues in the *New England Journal of Medicine* in 1993. According to Eisenberg's report, one in three Americans saw an alternative health care practitioner in 1990 and they paid more than 10 billion USD in out-of-pocket expenses for this care. In addition, patients did not tell their physicians of their use of CAM because they assumed the physicians would not be interested or would not approve. In a follow-up study now completed, the evidence of even greater use of CAM has been confirmed and is most striking : more than 40% of Americans currently use CAM and as much out-of-pocket money is spent for CAM care as is out-of-pocket money spent for all of conventional medicine. These facts confirm the need for readily available information to help physicians understand, evaluate, and address CAM treatments that their patients are receiving."

As mentioned, Alternative medicine is now a recognised entity in health care system in the WHO HQ with a section devoted to this and in the USA the highest centre of research namely NIH has a section devoted to this of which Robert Markson, MD is the director. All that have been stated so far may be concluded by saying that side by side with modern medicine, Alternative medicine has now attained a recognised place in health care in the developed countries like USA.

In Bangladesh context:

Bangladesh is one of the most populous countries of the world which has now reached a staggering figure of 130 million as against which the number doctors is limited to thousands.

Table- 1: Health Statistics of Bangladesh

Total Number of Population of Bangladesh	130 million
No of registered doctors (MBBS)	32,000 (Appx.)
No of Hospitals in Bangladesh (Govt.)	700 (Appx.)
No of Hospitals in Bangladesh (Pvt.)	700 (Appx.)
No of Medical Colleges	24 (13 are Govt.)

Source: BBS-2000

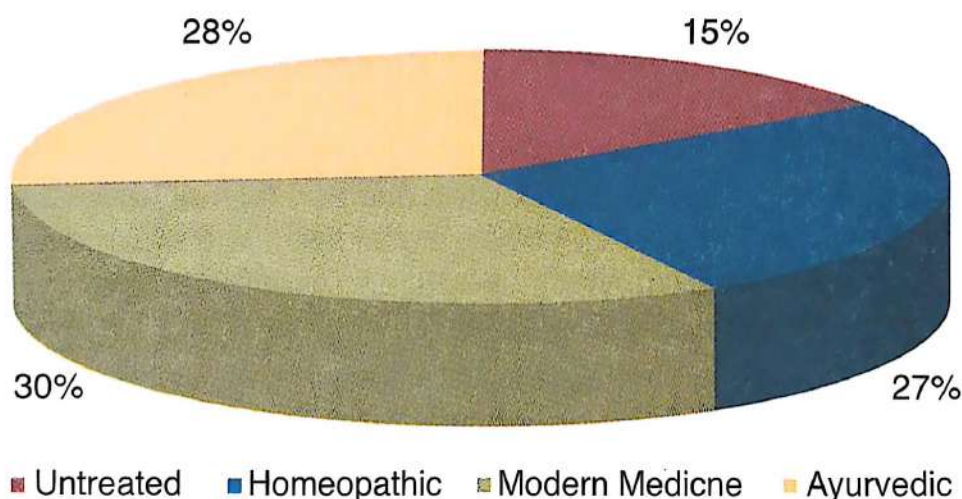
Table-I depict some health statistics in Bangladesh. This will show doctor-population ratio as 4100 (Appx.).

This is not the whole truth. Most of the doctors prefer urban life and are located in urban areas whereas rural population constitutes 80 percent of the population and are deprived of their service and under obligation are required to utilise the service of various categories of practitioners

ranging from unqualified or underqualified traditional healers, unani-ayurvedic practitioners and homeopathic.

Gram (village) doctors are a group of practitioners who start this practice having some experience in a pharmacy or with a physician. Some might have acquired their qualification from unrecognised institutions, some may be qualified homeopathic and yet a vast majority learn the profession from their family or parents.

A pessimist may criticise their role and an orthodox may label them as dangerous. But dispassionate, calculative, social scientist will consider them as useful component of the society. Even though accurate figures are not available the health care coverage by unani-ayurvedic, homeopathic and modern medicine or allopathic medicine are represented in figure which is collected from various sources.



It will be seen that some 10-20 percent of the people are deprived of any form of treatment, while the health care of the rest is more or less equally shared by the 3 systems of medicine viz. unani-ayurvedic, homeopathy and modern medicine or allopathic.

Even those 10 percent must have someone to look after them from among the general population. They may be called gram doctors or traditional healers or palli chikitsyak (meaning rural doctor). Many developed their skills from their ancestors, colleagues or local guide. They can advise people for minor maladies by way of first aid treatment and offer relief in some acute conditions.

In Bangladesh, I was made an attempt to utilise the primary school teachers and religious leaders for the health care delivery. The purpose and their activities can be summerised by including an abstract on the

subject under the title “**Utilising Under Utilised Manpower**” presented in an international conference.

Radical changes in our attitude and action during the last two decades towards complementary and alternative medicine have opened up wider opportunities for these branches for active participation in healthcare delivery, have removed many obstacles in their development because of conservation and for a developing country those have been opened extensive use of those neglected branches who had been offering services to the vast majority of population including even greater number in the rural areas. Present status of homeopathy, unani and ayurvedic system of medicine in Bangladesh are shown in Table. II.

Table- 2: Present status of hoeopathy, unani and ayurvedic system of medicine in Bangladesh

No. of Homeopathic Medical Colleges	33
Yearly Output from Homeopathic Medical Colleges	1,000 (Appx.)
No. of Unani Medical Colleges	10
Yearly Output from Unani Colleges	60 (Appx.)
No. of Ayurvedic Medical Colleges	06
Yearly Output from Ayurvedic Medical Colleges	30 (Appx.)

Source: BBS-2000

This table indicate a very extensive network spread over the country and each centre has some manpower who may not be educated and yet motivated to the health care of the people through their particular system. The antagonists expressed doubt about their efficacy and usefulness of their claim for cure of many diseases. The antagonist would say that their role and their contribution has not been well examined and comparatively evaluated in Bangladesh. Unless we are sure of their safety and efficacy it is not without risk to incorporate them with modern medicine for health care delivery to the people who remained uncovered by health system in the country. These arguments are scientific and sensible.

Conclusion

Traditional Medicine deserves a place even though it has been duly recognized by the WHO only a few years ago amidst dogmatism controversy and perhaps ignorance.

Alma Ata Conference 1978 on Primary Health Care was historic event aiming at HEALTH FOR ALL. The gulf of difference between the traditional and modern medicine started narrowing when the WHO incorporated some Traditional Medicine in its program in 1976. A genuine interest in the many traditional practices now exists among practitioners of modern medicine;

and growing numbers of practitioners of traditional, indigenous or alternative systems are beginning to accept and use some of the modern technology. Despite advances and improvement in the concept of practitioners of modern medicine, a wide gap still exists and the Complementary and Alternative Medicine remained neglected.

This book is intended to bridge the gap and establish harmony among the different systems of medicine viz. Allopathy, Homeopathy and Unani- Ayurvedic systems of medicine rather than throwing a challenge to one another.

Health For All is a slogan of the WHO according to the Director-General of the WHO, this can be achieved by the involvement of All for Health.

The knowledge gap in our understanding may be partly removed by this publication and help government in designing a National Health Plan and related training program.

I may conclude by quoting the remarks made in her Foreword by Dr. Poonam K. Singh, "Without losing any more time, let us start our work in right earnest in the field of traditional medicine. We have no more time to waste. Rather, we must remember what Cardinal John Henry Newman said: "Nothing would get done at all if a man waited until he could do something so well that no one could find fault with it".

To many people traditional medicine is not based on reason, but based on age-old values. These values influence the heart, while intellectual education only influences the head. Unfortunately, most medical personnel of today are trained only to act as per the calling of their heads, by suppressing the calling of their hearts. This, indeed, is very dangerous. Because it is the moral and ethical values which are ultimately of paramount importance for all health professionals."

Let us accept that Health For All is every body's right and our responsibility. In achieving "Health For All", all must play a role or in other words "All For Health" is a must for all. As an individual we can do a very little. Working together we can certainly win.

May this publication imbibe in all the spirit of Working Together, shunning hatred and distrust and for the spirit of love, understanding and cooperation for the welfare of all.

If this publication carries the message of goodwill and put all together, I shall feel amply rewarded and my dream will be fulfilled.

May we all work together for the benefit of mankind.

Working together we can always win.

Alternative Medicine Meets Science

Phil B. Fontanarosa, MD¹
George D. Lundberg, MD²

There is no alternative medicine. There is only scientifically proven, evidence-based medicine supported by solid data or unproven medicine, for which scientific evidence is lacking. Whether a therapeutic practice is “Eastern” or “Western,” is unconventional or mainstream, or involves mind-body techniques or molecular genetics is largely irrelevant except for historical purposes and cultural interest. We recognize that there are vastly different types of practitioners and proponents of the various forms of alternative medicine and conventional medicine, and that there are vast differences in the skills, capabilities, and beliefs of individuals within them and the nature of their actual practices. Moreover, the economic and political forces in these fields are large and increasingly complex and have the capability for being highly contentious. Nonetheless, as believers in science and evidence, we must focus on fundamental issues—namely, the patient, the target disease or condition, the proposed or practiced treatment, and the need for convincing data on safety and therapeutic efficacy.

Despite the increasing use of alternative medicine (also termed *complementary, integrative, or unconventional* medicine) in the United States and throughout the world, most alternative therapies have not been evaluated using rigorously conducted scientific tests of efficacy based on accepted rules of evidence. The lack of properly designed and conducted randomized controlled trials is a major deficiency. For some published studies, serious concerns have been raised regarding methodological quality. A National Institutes of Health expert panel concluded that current evidence is inadequate for development of practice guidelines for alternative therapies, largely because of lack of relevant outcomes data from high quality clinical trials. However, some advocates of alternative medicine argue that many alternative therapies cannot be subjected to the standard scientific method and thus, instead must rely on anecdotes, beliefs, theories, testimonials, and opinions to support effectiveness and justify continued use.

¹ Dr. Phil B. Fontanarosa, MD is Senior Editor, JAMA

² Dr. George D. Lundberg, MD is Editor, JAMA,

Regardless of the origin or type of therapy, the theoretical underpinnings of its mechanism of action, or the practitioner who delivers it, the critical questions are the same. What is the therapy? What is the disease or condition for which it is being used? What is its purported benefit to the patient? What are the risks? How much does it cost? And, perhaps most important, does it work? For virtually all medical therapies and interventions, whether conventional or alternative, determination of effectiveness and recommendations for clinical application should be based on the strength of the scientific evidence using explicit criteria for grading the quality of evidence (Table) and ratings for technology assessment⁴ (ie, “established,” “promising,” “investigation,” “doubtful,” or “unacceptable.”)

While acknowledging that many therapies used in conventional medical practice also have not been as rigorously evaluated as they should be, we agree that most alternative medicine has not been scientifically tested.⁵ However, for alternative medicine therapies that are used by millions of patients every day and that generate billions of dollars in health care expenditures each year, the lack of convincing and compelling evidence on efficacy, safety, and outcomes is unacceptable and deeply troubling. We believe that physicians should become more knowledgeable about alternative medicine and increase their understanding of the possible benefits and limitations of alternative therapies. By doing so, physicians will be able to serve as more useful sources of information for their patients and advise them appropriately. As with conventional therapies, advice should be based on data and scientific information rather than anecdotal information, misperceptions, or preconceived or unfounded notions about effectiveness or lack thereof.

This theme issue of *JAMA* and the annual coordinated theme issues of the 9 American Medical Association *Archives* Journals published this month on alternative medicine represent a planned, concerted effort by the editors of these scientific journals to address some of these issues by providing physicians and other health care professionals with clinically relevant, reliable, fresh scientific information on alternative therapies. In response to our call for papers on alternative medicine, we received more than 200 manuscript submissions to *JAMA* and many more manuscripts were received by the *Archives* Journals. The result, after our usual rigorous review process, is publication of more than 80 articles and editorials on alternative medicine in our 10 scientific journals, including 18 randomized trials and systematic reviews, on more than 30 different

topics, and from more than 16 different countries.

This issue of THE JOURNAL includes 6 randomized clinical trials that evaluate the use of 6 diverse alternative medicine therapies for treatment of common clinical conditions. The results are intriguing. Bove and Nilsson report that chiropractic spinal manipulation is not effective for episodic tension headache. Cardini and Weixi⁸ found that moxibustion (stimulation of an acupuncture point by heat generated from burning a specific herb) is helpful for correction of breech presentation in late pregnancy. Bensoussan and colleagues document that a Chinese herbal medicine formulation improves symptoms of irritable bowel syndrome. Shlay and coinvestigators demonstrate that acupuncture is no more effective than amitriptyline or placebo for relieving pain due to human immunodeficiency virus- related peripheral neuropathy. Heymsfield and coworkers determined that Garcinia Cambogia, a common component of commercial weight-loss products, lacks efficacy as an antiobesity agent. In a preliminary study, Garfinkel and co workers¹² report that a yoga-based intervention appears to hold promise for relieving some symptoms of carpal tunnel syndrome. In addition, a systematic review by Wilt and colleagues suggests that saw palmetto extracts improve urologic symptoms in patients with benign prostatic hyperplasia.

Categories for Rating Quality of Scientific Evidence for Effectiveness of an Intervention*

Quality of Evidence

- I. Evidence obtained from at least 1 properly randomized controlled trial*
- II-1. Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than 1 center or research group*
- II-2. Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than 1 center or research group*
- II-3. Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.*
- III. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.*

** Information is from Lawrence et al.²*

Perhaps just as important as the results of their studies, these investigators demonstrate that alternative medicine therapies and interventions can and should be evaluated using explicit, focused research

questions along with established and accepted rigorous research methods (eg, appropriate controls, effective blinding procedures, adequate power, state-of-the-art techniques for systematic reviews); incorporating measurable, objectively assessed end points (eg, blinded assessment); and reporting meaningful patient-centered outcomes.

Two other studies in this issue provide additional new information on alternative medicine. In a replication of their previous nationally representative survey, Eisenberg et al¹⁷ report that the prevalence of use of at least 1 of 16 specific alternative therapies during the previous 12 months has increased significantly (from 33.8% in 1990 to 42.1% in 1997), that the estimated number of visits to alternative medicine practitioners increased dramatically (from 427 million in 1990 to 629 million in 1997), and that only 38.5% of those who used alternative therapies discussed them with their physician. Total out-of-pocket expenditures associated with use of alternative medicine in 1997 were estimated at \$27 billion. In an analysis of data from malpractice insurers from 1990 through 1996, Studedert and colleagues¹⁸ found that claims against chiropractors, massage therapists, and acupuncturists generally occurred less frequently and usually involved less severe injury than claims against medical doctors. The authors also summarize the legal issues and principles for physicians to consider when advising or contemplating referral of patients to alternative medicine practitioners.

Taken together, the articles published in this issue of THE JOURNAL and in the Archives Journals' theme issues on alternative medicine add a substantial amount of new information and scientific data on alternative therapies to the peer-reviewed mainstream medical literature. However, given the burgeoning use of alternative medicine therapies, the increasing numbers of patients who consult both medical doctors and alternative medicine practitioners, and the increasing number of insurance companies and managed care organizations of fearing programs and benefits for alternative medicine¹⁹ the need for additional, carefully conducted, high-quality research is essential.

Priority for research funding for alternative medicine should be given to investigations of relevant clinical problems for which well-designed studies have shown encouraging results for alternative therapies, especially for conditions that are common and those for which conventional medicine has not been effective. Attention should be given to evaluation of safety and efficacy, but also to examining the effectiveness of a treatment strategy, with consideration of community practice settings, patient

expectations and compliance, and cost-effectiveness.²⁰ Collaborative research, especially among the federally funded centers for alternative medicine research in the US and with international alternative medicine research centers, may improve efficiency in answering important research questions. We encourage high-quality, rigorous research on alternative medicine and invite authors to submit their best papers for our objective evaluation and consideration for publication.

However, until solid evidence is available that demonstrates the safety, efficacy, and effectiveness of specific alternative medicine interventions, uncritical acceptance of untested and unproven alternative medicine therapies must stop. Alternative therapies that have been shown to be of no benefit (aside from possible placebo effect) or that cause harm should be abandoned immediately. Physicians, insurance plans, medical centers and hospitals, managed care organizations, and government policymakers should base decisions regarding incorporation of and payment for alternative medicine therapies on evidence-based research and objective cost-effectiveness analyses¹⁹ rather than on consumer interest, market demand or competition, well-publicized anecdotal reports, or political pressures from well-organized and influential interest groups.

Ultimately, answering fundamental questions about efficacy, safety, appropriate clinical applications, and meaningful outcomes for all medical therapies, including those considered alternative medicine, requires critical and objective assessment using accepted principles of scientific investigation and rigorous standards for evaluation of scientific evidence. For patients, for physicians and other health care professionals, and for alternative medicine practitioners- indeed, for all who share the goal of improving the health of individuals and of the public- there can be no alternative.

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Alternative Medicine- Learning From the Past, Examining the Present, Advancing to the Future

Wayne B. Jonas, MD

Medical practices outside the mainstream of “official” medicine have always been an important part of the public’s health care. Healers and herbalists, bonesetters and barbers, shamans and spiritualists have offered the public a multiplicity of ways to address the confusion and suffering that accompany disease. A century ago in the United States there was a period of “enchantment” with unorthodox medicine. Homeopaths, herbalists, psychic and magnetic healers, and “eclectics” proliferated- most with little to no training, regulation of practice, or standards for quality of care. The prominence and configuration of these “irregulars,” as they were called, has waxed and waned, depending on the perceived value of orthodox medicine, the needs of the public, and the changing values of society. The prominence of these practices subsided with the development of scientific medicine in this century and its dramatic advances in the understanding and treatment of disease. Historically, orthodox medicine fights these practices vigorously by denouncing and attacking them, restricting access to them, labeling them as antiscientific and quackery, and imposing penalties for practicing them. When these therapies persist and even rise in popularity despite this, mainstream medicine then turns more friendly, examining them, identifying similarities they have with the orthodox, and incorporating or “integrating” them into the routine practice of medicine.² In the past, orthodox medicine has benefited from their selective integration by abandoning ineffective therapies such as bloodletting, adopting new drugs such as digitalis, and developing more rigorous scientific methods with which to test these practices, such as blinding and randomization.^{2,3}

The increasing popularity of complementary and alternative medicine (now used by more than 40% of the public) reflects changing needs and values in modern society in general.⁴ This includes a rise in prevalence of chronic disease, an increase in public access to worldwide health information, reduced tolerance for paternalism, an increased sense of entitlement to a quality life, declining faith that scientific breakthroughs

will have relevance for the personal treatment of disease, and an increased interest in spiritualism.⁵⁻⁷ In addition, concern about the adverse effects and escalating costs of conventional health care are fueling the search for alternative approaches to the prevention and management of illness. As the public's use of healing practices outside conventional medicine accelerates, ignorance about these practices by physicians and scientists risks broadening the communication gap between the public and the profession that serves them.

Today, the overwhelming effort is toward attempts at "integrating" alternative practices into the mainstream. Sixty percent of medical schools have begun to teach about alternative medicine practices,⁹ hospitals are creating complementary and integrated medicine programs, health suppliers are offering expanded benefits packages that include the services of alternative practitioners,¹⁰ and biomedical research organizations are investing more substantial amounts toward the investigation of these practices. For example, the office of Alternative Medicine at the National Institutes of Health has just become the National Center for Complementary and Alternative Medicine, with a budget of \$50 million. The activities of the office of Alternative Medicine¹¹ and the publication of this issue of *JAMA* illustrate that quality scientific research can be conducted and published on alternative medicine topics. It appears that complementary and alternative medicine has again "come of age" in the United States. However, the rush to embrace a new integration of alternative and conventional medicine should be approached with great caution. Alternative medicine, like conventional medicine, has pros and cons, promotes bad ideas and good ones, and promises to hold both benefits and risks. Without critical assessment of what should be integrated and what should not, we risk developing a health care system that costs more, is less safe, and fails to address the management of chronic disease in a publicly responsible manner. The potential risks and benefits of alternative medicine must be examined carefully before heading into a new but not necessarily better health care would.

Risks of Embracing Alternative Medicine

Quality of Care : The formal components of medical physician licensure usually are not required of alternative medicine practitioners. These include the content and length of time of training, testing and certification, a defined scope of practice, review and audit, and professional liability with regulatory protection and statutory authorization complete with codified disciplinary action.¹² All 50 states do provide licensure

requirements for chiropractic practice, but only about half do so for acupuncture and massage therapy and fewer do for homeopathy and naturopathy. Many of these practitioners operate largely unmonitored. These products are available on the market as dietary supplements and may be contaminated or vary tremendously in content, quality, and safety. Garlic, for example, claimed for many years to have to have cholesterol lowering effects, may not produce such effects if processed in certain ways. Thus, even if one product is proven safe and effective, other similar products on the market may have quite different effects that preclude consistent dosing. Fifteen million Americans are taking high-dose vitamins or herbal preparations along with prescription drugs, thereby risking adverse effects from unknown interactions.

Quality of Science : The use of science for understanding alternative medicine is frequently missing from such practices. Most alternative medicine systems have been largely unchanged for hundreds of or thousands of years. Often they begin from the teachings of a charismatic leader that are not advanced with new observations, hypothesis-driven testing innovation, and peer-review. Claiming that their practices are too “individual” or “holistic” to study scientifically, many alternative medicine practices hide behind anecdote, case series, or “outcomes” research. To accept such views is to falsely label conventional medicine as nonholistic and reject the hard fought gains made in the use of basic biological knowledge, the randomized, controlled clinical trial, and evidence-based medicine for health care decision making.

To adopt alternative medicine without developing quality standards for its practices, products, and research is to return to a time in medicine when quackery and therapeutic confusion prevailed. Modern conventional medicine excels in the areas of quality health care and the use of science: alternative medicine must change to adopt similar standards. Conventional medicine is also the world’s leader in the management of infectious, traumatic, and surgical diseases, in the study of pathology, and in biotechnology and drug development. All medical practices have the ethical obligation to retain these strenghts for the benefit of patients.

Risks of Conventionalizing Alternative Medicine

Healing: Most alternative medicine systems carefully attend to the illness and suffering that accompanies all disease. The time spent with each patient by an alternative medicine practitioner usually exceeds that spent by the average conventional physician, and patients are often more satisfied with their interactions with unorthodox than orthodox medical practitioners.¹⁸

Alternative medicine practitioners provide patients with understanding, meaning, and self-care methods for managing their condition. Empowerment, participation in the healing process, time, and personal attention are essential elements of all medicine. These elements are easily lost in the subspecialization, technology, and economics of modern medicine. Conventional medicine must develop a better language for managing illness and suffering or lose this essential message that alternative medicine provides.

Adverse Effects: In the last century, unconventional medicine increased in popularity because of the use of severe treatments such as bloodletting, purging, and toxic metals by conventional medicine. The popularity of alternative medicine in this century is also driven by the perception that conventional treatments are too harsh to use for chronic and non-life threatening disease. Iatrogenic disease caused by conventional medicine is a major cause of death and hospitalization in the United States. While some alternative medicine practices have important toxicities, many have reduced potential for adverse effects when properly delivered. Conventional medicine can learn from alternative medicine how to “gentle” its approach by focusing on the patient’s inherent capacity for self healing.

Costs: Skyrocketing costs of conventional medicine also are driving the search for alternatives. Savings from managed care now are maximized and health care costs are predicted to double in the next 10 years. If low-cost interventions such as life style changes, diet, supplement therapy, and behavioral medicine can be delivered as substitutes for high-cost drugs and technological interventions, true cost reductions and the compression of morbidity might be achieved. If there is a single strength of alternative medicine that risks being lost in its “integration” with conventional care, it is an emphasis on self-healing as the lead approach for both improving wellness and for the treatment of disease. All the major alternative medicine systems approach illness first by trying to support and induce the self-healing processes of the person. If recovery can occur from this, the likelihood of adverse effects and the need for high-impact, high-cost interventions is reduced. It is this orientation toward self-healing and health promotion (salutogenesis rather than pathogenesis) that makes alternative medicine approaches to chronic disease especially attractive.

The Future of Alternative Medicine

The main “obstacles to discovery,” writes Daniel Boorsting, are “The illusions of knowledge.” Indeed, the capacity of humans to fool themselves by making claims of truth, postulating unfounded explanations, and denying

the reality of observations they cannot explain is endless. Science has emerged as one of the few truly powerful approaches for mitigating this self-delusionary capacity. The clinical experimental method, in the form of the randomized, controlled trial, examines to what extent attributions and explanations of these therapies are accurate.

The goals of medicine, no matter what the label, are the same for all practices.²⁶ Is the current trend toward "integrated" medicine a deluded temptation that will turn out to be a nightmare of unscientific practices? Or will these newfound tools of scientific medicine be used to look deeper into the processes of healing for their utility in treating disease and alleviating suffering? In the last 50 years, powerful social forces have transformed medicine. If a new evidence based "integrated" medicine does emerge, it will likely be subject to the same forces shaping the future of medicine in general. This includes the continued takeover of medicine by managed care, a more refined ability to manipulate individual susceptibilities using nanotechnology, and the ability to track quality of care and individual patient outcomes with networks of information monitoring.²⁷ Research in alternative medicine will help identify what is safe and effective and will further the understanding of biology by exploring, rather than marginalizing, unorthodox medical claims and findings.²⁸ Alternative medicine is here to stay. It is no longer an option to ignore it or treat it as something outside the normal processes of science and medicine. The challenge is to move forward carefully, using both reason and wisdom as we attempt to separate the pearls from the mud.

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***Western Medicine Opens the
Door to Alternative Medicine
(Law, Medicine and Socially Responsible Research)***

Kathleen M. Boozang

Physicians have struggled to defeat alternative medicine, and to obtain a monopoly over the health care of their patients, since physicians began systematically organizing in the United States. They claim to oppose alternative medicine because it lacks efficacy, may waste precious health care dollars and may harm patients. Part II of this Article examines the ongoing debate about alternative Medicine and the arguments that may wedge the door of Western Medicine open to alternative treatment methods. Alternative medicine's successful entry into Western practice depends on convincing conventional medicine of the efficacy of alternative treatments, a task that remains largely undone. Part III explains why the debate about unproven alternative therapies differs from previous discussions about human research, and therefore merits independent consideration. Part IV argues that it is not ethically appropriate for physicians to offer or agree to provide alternative therapies whose efficacy remain unproven or are of dubious potential. Part V defends the conclusion that physicians should not offer unproven alternative therapies, but if certain circumstances exist to justify pursuing alternative treatments, physicians should adhere to the model of informed consent that governs the conduct of experimental clinical trials.

Shutting Alternative Medicine Out : A Losing Battle

Organized medicine, since its inception, has fought to maintain a firm grip on the philosophy of health care generally, as on the specific treatments patients should have available to them. Lori Andrews succinctly captured this marshaling of power in her recent article about alternative providers:

In many instances, the barriers to the use of alternative providers have been erected due to pressures from their main competitors, physicians. Physicians convince legislatures to restrict the scopes of practice of other providers and pressure prosecutors to bring criminal actions against nonphysician providers. Physician groups have tried to eliminate the practice of various alternative health care providers including acupuncturists, chiropractors, homeopaths, midwives, naprapaths, and

naturopaths. In addition, since physicians are the main breadwinners for hospitals, health maintenance organizations, and other health care institutions, they exert a large amount of power over the fashioning of policies to govern these institutions. Physician groups have bullied hospitals into adopting policies that favor physicians and disadvantage or even eliminate alternative health care providers, even when there is no evidence that such policies are necessary to protect patients.

Despite centuries of physician dedication to eliminating alternative medicine and its practitioners, patients continue to be lured, now as much as ever, by unconventional therapies ranging from chiropractic, homeopathy, naturopathy and acupuncture to chelation therapy, light therapy and color therapy. The various offerings of alternative medicine fall into one of three categories: (1) pure quackery (invalidated), (2) plausible but not yet proven (nonvalidated), or (3) proven to be efficacious (validated). This Article questions whether physicians should offer invalidated or nonvalidated treatments to their patients and concludes that they should not.

Some of America's most famous physicians (if the Best Sellers List serves as a reliable indicator) have achieved notoriety by offering patients an appealing integration of the best that American medical expertise has to offer with natural medicine. The popularity of these physicians signals the beginning of the end of orthodox medicine's dominance of health care in the United States. Even more remarkable, and perhaps the greatest evidence of alternative medicine's resilience, is managed care's increasing willingness to cover complementary health care practices.

Patients show increasing reliance on alternative medicine and physicians show increasing openmindedness about the therapeutic possibilities of some alternative treatments. Nevertheless, vociferous debate persists about the efficacy of much that alternative medicine has (or does not have) to offer. Although some alternative therapies have been proven efficacious, many promising alternative practices have been resoundingly rejected on scientific grounds. Others have a plausible rationale but remain unproven. The reaction to the renaissance of alternative medicine is so negative in some quarters that a number of organizations and journals have been established largely to discredit alternative therapies. In the last few years, Congress has entered the debate. In 1992, Congress established the Office of Alternative Medicine (OAM) in the National Institute of Health (NIH). Current debate surrounds OAM's continued existence, funding, research grants, and its general standing and power

within NIH. The divisiveness over clinical testing of at least some alternative treatments is so acute that some critics reject the notion that efficacy research is appropriate at all. Some critics say testing would waste scarce research dollars on notions that are scientifically indefensible. Others, however, claim that natural therapies have stood the test of time and need not pass the rigors of scientific medicine, or that testing is impossible because of the unique nature of some forms of alternative medicine.

Some laypersons and policy-makers find it impossible to sort through the charges and countercharges between proponents of orthodox and alternative medicine. The medical profession's objections to alternative medicine are made against a backdrop of its own failures. These include a failure to test properly new treatments and procedures before use in the clinical setting, and a history of overzealous and self-interested control of health care (frequently to the detriment of cost containment and quality care). Interference with innovative practices that could benefit patients and improve care is not good public policy. Abusive criticisms of alternative practitioners and threats to their licensure solely because they offer their patients an integrated practice are similarly ill-advised. On the other hand, quacks and frauds unquestionably abound. If consumer protection means anything, it should protect people weakened by illness from the dangers attendant to unsound health practices.

Even as these battles about alternative medicine rage unabated, physicians are gradually succumbing to external pressures to integrate alternative techniques and conventional medicine. These pressures come from a variety of sources, including physicians' opportunistic desires, managed care interests and, most frequently, patient demands. Physicians' acquiescence to these pressures is problematic on a number of levels. First few physicians receive training in alternative medicine techniques. Even when alternative therapies offer proven therapeutic benefit, conventionally trained physicians may not be competent to realize such benefits or to co-manage a patient's care with an alternative provider. The problem of conventional physicians' competency to administer alternative medicine is not addressed in this Article but presumably can be addressed through hospital and managed care credentialing processes, professional organizations or the malpractice system. This Article focuses on the use of alternative techniques by physicians for the treatment of nonterminal patients in purely clinical (nonresearch) settings. The issue is whether physicians may offer treatments (either alone or jointly with an alternative practitioner) that are nonvalidated, or

that are quack remedies. As used here, “nonvalidated” treatments refer to interventions that may have a basis in scientific theory for use in medical care but that are otherwise unproven, innovative and/or experimental. “Quack remedies” refer to interventions that are “invalidated” because they have neither a proven nor any scientific basis for any health benefit. I use the terms unproven, nonvalidated or innovative to refer to the methods described in my first category, and the terms invalidated or quackery to encompass the second category.

This Article does not contemplate the physician-researcher who is engaged in either pure experimentation or a combination of treatment and research. Similarly, it does not focus on the patient who is terminally ill, and for whom no conventional curative option exists. This Article is mainly concerned with whether it is proper for physicians to offer, agree to manage jointly or to accede to patient demands for alternative therapies that may not be particularly harmful, but for which little or no proof of potential benefit exists. This Article concludes that physicians should never accede to patient demands for invalidated treatments. This prohibition should extend to nonvalidated treatments under two conditions: (1) if no or little evidence exists to suggest that treatment will be beneficial or (2) if some evidence suggests that treatment might be beneficial but, in the physician’s judgment, the treatment is unlikely to do any good. However, this article concludes that physicians may accede to patient demands for nonvalidated treatments under the following narrow conditions: if extant research results are very promising, if the physician believes that a particular patient may benefit, if the risk of harm is very low, and if the physician adheres to the conventions that govern the doctrine of informed consent for experimental treatment.

The Pressure to Provide Alternative Therapies

A. The Confusion of Definitions

The most recent alternative medicine resurgence largely results from a generational pursuit of independence and nonconformity. Paradoxically, as some alternative therapies have successfully undergone double-blind clinical trials (the “gold standard”) and have been proven to be efficacious, physicians who offer them are shedding the “alternative” label, in hopes that the therapy will gain the respectability of orthodox medicine. Consequently, confusion abounds as to what currently comprises alternative medicine. The following summary attempts to identify those alternatives most generally associated with the term.

1. Homeopathy: Americans spent \$165 million on homeopathic remedies in 1994 and sales since then have been increasing about twenty percent per year. First introduced by a German physician, Samuel Hahnemann, in about 1796, homeopathy relies on the “law of similars,” which suggests that natural substances that produce certain symptoms in healthy individuals cure those same symptoms when they appear in someone who is sick. Homeopathy also teaches that “life is a spiritual force (vitalism) which directs the body’s healing,” a process which can be stimulated with the smallest amounts of natural substances. Consequently, homeopathy begins with natural substances which are then subjected to a process of “succussion” or shaking, which dilutes the substance to eliminate the deleterious or toxic side effects of the substances being used without reducing its effectiveness. The “Law of Infinitesimals holds that the smaller the dose of a medication, the more powerful will be its health effects.” As such, homeopathic solutions are frequently diluted to the point where not even a single molecule of the active substance remains, in the belief that the alcohol or water substance “remembers” the original substance, due to some “spirit-like vital principle.” Although a paper published in 1988 (popularly referred to as the “Benveniste” paper) supports this hypothesis, no subsequent study has successfully duplicated the touted results and the theory is widely rejected outside of homeopathic circles. Beyond the dispute over the plausibility of the underlying theories of homeopathy, the hundred-plus controlled clinical trials of homeopathy concluded that there was no acceptable evidence that it is effective.
2. Chiropractic: Chiropractic epitomizes the recent history of alternative medicine because, although chiropractic may represent the most utilized alternative therapy in the United States, organized medicine has spared no expense or energy in attempting to eliminate it. Given this history, it is even more astounding that increasing numbers of physicians refer patients to chiropractors or themselves engage in “manipulative therapy.” Having successfully used the courts to quash physician opposition to their existence, chiropractors number about 45,000 in the United States and have licensing boards in every state. Despite this apparent assimilation into mainstream health care, as well as substantial scientific evidence that manipulative therapy can be employed successfully to relieve back pain, chiropractic remains controversial. First, some amount of discomfort remains regarding the underlying theory of chiropractic, which is based on

its founder's theory that ninety-five percent of diseases are caused by displaced vertebrae. Second, chiropractors resist any attempts to limit their practice to back care, applying their therapies to other ailments for which scientific support remains insufficient, leading to complaints by physicians that chiropractors manipulate spines inappropriately and misuse X-rays.

Finally, it has been suggested that chiropractic practice is extremely variable, with some practitioners increasingly mixing their treatment techniques with several other alternative therapies.

3. Acupuncture: Acupuncture adherents believe that "illness is caused by a disruption in the flow of qi (pronounced "chee"), the collection of energies that endow us with our vitality," Therapy involves the insertion of needles at certain points in the skin to activate qi. Acupuncture is used in the United States primarily for pain relief, although it is also suggested for "rheumatoid and osteoarthritis, muscle and nerve 'difficulties,' depression, smoking, eating disorders, drug 'behavior problems,' migraine, acne, cancer, and constipation." One of the most obvious problems in subjecting acupuncture to traditional clinical scrutiny is the difficulty in achieving double-blind trials. According to one recent article.

Two meta-analyses of acupuncture for pain relief indicate that the best-controlled studies show no difference in effectiveness between genuine acupuncture and control or sham procedures, whereas the worst-controlled studies show the greatest effectiveness. Acupuncture acts on pain probably through a combination of counterirritation and misdirection of pain, consensual expectations, and classical conditioning and reinforcement. Other factors that play a role may be political belief, disaffection, and economic interest. Endorphin secretion may lead to the temporary euphoria for conditioning, but probably has little to do with overall success. The needles themselves are not necessary for pain relief.

4. Additional Therapies: Alternative therapies include a host of other methods including aroma therapy, art therapy, biofeedback, bodywork/manual therapy, botanicals/herbs, environmental medicine, hyperbaric oxygen therapy, herb therapy, hypnosis, light therapy, magnetic stimulation, mind/body medicine, music therapy, nutrition, traditional Chinese medicine, yoga and supplements Visualization (imagery) combined with psychotherapy has been tested as a

possible cure for cancer. Other therapies listed on the OAM web page include anthroposophy, color therapy, eclecticism, electrical stimulation therapy, applied kinesiology, massages, moxibustion, organotherapy, radiesthesia, reflexotherapy, relaxation techniques, therapeutic touch, and tissue therapy. A renewed focus on spiritualism and healing has inspired interest in "Siberian shamanism, near-death experiences, Native American healing, Tibetan Buddhist spirituality, Indian Ayurvedic, homeopathy, nutrition, contacts with extra-terrestrials, creativity, brain longevity, trance-channeling, indigenous healing and astrology."

Patients encounter numerous alternative treatment offerings, which basically fall into four categories: "spiritual and psychological; nutritional; drug and biologic; and physical forces and devices." Whatever their nature, physicians are bound to aid their patients in sorting through their various promises of cure and relief, to see which truly have something to offer.

B. The Surge in Patient Demand for Alternative Therapies

The resurgence of alternative medicine stems from a number of phenomena. Some attribute renewed consumer interest of the 1960s and 1970s to alternative medicine's reliance on natural remedies and spirituality, which appealed to the anti-establishment, antitechnology, and counterculture tendencies of the times. Alternative medicine practitioners are also known for the greater attention they give to their patients at a time when medical doctors are increasingly criticized for their lack of compassion and personal interaction in their provision of care. Thus, to a great extent, it seems that patients seek out alternative practitioners for the humaneness that conventional care wants. Medicine remains substantially a white male profession, frequently inattentive or unresponsive to the needs and values of women, nonwhites, and those of lower socioeconomic classes. Physicians are also scarce in many communities, leaving patients no choice but to obtain their care from the practitioners who live and provide services among them, whom they may very well prefer in any event.

Today's sophisticated, technologically dependent health care system denies patients the degree of choice and control over their health care and their lives that they desire. Alternative medicine embodies variety, choice and accessibility. Consumers can educate themselves and become the experts that their physicians are not by simply going to the bookstore, surfing the internet or visiting their local natural food store. Many traditional therapies which are dismissed or disliked by practitioners of Western

medicine, yet accepted and embraced by alternative practitioners, originate from patients' superstitions or cultural practices. Finally, alternative medicine may in fact be helping some patients, whether by ameliorating their condition, by reducing anxiety and pain, or by helping the patient feel better for reasons traditional medicine cannot explain. Even if the benefit is broadly construed, it remains unclear which of these treatments actually contribute to a patient's well-being (however we decide to define that term) such that physicians should, on patient request, integrate them into the care they provide and charge for their provision.

Why this Discussion is Different

Have we not been down this road before? We have debated when physicians should offer nonvalidated or experimental therapies to patients; we have struggled over whether physicians must offer such therapies if they truly believe they are not in the patient's best interest because the chance of benefit is so unlikely; and we have agonized over what physicians should tell patients to whom they offer these nonvalidated or experimental therapies, especially if the physician does not think the patient should elect the treatment. We have refined the arguments to distinguish between situations where the physician provides the treatment solely for therapeutic purposes and more obscure scenarios where the physician is one of the primary researchers or inventors of the treatment or device being offered.

How is the question of physicians offering a nonvalidated "alternative" treatment different from their offering a nonvalidated experimental treatment? For one thing, the source of pressure to offer the treatment may differ. The traditional paradigm for an unproven treatment involves a clinician-researcher who recommends an innovative therapy. In such cases, the analysis is on the potential for patient coercion due to the possibility that clinician researcher may have an ulterior research motive. With alternative medicine, the pressure to integrate an unproven treatment into conventional not the physician having an ulterior research motive, but rather his offering an intervention that has neither a proven nor any scientific expectation of any health benefit.

Patients' demands for unproven alternative therapies are analogous to HIV-infected patients' demands in the 1980s to reform Food and Drug Administration (FDA) regulations to facilitate early access to unapproved drugs. The FDA responded by amending its regulations to permit "the availability of promising new drugs to desperately ill patients as early in the drug development process as possible," even to patients not involved

in clinical trials. Although controversial at the time, the extensive regulatory changes improved access to experimental drugs while still providing an unequaled degree of consumer protection in the drug/device area. The FDA limited access to unproven drugs to situations involving immediately life-threatening or serious diseases for which no comparable or satisfactory alternatives exist. Further, the FDA commissioner retains authority to deny requests for unproven drugs when evidence of safety or effectiveness is insufficient to support such use; the scientific evidence fails to provide a reasonable basis to conclude that the drug may be effective for its intended uses; or an unreasonable and significant risk of illness or injury exists. For the most part, these protections do not extend to patients seeking unproven alternative therapies.

Alternative health care proponents are not necessarily appreciative of the philosophy that governs access to drugs and medical devices. Rather, many patients prefer a system that ensures consumer access to information, but allows them the freedom to engage in the cost-benefit analysis of whether to pursue treatments that are risky or uncertain. Surprisingly, managed care may facilitate such choice.

Managed care organizations (MCOs) have begun embracing alternative care, and patients may feel particularly justified in demanding alternative treatment from their physicians if it is covered by their health plans. Patients are likely to interpret health plans' inclusion of a particular treatment as an imprimatur on its efficacy, especially because patients perceive health plans in today's market to be restrictive in their coverage decisions. Physician criticism of alternative therapies that are covered by the third-party payer may confuse patients, or breed suspicion about the physician's motivations, especially if the patient is using an alternative provider, rather than the physician, to supplement her health care regime.

Physicians may experience external pressure from MCOs that include an alternative health network or alternative therapies as covered benefits. Most obviously, if the plan covers alternative therapies, somebody must provide them; thus the plan may encourage physicians to offer the covered services. But other dynamics may cause physicians to feel pressure to participate in complementary medicine. First, to the extent that MCOs are using alternative medicine to save money or attract members, the plan presumably will not appreciate physicians who discourage patients from using alternative treatments. Second, MCOs that rely on primary care providers to coordinate patient care to ensure medical appropriateness potentially could be exposed to liability if their physicians

refuse or are not competent to integrate patients use of alternative therapies with the treatment being provided by patients' medical doctors. This problem is especially acute if the MCO requires referrals by the primary care provider to the alternative provider.

Managed care's coverage of alternative therapies represents a dramatic departure from the usual health insurer refusal to cover treatments considered experimental. If MCOs begin using coverage of alternative health care as a marketing tool, this barrier to premature access to nonvalidated therapies may be co-opted. And finally, where the inclusion of unconventional treatment methods results from successful lobbying efforts that produce mandated benefits statutes, managed care coverage of particular treatments may be a wholly unreliable signal that such treatment methods are medically appropriate and justified.

Responding to Patient Requests for Alternative Therapies

A. That which amounts to nothing more than "quackery"

Doctors should not besruck with quackery, even when such refusal risks termination of the physician's relationship with her patient or even if the physician believes that the alternative approach is unlikely to harm the patient. Quack remedies include any therapy that.

- a. is implausible on a priori grounds (because its implied mechanisms or putative effects contradict well-established laws, principles, or empirical findings in physics, chemistry or biology),
- b. lacks a scientifically acceptable rationale of its own,
- c. has insufficient supporting evidence derived from adequately controlled outcome research (i.e. double-blind, randomized, placebo-controlled clinical trials), (or)
- d. has failed in well-controlled studies done by impartial evaluators and has been unable to rule out competing explanations for why it might seem to work in uncontrolled settings.

Two retorts to this prohibition on physicians providing or co-managing invalidated treatments are readily apparent. First, this prohibition underestimates the value of the placebo effect, which can be of real benefit to some patients. And second, if what the patient seeks is harmless, and it will make her feel better or increase her confidence in or comfort with her physician, what harm exists in the physician going along with the patient's wishes? After all, one of the primary complaints about physicians is their failure to be responsive to their patients' human needs, which is precisely why alternative practitioners are so appealing

to consumers.

Patients have a range of expectations of their physicians, with different patients looking for different things, which may include hope, compassion and comfort. However, patients universally seek effective and safe treatment ; they want to be cured. Consequently, the legal and ethical systems that establish the parameters within which physicians practice must demand at the very least that physicians utilize their skills and knowledge to offer patients treatment which they reasonably believe will actually treat the condition from which they suffer. This minimum requirement precludes physicians from offering as medicine something that is not even if it will, in a psychological or emotional sense, make the patient “ feel better.” To do otherwise misleads the patient about what ultimately matters that she is receiving treatment for her condition.

Beyond this principle, however, medical history is replete with examples of innovative therapies that are believed initially to be miracle cures, but turn out to be disastrous because the cure itself harms the patient or her offspring, or because the patient forgoes something that could have helped her in favor of innovative therapy that fails to live up to its purported therapeutic powers. So, at least viscerally, the claim that a treatment will do the patient no harm should give us some reason for pause. As applied to a patient’s inclination to rely on an invalidated or unproven alternative therapy, the delay in obtaining conventional treatment could cause irreparable harm. Specific alternative remedies present their own hidden risks. Supporters of homeopathy, for example, frequently claim that their remedies are risk-free, but in fact, the remedies sometimes contain enough active ingredient which, if taken inappropriately, can be toxic. The combination of a conventional therapy with a “natural” substance could present a risk to the patient. For example, physicians are currently concerned about patients’ simultaneous use of St. John’s Wort and Prozac. Likewise, yoga can be dangerous after openheart surgery.

B. That which is simply unproven should not be provided

The struggle to determine when to introduce an unproven therapy into the nonresearch or clinical setting is not unique to alternative practices, but arises with the introduction of any innovative treatment :

[H]ow much and what kind of evidence about the safety and efficacy of new treatments is needed; how such things are to be measured; and whether, when, and how new treatments should be made available to patients. If we ought not to do what doesn’t work to benefit patients,

what “works”? How well does it have to work? What amount and kind of evidence of efficacy is sufficient?

FDA regulations govern testing and access to experimental drugs and devices and Department of Health and Human Services regulations govern the conduct of federally funded research. Neither of these provides guidance to physicians whose patients seek unproven alternative treatment.

Consequently, the decision to provide innovative treatment is left largely to the physician's own discretion, subject to the authority of the state licensing board, professional association and the deterrent effect of potential malpractice liability.

Growing dissatisfaction with the extant protocols governing randomized clinical trials as well as with the specific controversy over the applicability of clinical trials to alternative therapies makes the physician's task much more difficult. David Warren argues that the “gold standard” of randomized clinical trials simply does not fit with most of what alternative medicine, a holistic approach to health, is about: Thus, while orthodox medicine allows for scientific proof of the efficacy of particular therapies using composite groups of patients—for example, experimental and control groups—alternative medicine, because it is inherently individualized, does not. To put it another way, orthodox medicine relies on quantifiable, technical aspects of healing, while alternative medicine often responds to the patient on an emotional and intuitive level. This “softness” of alternative medicine, which many regard as its main strength, is from the standpoint of conventional regulation, its chief weakness. It cannot stand up to standard modes of scientific inquiry randomized clinical trials, double-blind studies, and the like because, in important dimensions, it is more a philosophy than a protocol.

It is insufficient to say that, because randomized clinical trials are inappropriate for unconventional treatments, no testing at all need occur before a new therapy becomes the standard of care. If new testing protocols are necessary, so be it. Alternative medicine proponents should assume the responsibility to produce or collaborate with representatives of conventional researchers to develop alternative protocols for clinical testing that satisfy scientific method.

Physicians should not rely on sporadic anecdotal evidence of a therapy's efficacy because such evidence is simply unreliable. The coincidence of the receipt of an alternative therapy with a perceived cure can result from

innumerable factors, including, but not necessarily, application of the alternative therapy. For example, the illness may have simply run its course or be in remission. Alternatively, the patient who uses alternative therapies with conventional medicine might experience a cure or abatement that she credits to the innovative therapy but actually results from the conventional treatment or vice versa. This can only be discovered by objective testing, from which the data will eventually benefit all patients. In short, alternative practitioners who seek integration with traditional medicine and coverage by third-party payers must come up with better evidence of efficacy than anecdotes. To the extent they legitimately charge that alternative medicine is being held to a higher standard than much of traditional medical practice, the response is not to let alternative medicine off the hook, but to equalize the standards.

Until actual safety and efficacy data become available, physicians should not offer or accede to patient demands for unproven treatments. If the treatment is the subject of ongoing research, the physician should refer the patient for participation in a study, or await the results before the clinician herself provides the treatment. Once an alternative therapy is shown to be curative, or important to patient wellness, physicians become obliged to include such options among those they offer to their patients. This strong disposition against acceding to patient demands for alternative therapies finds support in traditional ethical principles and is not, in my view, outweighed by the competing principle of patient autonomy.

The physician-patient relationship requires the physician to be truthful with her patient. This duty of truthfulness circumscribes the provision of care that the physician has no scientific basis for believing the therapy will help the patient. The very fact that it is a physician who prescribes the therapy will endow the treatment with a false sense of legitimacy. Physician assent to the pursuit of unproven alternative treatments will, like managed care coverage, affirm patients' beliefs that innovative treatment offers them some real benefit, and perpetuate a system in which patients' ignorance results in their pursuit of care that they likely would not have elected had they been better informed.

Even after the physician has fully disclosed the experimental nature, uncertainties and risks of a particular therapy, the patient may still want to try it. The physician's duty of competence, to use her skills only to the patient's potential benefit, requires her to decline the patient's request. It is only by resisting the pressures of patients' demands, even when approved by an MCO, that physicians can, in the long run, preserve patients' trust and physicians' integrity. Although patients expect that

physicians will not deny them potentially beneficial treatment due to their own biases or self-interests, they do not expect physicians to succumb to fads or illegitimate pressure to provide treatment that has no reasonable chance of helping the patient. In medicine, that hope is inspired by scientific proof, whether or not the treatment is conventional or alternative.

This affirmative obligation of candor derives not only from the physician's fiduciary obligations to her patient, but also from the obligations to use appropriately scarce resources. Our health care system has evolved to one in which physicians and patients must share with third-party payers the responsibility of efficient and thoughtful information about the likelihood of benefit from the treatment, which should be known, to the extent possible, by the treating physician. Thus, the physician's responsibility of stewardship militates restraint in pursuing what is essentially an experimental regimen that is not a last resort therapy for a terminally ill patient. This discussion, reframed, evokes much of the controversy over patient demands for medically futile treatment. The futility controversy focuses, however, on whether physicians may rebuff patient demands for treatment the physician believes is medically futile, while this Article suggests that physicians should refuse to honor nonterminal patients' requests for invalidated alternative therapies. Still, the analogy is analytically helpful. At its most basic level, the medical futility debate concerns whether patient autonomy justifies affording access by dying patients to treatment that probably will not do the patient, as a person, any good. When the treatment is unlikely, statistically, to contribute to the patient's medical well-being, or would perpetuate a very low quality of life, health professionals and ethicists are divided about the patient's right to demand treatment. In those instances where the physician believes treatment is futile because it will do the patient no good, a general consensus exists that the physician is obligated neither to offer nor to provide the futile treatment. Most would even say that the physician should refuse treatment that, physiologically, will do no good. From this, it is a short leap to the proposition that physicians must refuse to honor requests for invalidated treatment. In the case of nonvalidated treatment, physicians should start with a strong presumption against acceding to the patient's demands.

Disagreement between physicians and patients (or families) over access to a particular kind of treatment, whether it be futile care or alternative treatment, is a "man bites dog" issue which contains an element of patient coercion of physicians. When a patient demands treatment that a physician believes is futile, the physician risks a lawsuit either for

malpractice or for abandonment. Although it is unlikely that a patient has a viable cause of action against a physician who refuses nonvalidated or invalidated treatment, the patient may have leverage against a physician through an MCO, which, if marketing alternative therapies, has accepted a premium from the patient who desires that care, and can terminate an uncooperative physician.

Further, nonvalidated alternative therapy differs in at least a few significant respects from futile treatment. First, the futile treatment debate centers on patients who are terminally ill or have “profoundly diminished lives”; they are seeking treatment that physicians usually must acknowledge may extend their lives, though it is admittedly unlikely. That they are critically ill and the treatment could in fact continue life makes the demand for “futile treatment” more compelling than the demand by nonterminal patients for unproven alternative medicine. Second, futile treatment might, although the probability admittedly is low, provide some benefit to the patient. With unproven alternative therapies, neither the patient nor the physician has any idea (though they may hope or believe) whether it will do the patient any good—the data just do not exist. The medical futility debate is usually about value judgments and risktaking, which falls within the purview of patient autonomy. Whether a particular alternative method has been found to be efficacious, and is a legitimate treatment option for the patient’s condition, is a medical judgment that should remain impervious to claims of patient autonomy. This position is justified by Benjamin Freedman et al.

“Medical treatment” as a normative concept, however, must be defined and delimited by medical expertise rather than by a patient’s beliefs. The right to medical treatment does not encompass every drug or intervention that a patient considers therapeutically worthwhile, on whatever evidence he or she has found convincing. Until the therapeutic advantage of an innovation has been demonstrated to the satisfaction of the community of expert practitioners, an innovation is not medical treatment, and so is not covered by a patient’s right to access to medical treatments.

Once the treatment is proven to benefit someone in the patient’s situation, patient autonomy demands that her physician so advise her, and, if she chooses that treatment, that the physician accede to her wishes or refer her to a competent provider.

Patients may argue that physician refusal to provide alternative therapies for which no evidence of harm exists smacks of paternalism. These patients are right—the physician’s response is paternalistic, but that does not make it necessarily wrong. The regulatory regime of the FDA,

grounded in consumer protectionism, is paternalistic, and justifiably so. It is a regime designed to ensure safety and achieve efficacy, and, in aspiration at least, serves as the model for the rest of medicine to follow.

C. Informed Consent to Unproven Alternative Treatments

If, in the exceptional case, a physician decides that sufficiently positive data exist about an alternative therapy that is not yet the standard of care, and she believes it might benefit a particular patient, the question of what the physician should tell the patient is comparatively easy. Physicians who themselves provide, or agree to co-manage, the patient's receipt of an innovative alternative therapy should advise the patient, in addition to that information generally given as part of the informed consent process, that she should consider the treatment to be experimental. The physician should share at some level of detail the lack of evidence to support the patient's expectations for the treatment, and risks that might attend the patient's use of the therapy, some of which may be presently unknown. The case law governing informed consent to experimental treatment remains surprisingly undeveloped. Case law does support, however, the proposition that the patient should be told when a treatment or procedure is experimental, and the importance of telling patients that uncertainty exists regarding the attendant risks, some of which can only be projected. The courts can deem a treatment "experimental"—and deserving of a heightened informed consent standard—whether or not the treatment is the subject of a clinical trial.

Conclusion

Physicians should withstand the pressures to offer prematurely unproven alternative medicine therapies. They need also recognize, however, that they are largely responsible for patients' dissatisfaction and distrust that propel patients to seek alternatives. One of the primary reasons patients pursue complementary therapies that offer no real benefit is that alternative practitioners are compassionate, spend time with their patients, and are attentive to patients' emotional needs. Pursuit of unconventional therapies also gives patients a feeling of much greater control over their health care and their lives. Some alternative treatments may be superior to conventional medicine, because they offer relief, have fewer side-effects, or are less expensive. It is past time that the medical profession consider what value alternative medicine has for patients, not because managed care compels it or because it is the only way to maintain a sufficient patient base, but because it or because it is the only way to maintain a sufficient patient base, but because it could benefit patients.

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Factors That Shape Alternative Medicine

Daniel P. Eskinazi, DDS, PhD, LAc

The lack of relevant high-quality scientific research has often been given as a reason to explain why a large number of health care practices are termed *alternative*. However, the fact that it required congressional intervention for the National Institutes of Health (NIH) to earmark 0.02% (\$2 million) of its \$10.7 billion 1992 budget to evaluate practices used by more than 35% of the US population suggests that issues beyond the scientific were involved. Nonscientific factors have played a major role in limiting scientific exploration of these areas, have discouraged potential investigators, and have dictated greater profitability elsewhere. This article examines current definitions of alternative medicine and proposes a new one, outlining those factors, sociological (academic), political, regulatory, and economic, that must be considered when exploring this field.

Definitions of Alternative Medicine

Despite increasing use of alternative medicine the creation of the NIH Office of Alternative Medicine (OAM), and increasing health insurance coverage for alternative therapies, no clear definition of alternative medicine has been established. When definitions have been proposed, they included either ad hoc lists of practices felt to be alternative or categorical criteria that are changing rapidly and, therefore, do not allow for a lasting definition of alternative medicine.

Lists of alternative medical practices are disparate and encompass complex traditional health care systems, eg, Chinese (traditional Chinese medicine), East Indian (Ayurveda), Native American, as well as their integrated and complementary components practiced as distinct entities (eg, medicinal herbs, acupuncture, dietary principles, and spiritual practices). These lists also include a wide variety of discrete modalities and products more difficult to categorize. Furthermore, among the proponents of practices such as hypnosis, osteopathy, and chiropractic (which have been taught in degree-granting institutions for more than a century), there is little consensus as to whether these modalities are alternative or mainstream.

Alternative medicine also has been defined as what is not taught in medical schools or not covered by insurance. These definitions also have

drawbacks because their reference criteria are changing rapidly and are not consistent across the country. For example, in the 75 US medical schools that offer courses in alternative medicine, the curriculum varies widely. Health insurance coverage for alternative practices also varies widely among insurers and regionally. Most important, these definitions do not provide a rationale for the term *alternative medicine* to encompass such diverse practices.

Commonalities Among Traditional Health Care Systems

Comprehensive traditional health care systems and their components form much of what is generally understood in the United States as alternative medicine. Other alternative practices or products not originating in a traditional health care system also represent a substantial but less coherent grouping .

Traditional health care systems represent philosophical approaches to managing health and disease that differ substantially from those of Western biomedicine. The question of what is common to these traditional systems has been largely overlooked, but 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 health care. For example, the ancient Chinese health care system was influenced by several spiritual schools, in particular Taoism. Ayurveda, a traditional medical system of India, reflects the traditional Hindu world view.¹³ Similarly, Tibetan physicians practice Buddhist meditation as an integral part of their medical training.

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, and vital force in Western traditions (eg, 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.

Also common to traditional health care systems is the belief in a unity underlying all diversity, implying holism (or wholism), that nothing can be considered in isolation. In the realm of health, these principles lead to considering the persons an indivisible whole, rather than as dissected anatomic parts. Thus, diagnoses and treatments are based primarily on concepts of organ functions, although 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 (eg, sound, color, and taste) for any of the 5 senses, as these allow the individual to interrelate with his or her environment. Similarly, means of communication with the “invisible” environment (eg, meditation or prayer) form an important part of the therapeutic approach.

Conceptual Differences and Commonalities Between Biomedicine and Traditional Health Care

The characteristics common to traditional (alternative) 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.” While biomedicine does not necessarily reject religion or spirituality, it does not routinely incorporate these aspects into diagnosis and treatment (unlike traditional systems). Consistent with this philosophical theory, biomedicine considers biological entities more or less as equal to the sum of their anatomic 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.

As it has not been scientifically demonstrated that “physical matter is the only reality,” materialism, therefore, is akin to a religion, ie, “a system of beliefs held to with ardor and faith.” 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.

Proposed Definition of Alternative Medicine

I propose that *alternative medicine* be defined as a broad set of health care practices (ie, already available to the public) that are not readily integrated into the dominant health care model, because they pose challenges to diverse societal beliefs and practices (cultural, economic, scientific, medical, and educational). This definition brings into focus factors that may play a major role in the a priori acceptance or rejection of various alternative health care practices by any society. Unlike criteria of current definitions, those of the proposed definition would not be expected to change significantly without significant societal changes.

Applications of this definition to Western society include the following:

- (1) *Cultural* : health care systems may have developed outside mainstream American culture and may not be consonant with our cultural values;
- (2) *Economic* : therapies similar to conventional pharmacological approaches (ie, based on the use of purified molecular species, eg, antineoplastons) can be considered alternative. These tend to be therapies that are developed by private practitioners, bypass established economic networks (eg, pharmaceutical industry, research institutions, and hospitals) and have difficulties going through the steps generally required to achieve acceptance in conventional medical practice;
- (3) *Scientific beliefs* : there exists no scientific explanation for how some practices (for example, homeopathy and noncontact practices such as *Reiki* and *Qi gong*) could possibly work. However, the paucity of research data is most likely due to their being alternative;
- (4) *Medical* : holistic medicine practices often focus on preventive and therapeutic enhancement of existing biological mechanisms (eg, the immune system), and do not follow the allopathic model; and
- (5) *Educational standards* : some practices are passed on from generation to generation through oral tradition, rather than through formal training at special schools or institutions.

The proposed definition also is relevant to whether the term *alternative or complementary* is used. The origin of a practice may be alternative (eg, culturally or economically different), while its use can be complementary with biomedicine (or other alternative practices).

Sociological and Academic Parameters

For decades Western academia has excluded alternative medicine research and practice; this has contributed much to the paucity of data in this area. Established academic researchers have been discredited and have had difficulties when attempting to conduct alternative medicine research. At times, explicit threats were made by mainstream medicine to individuals and institutions that would associate with alternative medicine practitioners. Consequently, most alternative medicine research has been conducted outside of academia by individuals with limited research training and resources, and their investigations are often methodologically inadequate. Conversely, those studies deemed

methodologically sound may lack comparability and replication. For example, lack of funding differences among individual investigators' resources, and personal research interests have limited replication of studies in homeopathy and acupuncture.

This atmosphere, in which academic investigators were concerned about the impact that their interest in alternative medicine might have on their good standing and their livelihood has been particularly unfavorable to the development of high quality academic research. This is changing, as the creation of the OAM has helped to legitimize alternative medicine evaluation and allowed these investigators to manifest openly their interest. The result has been the creation of 13 academic centers dedicated to alternative medicine assessment at major US institutions.

Political, Economic, and Regulatory Parameters

The interaction of politics and science in the arena of health care, one of the most lucrative industries in the United States, has played a significant role in recent development of alternative medicine in the United States. For example, in October 1991, the US Congress instructed the NIH to create an Office of Unconventional Medical Practices, later renamed the Office of Alternative Medicine. The congressional mandate was met with a less than enthusiastic response from the NIH, but simultaneously with high public expectations. Compounding the difficulties, other key governmental agencies, in particular the Food and Drug Administration (FDA), were overlooked in the mandate, although their role was necessary and complementary to that of the OAM.

Similar to other federal programs, the activities of the OAM must comply with FDA regulations and policies. Yet, FDA regulations designed for conventional drugs and devices are not always applicable for alternative medicine products. For example, regulations are designed for conventional products that require research before becoming publicly available. Considerable economic incentives usually justify corporate sponsors of new therapies to submit to the FDA's stringent and onerous regulations. Conversely, alternative medicine products are, by definition, already available, which lessens the drive for research. In addition, there is little incentive for conducting alternative medicine research, as it seldom leads to significant economic benefit. For example, research into homeopathy or medicinal plants usually does not lead to economic advantages for sponsors, because these products are not proprietary. Similarly, lack of economic incentive (due to limited markets) also led to insufficient research in the biomedical area of rare diseases and required special governmental incentives.

There are several reasons, other than economic ones, that current regulatory criteria may be difficult to apply to alternative practices, in particular traditional practices from other cultures. For example, these practices follow different diagnostic classifications than biomedicine, and the complex substances (eg, botanical, animal products) they use cannot easily meet the criteria established for essentially pure drugs or even for conventional biologics. However, the FDA recently has begun addressing the issues posed by evaluation of alternative medicine products. Representatives from the FDA actively participated in the organization of 2 conferences that addressed the special considerations of acupuncture and of botanical medicines.

Conclusion

Nonscientific factors contribute to defining the scope of alternative medicine and the context for its evaluation. Economic promise of growing markets may lead to a focus on developing profitable alternative medicine products rather than on improving health care and also may lead away from addressing issues that have prompted the public to seek alternative medicine practices. Nonscientific and scientific factors are shaping this unusually heterogeneous and potentially fruitful field and must be taken into account for a thoughtful evaluation to yield more than incremental progress.

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Physicians' Ethical Obligations Regarding Alternative Medicine

Jeremy Sugarman, MD, MPH, MA
Larry Burk, MD

A Substantial proportion of patients use alternative medicine, spending an estimated \$13 billion each year. Complementary and alternative medicine incorporates "all health systems, modalities, and practices other than those intrinsic to the politically dominant health system of a particular society or culture" and "includes all practices and ideas selfdefined by their users as preventing or treating illness or promoting health and well-being." Under this definition, the scope of professional obligations regarding alternative medicine for clinicians who provide conventional medical care is unclear. Despite the popularity of alternative medicine, conventional medicine is arguably the politically dominant health system with a somewhat circumscribed set of practices that differ from alternative therapies. However, given the strong professional obligations clinicians have toward helping patients meet health related goals, the scope of these obligations with respect to alternative medicine deserves discussion.

Alternative medicine and conventional medicine share some important goals, which provide some support for a limited professional obligation toward alternative medicine. Nevertheless, fundamental differences in these approaches raise questions about cultural relativism. While these questions are challenging, using a principle- based analysis, we describe the scope of the professional obligations of clinicians who typically practice conventional medicine toward alternative medicine. We do not directly address the full range of ethical issues, including the professional responsibilities for alternative medicine practitioners, despite the obvious implications for patients. Therefore, our arguments are relevant only in those situations in which alternative medicine practitioners hold the interests of patients foremost and alternative medicine is practiced with integrity and honesty. For clarity, we use "Clinician" to refer to those who provide conventional medicine and "Practitioner" to those who render alternative medicine.

Comparing Modalities

Conventional modalities (such as surgery and drug therapy) rely on the scientific method whereas alternative medicine modalities (such as acupuncture and therapeutic touch) do not. However, there are considerable similarities among conventional medicine and some forms of alternative medicine. For example, alternative dietary supplements may be a pill or capsule and dietary therapy is an established element of the conventional treatment of heart disease.

Similarly, while the definition of alternative medicine alone sets it apart from conventional medicine, their core health related goals may not differ radically. Bratman describes 4 values espoused by alternative medicine practitioners: (1) Use of natural remedies rather than artificial drugs, (2) Getting to the root of problems rather than treating symptoms, (3) Treating the person instead of attacking the disease, and (4) Preventing illness rather than treating it after the fact, and promoting wellness rather than the mere absence of disease. Conventional clinicians share similar values. For instance, a recent international project specified 4 goals of medicine; (1) The prevention of disease and injury and the promotion and maintenance of health. (2) The relief of pain and suffering caused by maladies, (3) The care and cure of those with a malady, and the care of those who cannot be cured, and (4) the avoidance of premature death and the pursuit of peaceful death.

The concordance of these values is tangible in the current national dialogue about death and dying in which both alternative medicine and conventional medicine now hold that death is not necessarily a negative outcome and palliative care is considered an appropriate option. Both approaches also endorse attention to healing as well as curing, particularly for chronic illnesses in which a cure is often not possible. Shared health related goals and values such as these lend some support for a limited professional obligation toward alternative medicine that is consistent with a professional obligation toward helping patients achieve these goals. Nonetheless, this obligation is certainly limited to steps that have been proven to be safe and effective, but it may be further limited by the range of practices that fall within the domain of conventional medicine.

Distinct Cultures of Healing

Despite shared values and goals, alternative medicine and conventional medicine differ in important ways. First, many alternative medicine modalities are derived from cultures other than the Western one in which conventional medicine was developed, and many of the practitioners

subscribe to a different worldview. Second, by definition, alternative medicine represents a different approach to healing. Third, users of alternative medicine tend to perceive these modalities, in comparison to conventional ones, in greater concordance with their views toward health care. Thus, there seems to be distinct cultures of healing, which is somewhat analogous to situations that conventional medicine encounters in other cultures. For instance, what constitutes appropriate research in developing countries? Should patients be told about a diagnosis of cancer? Should advance directives be discussed with patients whose culture proscribes these discussions? How should clinicians respond to requests for female circumcision? In each of these cases, just as when clinicians encounter alternative medicine, it is essential to determine an appropriate response. When is a *laissez-faire* approach acceptable? When is there an obligation to intervene on behalf of patients? In making such determinations, it is essential to be vigilant in ensuring that these determinations are not clouded by hegemonic concerns about social status, market share, unfamiliarity, or prejudice.

The spectrum of possible responses to alternative medicine is quite broad, ranging from an obligation to stifle harmful practices to mere acceptance of nonharmful modalities, to encouraging the use of beneficial interventions. Obviously, none of these singular approaches is adequate or appropriate in all cases. Rather, given the diversity of modalities embraced by a broad definition of alternative medicine and medical uncertainties regarding safety and efficacy, each approach is at times correct. The patient, the illness, and the alternative modality shape the appropriate set of obligations in a particular case. This obligation is refined and justified by attending to a set of inherent ethical principles of the medical profession: respect for persons, nonmaleficence, beneficence, and justice.

Respect for Persons : The ethical obligation of respect for persons, or autonomy, finds application in now well-established expectations of shared medical decision making and informed consent. Such expectations have been endorsed not only on ethical grounds, but also on prudential grounds such as enhanced compliance. Respect for persons also helps prescribe appropriate behavior in the setting of cultural relativism. A thorough respect for persons permits patients to reject unwanted interventions and to make choices that are consonant with their values.

Given the ready availability of information about alternative medicine,

many patients may be quite familiar with particular modalities. While a knowledge gap between clinicians and patients regarding alternative medicine modalities may exist, it does not necessarily follow that respect for patients in making decisions regarding alternative therapies excuses conventional clinicians from playing any role whatsoever. Rather, clinicians have an obligation to discuss treatment alternative with their patients and should be frank about their level of understanding of nonconventional interventions. Even without previous knowledge of particular modalities, clinicians can help patients focus their inquiry and thereby enhance their decision making. For instance, clinicians should ensure that patients have received information about safety (including potency, bioavailability, and drug interactions) as well as efficacy.

Respecting persons also include making recommendations and using persuasion to help them reach accepted health related goals. The efficacy, acceptability, and safety of conventional and alternative medicine approaches for treating a particular disorder are critical in determining the precise role in a given situation. For example, it is less appropriate for professionals to exert strong influence on patients' decision making regarding alternative medicine for diseases in which there is no clearly effective conventional treatment (eg. fibromyalgia), whereas such influence is appropriate when there are known effective therapies for a life-threatening disease (eg, a treatable bacterial infection).

More difficulty arises in determining the appropriate role of clinicians when there are alternative medicine approaches for conditions in which conventional therapies have some efficacy although treatment is not completely satisfactory. For example, while conventional medicine offers both disease modifying and symptomatic treatments of rheumatoid arthritis, it would be advantageous if complementary approaches could diminish the need for the use of drugs that have deleterious adverse effects (eg, steroids). Such situations are difficult because of insufficient information regarding the safety, much less the efficacy, of using alternative medicine alone or in combination with conventional medicine. This uncertainty makes truly informed decision making difficult at best and hazardous at worst. Nevertheless, clinicians should be prepared to give patients available and appropriate information about the safety and efficacy of conventional therapies in treating their illnesses, encouraging them to seek similar, reliable information about alternative medicine.

Nonmaleficence : Not harming patients unnecessarily in the process of providing care is a well-recognized ethical principle. Although clinicians

may not be prescribing or providing alternative medicine, the obligation for nonmaleficence still plays an important role. In short, it is incumbent on clinicians to elicit information about patients' use of alternative medicine modalities. Such information is part of taking a comprehensive medical history since use of alternative medicine might be having some influence on patients' complaints and also may guide decisions about appropriate treatment. This is critical since some alternative medicine therapies are known to be harmful. In addition, there may be harmful interactions between conventional and alternative medicine therapies. For example, conventional antidepressants act on the same neurotransmitters within the central nervous system as does St John's wort.¹⁵ Thus, a medical history that includes information about a patient's use of alternative medicine is critical in avoiding harm.

Beneficence : Clinicians have a clear obligation to help patients achieve legitimate goals of medicine such as promoting health, prolonging meaningful life, and attenuating suffering. Accordingly, effective interventions obviously should be considered in determining a plan of care for patients. Therefore, a limited obligation does exist on the part of clinicians to make patients aware of safe and effective alternative medicine modalities. Unfortunately, although efforts now are under way to provide systematic data regarding some forms of alternative medicine, few systematic data are currently available to help clinicians and patients aware of safe and effective alternative medicine modalities. Unfortunately, although efforts now are under way to provide systematic data regarding some forms of alternative medicine, few systematic data are currently available to help clinicians and patients make important decisions in this regard.

In the face of popular enthusiasm about alternative medicine, physicians may feel pressured to learn to prescribe beneficial alternative medicine modalities. While learning such interventions may be beyond the scope of clinicians' professional obligations, should individual clinicians elect such training, the training itself must be adequate and appropriate. Efforts are under way to provide this sort of training. As with conventional medicine, physicians should not adopt interventions until they have sufficient experience to use interventions safely and effectively. Accordingly, there is room for appropriate referral and consultation with alternative medicine practitioners. This includes referral and consultation when there is both an increased likelihood that the patient will benefit from the interaction and that the practitioner is experienced as well as accredited or licensed.

Justice— A central concern of justice in health care relates to fairness. Fairness suggests that patients have fair access to alternative medicine therapies as well as conventional therapies that are known to be safe, effective, and appropriate for their conditions. Nevertheless, because little clinical research has evaluated alternative medicine, few data support claims for fair access to these therapies. This predicament, similar to that encountered in caring for children and pregnant women (groups for whom there is a relative paucity of data regarding safety and efficacy of conventional therapies to guide treatment decisions) suggests the need for research efforts in this area. Given the broad use of alternative medicine, as well as the possibility that some modalities will prove to be beneficial, clinicians ought to endorse legitimate efforts aimed at the careful evaluation of conventional and alternative interventions so that they will be better positioned to help guide medical decision making. Despite this argument, some skeptical clinicians may still object, claiming that investigating these approaches wastes scarce research dollars and encourages patients to invest their money in sources of false hope. Nevertheless, if this research is conducted properly, the extent to which alternative medicine therapies meet patients' expectations will be clear. Armed with these data, harmful or useless practices could be abandoned and clinicians would be better positioned to help their patients make informed decisions to reach essential health-related goals.

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Investigating Alternative Medicine Therapies in Randomized Controlled Trials

Arthur Margolin, PhD¹

S.Kelly Avants, PhD¹

Herbert D. Kleber, MD²

Because alternative medicine therapies are used by a significant number of Americans and people worldwide,³ there is an urgent need for their efficacy to be evaluated formally. The most stringent evaluation would take place within the “gold standard” for clinical research: the randomized controlled clinical trial (RCT). However, alternative medicine comprises a large and heterogeneous group of treatments,⁴ many of which are procedures that are not readily testable under blinded conditions and for which the choice of appropriate control conditions is by no means straight forward. Furthermore, alternative medicine therapies may also possess a theoretical basis, may stem from a cultural tradition that is seemingly antithetical to a quantitative, biomedical framework, or may possess little foundational research on which to base a controlled evaluation. In this article, we discuss a number of key methodological issues that arise in the controlled evaluation of one widely used alternative medicine procedure acupuncture for the treatment of cocaine addiction, and we offer some suggestions for how these issues may be addressed.

Basis for Undertaking a Controlled Trial

An important principle governing the justification for conducting an RCT is that a condition of genuine clinical uncertainty, or equipoise, exists among clinical experts regarding the relative benefits of the trial's treatments. However, the application of this principle entails a community of colleagues sharing basic assumptions and a common knowledge base, with consensus views founded on empirical investigations. These conditions may not be satisfied with respect to considerations of alternative medicine, which typically involve heterogeneous groups comprising incommensurate cultural and evaluative frameworks and, more often than not, a paucity of systematically derived data. Even within the biomedical community, alternative medicine generates considerable controversy. The application of traditional concepts of

¹ Substance Abuse Center, Yale University School of Medicine, New Haven, Conn

² Center on Addiction and Substance Abuse at Columbia University, New York, NY

“clinical equipoise” to alternative medicine is therefore an unsettled question, much in need of elucidation and a statement of general principles. Lacking this, investigators of an alternative medicine treatment must negotiate the justification to conduct the trial, as well as criteria for informed consent, on a case-by-case basis. Relevant to this discussion is whether the alternative medicine treatment is being compared with conventional treatment is being compared with a conventional treatment as an alternative, as a supplement, or, where no effective conventional treatment is available, with an inactive control condition, along with whatever preliminary evidence concerning safety and efficacy is available.

Auricular acupuncture for the treatment of cocaine addiction demonstrates how a confluence of circumstances, within both Western medicine and alternative medicine, creates a context within which the evaluation of an alternative treatment can generate board support. Among the circumstances that support a formal investigation of acupuncture for the treatment of cocaine addiction are (1) Cocaine addiction is a serious public health problem. (2) There is a lack of effective conventional treatments for the disorder. (3) There is widespread provision of acupuncture for cocaine addiction. Currently more than 300 clinics in the United States offer acupuncture as part of their addiction treatment programs. (4) Preliminary studies investigating the effectiveness of acupuncture in the addictions have reported positive results.

Is the Treatment to Be Evaluated Codified and Accepted?

Because alternative therapies do not possess well-established clinical practice guidelines, wide variations may exist in the treatment provided for a given disorder. This raises the issue of whether the experimental treatment is regarded as representative of common practice in the field, and, if so, whether the treatment has been standardized for the trial’s Diagnostic category. The credibility of the study will depend in part on whether before a trial is undertaken, a consensus has been reached that the treatment being tested is the most appropriate for the target disorder. This consensus can be inferred either by expert opinion. or, where it exists, through standards of practice guideline. In addition, like conventional treatments, alternative treatments are most cogently investigated in trials that pose well-defined questions with respect to specific diagnostic categories based on validated assessment instruments. Auricular acupuncture for treating cocaine addiction satisfies these conditions insofar as the experimental treatment is codified in the widely used protocol established by the National

Acupuncture Detoxification Association and can be delivered to patients meeting Diagnostic and *Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)* criteria for cocaine abuse or dependence by practitioners trained by the acupuncture association.

Identification of Objective Outcomes

Similar to any treatment, alternative medicine therapies are prone to expectancy effects and other influences that may lead to biased self-reports of outcomes. For this reason, and in view of the possibility of selection bias as well as the need to enhance the credibility of alternative medicine research, it is important that objective measures be included in alternative medicine studies whenever possible. For example, an RCT designed to test the efficacy of acupuncture in treating cocaine addiction could address this straightforwardly by obtaining urine toxicology screens 2 or 3 times a week. Identifying objective outcomes of other alternative medicine therapies or other target disorders may present a greater challenge.

Devising Adequate Controls

The development of control conditions for alternative medicine therapies poses a number of problems, such as the mechanism of action is usually not well understood, the treatment is typically a procedure that involves some degree of interaction between patient and treatment provider, and the development of controls for procedures is significantly more complex than for pharmacotherapies.¹⁵ Yet, given the controversy and outright skepticism concerning alternative medicine treatments, the use of well-designed controls in their evaluation is an important factor in establishing the credibility of the trial and, therefore, the treatment being evaluated. For auricular acupuncture, controls for both needle-insertion effects and nonspecific effects, such as relaxation, may be required. Controlling for needle insertion, a “ritual” that might elicit a placebo response in drug users independent of any acupuncture specific mechanism involves inserting needles into so-called “sham” points, which are presumed to be ineffective for the target disorder. This simple statement belies numerous complexities. Traditional Chinese medicine does not include the concept of a “placebo,” and the organismic model that underlies traditional acupuncture theory does not embody a concept of an “inert” treatment. Furthermore, within a Western framework, there is no biochemical “marker” of an active auricular treatment, nor is there one that would differentiate an active from a control treatment. Hence, unknown relative levels of therapeutic activity between active and control conditions constitutes a potentially serious impediment to the interpretation of findings in acupuncture research.

Key issues to consider when devising a needle insertion control include ensuring the comparability of control and active treatment with regard to any aversive effects that may affect dropout or subjective response to treatment (eg, pain or discomfort caused by the treatment), and identifying a theoretical and empirical basis for regarding the control treatment as less active than the experimental treatment as less active than the experimental treatment. In addition, there would ideally be an objective method for determining specifically where the needles are to be inserted within the hypothesized “active” and control regions. In seeking guidance on these issues, the extant literature should be approached critically. For example, in preliminary studies, we found that (1) a commonly used control in auricular acupuncture studies, insertion of needles proximate to active points, though no more painful than active sites, is probably too active to be suitable control; (2) needling of regions on the ear helix, in points relatively removed from the active sites and that are not indicated for the treatment of addiction, is rated least active and least preferred by patients who use cocaine compared with 3 other auricular needle configurations and, therefore, may represent a more appropriate control; and (3) “active” auricular sites can be differentiated from control sites on the basis of their electrical resistance characteristics. However, some commercially available “electrical point finders”, used to select points for needle insertion, may be unreliable due to circuit design problems and pressure artifacts.²³ The development of adequate needle-insertion controls is an area still much in need of further research. Consideration should also be given to controlling for nonspecific effects of the treatment context that may affect the target disorder. In the case of addiction, this may include controlling for the effects of relaxation induced by sitting quietly for 40 minutes daily to receive the acupuncture treatment, because relaxation has been associated with reduced drug craving. Control conditions should possess the nonspecific elements of the acupuncture treatment context, including credible rationale, equivalent time demands, and similar patient-staff contact. We note that standard care comparison groups do not usually contain these elements. Precisely what aspects of the experimental treatment such groups control for should be carefully considered in determining their suitability in an RCT.

Difficulties of Blinding Procedures

Blinded conditions in an RCT control for a host of potential confounds and biases, and they provide conservative estimates of treatment efficacy. However, evaluations of procedures, unlike those of pharmacotherapies, are nearly impossible to conduct under conditions in which both the

patients and practitioners are blinded. Training and competency are a prerequisite to providing the treatments, and experienced practitioners will know which treatment is hypothesized to be active. Unlike pharmacotherapy studies in which the active medication and the pill placebo can be made to be identical in appearance, procedures are observably different to all of the participants in the study. Therefore, acupuncture RCTs may need to be conducted unblinded, with multiple checks on bias.

Guarding Against and Checking on Bias

Following Pocock, at least 3 categories of participant bias that may be considered in RCTs of alternative medicine are treatment providers, patients, and staff. For any procedure, the interaction and ongoing relationship between the treatment provider and patient presents opportunities for the treatment provider to influence outcome, knowingly or unknowingly. Several approaches to check this tendency can be implemented in RCTs of alternative medicine by imposing constraints on the patient-treatment provider interaction; monitoring these interactions by a third party; and evaluating the practitioner-patient relationship across treatment groups. Various factors associated with study patients also represent a potential source of bias. In any RCT, the treatments must be described simply and factually to patients to ensure properly informed consent. However, this information should be communicated in a way that minimizes expectancy effects; it should neither enhance the experimental treatment nor introduce bias against the control conditions. Treatments that are regarded as credible when administered, even if they are subsequently shown to be ineffective, can result in significant improvement in the target disorder. Hence, for studies of alternative medicine, it is important to design the active and control treatments to be equivalently credible and to assess the credibility of the treatments. One way to accomplish this is through multiple administrations of a treatment credibility assessment instrument, which permits for comparisons across groups of patient- perceived credibility of the assigned treatment. In any RCT, staff bias can operate on a number of different levels and must be protected against. This may be especially important in the evaluation of controversial therapies or in treatments about which participants may be thought to have strong positive or negative opinions. The use of a primary objective outcome (eg, urine toxicity screens in addiction studies) may protect against patient bias as well as staff bias from influencing patients' self-reported change, assessment interviews should be conducted by staff members blind to treatment assignment.

Conclusion

The validity and credibility of alternative medicine investigations will be enhanced by using research designs that embody the highest standards for demonstration of efficacy: the randomized clinical trial. However, controlled evaluation of alternative medicine therapies may require its practitioners to undertake a fundamental conceptual shift from a view of patients as requiring individualized treatment that may vary at each session to one in which trial participants are regarded as members of an equivalence class, defined by the diagnosis, who all will be given a standard prescribed treatment. Although in this article we have urged the use of RCTs for evaluating alternative medicine therapies and have discussed some of the problems that arise in this endeavor, we recognize that this approach may be viewed by others as irremediably distorting the content of those treatments. This complex issue, comprising a wide range of opinions concernig the cultural relativeity of methodological principles, has yet to be resolved.

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Complementary Medicine and the Cochrane Collaboration

Jeanette Ezzo, PhD¹ ; Brian M. Berman, MD¹
Andrew J. Vickers, MA² ; Klaus Linde, MD³

Every year, millions of US consumers spend billions of dollars on alternative and complementary medical treatments. A similar trend exists in the United Kingdom and Australia. As people increasingly use these treatments, questions arise from consumers, clinicians, payers, and policymakers as to the effectiveness of these interventions.

The Cochrane Complementary Medicine Field

To meet the increasing demand for evidence-based complementary medicine (CM), a CM Field, funded by the National Institutes of Health Office of Alternative Medicine, was established within the Cochrane Collaboration in 1996. The goal of the Cochrane Collaboration is to produce, maintain, and disseminate systematic reviews on all topics in health care. The CM Field focuses on CM topics. Two major products of the Cochrane Collaboration are a database of systematic reviews and the Cochrane Controlled Trials Registry, the largest registry of its kind. Both databases are updated quarterly with information added regularly by the CM Field.

The systematic review is a method par excellence for synthesizing evidence on a given topic, and policy agencies are increasing use of it to summarize evidence. Cochrane reviews are more transparent than other reviews, so that conclusions are replicable and methods are explicit. Systematic reviews are valuable even when the results are inconclusive because reviews point out where knowledge gaps exist.

Search Strategies to Retrieve Randomized Trials of CM

Since the CM Field has been functioning, a great deal of effort has focused on laying the groundwork for reviews by constructing a database of randomized controlled trials (RCTs) on CM topics. Capturing all relevant trials in MEDLINE has yielded surprising challenges. The scope of practices defined as complementary within the CM Field is broader

¹ Complementary Medicine Program, School of Medicine, University of Maryland, Baltimore

² Research Council for Complementary Medicine, London, England

³ Center for Complementary Medicine Research, Technical University, Munich, Germany

than those captured in a MEDLINE search of the term *alternative medicine*. For example, Chinese movement therapies such as Qigong and Tai Chi are considered complementary therapies by the Field's standards, but are not accessed by a hierarchical MEDLINE search of the term *alternative medicine*. Similarly, herbal remedies may be described by MEDLINE as plant extracts rather than by any alternative medicine term. To aid MEDLINE searching, a 250-line MEDLINE search strategy has been written and is available for public use.

Assessments of MEDLINE sensitivity (the proportion of RCTs identified by a MEDLINE search relative to a "gold standard" of the known number of RCTs) have demonstrated that on average, MEDLINE searches yield only half of all known trials on a given topic, with CM topics usually scoring below average (eg, 17% for homeopathy, 31% for *Ginkgo biloba*, and 58% for acupuncture). The first reason for low MEDLINE sensitivity may be that articles are appearing in journals not indexed by MEDLINE. This is true for acupuncture and vitamin C for the common cold. Of approximately 16000 serial medical journals worldwide, MEDLINE references about 3700 (23%). Of the 695 CM journals worldwide identified by the Office of Alternative Medicine and the National Library of Medicine, MEDLINE indexes 69 (10%). Collaborations between the National Library of Medicine, the CM Field, and the Office of Alternative Medicine should soon result in increasing the number of indexed CM journals and expanding the MEDLINE thesaurus to include more CM search terms. To retrieve studies indexed in other databases, the CM Field is searching both standard medical databases and specialized CM databases. By mid-1998, the Cochrane CM Trials Registry contained more than 3500 RCTs, with only 33% identified by a MEDLINE search for RCTs in alternative medicine and 20% not found in MEDLINE. Periodically, the CM registry uploads its trials to the Cochrane Controlled Trials Registry, making these trials available to individuals with access to the Cochrane library. The CM Field maintains the CM registry, adds new trials, assists reviewers doing CM reviews, and proactively provides references to all 40 Cochrane Collaboration reviews and protocols that have a CM component. A second reason for low MEDLINE sensitivity is that articles exist in journals that are not indexed by any electronic database. Volunteers within the CM Field are now searching by hand approximately 40 indexed and nonindexed journals in English, German, Italian, Japanese, and Spanish and are reading every article published in these journals back to their first issues to locate every RCT.

Publication Bias

A third reason for low MEDLINE sensitivity is that studies exist that have never been fully published in any journal ("gray literature"). Estimates from conventional medicine show that only about 50% of the RCTs that appear as conference proceedings ever materialize into published journal articles. Some observations estimate CM gray literature to be at least as plentiful. Complementary medicine gray literature includes expected sources, such as conference proceedings and dissertations, and unexpected sources such as US patents records.

Beyond the hard-to-find trials in the gray literature lie the even harder to find studies that do not appear in print anywhere and exist only in homeopathic company data files or researchers' file drawers. Gray literature plus unpublished data are collectively termed unpublished studies. Publication bias is "the tendency of investigators, reviewers, and editors to differentially submit or accept manuscripts for publication base on the direction or strength of the findings." To the extent that publication bias exists, systematic reviews that omit unpublished studies risk overestimating treatment effects. Bias has been demonstrated both in what investigators submit to journals and what conference abstracts editors accept. However, whether to include unpublished studies in reviews is still a source of debate. The influence of unpublished studies in CM systematic reviews is being analyzed by the CM Field as part of a review of 164 CM systematic reviews. Until the value of including CM unpublished studies can be answered more conclusively, the CM Field will continue to search for unpublished studies to help answer a frequently asked question: How much evidence exists in CM?

Examining how publication bias skews the CM evidence is important for the CM Field because some forms of publication bias may be unique to CM. One question is whether both positive and negative publication biases exist in CM. Asked another way, do CM journals tend to publish results favoring CM treatments and conventional medical journals publish results not favoring CM treatments?

Examining publication bias is not always straight forward. A study by the CM Field found that studies published in Russia and China had a disproportionately high number of statistically significant results (97% and 99%, respectively) when compared with England (75%) It is not yet evident whether these high proportions are due to extreme forms of publication bias or low study quality, which overestimated treatment effects. The CM Field is obtaining translations of these studies to examine study quality.

The qualitative results will determine whether it is practical to devote efforts to the tedious task of identifying unpublished studies.

Language Bias

Moher and colleagues demonstrated that the quality of studies published in French, German, Spanish, and Italian is comparable with those published in English. The present research of the CM Field will extend methodological quality knowledge into studies from Russia and China. Egger and colleagues demonstrated that a language-related publication bias exists in which authors who publish in both German and English tend to report nonsignificant findings in German and significant findings in English. Preliminary observations suggest that an additional language bias may exist for CM. Regardless of whether results are significant, some CM topics are almost exclusively published initially in languages other than English. Asystematic review on St John's wort for depression noted that none of the trials had been originally published in English, although some were subsequently published in English. A similar experience has been reported for *Ginkgo biloba* for cerebral insufficiency, which suggests that for certain topics in CM, there may be a language-related publication lag time-a trend not reported for conventional medicine. Trends such as this underscore the importance of the CM Field's effort to retrieve trials in languages other than English and to identify biases that may be unique to CM.

Quality Assessment of RCTs

Assessing study quality also may improve the validity of systematic reviews. The finding that low-quality studies have repeatedly yielded exaggerated treatment effects has been documented for conventional medicine and acupuncture. Yet, methodological assessments are sometimes absent from non-Cochrane Collaboration CM systematic reviews. A summary of 29 meta-analyses of mind-body techniques, for example, demonstrated that only about half assessed study Quality. Although assessing study quality cannot compensate for fraudulent or inaccurate reporting, it can provide additional validity related information to guide reviewers' conclusions. For CM, quality assessments will provide needed answers to another commonly asked question: How good is the quality of CM trials?

Titles of Cochrane Systematic Reviews Pertaining to Complementary Medicine

● Reviews completed

- Acupuncture for asthma
- Acupuncture for nicotine addiction
- Balneotherapy (spa therapy) for arthritis
- Cabbage leaves to reduce breast engorgement in nursing mothers
- Garlic for lower-limb atherosclerosis
- Homeopathy for asthma
- Hypnosis for smoking cessation
- Massage for low-birth-weight infants
- St John's wort for depression
- Vitamin E for intermittent claudication
- Vitamin C for the common cold

● Reviews in progress

- - Acupuncture for lower back pain
- Acupuncture for headache
- Acupuncture for osteoarthritis
- Alexander technique for asthma
- *Echinacea* for the common cold
- Evening Primrose Oil for premenstrual syndrome
- *Ginkgo biloba* for dementia
- *Ginkgo biloba* for intermittent claudication
- Manual therapy for neck pain
- Manual therapy for asthma
- Marine oil supplementation for type 2 diabetes mellitus
- Music therapy for dementia
- Padma 28 for intermittent claudication
- *Pygeum africanum* for benign prostatic hyperplasia
- *Secale cereale* for benign prostatic hyperplasia
- *Serenoa repens* for benign prostatic hyperplasia
- *Spinal manipulation* for low back pain
- Therapeutic Touch for wound healing
- Yoga for epilepsy

This quality question is usually raised as an implication that CM trials reflect lower methodological quality than conventional medicine trials. To examine this notion, Cochrane Collaboration methodologists are collaborating with members of the CM Field to compare the methodological quality of CM trials with conventional medicine trials on the same diseases. Low-quality meta-analyses for analgesic interventions have been found to be associated with more positive results than high-quality meta-analyses. The analysis of CM reviews is to examine whether this can be replicated in low-quality vs highquality CM reviews, and how conclusions of low-quality vshighquality CM reviews on the same topic differ.

Reviews completed by the CM Field

The CM Field has completed systematic reviews on acupuncture, massage, homeopathy, and herbal medicine. Nineteen reviews are in process (Table), and the CM Field has commented on protocols of 12 planned and completed reviews.

Conclusion

Although there is no guarantee that systematic reviews will result in changing policy and practice, there is increasing evidence that policy organizations rely on systematic reviews more than they have in the past and that practitioners rely on reviews as a primary information source. It has also been suggested that consumers can use reviews to guide decision making. Traditional literature reviews, however, have lacked explicit methods and have been susceptible to biases that generally tend to overestimate treatment effects. Therefore, at a time when the public is using CM treatments in record numbers and an explicit peer-reviewed and regularly updated systematic review method exists, it is imperative to apply this method to CM. The Cochrane Collaboration provides a forum of interdisciplinary cooperation in which to produce these reviews that we hope will result in improved patient care.

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Medical Malpractice Implications of Alternative Medicine

David M. Studdert, LLB. ScD. MPH¹; David M. Eisenberg, MD²;
Frances H. Miller, JD³; Daniel A. Curto, JD⁴;
Ted J. Kaptchuk, OMD²; Troyen A. Brennan, MD. JD. MPH¹

Many Americans seek medical care from practitioners of alternative medicine. (We define *alternative medicine* as medical interventions not taught widely at US medical schools or generally available at US hospitals. In 1990, chiropractors, acupuncturists, massage therapists, naturopaths, and a variety of other practitioners of alternative medicine received 425 million visits, for which patients paid \$10.3 billion in out-of-pocket expenses. Financial analysts have suggested that consumer spending on alternative medicine may have surged 69% since 1989, and the market may be growing as fast as 30% annually. Employers and insurers, including several major managed care organizations such as Oxford Health Plans and Health Net, have recently begun to respond to this demand by adding alternative therapies to their insurance products. As well, state legislatures have enacted laws that require health insurers to include alternative treatments in the benefits they cover.

Despite this activity, coordination between alternative and conventional medical care remains poor. An estimated 90% of patients using alternative medical care are not referred by their physicians (MDs or DOs) but are, instead, self-referred. This lack of communication and the absence of proactive referral for alternative treatment or, when appropriate, professional advice to avoid alternative care are unfortunate from a quality perspective. Various measures to improve the coordination between physicians and alternative medicine practitioners have been proposed.

Improved quality of care in this area is frustrated by a long-standing professional rivalry between organized medicine and unorthodox health care practitioners. However, a more fundamental obstacle is physicians' lack of knowledge about the appropriateness and efficacy of alternative medicine. While anecdotal evidence abounds, only a few well-designed clinical studies have examined the efficacy of alternative medicine therapies. Additional outcomes studies and randomized trials are only now being launched.

¹ Department of Health Policy and Management, Harvard School of Public Health

² Center for Alternative Medicine Research, Department of Medicine, Beth Israel Deaconess Medical Center, Harvard Medical School

³ Boston University School of Law

⁴ Harvard Law School, Boston, Mass

A subset of these general doubts and concerns about alternative medicine relates to medical malpractice. We believe physicians worry that they will be sued if a patient they refer to an alternative medicine practitioner suffers a poor outcome. Even when patients have independently chosen to submit to alternative treatment, physicians may be reluctant to discover or discuss this care with them for fear that, if they know about it, they will be deemed to endorse it.

To address these issues, we have examined available data on rates of claims against chiropractors, acupuncturists, and massage therapists. Next, we explore the kinds of situations in which physicians may be exposed to liability for the referrals they make. Finally, we note the approach courts have adopted in assessing the malpractice liability of alternative medicine practitioners. We conclude that malpractice concerns alone should not inhibit physicians from referring patients to alternative medicine practitioners, particularly where those practitioners are licensed and accredited. A caveat to our conclusions is that legal principles in this area are not well developed-a situation that is poised to change as conventional and unconventional medicine become increasingly integrated in health care delivery systems.⁸

Claim Experience

Alternative medicine accounts for approximately 5% of the total medical malpractice insurance market, and coverage is provided by fewer than 50 insurers. We collected claims information from the leading indemnity insurers in the country serving chiropractors, massage therapists, and acupuncturists. Together these 3 groups of practitioners account for approximately two thirds of the estimated 425 million visits made annually to offices of alternative medicine practitioners.

Chiropractic data were obtained from NCMIC Insurance Company (NCMIC) of Des Moines, Iowa. NCMIC insured 25 103 chiropractors in 1996, nearly half of all licensed chiropractors practicing in the United States. We obtained data on claims against massage therapists from Albert H. Wohlers and Co of Park Ridge, Ill. Wohlers has provided professional indemnity insurance services to members of the American Massage Therapy Association (AMTA) since 1993 and currently insures approximately 27000 massage therapists throughout the country- again, almost half of all licensed practitioners in this area. Acupuncture Insurance Services of Elmhurst, Ill provided information on acupuncture claims. With approximately 1500 policyholders in 1996, it is the largest carrier of insurance for acupuncturists in the United States.

Table-1: Selected Claims Information for Massage Therapy, Chiropractic, and Medicine, 1990-1996

Year	Claims per 100 Policy Holders			Average Indemnity Payment Per Paid Claim			Claims Paid. %	
	Massage Therapy ¹	Chiropractic ²	Medicine (Primary Care) ³	Massage Therapy	Chiropractic	Medicine (Primary Care) ⁴	Massage Therapy	Chiropractic (Primary Care)
1990	-	27	77(59)	—	33625	137900	—	49.1 31.9(25)
						(123213)		
1991	-	27	82(57)	—	43670	159788	—	49.1 31.9(25)
						(148633)		
1992	-	28	91(69)	—	40821	183541	—	49.1 31.9(25)
						(143730)		
1993	0.2	3.0	9.8(7.1)	12011	52231	185243	—	49.1 31.9(25)
						(1470841)		
1994	0.2	27	95(67)	4251	65597	183541	—	49.1 31.9(25)]
						(151001)		
1995	0.2	26	90(62)	4864	52385	179732	—	49.1 31.9(25)
						(148028)		
1996	0.1	22	—	4253	60985	120272	—	49.1 31.9(25)
						(16379)		

¹ Date from Albert H. Hohler & Co. Park Ridge, Ill. Ellipses indicate data were not available prior to 1993.

² Date from the NCMIC Insurance Company, Des Moines, Iowa,

³ Data from Gonzales

⁴ Data from PIAA Data Sharing System, Rockville, Md.

The data used to describe the claims experience of physicians are drawn from 2 sources. Information on claims paid against physicians comes from the Physician Insurers Association of America's (PIAA's) Data Sharing Project. Information on claims frequency comes from the American Medical Association's annual core survey of a national sample of physicians. In contrast to our other claims data, the survey data reflect the experience of a general physician population (excluding federally employed physicians) rather than a discrete population defined by a specific insurer.

To maximize comparability of the data, we specified a number of parameters: (1) a claim was defined as a formal demand for compensation arising from health care (ie, incident reports were excluded); (2) multiple claims against a single insured that related to the same incident were counted as a single claim; (3) claims against multiple practitioners relating to the same incident were counted separately; (4) all claims for which a nonzero indemnity payment was made to the plaintiff were counted as paid claims; and (5) claims were assigned to years according to file date, and payment figures were assigned to years according to closure date.

Table 1 compares the claims rates, average amount on paid claims, and percentage of claims among massage therapists, chiropractors, and primary care physicians for 1990 through 1996. Claims rates against chiropractors insuring through NCMIC have remained steady at 2 to 3 claims per 100 policyholders per year through the 1990s. The average severity of claims against chiropractors, as measured by average indemnity amounts on paid claims, increased by 81%. Conventional medicine experienced this same trend with a 47% increase. NCMIC resolved approximately half of its claims with payment, 18% more on average than did PIAA insurers. Table 2 shows the percentage of claims received by NCMIC in various injury categories during 1992 through 1996.

Table 1 also shows that rates of claims against massage therapists are less than one tenth of those against physicians and decreased in 1996. Table 3 shows the percentage of claims against AMTA members received by Wohlers in various injury categories during 1993 through 1996. Most claims (61%) relate to minor injuries, although a significant proportion (14%) relate to sexual misconduct.

Less information is available on rates of claims against other practitioners of alternative medicine. We were unable to obtain comprehensive data

on claims against acupuncturists; however, some information on claims history was obtained from Acupuncture Insurance Services. Although this company insures one sixth of the 8900 licensed acupuncturists in the country,³⁰ it has had ongoing difficulties underwriting its policies because of its relatively small insurance pool.

After working through several offshore underwriters during the 1980s, a relatively stable relationship with a domestic underwriter was disrupted when a single acupuncturist apparently infected 35 people with hepatitis³¹, of whom filed claims (Martin shaw, president, Acupuncture Insurance Services, oral communication, March 1997). The other major claims experienced by Lincoln in its 15 years of operation include a case of irreversible nerve damage, several burns, and 2 cases involving pneumothorax.

Table-2: Categories of Claims Against Chiropractors, 1992-1996*

Type of injury	Total Claims, %	Paid Claims, %
Disk	27.1	27.6
Failure to diagnose	12.2	11.3
Fracture	13.5	10.3
Aggravation of existing condition	7.6	9.9
Cerebral vascular	5.4	2.9
Vicarious liability	3.5	4.5
Other	30.7	33.5

* Data obtained from the NCMIC Insurance Compny, Des Moines, Iowa.

The best explanation for the relative infrequency and lower severity of claims against alternative medicine practitioners concerns the nature of alternative therapies.³² Since rates of medical injury increase with invasiveness of therapy, fewer bases for suit are likely to present in the largely noninvasive alternative medicine setting. Moreover, injuries that do occur may not be as severe.

Another explanation may be the immature state of medical malpractice law and claims consciousness outside conventional clinical medicine- a phenomenon that may change as use and awareness of alternative therapies grow and as these therapies are progressively integrated into health care delivery systems. A third explanation may be that personal characteristics of alternative medicine practitioners and their patients or the dynamics of that patient-practitioner relationship are associated

with a reduced propensity to sue, whether or not negligence occurred.

From the perspective of a physician who is concerned about the malpractice implications of referring to alternative medicine practitioners or comanaging patients with them, these findings should offer a degree of reassurance: they diminish the practical importance of situations in which practitioners might be exposed to liability for mere referral. Nonetheless such situations can arise and should be taken seriously, particularly in light of uncertainty about how courts will decide medical malpractice cases.

Liability for Referral to Alternative Medicine Practitioners

As a general rule, a physician's mere referral of a patient to another physician, without more, does not expose the referring physician to liability.³³⁻³⁵ This rule has been applied by courts throughout the country in cases involving referral among physicians. Yet in certain circumstances- alluded to in the qualification, "without more"- the rule does not hold. These exceptional situations in the context of alternative medicine can be divided into 2 categories : (1) situations in which a decision to refer the patient for alternative medical treatment is negligent and (2) situations in which the referring physician is held liable for the treating practitioner's negligence because the physician supervised the care, jointly treated the patient, or know the practitioner to whom the physician referred the patient was incompetent.

In the first category, the referral itself falls short of the reasonable practice standard and is sufficient to form the basis of a malpractice lawsuit, regardless of the quality of care delivered by the practitioner to whom the referral is made. The law still requires that the patient suffer injury causally related to the substandard referral. But if, for example, a physician refers a patient to an alternative medicine practitioner instead of to some other, more appropriate practitioner and the referral delays, decreases, or eliminates the opportunity for the patient to receive important care, the referring physician could be held liable.³⁶

Table-3: Categories of Claims Against Massage Therapists 1993-1996*

Type of Injury	Total Claims
Minor ¹	61
Major ²	5
Grave ³	1
Nonphysical	15
Sexual Misconduct	14
Other	4

- * Data obtained from Albert H. Wohlers & Co. Park Ridge, Ill.
- ¹ Includes soft tissue injuries, minor fractures, and minor scarring with no residuals
- ² Includes fractures, serious internal injuries, serious back injuries (ie. Fusions, ruptured disks, laminectomies), loss of vision in 1 eye, and serious scarring
- ³ Includes brain damage, quadriplegia, severe burns, fatalities, dismemberment of 1 or more major limbs, and extremely serious multiple fracture cases.

Available empirical evidence on alternative medicine use suggests that this type of referral liability may be a theoretical concern more than a practical one: the most commonly used alternative therapies treat minor ailments or serious conditions for which conventional medicine can offer little in the way of therapeutic benefit.¹ Nonetheless, it does highlight an important reason why physicians who refer to alternative medicine practitioners should be familiar with the efficacy of various alternative therapies. As knowledge about the appropriateness of alternative therapies expands, courts may determine that physicians act negligently when they refer patients for particular therapies that they know or should know offer no practical benefit to the patient.

Another complicating issue with regard to the choice of referral is the increasingly complex set of influences brought to bear on physician decision making. Guidelines, incentives, and restrictions aimed at influencing physicians' referral decisions are hallmarks of the managed care environment.³⁸⁻³⁹ Managed care organizations typically seek to minimize the use of specialist care and limit expensive tests that offer little or no marginal benefit.⁴⁰⁻⁴¹ Analogously, a plan that covers alternative medicine services may, for example, determine that its enrollees should be referred to chiropractors rather than to orthopedic surgeons, given certain clinical indications. Were liability for this type of referral to be considered by the court, the plan's guidelines or incentives could potentially mitigate the referring physician's exposure to liability, although such "reallocation" of liability has been slow to develop because of a range of barriers to holding managed care organizations liable for malpractice.⁴² Yet another complication is the increasingly common practice of using alternative medical care as an adjunct to allopathic care.

The second category of exceptions to the general rule of nonliability for referral arises when the practitioner to whom a patient is referred renders negligent care that injures the patient and for which the referring physician is then considered partially or wholly responsible. There are several

situations in which courts may impute liability in this way, all of which involve *vicarious liability*, defined as liability of a person or organization for the negligence of an employed individual. (Vicarious liability includes liability of supervisors [*respondent superior*] and apparent authority, that is, when one individual apparently represents an organization.)

First, when physician A refers a patient to physician B and then exerts authority over the way physician B treats that patient, physician A may be held liable for physician B's negligent acts. In finding vicarious liability, the law considers that physician B merely acts as physician A's agent. The question of whether an agency relationship exists and hence whether vicarious liability may be appropriate for that reason depends on the level of actual (or apparent) control maintained by the referring physician.

Courts have generally been reluctant to find that one physician controls another, setting a fairly high threshold for plaintiffs who attempt to establish liability on this basis. However, referral to an allied health professional- for example, a nurse practitioner or physician assistant- presents a slightly different situation. A physician may be held liable for the negligent acts of allied health professional, such as nurses, when the physician takes charge or supervises the care provided. The same is true if a health care organization supervises the allied health professional. Moreover, by requiring the adoption of written protocols for collaboration, professional regulation in many states explicitly commits physicians to a supervisory role over allied health professionals such as nurse practitioners, physical therapists, and physician assistants, particularly in the area of drug prescription.

Leading cases addressing this type of vicarious liability have considered care delivered in the operating room setting, rather than referrals;^{46, 47, 50} they have also involved practitioners using the same approach to healing (ie, conventional medicine). Nonetheless, the manner in which alternative medicine services are integrated with conventional medical services will be important in determining whether referral involves the requisite level of actual or apparent control that courts have demanded to establish the agency relationship and so constitute an exception to the general rule of nonliability for referral.

Physicians who maintain a supervisory role over the patient's care or who refer in circumstances where the patient might reasonably expect that care will be supervised could be held to account for the negligent acts of the treating practitioner. From the perspective of physicians and health plans, the agency exception to the general rule of nonliability for referral would suggest good reason for allowing alternative medicine

practitioners to practice their craft freely once referral is made and also for ensuring that patients understand that referral initiates a new and separate patient-practitioner relationship. These recommendations would, however, be qualified if the alternative medicine practitioner is not licensed or is in an organization subordinate to the referring physician.

Second, liability may be extended to the referring physician in situations when the care given exhibits characteristics of a joint undertaking. Cases that have bound defendants together in this manner have looked for a fairly high degree of unity in the practitioners' approach to treatment.^{51, 52} In fact, joint undertakings typically involve practitioners who act in concert, simultaneously administering treatment to a patient, rather than being separated by the referral process.

Under current health care arrangements, it seems unlikely that this kind of situation will arise between physicians and alternative medicine practitioners. However, it could emerge as a possibility if the practitioners are employed by the same hospital or health plan and collaborate closely in providing patient care. This level of collaboration could also exist in situations where physicians and alternative medicine practitioners render care in a jointly owned or operated clinic. Similarly, as alternative medicine practitioners units within a hospital or clinic, the possibility of a joint-undertaking situation does arise.

Third, the general rule of nonliability for referral may not apply when the referring physician knows that the practitioner to whom she or he refers the patient is incompetent.

For example, if a physician is aware that a particular acupuncturist uses unsterilized needles or that the acupuncturist has recently been the subject of serious disciplinary action by a professional board, then the physician may be considered negligent if a patient referred to the acupuncturist suffers iatrogenic injury.

While the physician's own liability is certainly a consideration in the above scenario, the courts have been far more active in holding institutions accountable in this area. Hospitals and managed care organizations have a legal obligation to be diligent in selection, retaining, and evaluating health care professionals; this same obligation will extend to their relationship with alternative medicine practitioners. Therefore, the plan that credentials an incompetent acupuncturist may face liability as a corporation when a physician refers a patient to this practitioner for treatment, especially when it has established incentives or guidelines to facilitate this referral.

All of the above recommendations are contingent on the assumption that courts are not prepared to make presumptive judgments about the incompetence of alternative medicine practitioners, based solely on their idiosyncratic approaches to health care. If the courts were so prepared, this possibility has serious legal ramifications because it would allow liability of the referring physician to be inferred in a much wider range of cases- not merely those in which there is knowledge about a particular practitioner's incompetence. Once again, the courts do not yet appear to have considered this issue directly. However, we can find important clues about how they might deal with the situation by returning to litigation against alternative medicine practitioners and examining more closely how these cases have been decided.

Regulation and Liability of Alternative Medicine Practitioners

A widely accepted rule of medical malpractice states that "a physician is entitled to have his treatment of his patient tested by the rules and principles of the school of medicine to which he belongs, and not by those of some other school. Although this rule is most often used as a basis for delineating different standards of care among conventional medical specialties, it has also been used to set standards for practitioners of alternative medicine in schools ranging from chiropractic to homeopathy, naturopathy (the resurgent remnants of the "drugless practitioners" of an earlier era), and even Christian Science healing.⁶²⁻⁶³ An important rationale underlying school-specific standards is that, when a patient elects or gives informed consent to receive care from a particular practitioner, the patient is presumed to have also elected to be treated with an ordinary level of skill and care common to that practitioner's field of practice.

But courts have not applied a school-specific standard of care in situations where they do not recognize the school to which a defendant claims membership. How do judges make this decision? Licensure has thus far been the decisive piece of evidence in determining whether an identifiable school of medicine exists; the regulatory apparatus that accompanies licensure defines its scope. As one court stated: Through the enactment of this legislation, the legislature has recognized the practice as a separate and distinct health care discipline". Another piece of evidence likely to be important in signaling a school's identity and validity is state legislative mandates that compel insurance companies to cover certain alternative medicine treatments in all policies sold.

The chiropractic profession is the best example of an easily recognizable school of alternative medicine. Chiropractors are licensed in all 50 states and the District of Columbia (Table 4). Forty-two states mandate coverage of chiropractic service in health insurance policies (Susan S. Laudicina, director of state services research, Blue Cross Blue Shield Association, oral communication, March 1998). Courts apply a standard of care in malpractice actions against chiropractors enunciated by experts in the chiropractic profession itself. They will rarely hear the testimony of a physician for purposes of establishing the appropriate chiropractic standard of care.

Table- 4. Statutory Licensure of Alternative Medicine Practitioners.

Chiropractic			
Licensed in 50 states and District of Columbia*			
Massage Therapy			
AL	§34-43-2	NM	61-12C-1
AK	§17-86-102	NY	\$7802
CT	§20-206	ND	43-25-01
DE	24 del C 5306	OH	\$503-42
DC	§ 2-3305	OR	\$687-011
FL	§480.033	RI	\$23-20 .8-1
HI	§452.3	SC	\$40-30-110
IA	§152C	TN	\$63-18-201
LA	37.3556	TX	4512K
ME	32 MRS 14306	UT	58-47b-304
MD	HOcc 3-5A-0a	VT	26 VSA 3405
MA	C140 §51	VA	\$54-1-3029
NE	§71-1278	WA	18.108.005
NH	328-B-4		
Acupuncture			
AK	§ 08.06.030	NH	328-E:12
AX	§ 32-2901	NJ	45:5B-8
AR	§17-102-101	NM	61-144-4+
CA	BPC §4925+	NY	§8214
CO	§12-29.5	NC	§90-455
CT	§20-206bb	OR	§677.759+
DC	§2-3302.3	PA	63 PS §1803
FL	§457.105+	Ri	§5-37.2-12
HI	§436E-3	SC	§40-47-40
IL	225ILCS 2/15	TN	§63-1-102
IA	§148E.3	TX	4495b

LA	37:1357	UT	58-72-101
ME	32 MHS 12511	VT	26 VSA 3401
MD	HOcc 1A-201	VA	§54-1-2900
MA	c112 §b152	WA	18.06050+
MN	§147B.02	WV	§30-36 1
MT	37-13-301+	WI	451.04
NV	§634A.120+		

Naturopathy

AK	§ 08.45.020	ME	32 MRS12521
AS	§32-1555	MT	37-26-401
CT	§20-34	NH	328-E:14
DC	§2-3309.1	OR	§685.02
FL	§462.18	UT	58-71-102
HI	§455-3	VT	26 VSA .3041
KS	§65-2472a	WA	18.36A.030

Homeopathy

AZ	§ 32-2915	NE	§ 630A.230
CT	§ 20-10	WA	18.36A.030

* Mandates for coverage of chiropractic service are in force in all but 8 states (CO, HI, ID, NH, OR, SD, VT, WY) and the District of Columbia.

+ Coverage of acupuncture services in health insurance products is mandated by state law

Other schools of alternative medicine besides chiropractic have established systems of licensure and regulation (Table 4). Thirty five states license acupuncturist (with 7 states mandating insurance coverage of acupuncture services), 27 states license massage therapists, 14 states license naturopaths, and 4 states license homeopaths. Few reported cases in the modern era have considered the liability of licensed practitioners of alternative medicine practicing in these areas. Nonetheless, it is entirely consistent with prevailing legal principles to expect that their conduct will be judged in the same way as chiropractic medicine.

In contrast, where practitioners of alternative medicine are unlicensed, courts tend not to recognize them as belonging to an identifiable school of medicine and hence do not apply a school-specific standard of care. Instead, the allegation of negligence will be judged according to conventional medical⁷⁰ or lay⁶⁵⁻⁶⁷ standards of care. A court's decision to adopt either of these alternate standards, rather than standards, set by the defendant practitioner's own school, has a significant bearing on case outcome: it becomes more likely that the conduct under scrutiny will be judged negligent.

Conclusion

Opening a professional dialogue between physicians and practitioners of alternative medicine is crucial to better health care for those patients who choose alternative therapies. This need can be expected to grow with use of alternative therapies, particularly as health insurance plans include such therapies in the benefits they offer. The larger solution lies with better education for physicians about alternative medicine and further outcome studies and randomized trials that comprehensively assess the efficacy and relative safety of alternative therapies. Some of this work has begun, spurred by such developments as the Office of Alternative Medicine at the National Institutes of Health.⁷¹ However, clarification of the medical liability issues involved should remove a significant obstacle to integration and continuity of patient care.

Physicians who currently refer patients to practitioners of alternative medicine or who are contemplating doing so should not be overly concerned about the malpractice liability implications of their conduct. The same commonsense considerations applicable to other conduct. Referrals will be a reasonably reliable guide regarding acceptable practice. However, it may be useful to ask the following questions. First, is there evidence from the medical literature to suggest that the therapies a patient will receive as a result of the referral will offer no benefit or will subject the patient to unreasonable risks? Second, is the practitioner licensed in my state? (Some added comfort can be derived from knowing that the practitioner carries malpractice insurance). Third, do I have any special knowledge or experience to make me think that this particular practitioner is incompetent? And fourth, will this be the usual kind of referral (ie, basically at arm's length, without ongoing and intrusive supervision of the patient's management)?

If the answers to the first and third of these questions are no and the answers to the second and fourth questions are yes, then this should remove many of the concerns a physician has that the referral decision itself will be construed as negligent. This conclusion holds even if the patient suffers an injury caused by the alternative medicine practitioner's negligence. That practitioner should be held accountable for his or her autonomous actions and should be judged according to standards set by fellow practitioners.

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(Source: JAMA, Nov. 1998)

Homeopathy as an Integral Part of TST (Three System Together) Program in Bangladesh

Dr. Md. Abdul Matin, BHMS, MD, DF

Homeopathy is a system of medical treatment started by a German Physician Dr. Samuel Hahnemann (1755-1843). Homeopathy is based on the premise that the symptoms of a disease are evidence of a curative process going on in the body in response to the disease. The homeopathic physician attempts to promote the further development of this system in order to accelerate the body's self cure. Though homeopathy is a new science developed primarily in Europe and not having its roots embedded in tradition and history, it has over the years, become an integral part of the Bangladesh way of life. Partly due to its remarkable healing capacity and partly to the low cost of medicines involved, it is widely used by a large segment of the Bangladeshi population especially 65% in the Rural areas according to the estimate given by WHO. Bangladeshi homeopaths have contributed to its growth by developing and adding modern conception derived from the out side world based on their study of their prevalent modern and natural system of medicine in the country.

"Similia Similibus Curantur"- "Like cures like"- is the guiding principle of homeopathy. In practice this means that a drug which is capable of producing a certain set symptom in a healthy body when taken in large physiological dose, will relieve or cure a similar set of symptoms in the diseased organism when it is given in small homeopathic doses, the body's tissues. They are supplied by nature in a pure and atomized form in certain proportions in all tissues of the body, in all plants and in all foods they are abundantly available in their crude and impure state on the earth. The composition of the 12 remedies formulated by Dr. Schussler corresponds with the principle inorganic elements found in the body. Absolutely harmless, these tissue salts or mineral salts are not drugs in any sense of the word. They simply provide the system with its deficient inorganic elements, prepared homeopathically, in an extremely fine form which ensures their ready assimilation and a speedy restoration of the balance and harmony in the system.

The aim of achieving and maintaining an optimum state of health has always exercised the mind of men since the earliest of times and as a consequence various system of healing developed in different part of the world.

In this process of evolution of healing process, the modern allopathic system of medicine has developed as the fast acting, and most effective means of relieving the sufferings of human body due to diseases which helped the allopathic system to get the recognition as the life saving system of therapeutics, although the scientists knew fully well that this mode of treatment is not really curative rather palliative only.

Moreover the scientists of allopathic system of medicine has realised that allopathy with its powerful drugs often creates a toxic burden for the body that the excretory organs like kidney, liver etc. are unable to eliminate and which impairs necessary organic physiological process.

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Moreover the scientists of allopathic system of medicine has realised that allopathy with its powerful drugs often creates a toxic burden for the body that the excretory organs like kidney, liver etc. are unable to eliminate and which impairs necessary organic physiological process aspect of medicinal products, helped homeopathy to come closer to the general

mass of the country.

The Government also recognised homeopathy together with other two system of naturopathy i.e. the Ayurveda and Yanani system in Bangladesh. Educational institutions and hospitals were established under the patronage of government and private sectors. About 32 colleges in the diploma level and two Govt. degree colleges were established under the direct affiliation with the University of Dhaka. Various charitable organisations also came forward to help the process considering the pecuniary circumstances of the general mass. About four hundred teaching staff and two hundred non-teaching staff are engaged in all over the country. There exist charitable dispensaries attached to the colleges also to help the ailing mass. About 35% of the total population of the country are covered under this homeopathic health care system. Even a research center under the guidance of the Royal London Homeopathic Hospital of London is supposed to be set up in this country in near future under the financial support of the Government of Bangladesh.

With this infrastructure, the homeopathy is a part of the traditional system of medicine in Bangladesh has gone closer to the health care service rendered by the modern allopathic system of medicine for the less privileged population of the country.

This realisation has developed an increased interest towards holistic or traditional system of healing approach to health especially towards the least toxic and least harmful system of homeopathy

In the western world the lifestyle was so busy that the fast acting mode of treatment by allopathy got the priority and was accepted by all. But as the eastern part was less industrialised, the oriental scientists could allow for the sick necessary time to apply the slow acting but curative process of perfect healing without causing damage to the vital organs.

Hence the total process of development of allopathic system of medicine in the past millenium and the present approach of alteration towards the traditional system of medicine, especially towards homeopathy, is the natural mode of development of medical science which was to take place like all other branches of pure science in the world.

However like homeopathy, two other system of medicine called Ayuryeda (the Indian) and Yunani (the Arabian) existed in Bangladesh as the traditional system of medicine. Later on Homeopathy came to be practiced and attained popularity and become part of the traditional system of medicine.

The educated class of people among the total population of Bangladesh as well as the Indo-Pakistan- Bangladesh subcontinent became more attracted towards the Homeopathic system than the ancient Ayurvedic and Yunani system of medicine due to various factors. The language played an important role, as the basic language of the literature of Ayurveda was Sanskrit and the Yunani system followed Arabic but the educational institution for homeopathy followed the English and the local languages.

Homeopathy Facilities in Bangladesh at present

Government Degree Homeopathic College & Hospital, Mirpur, Dhaka

No of students	388
No of graduated	160
No of teacher	24
No of DS. RMO. medial officer (Hospital)	15
No of Staff (College & Hospital)	122

Non Government 32 Homeopathic medical College & Hospital

Location	As per description
No of Student	15,000
No of Physician (Diploma) / year.....	above 1,500
No of teacher, medical officer	400
No of Staff	200
No of qualified physician	25,000

List of Homeopathic colleges

1. Bangladesh Homeopathic Medical College & Hospital, Dhaka
2. Federal Homeopathic Medical College & Hospital, Dhaka
3. Tanjim Homeopathic Medical College & Hospital, Narayanganj
4. Gazipur Homeopathic Medical College & Hospital, Gazipur
5. Mymensing Homeopathic Medical College & Hospital, Mymensing
6. Jamalpur Homeopathic Medical College & Hospital, Jamalpur
7. Sharishabari Homeopathic Medical College & Hospital, Jamalpur
8. Faridpur Homeopathic medical college & Hospital, Faridpur
9. Rajbari Homeopathic Medical College & Hospital, Rajbari
10. Dr. jakir Hossan City Corporation Homeopathic Medical College & Hospital, Chittagong
11. Chittagong Homeopathic Medical College & Hospital, Chittagong
12. Azizur Rahman Homeopathic Medical College & Hospital, Chittagong
13. Hahnemann Homeopathic Medical College & Hospital, Comilla
14. Dinajpur Homeopathic Medical College & Hospital, Dinajpur
15. Nilfamari Homeopathic Medical College & Hospital, Nilfamari
16. Gupalgonj Homeopathic Medical College & Hospital, Gupalgonj
17. Bagerhat Homeopathic Medical College & Hospital, Bagerhat.
18. Bharmonbaria Homeopathic Medical College & Hospital, Bhramonbaria
19. Jalalabad Homeopathic Medical College & Hospital, Sylhet
20. Khulna Homeopathic Medical College & Hospital, Khulna

21. Dr. D.B. Khan Homeopathic Medical College & Hospital,
Sathkhria
22. Joshore Homeopathic medical college & Hospital, Joshore
23. Khustia Homeopathic Medical College & Hospital, Khustia
24. Norail Homeopathic Medical College & Hospital, Norail
25. Apex Homeopathic Medical College & Hospital, Barishal
26. Loins Homeopathic Medical College & Hospital, Bhola
27. Rajshai Homeopathic Medical College & Hospital, Rajshahi
28. Bogura Homeopathic Medical College & Hospital, Bogura
29. Pabna Homeopathic Medical College & Hospital, Pabna
30. Rangpur Homeopathic Medical College & Hospital, Rangpur
31. Syedpur Homeopathic Medical College & Hospital,
Nayabazar
32. Tangail Homeopathic Medical College & Hospital, Tangail

Present State of Herbal Medicine in Bangladesh

Hakim Mohammed Said

The Unani and Ayurvedic systems of Traditional Medicine are the two systems which are widely practiced throughout the country. The Homeopathy system of medicine is also popular. All the three systems of medicine are recognised by the government.

Herbal Medicines prepared in Bangladesh may broadly be classified into three groups :

- i) Unani Literature
- ii) Ayurvedic Literature and
- iii) Modern official Literature (National Formularies, Pharmacopoeias).

Homeopathic medicines are also being prepared following homeopathic Pharmacopoeia.

Ayurvedic and Unani Medicine are usually being prepared following the age old traditional methods. In some factories, however, the manufacturers have started modernisation of methods of preparation of their medicines. Some manufacturers of the herbal medicines are adopting scientific techniques to a great extent in order to keep the therapeutic value of the active constituents intact following modern manufacturing procedures as adopted in the preparation of synthetic drugs. In the manufacture of a particular medicine, they are using several medicinal plants of similar efficacy which produce particular synergistic effect of active constituents present in the plant materials.

At present, there are more than 300 Ayurvedic and Unani manufacturing firms in the country. Out of these, some are quite big and they are supplying most of the herbal medicines of the country and catering to the needs of the people. There are about 500 types of Ayurvedic and Unani preparations in the field and 200-300 medicinal plants of high therapeutic value are used in these preparations. Most of these plants are of indigenous sources and appreciable quantities are imported from neighbouring countries.

The Government is now contemplating to incorporate herbal traditional medicine in primary health care services. An experimental study has been arranged recently in six places of the country to find out effective and low cost medicines for common ailments with WHO's assistance.

Founder, Madinat-Al-Hikmah, Karachi, Pakistan

Training of Traditional Medicine Practitioners

At present seventeen (17) Unani and Ayurvedic teaching institutions including one government institution are functioning in the country. The names and places of the Unani and Ayurvedic institutions are as follows:

- i) Government Unani Ayurvedic Degree College, Mirpur, Dhaka
- ii) Hamdard Unani Medical College & Hospital, Bogra
- iii) Government Tibbia College, Sylhet
- iv) Tibbia Habibia College, Dhaka
- v) Unani Tibbia College, Chittagong
- vi) Chandpur Unani Tibbia College, Chandpur
- vii) Bhola Islamia Unani College, Bhola
- viii) Momenshahi Unani Medical College, Momenshahi
- ix) Khulna Unani Medical College, Khulna
- x) Akbar Ali Khan Technical & Commerce College, Comilla
- xi. Momenshahi Ayurvedic College, Momenshahi
- xii. Noor-Majid Ayurvedic College, Dhaka
- xiii. Mujaher Ayurvedic College, Chittagong
- xiv. Kundeshari Ayurvedic College, Chittagong
- xv. Prafulla Singh Ayurvedic Medical College, Magura
- xvi. Srightta Sanskrit College, Sylhet

The Government Unani and Ayurvedic Degree College in Dhaka offers a five years degree course plus one year internship in the attached 100 bedded hospital with facilities of research work.

Another institutions offer a diploma course of four years plus six months internship training. After completion of course certificates of registration are awarded to the successful candidates.

The Government has taken up crash programme to train the existing 2000 untrained Unani and Ayurvedic practitioners in the country in phases. The duration of the course is of two months.

It is estimated that in view of low costs of medicines and use of local herbs and plants to produce these medicines, greater section of the country who are basically poor, will be able to avail better health care facilities if arrangements are made on government level to produce and supply traditional medicines in various corners of the country.

Whatever modern health care facilities have been developed are limited to certain areas. So, in the remote areas where there is no modern allopathic medicine facility, the traditional herbal (Unani/Ayurvedic) medicine still plays a big role in providing health care facilities to the common people. There

are about 6,000 Unani and Ayurvedic Registered and Unregistered practitioners in the country and out of them about 700 institutionally trained.

Role of Herbal Drugs in the Health-Care System of Bangladesh

About 25% people of Bangladesh use modern medicines. Another 20-25% may be covered by the herbal drugs. The per capita consumption of drugs is about Tk. 10-12 only, and this figure is one of the lowest in the world. Herbal drugs can improve this situation and can give a tangible coverage of medication to the people. Since, modern science has definitely proved the efficacy of herbal medicine, there is every reason to accept this easy option.

At present, the herbal medicines are being used mostly in the rural areas and comparatively few educated people use it. For the maximum use of herbal medicines as complementary to synthetic medicines, it is essential that herbal medicine should be developed to a stage acceptable to the educated people also. Hamdard Bangladesh has started training programmes for marketing the finely prepared compound medication and it is appreciable that their herbal drugs are being prescribed by the traditional practitioners as well as by the allopathic doctors.

Bangladesh being a poor and developing country, cannot afford to spend a huge amount of foreign currency for the import of finished medicines, pharmaceutical raw materials including medicinal and aromatic plants and herbs. It has to develop its own technological background to manufacture drugs from its own resources, specially from indigenous medicinal plants. In order to reach that goal, research and development of herbal medicine is essential. This has already been started in China, India, Pakistan, Bangladesh, Sri Lanka, Nepal, Thailand and United Kingdom. In these countries by applying modern knowledge of pharmaceutical chemistry, pharmacology, toxicology and pharmacognosy, the herbal drugs have been developed to standard close to that of synthetic drugs and they have been successful to a great extent to minimise their dependence on modern drugs.

Some phytochemical, biomedical and pharmacological research works on a few important indigenous medicinal plants of Bangladesh have been performed in the BCSIR Laboratories in collaboration with BSMMU, Sir Salimullah Medical College, Dhaka and Leprosy Control Centre, Mohakhali, Dhaka.

On the basis of the results of research in the BCSIR Laboratories, processes have been developed from the indigenous medicinal plants

of Bangladesh for the production of Garlic Oil, Garlic Pearl and Garlic Tablet from raw garlic, Reserpine from *Rauwolfia serpentina*, Berberine hydrochloride from *Berberis aristata*, Scopolamine hydrochloride and hydrobromide from *Datura* etc. Serious attempts have been made for the commercialisation of the processes of Garlic Pearl and Garlic Tablet. But it has been unfortunately noted that the authority is not giving facilities to the entrepreneurs for commercialisation of such processes. If such indigenous technologies developed in the country from indigenous medicinal plants are not given due importance, herbal drugs cannot prosper and thrive in the country and it would be a great set back for the development of Bangladesh. It is very unfortunate the Government is not giving due attention in utilizing the appropriate indigenous technologies developed in the research laboratories for the commercialisation of the processes on medicinal plants.

For providing health care for all in shortest possible time, integration of herbal medicines with modern allopathic drugs is essential. To accomplish this, the Government must give proper facilities, on priority basis, to the industrialists for the commercialisation of the processes on medicinal plants. But the situation is reverse in this country so far.

The British Pharmacopoeia has some 66 entries on herbal drugs. The Extra pharmacopoeia has a lot of entries of herbal medicines. Medical Scientists in Bangladesh are of the view that they should not wait for inclusion of the herbal drugs prepared in Bangladesh in the B.P. or I.P. They are of the opinion that these are their own processes and are to be included in Bangladesh Pharmacopoeia. Why should they borrow even the very ordinary technology for abroad instead of looking into what they have of their own!

Research and Development

Research works have been carried out with a good number of medicinal plants in BCSIR Laboratories on plants like: *Abrus precatorius* (B. Kunch), *Aegle marmelos* (B. Bell), *Allium Sativum* (B. Rasun), *Alstonia scholaris* (B. Chhatim), *Centella asiatica* (B. Thankuni), *Cinchona succirubra* (B. Quinine), *Coccinia indica* (B. Telakucha), *Berberis aristata* (B. Daruharidra), *Datura fastuosa* (B. Dhatura), *Madhuca latifolia* (B. Mahua), *Rauwolfia serpentina* (B. Sarpagondha), *Syzygium cumini* (B. Kalojam), *Strychnos mix-vomica* (B. Kuchila), *Tinospora cordifolia* (B. Gulancha), etc. and a number of industrial processes have been

developed. The processes for the production of scopolamine hydrochloride, Berberine hydrochloride, Garlic Tablet and Garlic Oil have been leased out to industrialists for their commercial exploitation. Datura Oil has been proved to have anti-fertility effect after series of experiments on rats.

Collaborative research works in BCSIR are sometimes carried out with BSMMU, BIRDEM, Leprosy Hospital, Dhaka University and Jahangir Nagar University. Phytochemical and Biochemical studies on *Rauwolfia serpentina* in BCSIR revealed that the plant of 1-3 years old gave 50%-75% of alkaloids, 4-7 years old plant gave 90%- 100% of alkaloids and 11-12 years old plant practically gave no alkaloids. So the age of the medicinal plants should also be considered before their use.

From all the above discussions, it is evident that herbal drugs like the past may play a very important role in the future health care programme among the common people of Bangladesh. However, ways and means have to be found out for its modernization through research and development so that people can get maximum benefit out of it.

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Medicinal Plants: Traditional Uses and Potential for Growth in Bangladesh and Pakistan

Hakim Naimuddin Zubairy
Muhammad Afzal Rizvi

Life and diseases go together: where there is life, diseases are bound to exist. Dependency and sustainability of man and animal life has been revolving around plants through their uses as food, fibers and shelter, but also plants have been used to control and ease diseases therefore the use of plants as medicine is an ancient and reliable practice. Ailments and medicinal plants vary in the world, hence their nature, frequency and method of administration can change in relation to geography, time and knowledge (Arshad *et al.*, 2001). A map of Bangladesh on the distribution of medicinal plants would reveal the wonderful variety and number of plants that are naturally available in this country. Bangladesh is a store house of medicinal plants capable of being grown in all types of climates, soil and its distinctive vegetation (Said, 1993).

In developing countries medicinal plants are widely used by the traditional practitioners in their day to day practice. According to a WHO survey, native healers treat 65% patient in Sri Lanka, 85% in Burma, 80% in India, 60% in Indonesia, 75% in Nepal and 90% in Bangladesh. Pakistan has about forty thousand registered practitioners of traditional medicine and majority of the population, specially in villages, is getting health care by traditional practitioners : *Tabibs / Hakims*. According to estimates about 80% of the population is being catered to by the traditional practitioners who prescribe mostly herbal preparation (Haq, 1983). A wide variety of medicinal plants are distributed in the natural climate of Bangladesh. Many references are available on their occurrence, availability and utilization in various folk or traditional practices. A brief survey about their natural distribution and uses is being mentioned here (Anonymous, 1950, 1956, 1959, 1976, 1985, Wahid *et al.*, 1961, Hameed, 1982, Said, 1982, Srivastava, 1989, Behal *et al.*, 1993, Chatterjee, 1996, Said, 1996, Saralamp *et al.*, 1996):

Naturally Occurring Medicinal Plants in Bangladesh

Adiantum capillus - veneris L. (Para - Siyavashan). Found in Chittagong. Regarded as demulcent, expectorant, diuretic emmenagogue, tonic and febrifuge. Entire herb used as an aromatic and emollient in cough. Used in seasonal cold and fever.

Aegle marmelos Corr. (Bel). Occur in Bangladesh. The unripe fruit is regarded as astringent, digestive, stomachic. It is also used for the treatment of diabetes mellitus. The root is used in palpitation of the heart. Leaf extract possessed antifungal activity. Paste made of leaves of the tree helps sore and inflamed eyes exude pus.

Anacardium occidentale L. (Kaju). A medium sized tree found in Chittagong. The fruit is eaten as a remedy for scurvy. The juice is used as a diuretic and useful for kidney troubles and advanced cases of cholera.

Aquilaria agallocha Roxb. (Agaru). It is a large tree and grows in Sylhet. Agar wood is medicinally, the fragrant resinous substance is used in gout, rheumatism and to check vomiting.

Bombax malabaricum DC. (Semul, Simal). Occur in Bangladesh. Fresh fruits are stimulant, young roots used as restorative and brain tonic. Uterotonic activity on isolated uterus of rats, rabbit, dog and human, the bark is efficacious in dealing with abscesses.

Bryophyllum calycinum Salisb. (Pathar kuchi, lohachur). A fleshy herb available in Rajshahi. The leaves are used for poulticing the sores. The crushed leaves applied on forehead for headache.

Caesalpinia bonduc Roxb. (Karanja). A spiny shrub commonly found in Bangladesh. Seeds used as tonic, antiperiodic, anthelmintic. Oil from seeds to remove freckles from face. Also used for stopping discharges from ear.

Canscora decussata (Dankuni). It is an annual herb and found in the plains of Bangladesh. Regarded as laxative, alterative, tonic. The fresh juice of the herb is prescribed in epilepsy and nervous debility. It is a specific for purifying blood, spermatorrhoea and diabetes, acts as a prophylactic for smallpox.

Carthamus tinctorius L. (Qurtum, Kusumphul). An annual herb available in Bangladesh. Flowers are regarded as stimulant, sedative and emmenagogue. Externally, seed used as anti-inflammatory, treatment of skin diseases. Oil, prevents increasing blood cholesterol level in both patients with high cholesterol and normal groups.

Croton tiglium L. (Jaypal, Jamalgota). Available in Bangladesh. Oil is regarded as a valuable medicine and the seeds are used as a drastic purgative. It is used to limited extent as drastic cathartic, usually in admixture with diluents; more frequently it is used as a constituent of rubefacient liniments, in case of pneumonia and sciatica.

Dipterocarpus turbinatus Gaertn. (Gurjan). Very common in Chittagong forests. Garjan balsam is valued in bronchitis. Oil is very useful in venereal

diseases. The oleo-resin- is used as an external application for ulcers, ring-worm and other cutaneous affections. It has been used in gonorrhoea and gleet.

Elephantopus scaber L. (Gojialata). A stiff hairy herb and abundant in forests of Bangladesh. The stem is said to be used as a preventive after child birth, useful in cough and venereal diseases.

Flacourtia cataphracta Roxb. (Panials). This shrub is found in Bangladesh. The leaves are prescribed in diarrhoea, weakness and consumption. The leaves and bark are useful for bleeding gums and toothache. Young shoots are astringent and stomachic.

Glycosmis pentaphylla Correa. (Ashshoura). This shrub is found in Bangladesh. The roots are boiled and the decoction drunk for facial inflammation.

Hemidesmus indicus R. Br. (Anantamul). It is a climber and found in the Sunderbans, a beautiful forest. The decoction of the roots juice is given as tonic and blood purifier.

Ipomoea biloba Forsk. (Chhagalkhuri). A prostrate herb commonly available in Chittagong sea shore. The juice is given as diuretic in dropsy.

Jatropha curcas L. (Erandu-gachh). Shrub is very common in Bangladesh. The seeds are said to be used as purgative. Leaves are also applied to wounds after healing.

Kalanchoe laciniata DC. (Himsagar). An erect stout herb found in Bangladesh. Medicinal properties are similar to *B. calycinum*. The leaves are considered styptic, astringent and antiseptic crushed leaves are applied in poultices to wounds, cuts, ulcers and abrasions.

Litsea sebifera Pers. (*Kukurchita*). Available in Bangladesh. Because of its feebly balsamic and mucilaginous nature are largely used as a demulcent and astringent in diarrhoea and dysentery.

Mallotus philippinensis Muell. (Kamela, kamalagundi). Very common in Bangladesh. Used in certain parasitic skin diseases. Fruit is used as vermifuge and purgative. Kamela powder alone is applied over syphilitic ulcers.

Nelumbium speciosum Willd. (Padma). An aquatic herb available in Bangladesh. Petals are astringent and useful in diarrhoea. A paste of the rhizome is applied in ring- worm and cutaneous affections. Carpels are demulcent and nutritive and are used to check vomiting. A sherbet

prepared from the plant is used as a refrigerant in small-pox and is reported to stop eruption.

Opuntia dillenii Haw. (Phanimansa). A fleshy herb found in Bangladesh. It is said to be useful in gonorrhoea and the warm leaf applied to boils hastens suppuration. The baked fruit is said to be given in whooping cough and a syrup of the fruit is said to increase the secretion of bile and control spasmodic cough and expectoration.

Phyllanthus emblica L. (Amla, amlaki). It is found in Bangladesh. Rich in Vitamin "C". Regarded as refrigerant, diuretic and laxative. Effective against palpitation, scurvy, cardiac and stomach debility, for biliousness and blood heat.

Rauwolfia serpentina Benth. (Chandra, Chotichand). A small herb available in Rajshahi, Dhaka and Chittagong. Effectively reduces blood pressure. Root is bitter tonic and well known for its sedative and febrifuge properties.

Saraca indica L. (Asoka). Found plentifully in Bangladesh. The tree is considered to be a "Feminine- specific" effective against uterine disorders. It is said to have a stimulating effect on the endometrium and ovarian tissue.

Semecarpus anacardium L. (Bhallataka). It is a moderate size deciduous tree. Recent study showed that the aqueous extract of the nuts of (*S. anacardium*) exerted moderate analgesic and inflammatory activity. It is useful in scabies and psoriasis.

Terminalia chebula Retz. (Haritaki). The tree is wild in Bangladesh forests. Fruit regarded as alterative, tonic and laxative. Dried fruit is effective astringent and act as antidiarrhoeal. It is also useful in bloody piles. The fruit-pulp is used as a dentifrice to cure bleeding and ulceration of gum.

Urginea indica Kunth. (Ban piaaj). Commonly occur in Bangladesh. The bulb is prescribed in paralytic affections. The drug, in small doses, possesses cardiotonic, stimulant, expectorant and diuretic properties. The squill is used chiefly as a powerful expectorant in the treatment of cough, especially in chronic bronchitis and asthma. The expectorant action is due to mild irritation of the gastro- intestinal tract.

Vallisneria spiralis L. (Haparmali). It is found in Sylhet. The milky juice is useful in chronic ulcers. The bark is bitter and astringent and chewed by the Kols for fixing loose teeth. It is a popular remedy for toothache and inflamed gums.

Wedelia calendulacea Less. (Kesraj). It is found in marshy places of Bangladesh. The leaves are regarded as tonic, useful in cough, skin

diseases. A decoction of the herb is used in uterine haemorrhage and menorrhagia. The leaves are very useful in alopecia.

Xanthium strumarium L. (Ban-okra). A coarse annual herb. Available in Bangladesh. The fruit is considered cooling and efficacious in small-pox. Its decoction is recommended in chronic malaria, leucorrhoea and urinary diseases.

Zanonia indica L. (Chirpoti). A climbing shrub found in Bangladesh. The fruit is said to possess acrid, cathartic and antiseptic properties, they are said to be useful in cough and asthma. A decoction of the leaves is used as a bath to cure nervous irritation due to boils.

In addition to the above cited examples, various other medicinal plants are available in Bangladesh. For example *Acacia nilotica* (Babla), *Acacia catechu* (Kuth), *Allium sativum* (Lashan), *Ananas comosus* (Anarash), *Bassia latifolia* (Mahu), *Cassia alata* (Dadmari), *Cassia fistula* (Banarlathi), *Cuscuta reflexa* (Algusi-latta), *Eugenia jambolana* (Kala Jam), *Ficus religiosa* (Asvatha), *Holarrhena antidysenterica* (Kurchi), *Ipomoea turpethum* (Teori), *Nymphaea lotus* (Shaluk), *Piper betle* (Pan), *Piper longum* (Pipal), *Sapium indicum*. (Batul), *Saraca indica* (Asoka), *Tephrosia purpurea* (Bannil), *Urtica indica* (Bichu), *Vitex peduncularis* (Goda), *Zea mays* (Janara) etc.

Trade and Marketing

Medicinal plants have market of considerable size both Nationally and Internationally. There are a number of medicinal plants that can be cultivated in Pakistan as well as in Bangladesh. Traditional use over the centuries established demand for their raw material/ active principles in the International trade. These are : *Abroma augusta*, *Adhatoda vasica*, *Alpinia galanga*, *Bambusa arundinacea*, *Carthamus tinctoria*, *Carum copticum*, *Cinchona* sp., *Cinnamomum camphora*, *Citrus medica*, *Cocos nucifera*, *Cuminum cyminum*, *Curcuma zedoaria*, *Cymbopogon jawarancusa*, *Cyperus rotundus*, *Gloriosa superba*, *Mimosa pudica*, *Morus indica*, *Nigella sativa*, *Ocimum sanctum*, *Onosma echioides*, *Phyllanthus niruri*, *Rauwolfia serpentina*, *Ricinus communis*, *Zingiber officinale*, etc. (Rizvi *et al.*, 1999).

Pakistan is amongst the eight leading countries that export medicinal plants. According to the Export Promotion Bureau, there was an export of over 8,500 tons of medicinal herbs in 1999, which fetched a petty amount of \$ 6 million, as compared to \$ 31 million spent on the import of herbal products (Gilani, 2001).

Conclusion and Future Strategies

Number of challenges and opportunities are available to scientists, industrialists, policy makers in Pakistan as well as in Bangladesh to increase area for improving the productivity, income and increasing export earning through cultivation of different medicinal plants. Qualitatively diverse soil and favourable climatic conditions are the factors which facilitate improvement in productivity. The importance of medicinal plants will further grow as more medicinal food, cosmetic and perfumery industries shall come up to meet the growing demand of our population.

A strong meaningful and well coordinated linkage between the industry, agriculture, medicine, scientists, export and import agencies is desired to develop a strong base and future pattern for the development of medicinal plant based industries in Bangladesh as well as in Pakistan.

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Therapeutic Evaluation of 'Lashun Siddha Ksheer' on Hypercholesterolemia

Dr. US Nigam, MD, PhD

Introduction

Today the life of man has become very mechanised due to fast moving technology. People are forgetting simple principles of healthy life. According to Ayurveda the concept of healthy person is not restricted only on physical or body level but the physical, spiritual and mental, all the three states must be in proper condition. That is the equilibrium state of a healthy person.

Holman at, al says that *"While mental disease is our greatest socio-economic problem, cancer our greatest anigma, arthritis and rheumatism our gratest crippler, and accidents our greatest disgrace, artreosclerosis is by for our greatest killer."*

A number of risk factor have been identified as strongly associated with coronary heart diseases. Hypercholesterolemia is one of the major cause of coronary artery diseases. It has been established beyond the doubt that lowering the elivated blood cholesterol level of law density lipoprotein (L.D.L.) will reduce the risk of heart attack caused by the coronary artery diseases.

According to Ayurveda, the patients having disorders of liquid metabalism suffer from two kinds of diseases. One due to adiposity itself and other due to partial or complete obstruction of channels in the metabolic pathways reducing in ***dhatwagni-mandya*** or an impairment of enzyme system concerned with intermediater metabolism.

Hypercholester olimia with ischeamic heart diseases has stimulated the search for agents which reduce the cholesterol levels in the blood.

Lashun (Garlic) has been used in different form as medicine and diet since most ancient times, earlier studies have shown the hypo-cholesterolemic effect of Lashun.

Acharya Charak has mentioned "Lashun siddha Ksheer" for the treatemt of heart disease so here Lashun Siddha Ksheer has been selected for the study of its hypocholesterolemic effect.

Professor & Head of the Department of Post Graduate on Kayachikitsa,
Government Dhanwantari Ayurvedic College, Ujjain (M.P.)

Methods and Materials

1. Only ten patients of hypercholesterolemia was studied in the present trial. Further study is going on.
2. This study includes the cases attending the outdoor clinic of Govt. Ayurvedic hospital Ujjain and were divided at random into two groups.
3. First group of five patients were treated with "Lashun Siddha Ksheer" for one month and five patients of second group were kept under control group, who were treated with placebo. In all the 10 cases of hypercholesterolemia has been given fat free restricted diet during the treatment period of 30 days & clinical pattern were observed in all the cases of both the groups after 30 days.
4. The patients were finally selected after estimation of serum cholesterol, when elevated from the normal value.

Preparation of Lashun Siddha Ksheer and method of administration

Ingredients		Amount
Lashun	-	25 gms
Milk	-	200 ml
Water	-	200 ml

Firstly crush lashun and make a paste then add milk and water. It should be slowly heated up to when only milk remained. This 200 ml quantity of lashun siddha Ksheer should be given daily in two divided dose in empty stomach morning and evening for one month duration. Patients were advised to avoid butter, ghee, and all forms of saturated fat.

Parameters

- A) Subjective: Some following very important symptoms found in the patients of hypercholesterolemia which were observed B.T and A.T.
1. Utsah hani (inability to work)
 2. Ati-Sweda (Excessive perspiration)
 3. Ati-Nidra (Excessive sleep)
 4. Kshudhadrakya (Excessive appetite)
 5. Pipasadrakya (Excessive thirst)
 6. Kandu (Irritation in skin)
 7. Gauravata (Heaviness of the body)
 8. Kshudrashwas (Dyspnoea on exertion)
- B) Objective :
1. Patients having elevated serum cholesterol level above 200 mg/100 dl of blood with or without any symptoms were diagnosed as Hypercholesterolemia in the present study. Therefore total serum cholesterol estimation (On step method) had been done in every patient B.T. and A.T.
 2. Routine laboratory investigation had been done such as T.C., D.C., Hb % and ESR.

Results & Observations

Table -1 : Profile of patients (No. of patients 10)

Age	Range in years	40-70
sex	Male	6 (60%)
	Female	4 (40%)
Religion	Hindu	4 (70%)
	Muslim	3 (30%)
Economical status	Poor	2 (20%)
	Middle	6 (60%)
	Rich	2 (20%)
Habitat	Rural	3 (30%)
	Urban	7 (70%)
Marital Status	Married	4 (80%)
	Unmarried	2 (20%)
Heredity	Non-Hereditary	6 (60%)
	Hereditary	4 (40%)
Nature of work	Sedentary	5 (50%)
	Moderate	4 (40%)
	Hard workers	1 (10%)
Day sleep	Upto 1 hours	8 (80%)
	Upto 2 hours	2 (20%)

Table- 2: Incidence of cardinal symptoms

S.No.	Cardinal symptoms	No. of patients	Percentage (%)
1	Utsah-hani	8	80
2	Ati-Sweda	4	40
3	Ati-Nirdra	5	50
4	Kshudhadrhikya	6	60
5	Pipasadrhikya	3	30
6	Kandu	3	30
7	Gauravata	8	80
8	Kshudra-shwas	6	60

Table -3: Showing the effect of treatment on cardinal symptom in both groups, patients wise

Symptoms	GROUP -1			GROUP-2		
	No. of Patients B.T.	No. of Patients A.T.	% of relief	No. of Patients B.T.	No. of Patients A.T.	% of relief
Utsah-hani	5	2	60	4	3	25
Ati-Sweda	3	1	67	4	3	25
Ati-Nirdra	3	1	67	3	2	33
Kshudhahikya	4	1	75	5	4	20
Pipasadhikya	4	1	75	5	4	20
Kandu	2	0	100	2	2	0
Gauravata	4	1	75	4	3	25
Kshudrashwas	4	1	75	4	4	0

Table- 4: Showing the efficacy of treatment on cardinal symptoms according symptom index in both group

Symptoms	GROUP -1				GROUP-2			
	S.I. B.T.	S.I. B.T.	Relief in S.I.	Relief in %	S.I. B.T.	S.I. B.T.	Relief in S.I.	Relief in %
Utsah-hani	14	7	7	50	15	10	5	33
Ati- Sweda	15	6	9	60	16	10	6	37
Ati-Nirdra	15	5	10	50	14	11	3	21
Kshudha dhikya	10	4	6	60	15	11	4	26
Pipasa dhikya	16	6	10	63	15	10	5	33
Kandu	9	4	5	56	6	4	1	16
Gauravata	16	5	11	67	16	12	4	25
Kshudra-shwas	12	3	9	75	16	10	6	37

Table- 5: Showing the cholestrol level (mg/dl) in both group B.T. and A.T.

	<u>GROUP -1</u>		<u>GROUP-2</u>	
Case No.	B.T.	A.T.	B.T.	A.T.
1.	266	170	260	240
2.	256	160	220	200
3.	260	180	240	230
4.	266	150	250	240
5.	252	162	220	215

Table- 6: Showing the statistical analysis datas on cholestrol level (mg/dl) in both group B.T. and A.T.

Group	Mean	S.D.	S.E.	t	P
Group-1					
B.T.	260-27	15.43	4.66	-	-
A.T.	204-81	17.11	5.15	124.68	70.001
Group-2					
B.T.	233-33	4.94	2.02	-	-
A.T.	258-00	16.03	7.18	-3.52	<0.10

Discussion & Conclusion

1. 10 cases of hypercholesterolemia were taken in the present clinical trial having 5 patients in trial group 1 and 5 patients in control group 2.
2. In this study patients were found in the age group of 55-65 years, out of them 60% were male and 40% were female. 70% patients were hindu and 40% muslim, out of them 60% patients were from the middle class.
3. Out of 10 patients 70% were from urban area and 10% were from rural area, out of them 80% were married 40% patients have reported hereditary predisposition.
4. Out of total case only 10% patients were hard worker, 50% patient were found sedentary habits and 40% patient had reported of moderate type of work. 80% patients were having day sleep habit upto 1 hour.

5. The state of hypercholesterolemia is not a disease, so symptoms of this state is not narrated in any literature, but in Ayurveda this condition may be correlate to the medoroga. Only 8 symptoms of medoroga has been selected for this study, out of total cases, 80% patients has reported has been selected for this study, out of total cases, 80% patients has reported Utsahhni and gauravata, 60% patients had Kshudhadrhikya and Kshudrashwas, 50% patients complained Ati-Nidra, 40% patients were havig Ati-Sweda and 30% patients had pipasadrhikya and Kandu.
6. The trial group-1 the percentage relief in Kandu was 100%, Khshnudhadrhikya, Pipasadrhikya, Gauravata and Kshudra-Shwas was 75%. In symptoms of Ati-sweda, Ati-Nidra the relief of percentage was above 60% while in the control group-2, the average relief percentage was below 25% (Table-3)

According the symptom index the total average relief was found above 60% in trial group-1, but in control group-2 the relief was found less than 28% (Table- 4)

The main criteria of assesment was estimation of serum cholestrol. According the Table- 5, the mean value of cholestrol B.T. was 260 mg/dl and after treatment of 30 days, it was reduced to 164 mg/dl and after treatment of 30 days, it was reduced to 164 mg/dl. On statistical analysis the "P" value was found highly significant in trial group (Table - 6).

The mean value of cholesterol in control group-2 B.T. was 238 mg/dl and reduced only to 225 mg/dl A.T. The "P" value was found in significant. On comparative analysis of data of both group in subjective and objective parameters, it has been observed that a very significant effect was found in trial group.

On the basis of the above finding it can be concluded the "Lashun Siddha Ksheer" plays a definite role in the regression of serum cholestrol level. No. clinical side effects were noted during the study period.

Further study is require in more patients which is going on in our institution.

Experiences with Alternative Systems of Medicine in India

Professor RH Singh

Introduction

India is the largest country in South East Asia with many unique social, cultural and economic features. Its population is over 1000 million with notable rising trend and the living settings are more of rural type. The economy is of developing nature and the health sector is one of the major challenges. Although western modern medicine is well developed and is liberally used in India, the population depends to a significant extent on traditional medicine for its health needs. India is a real example of medical pluralism where as many as six systems of medicine are officially practised such as Ayurveda, Unani, Siddha, Naturopathy, Yoga and Homeopathy in addition to the main stream medicine i.e. Allopathy. All systems have their independent working infrastructure in the sector of medical education, practice and research. Ayurveda is the major alternative system of Medicine in India.

Ayurveda is not just a traditional folklore but is a highly evolved and codified ancient life and health science based on its own unique fundamental principles, its origin going back to the ancient Vedas. Ayurveda makes a holistic approach to life and the universe which exist as interdependent continua. Ayurveda follows the laws of nature and propounds a number of applied doctrines for the understanding of life, health, disease, diagnostics and cure. Many of these doctrines are valid even today and may throw new light on several unresolved issues of the science of medicine as a whole today. And as such it is considered a treasure of ancient wisdom. The subtle knowledge of the science of ayurveda appears to have been developed through keen observation and intuition over the phenomena of nature and its laws by the seers. Full proof theories and their reasonable applications in the field of health and disease were evolved at least few thousand years before. The transmission of the knowledge and transaction of the profession took place through Guru Sisya tradition in Gurukuls. The Ayurvedic classics available today like the Charaka Samhita exhibit a glorious glimpse of this tradition.

The Traditional Treasures

The original ancient knowledge of Ayurveda has been passed on to the present times through two sets of authentic ancient texts written in Sanskrit, now all translated in many modern languages including English. They are:

Name of the Text	Author	Historicity	Subject Matter
I. Brihatrayis (Three Big Books):			
1. Caraka Samhita	Caraka	700 BC	Medicine (Principles & Practice)
2. Susruta Samhita	Susruta	600 BC	Anatomy & Surgery
3. Samhitas of Vagbhata	Vagbhata	300 AD	Therapeutics
II. Laghutrayis (Three Small Books):			
1. Madhava Nidana	Madhava	900 AD	Diagnosis
2. Sarangdhara Samhita	Sarangadhar	1300 AD	Therapeutics
3. Bhava Prakasa	Bhava Mishra	1600 AD	Drugs

Even in the ancient classical period Ayurveda was already a well developed science of medicine and was practised in the form of Astanga Ayurveda i.e. medicine with eight specialities viz.:

1. Kayachikitsa (Internal Medicine)
2. Salya Tantra (Surgery)
3. Salakya Tantra (Ophthalmology & ENT)
4. Kaumar Bhritya (Paediatrics and Gynaecology)
5. Agad Tantra (Toxicology)
6. Rasayana Tantra (Geriatrics)
7. Bajikarana (Sexology & Reproduction)
8. Bhutavadya (Psychiatry)

The Present Status

During last 200 years trends of institutionalisation began when gradually some Ayurvedic schools were started. This trend took over a century to reach the present status of institutionalisation and university level education in Ayurveda. Today there are nearly 200 full fledged Ayurvedic colleges spread all over the country affiliated to different leading universities and financed by State Governments providing five and half years degree courses in Ayurveda and specialisation programme. With the growing institutionalisation of education in Ayurveda in the present century need has been felt to launch research and development activities in order to update it in terms of its understanding and application to the present day needs of the people. Although there are controversies in

India about the approach and methodology of research in Ayurveda and about the quantum of utilisation of western modern science for this purpose. However consensus is in favour of utilising all possible aids of modern science and technology to investigate the problems of Ayurveda and to generate evidence for the safety and efficacy of its medications. Thus, research interests are the main feature of ayurveda today in India. As a matter of fact Ayurveda today is an official system of Medicine undergoing fast revival and development on scientific lines towards the need of the nation. Mainstreaming and Globalisation of Ayurveda is the goal of ongoing attempts in India today.

The above perception gave birth to the need of postgraduate education in Ayurveda. During last few decades several Indian Universities have started postgraduate specialisation courses in Ayurveda leading to MD Degrees of three years duration in as many as 15 specialised branches of Ayurveda. These postgraduate courses provide higher proficiency training and research career to selected scholars. Presently there are over 50 institutions providing postgraduate education in Ayurveda. Faculty of Ayurveda at Banaras Hindu University, National Institute of Ayurveda, Jaipur and Gujarat Ayurveda University Jamnagar are the Apex institutions in Ayurveda in India today.

The education and research in Ayurveda is controlled by two autonomous councils set up by the Government of India by acts of parliament viz., Central Council of Indian Medicine (CCIM) regulates the standard of Ayurvedic education and registration of Ayurvedic Doctors in the country, while Central Council for research in Ayurveda and Siddha (CCRAS) promotes and funds Ayurvedic research. Besides financing individual research projects the CCRAS maintains five central research institutes, seven regional research institutes, ten regional research centres and over 50 research units in Ayurveda fully devoted to research in Ayurveda. The following tables exhibit a summary of the existing infrastructure available in India in the sector of Ayurveda and other indian Indigenouse systems of medicine.

Table-1: Summary of Service Facilities in the Sector of Indigynous Systems of Medicine and Homeopathy in India

Number of Hospitals	3,000
Number of Hospital Beds	60,000
Number of Dispensaries	23,000
Number of Licenced Pharmacies	10,000
Number of Registered Practitioners	6,81,124

Table- 2: The strength of Educational Facilities

Facilities	Aurveda	Unani	Siddha	Homeopathy	Total
Undergraduate Colleges Admission Capacity	198	39	02	166	405
					16,845
Postgraduate Colleges Admission Capacity	53	05	02	17	77
					821
Reg. Practitioners	427504	42445	16599	194147	681124

The Contemporary Features

During last hundred years the education and practice of Ayurveda has passed through a fast transition from Guru Sisya tradition to an institutionalised training system and hospital/dispensary based practice both in private and public sector. Thus the practice of Ayurveda as a system of medicine has had an unbroken tradition since ancient times in different forms. The present estimated number of registered traditional practitioners in India is about 50,000. This number is higher than the number of conventional modern doctors in the country. Such practitioners form a huge professional manpower available within the country. If given support and provided time to time training and supplied working facilities, they could prove a big help in national health care delivery system for the masses of this vast developing country which is still facing multifaceted health problems. 70% of the Indian population live in rural areas where western modern medicine is not accessible and practitioners of indigenous systems of medicine are the main help. These systems are working at a very low cost. It may be mentioned that indigenous systems of medicine which provide health care coverage to over two thirds of the population in different ways, share only 2% of the total health budget of the nation. Rest of the budget is spent on facilities for conventional modern medicine. The anomaly is now being examined for taking corrective steps by Government of India.

It is believed that given full support at the level of policymaking and financial input, the indigenous systems of medicine in India have the potential to occupy the role of main stream health care delivery, where conventional modern medicine may limit its role to referrals only.

Ayurveda and other indigenous systems of medicine have two-fold contemporary strength which need to be utilised:

1. In Primary Health Care where Ayurveda has strength in promotive and preventive Health Care through its time honoured life style measures, dietetic regimen and restorative and rejuvenative remedies of Rasayana Tantra.
2. In Tertiary Care of Chronic Intractable Diseases and degenerative disorders where conventional modern medicine has not much to offer. These two are the important sectors of health care delivery system today and in both these sectors Ayurveda and ISM have real strength.

Intergation and Mainstreaming of ISM

Recently with the establishment of a separate department of Indigenous Systems of Medicine (ISM) in the Ministry of Health, Government of India the endeavour to support the growth and to maximise the use of ISM has started yielding results. Integration of ISM with conventional medicine and its mainstreaming is being attempted at all levels. Attempts are being made to start service facilities of traditional medicine specially Ayurveda in major modern medicine hospitals too. A course capsule is being developed to introduce Ayurveda in the formal curriculum of graduate studies of modern medicine in conventional modern medical colleges. The Ayurvedic Colleges have already incorporated Basic Modern Medical Sciences and Diagnostics in the syllabi of Ayurvedic graduate courses. Banaras Hindu University is conducting for many years 3-Years MD Ayurveda courses for modern MBBS graduates besides short term courses in Ayurveda for modern doctors and medical students both on full time and elective patterns open to foreign nationals. Several overseas universities particularly US Universities have shown interest to send their medical students for elective training in Ayurveda. All this is gradually bringing Ayurveda in the mainstream of medicine and is helping its integration. It is hoped that this trend of integration and interdisciplinary development will globalise Ayurveda. However one problem which comes in the way of globalisation of Ayurveda is its distinct uniqueness and the ideological and the linguistic differences from the main stream of medical sciences of today. An international convention on Ayurveda held at the Indic Research Centre of Columbia University, New York in 1994 which was also attended by the author of the present paper, concluded that:

1. The Ayurvedic system of medicine uses a different theoretical construct to describe the human being and the mechanisms of disease than that used by western medicine.
2. The Ayurvedic theoretic construct of human being dictates a significantly different methodology for disease prevention, diagnosis and treatment.

3. A variety of Ayurveda's wide variety of treatment modalities do not have obvious parallels in western medical treatment. Ayurveda also includes a large and sophisticated materia medica based primarily on the use of whole plant substances, although also incorporating significant amounts of animal and mineral products.
4. The challenges of integrating Ayurveda and western medicine are large and complex, yet the potential benefits for health care are significant both in economic savings and in improvement of over all health.
5. Reasonable progress towards an integration of Ayurveda and western medicine will require substantial amount of time and money invested in a broad based cooperative venture involving many people from both traditions.

Research Strategies in ISM

Interdisciplinary multi-faceted research is the most important prerequisite for the integrative main-streaming drive of ISM In India lot of efforts are being made in this direction. Researches which are being promoted are designed to generate evidence for the validity of the system and its fundamental principles besides evidence for the safety and efficacy of the medications used as well as new treatment development. The current research dimensions in Ayurveda are:

1. Literary research
2. Conceptual and Fundamental research
3. Clinical research on disease, diagnostics and therapies.
4. Drug development research
5. Medicinal Plants: conservation, cultivation and good use.

Drug research is the hallmark of current Ayurvedic research. Varied strategies have been projected for this purpose. For developing evidence of efficacy and safety of medications one can adopt two approaches:

1. Rapid screening of many herbs of similar expected activity on one screening model *in vivo* or *in vitro* in an experimental setting.
2. Clinical evaluation of single or compound drugs in patients with different diseases through open or blind trials, adopting a "Reverse Pharmacology Approach" in view of the fact that the Ayurvedic/ISM drugs are already in human use by tradition and as such there is no danger in starting direct human trial.

Traditional Medicine and the Patent Regime

The idea of using patents to protect the rights of an inventor is not new. Eversince commercialisation started the use of patent and copy rights also began throughout the world. In the beginning it was more an issue of trust and respect but gradually it became the matter of law, firstly within countries and lately internationally. In the present times the patent system is an extremely aggressive legal order and the growing trade and commercial temper has created a patent culture in western countries with aggressive tone. The debate on the comparative benefits of the patent regime to developed and developing countries has still not concluded. The developed countries argue that the patent system will help the developing countries for their economic growth while on the other hand other people believe that the patent regime will benefit more that developed countries like US and will help them to monopolise the world trade and economy. However the patent regime is to be considered in the present context in the totality of Indian Patent Act, GATT, TRIPs and the issues of intellectual property rights.

Ayurvedic medicine and Indian herbs form one of the most vulnerable sectors in the context of patent regime. A number of known herbs and plant drugs of India have been patented by outsiders on the basis of secondary researches. Neem, Haladi, Sunthi and Ashwagandha are few among any examples. Because of lack of awareness and fallacies in the law, patents are being granted to individuals on the basis of minor secondary researches ignoring the obvious traditional knowledge. In order to promote traditional medicine in any country there is an urgent need to change the Patent laws designed to protect the national heritage of a country which should be considered its intellectual property and should not be allowed to be patented in the names of any individual, national or foreigner. An ancient traditional knowledge claimed to have originated exclusively from a country should be treated as the national intellectual property of that country and that land should be entitled for world patent with exclusive rights of benefit for that nation. There is a need of making necessary legal provisions for national heritage patent. For this, there is a need of nation-wide awareness and national debate. The first task is to precisely define and describe the "National Heritage Intellectual Property" of the country with substantial proof and textual records. It would be necessary to enlist and to officially register the ancient classical texts and oral traditions historicity-wise which may be projected as "National Heritage Record" to be used as a document in support of a National

claim. The so registered 'National Heritage Texts and Traditions' should be analysed for their contents viz. ancient concepts and theories, processes and drugs. Such contents which may be possessing potential of commercial utility should be redescribed in a language understandable to the professionals of today and patent administrators. Such a home work and suitable law reform may go a long way in protecting the ancient heritage knowledge of a country from being patented by the foreign agencies. The respective Governments as well as the individual scientists will have to keep a constant watch on their intellectual properties to prevent any kind of piracy or infringement. The interim strategy should be tilted more towards "Protection" than to "Patent". In view of the prevailing situations the strategy should be "Patent or Publish". If one cannot patent his invention due to his limitations, he should publish the same in order to protect it from being patented by others.

Certain corners in India have been raising the slogan of "Swadeshi" to combat the negative impact of globalisation on our nation. But in spite of being a solid reality 'Swadeshi' has so far been used only as a slogan, not as a realistic work strategy. Only slogans never save unless transformed into action. The new patent regime is to be viewed seriously and more deeply. The issue is not only technoprofessional but is essentially a matter of economic and political activism and is targeted at the rivalry between globalisation and national overignty. As such the developing countries like India are carrying a big risk which can be overcome only by reasonable defensive strategies and by generating the sense of activism and work culture among our people.

Summary

India is one of the very few countries in the world where traditional systems of medicine are practised on full official footings and are provided with a huge working infrastructure. Serious attempts of integration and mainstreaming are in progress. Multidimensional research and development on scientific lines is the main feature of Contemporary Ayurveda and ISM in India today. Ayurveda, which has already been a highly evolved and codified system of traditional medicine with an unbroken tradition of practice for thousands of years, is now growing fast in tune with the needs and expectations of present times. The crisis arising out of the new patent regime and IPRs, needs to be addressed to protect the interest of these systems and national heritage claims.

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Treatment of Irritable Bowel Syndrome With Chinese Herbal Medicine A Randomized Controlled Trial

Alan Bensoussan, MSc¹ ; Nick J. Talley, MD²
Michael Hing, MBBS, FRACP³ ; Robert Menzies, PhD⁴
Anna Guo, PhD⁵ ; Meng Ngu PhD⁶

Irritable bowel Syndrome (IBS) is a common functional bowel disorder that accounts for a significant proportion of patients seen in gastroenterology of fices and is characterized by chronic or recurrent abdominal pain and disturbed defecation. Studies in the United States and Australia suggest that between 10% and 20% of the population have this disorder. No single available treatment is reliably effective for this condition, and patients use a variety of approaches for symptom management, including drugs, dietary modifications, and counseling.

To date, no strong scientific evidence available supports the use of Chinese herbal agents in IBS. However, CHM has been used for centuries in the treatment of functional bowel disorders and is routinely used for this purpose in China. Several Chinese studies have suggested the potential effectiveness of CHM for treatment of IBS, although these have all lacked rigor in clinical trial protocol and have had poor randomization techniques and lack of blinding.

According to the fundamental Chinese principles of traditional Chinese medicine, treatment should be tailored to the individual clinical presentation of patients, even though they all may have the same medical diagnosis. Furthermore, treatment needs to be modified at different stages of the patient's illness or recovery. In this study, we evaluated the effectiveness of CHM in the treatment of IBS. We compared individualized therapy against a standard Chinese herbal formulation for IBS and a placebo using a randomized, double-blind, placebo-controlled study design.

¹ Research Unit for Complementary Medicine, University of Western Sydney, Australia

² Department of Medicine, Nepean Hospital, Sydney, Australia

³ Department of Behavioral Sciences, University of Sydney, Australia

⁴ Bandi Junction Endoscopy Centre, Sydney, Australia

⁵ Balmain Chinese Herbal Centre, Sydney, Australia

⁶ Gastroenterology Unit, Concord Repatriation General Hospital, Sydney, Australia

Methods

Setting and Patients

Patients were recruited from gastroenterology units in 2 teaching hospitals in Sydney, Australia, and through 5 private practices of gastroenterologists. After patient screening and subsequent review in these centers, patients' conditions were further diagnosed (according to Chinese medicine principles) and treated in 3 Chinese herbal clinics by 3 Chinese medicine practitioners.

A clinical trial notification was filed with the Therapeutic Goods Administration, Commonwealth Department of Health, Housing, Local Government and Community Services, Canberra, Australia. All herbal substances used in this trial were listed with the Australian Therapeutic Goods Administration, have been acknowledged as suitable for human consumption, and were administered within standard dosage levels. All herbs used in this trial are available over-the-counter throughout Australia. No product used in this trial was a controlled substance, animal product, or endangered species. The trial protocol was approved by the ethics committee of the University of Western Sydney Macarthur and the ethics committees of the 2 participating hospitals.

Patients between the ages of 18 and 75 years (inclusive) were screened by a gastroenterologist. Screening involved a routine clinical workup for IBS with diagnostic tests as determined appropriate by the specialist. Patients were assessed according to the Rome criteria, an established standard for diagnosis of IBS. If diarrhea was a prominent symptom, lactose intolerance was excluded by hydrogen breath testing or during a 2-week lactose exclusion period. The inclusion and exclusion criteria are shown in Table -1. Written informed consent was obtained from all patients before entering the trial. Patients were free to withdraw from the study at any time.

Table -1: Inclusion and Exclusion Criteria

Inclusion Criteria

Age, 18-75 y inclusive

Colonic evaluation (colonoscopy or barium enema) within the previous 5 years (for 14-60 y) or within the previous 3 y (for 61-75 y)

Irritable bowel syndrome by Rome Criteria At least 3 mo of continuous or recurrent symptoms of :

Abdominal pain or discomfort with at least some discomfort present within the last 2 wk; and ≥ 2 of the following on at least a quarter of occasions or days

Abdominal distention that is visible or felt by light clothing

Pain relief with bowel action

More frequent stools with onset of pain

Looser stools with onset of pain

Mucous in stools

Feeling of incomplete evacuation

At least 1 marking on the visual analog scales for IBS symptoms to be at least 20 mm from the "not present" end of the scale

Normal liver function test and full blood cell count and urea and creatinine levels (within the last 2 wk)

Exclusion Criteria

Pregnancy or breast-feeding Liver disease

Medications: anticholinergics, lactulose, smooth muscle relaxants, motility stimulants, and/ or antidepressants. Use of these is accepted provided patient is still symptomatic for IBS, medications have been used for 3 mo and effects of medications are stable

Current alcoholism or drug abuse

Current psychiatric illness or dementia Allergies to food additives

Lactose intolerance - no obvious clinical indications Inflammatory bowel disease (ulcerative colitis, crohn disease)

Gastric and duodenal ulcers

Cancers of the gastrointestinal tract

Celiac disease

Diabetes mellitus

Treatment Schedule

After initial gastroenterological screening (week 0), all patients entered a 2- week run-in period. A Bowel Symptom Scale (BSS) was completed at the beginning and end of the 2- week period to assess measurement reliability and to account for any degree of improvement based simply

on admission to the trial. Patients were seen on specified days by 1 of 3 herbalists during the trial period and were not permitted to change herbalist during the course of the treatment. The first consultation with the Chinese herbalist occurred at week 2, at which time the patient was randomized (by an assistant) to placebo, standard CHM, or individualized CHM treatment. The patient was reevaluated by the Chinese herbalist at 2- week intervals for 2 occasions and then at monthly intervals for 2 further occasions. Continuous treatment was administered for 16 weeks. No special instructions were given to patients regarding diet, other than to continue consumption of foods they felt comfortable with and to avoid foods known to cause them gastro-intestinal tract irritation. All patients were evaluated by their gastroenterologist after 8 weeks of treatment and again at the end of the 16- week treatment period. Patients were closely monitored for any adverse effects or worsening of symptoms. Liver function tests were performed after 8 weeks of treatment. Follow-up questionnaires were sent to all patients 14 weeks after completion of the treatment period. Treatment codes were broken and revealed to patients only after completion of the follow-up questionnaires.

Table- 2: Standard Formula (Capsule Ingredients)*

Chinese Name	Pharmaceutical Name	Powdered Herb %
Dang Shen	Codonopsis pilusulae, radix	7
Hub Xiang	Agastaches seu pogostemi, herba	4.5
Fang Feng	Ledebouriellae sesloidis, radix	3
Yi Yi Ren	Coicis lachryma-jobi, semen	7
Chai Hu	Bupleurum chinense	4.5
Yin Chen	Artemesiae capillaris, herba	13
Bai Zhu	Atractylodis macrocephalaes, rhizoma	9
Hou Po	Magnoliae officinalis, cortex	4.5
Chen Pi	Citri reticulatae, pericarpium	3
Pao Jiang	Zingiberis officinalis, rhizoma	4.5
Qin Pi	Fraxini, cortex	4.5
Fu Ling	Poriae cocos, scierotium (Hoelen)	4.5
Bai Zhi	Angellcae dahuricae, radis	2
Che Qian Zi	Plantaginis, semen	4.5
Huang Bai	Phellodendri, cortex	4.5
Zhi Gan Cao	Glycyrrhizae uralensis, radix	4.5
Bai Shao	Paeoniae lactiflorae, radix	3
Mu Xiang	Saussureae seu vladimirae, radix	3
Huang Lian	Coptidis, rhizoma	3
Wu Wei Zi	Schisandrae, fructus	7

* Pharmaceutical terminology from Hsu

Randomization

Randomization was done by selection of a sealed envelope from a closed bag. Seventy sealed envelopes were prepared for each of the standard and individualized groups, and 60 envelopes were prepared for the placebo group. Patients were aware that there was a greater chance of receiving active treatment. Success in blinding was evaluated using a treatment credibility scale administered during the trial.

Herbal Preparation and Dispensing

All herbs were administered in the dried powdered form and encapsulated. A period of preparation was required before commencement of the trial to develop a suitable dispensary of 81 individual dried powdered Chinese herbs for dispensing to patients in the individualized treatment group. The standard herbal formulation was designed by Chinese herbalists and prepared by the principal supplier, Mei Yu Imports, Sydney, Australia (Table-2). The placebo preparation was prepared and encapsulated by a pharmaceutical contractor and was designed to taste, smell, and look similar to a Chinese herb formula. After testing on 5 independent volunteers, the placebo was deemed indistinguishable from raw powdered Chinese herbs. All herbs and the placebo formulation were supplied in the same opaque capsules. Patients in all 3 groups were required take 5 capsules 3 times daily.

After consulting with the Chinese herbalist, all patients were required to complete a series of questionnaires and wait 30 minutes for the preparation of their capsules. The wait time was used to avoid patients identifying whether they were receiving prepared capsules (Standard or placebo) or individualized formulations that were made at the treatment center. All medication preparation occurred in a closed room by assistants who were restricted from contact with the patients. Treatment codes were held by these assistants and by the chief investigator (A.B.). A blinded primary research assistant managed all the questionnaire and was responsible for giving the capsules to the patients. All patients were treated in an equivalent fashion. Compliance was assessed by an item included in the BSS and by pill count.

Measurement Instruments

The BSS was used to assess change in IBS symptoms during the course of the treatment. The BSS consists of 100mm visual analog scales related to each symptom of IBS (pain/ discomfort, bloating, constipation, and diarrhea) and an overall severity scale. Patients and gastroenterologists completed this scale independently at the beginning and end of the treatment period. Patients also were monitored during the course of the

trial using this scale. The BSS also included items for assessing rate of stool passage, rating the degree to which IBS symptoms interfered with life activities, and recording changes in medications usage and fiber consumption. To assess the success of patient blinding, a brief questionnaire was administered to patients after 2, 4, 10, and 16 weeks of treatment. This 4-item scale has been used to test credibility of different forms of psychological treatment but also has been successfully used in acupuncture trials and shown to have good internal consistency and test-retest reliability.

Statistical Analysis

Pearson product moment correlation was used in the analysis of reliability and validity data, and factor analysis was used to determine construct validity of the credibility scale. Outcome measures with categorical responses were analyzed using X^2 and Fisher exact tests. For the BSS, analysis of variance was used to determine the differences among groups at baseline, end of treatment, and follow-up. All P values were 2 - tailed, unless otherwise indicated, and the α level of significance was set at .05. Missing scale and item scores were not replaced. Data are presented according to an intention-to-treat protocol, in which patients who withdrew from the trial were recorded as having worsened (if appropriate) for categorical items only. Data for all other outcome measures are presented as per protocol analysis.

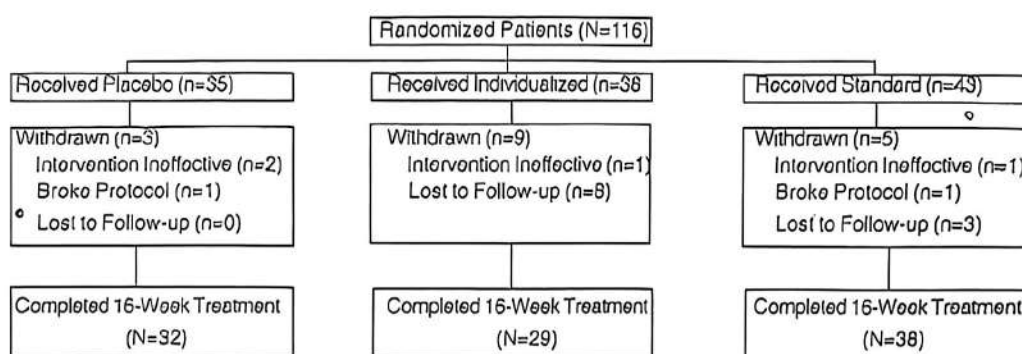
There were no reliable data that could be used to accurately predict the anticipated effect size between placebo, standard, and individualized treatment groups. We estimated that for adequate power (80%) to detect a 20% difference on the BSS scores at the $\alpha=.05$ level (1- tailed test), 35 patients were needed in each group.

Results

A total of 116 subjects were recruited during an 18-month period : 35 were randomized into the placebo group, 43 into the standard group, and 38 into the individualized treatment group (Figure). Fifteen patients withdrew during the 4-month course of the trial, and 2 patients were withdrawn from the trial for commencing a variety of relevant medications during the treatment period. Patient data on study entry are shown in Table 3. Patient groups were similar in terms of age, weight, and sex distributions. There were no significant differences among patients in the 3 groups in terms of total severity of symptoms as judged independently by both the patient and gastroenterologist, or in duration of the disease as reported by patients. Patients allocated to the placebo

group had a higher mean score for constipation, while patients allocated to the standard treatment had a higher mean score for diarrhea. Compliance with study medication was high as measured by a questionnaire item and by random pill counts and did not differ between groups (95% for standard CHM, 94% for individualized CHM, and 95% for placebo). Fiber and non study medication consumption did not change significantly for any group during the treatment period.

Table- 3: Patient population Characteristics Before Treatment and Main Total Bowel symptom scores *



Patient progress through stages of the trial

Variables	Group. No. (SD)			P Values
	Placebo (n=35)	Standard (n=43)	Individualized (n=38)	
Characteristic				
Weight, kg	72.(12.8)	66.7(16.8)	69.1(14.4)	.29
Age, Y	45.0(13.9)	47.6(15.1)	47.4(13.4)	.68
Sex ratio (male:female)	0.46	0.65	0.52	.75
Baseline date				
Gastroenterologist total BSS score	172.7(65.4)	172.2(72.6)	166.6(63.6)	.59
Patient total BSS score	191.2 (69.4)	189.7(64.8)	178.5(69.8)	.67
End of treatment				
Gastroenterologist total BSS score	147.(86.6) (n=30)	70.9(63.2) (n=35)	100.4(83.6) (n=25)	.001
Patient total BSS score	150.0(81.6)	106.1(73.7)	103.0(74.7)	.03
At follow-up 14 weeks after study completion				
Patient total BSS score	155.7 (84.2)	132.6(90.2)	99.4(74.8)	.10

* Data are reported by patients and gastroenterologists at start and end of treatment period and at follow-up. BBS indicates Bowel Symptom Scale.

Reliability and Validity Testing

The reliability of the BSS (ie, consistency of the measure) was determined by a test-retest assessment during the run-in period prior to treatment commencing (week 0-2). Correlation between the BSS completed during the initial interview with the gastroenterologist and then 2 weeks later at the clinical treatment centers was high for total score ($r=0.7$; $p<.01$, 2-tailed) and for each individual symptom (bloating [$r=0.8$], pain [$r=0.6$], diarrhea [$r=0.8$], and constipation [$r=0.7$]).

The credibility scale also was examined for test-retest reliability. Correlation between the first and second administration of this scale was significant ($r=0.6$; $p<.01$, 2-tailed), the correlation coefficients for each of the 4 scale items were in the range of 0.47 to 0.65. The internal consistency of the credibility scale based on interitem correlations or both occasions were uniformly high and Cronbach coefficient α (Representing average interitem correlations) was 87 and 86 for the first and second occasions, respectively.

The visual analog scales within the BSS had high face validity (100-mm lines with severity marked at the extreme right and absence of symptom marked at the extreme left.) and have high content validity (ie, they incorporate the key domains of interest-pain and discomfort, bloating, constipation, and diarrhea). Testing items in the scale for concurrent validity at the commencement and end of treatment showed that the gastroenterologist's assessment of the patient correlated highly with the patient's own perception of severity of symptoms. For both, Pearson correlation coefficient was in the range of $r=0.63$ to 0.84 for any 1 item (symptom) or for the total symptom score ($P<.01$ on all occasions).

Assessment of the credibility scale for construct validity through a principal components factor analysis based on the first administration revealed only 1 factor with an eigen value greater than 1 (2.89). This factor accounted for 72.2% of variance in this data set. All items had a high correlation with this first factor, suggesting satisfactory construct validity.

Main Outcome Measures

For all 5 main outcome measures- total mean BSS scores and global improvement as assessed by patients and gastroenterologists, and interference with life as assessed by patients - patients receiving the standard CHM formulation responded significantly better than patients in receiving placebo. Patients receiving individualized CHM treatment also responded significantly better on 4 of 5 scores than patients receiving placebo. Overall, patients receiving individualized CHM fared slightly worse than those receiving standard CHM treatment.

At the end of treatment, there was a significant difference between the mean total BSS scores as assessed by patients, with patients in the standard CHM group and those in the individualized CHM group responding significantly better compared with placebo (Table-3). No significant differences were noted between standard and individualized CHM treatment groups.

The BSS scores completed by the gastroenterologist at the end of treatment showed a significant difference between the mean total BSS scores for patients in each group, with patients receiving standard and individualized CHM responding significantly better compared with those taking placebo ($p=.001$). A post hoc Bonferroni test demonstrated that this difference was significant for patients in the standard group ($p=.001$) but not for those in the individualized group ($p=.08$).

Patients receiving standard herbal formulations improved by 44% (according to patients) and 59% (according to gastroenterologists), in contrast to patients in the placebo group who improved 22% (according to patients) and 19% (according to gastroenterologists). Patients receiving individualized CHM improved by 42% (According to gastroenterologists).

Table-4: Perception of Improvement by Treatment Group*

Compared With Before Trial	Group. No. (%)			
	Placebo	Standard	Individualized Values	
Patient rating of response				
Improved	11(33)	29(76)	18(64)	.007
Stayed the same	19(57)	8(21)	8(29)	
Worsened	3(9)	8(3)	2(7)	
Gastroenterologist rating of response				
Improved	9(30)	29(78)	15(50)	.002
Stayed the same	19(63)	7(19)	12(40)	
Worsened	2(7)	1(3)	3(10)	

* Group differences calculated by using χ^2

There was a significant association between the treatment groups and the change in the degree to which IBS symptoms caused interference with life and activities by the end of treatment ($P=.03$). Of patients receiving the standard formulation and of those receiving individual formulations, 63% and 54%, respectively, stated that treatment resulted in IBS causing less interference in their lives and activities, compared with 37% of patients in the placebo group.

At the end of the trial, the ratings of both gastroenterologists and patients who believed that the IBS symptoms had improved, stayed the same, or worsened (Table 4) showed a significant association by treatment group ($p=.007$). Of patients receiving standard CHM and of those receiving individual CHM, 76% and 64, respectively, stated they had improved during treatment. In contrast, only 33% of patients receiving placebo stated they had improved during treatment.

The gastroenterologists' responses also demonstrated a significant association between the treatment group and how patients felt at the end of treatment ($X^2_{24}=17.1; p=.002$). Seventy-eight percent of patients receiving the standard CHM formulation, 50% of those receiving individual CHM, and 30% of those receiving placebo were judged by the gastroenterologist as having improved during treatment. There significant correlation between patients' and gastroenterologists' assessment of global improvement and of total BSS scores at the beginning and end of the trial (all $r>0.5$, all significant to $P\leq.01$ level, 2- tailed).

Adverse Effects

Two patients withdrew from the trial because of discomfort associated with the treatment. One patient developed upper gastrointestinal discomfort while taking the standard CHM formulation. A second patient developed headaches (although a history of headaches existed), which gradually subsided on discontinuation of therapy. Recommencement of treatment caused gastrointestinal discomfort, and the patient was subsequently withdrawn from the study. No other major adverse effects were noted. Liver function tests obtained after 8 weeks of treatment showed no abnormal values.

Follow-up Assessment

Results of the BSS administered to patients 14 weeks after completion of the course of treatment (but before treatment codes were revealed) demonstrated that the treatment effect weakened, with only the individualized CHM group maintaining improvement ($P<.10$) Table 3. However, there was significant association between the treatment group and how patients felt at the 14-week follow up ($p=.02$). Of patients who had received the standard CHM formulation and of those who had received individual CHM formulations, 63% and 75%, respectively stated that they still felt an improvement compared with 32% of patients who received placebo.

Blinding

The success of blinding patients to treatment was tested at the beginning end, and on 2 other occasions during the course of treatment. At 2

weeks inter treatment, the overall mean on this 6 point scale was 4, indicating that patients on average viewed CHM as only moderately credible and were not a self-selected group with a bias in favor of complementary medicine. No significant difference was noted between groups at outset and at end of treatment. However, the mean credibility score decreased slightly with time for the placebo group and remained strong within the standard CHM group. Since the standard CHM treatment proved the most effective, the increased difference incredibility toward the end of the treatment may be a reflection that this group of patients was receiving the most benefit. There was a significant negative correlation between the final mean credibility score and the final patient-rated BSS Score ($r=-0.43$; $P<.01$) and the final gastroenterologist-rated BSS score ($r=-0.58$; $P<.01$).

Comment

To our knowledge, this is the first clinical trial in CHM that fully adheres to the traditional Chinese diagnostic and treatment processes while using a strict and accepted methodological protocol. Our study demonstrated that CHM is effective in the management of symptoms related to IBS with, in some cases, effects lasting up to 14 weeks after completion of treatment. Patients receiving standard or individualized CHM treatment demonstrated significantly better outcomes (both clinically and statistically) than patients receiving the placebo on all 5 key outcome measures. However, patients receiving individualized CHM formulations had less improvement during treatment than patients receiving the standard formula, although this difference was not statistically significant. The first null hypothesis that CHM treatment of IBS with a standard herbal formula is of no value is rejected. The second null hypothesis that individualized treatment of IBS according to the principles of traditional CHM is of no added value to treatment with a standard formula is partially accepted. While there were no significant differences between patients receiving standard or individualized treatment at the end of the treatment period, on follow-up, patients in the individualized treatment group had maintained more substantial improvement.

Three Chinese herbalists with contrasting Chinese medicine education backgrounds participated in this trial. In theory, their degree of education in Chinese herbalism should affect their ability to successfully tailor treatment for patients. While outcome differences between practitioners were observable for this cohort of patients, sample sizes were too small to make reliable conclusions. Furthermore, the overall differences

between standard and individualized CHM may be relatively small (as both are active treatments) and require larger sample sizes. This does not, however, account for the notable improvement that was maintained in the individualized CHM group after cessation of treatment.

One plausible explanation may be that the standard CHM formulation was suitably designed to treat the complex presentations of IBS but was incapable of successfully dealing with underlying causes for most patients as viewed by Chinese medicine. The tailored formulations may have permitted the herbalists to individually address these underlying causes and deficiencies. Moreover, there may be active ingredients in the CHM formulation with properties similar to antispasmodic or anxiolytic drugs. Chinese herbal formulas are complex and viewed as a number of active ingredients working together, rather than 1 specific active substance. The standard formulation used in this study is not a sedative or anxiolytic preparation in traditional CHM terms but is a formulation considered to regulate and strengthen bowel function.

In our study, all efforts were made for the approach in the 3 treatment groups to be indistinguishable. The credibility scale was demonstrated to be a reliable and valid instrument and presents strong evidence that blinding was maintained throughout the trial. The slight decrease in credibility score seen in the placebo group toward the end of the trial was accounted for by its significant correlation with the actual treatment outcome. The authors are convinced that patients, herbalists, and gastroenterologists were all successfully blinded.

There were minimal adverse effects reported during the study. Liver function screening was included as a precaution because liver dysfunction associated with the use of Chinese herbs has been noted in other studies.^{8,22} Liver dysfunction was not expected with the type and form of herbs used in this study. In our study, liver function was reassessed after 8 weeks of treatment. We have no data on liver function after that time, and therefore cannot comment on longer term safety of these CHM products. Raw herbs used as starting products are partly regulated in Australia.

We conclude that Chinese herbal formulations may offer symptom improvement to some patients with IBS. In this randomized, double-blinded, placebocontrolled trial CHM was shown to be effective in the management of IBS. Patients receiving the standard CHM formulation fared best during the course of treatment, while patients receiving the individualized treatments found that the benefit gained lasted beyond

the treatment period. Although not all patients responded to this therapy, our findings support the consideration of further investigation of Chinese herbal medicine as a treatment option for IBS.

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Indian Indigenous Pharmaceuticals

Tradition, Modernity and Nature

Maarten Bode

That India is now a big city culture and certainly in my generation and much more so in subsequent generations, that India includes large amounts of what you may call adulterated materials For me this notion of hybridity, of melange, of things being mixed together, has been essential.

(*Salman Rushdie in India Today*, 17 July 1997)

In the last decades of the nineteenth century Indian entrepreneurs started the industrial production of Ayurvedic and Unani (Greco-Islamic) medicines. At the end of the twentieth century the turnover of this industry was much larger than government funding of Ayurvedic and Unani education, treatment and research. However, in contrast to government policy towards Indian medicine this industry has not received much attention from scholars interested in the study of contemporary Indian medical traditions.

Around 8,000 licensed pharmacies produce a wide range of Ayurvedic and Unani medicines. It is common for Unani firms to produce Ayurvedic medicines such as 'Supari Pak' and 'Chyawanprash'. Among these companies, many are small and have a largely local clientele. I will focus on three of the biggest companies which sell their products all over India and, increasingly, abroad. The Ayurvedic companies Dabur and Zandu hold around one third of the market in Ayurvedic products while Hamdard produces around 70 per cent of the Unani pharmaceuticals in India. The total sale of Ayurvedic products in 1997, including Ayurvedic soaps and cosmetics, was estimated to be between Rs. 1,500 crores (US\$ 375 million) and Rs. 2300 crores (US\$ 27.5 million). Though Hamdard boasts as many as 1200 pharmaceutical products and the therapeutic indexes of Dabur and Zandu mention at least 300 products, a handful of these are responsible for the large sales figures. For example, three products (a tooth powder, a hair oil and a vitality booster) comprise around 40 per cent of the sales of Dabur while 'Rooh Afza', a sarbat (sweet syrup, sweet medicine) for which many health benefits are claimed, does the same for Hamdard.

The marketing of Indian indigenous pharmaceuticals has substantially determined the way the Indian public looks upon its medical traditions. Indian medicines are not only the fresh drugs prescribed by a professional 'naturalist' or the home remedies prepared in Indian kitchens, but increasingly high tech products associated with factories and laboratories. Their ambiguity challenges dichotomies which have been too easily taken for granted such as 'Western/indigenous' and 'traditional/modern'. Nowadays the term 'modern' can also be applied to Indian health traditions such as Ayurveda and Unani tibb. Though Ayurvedic and Unani preparations have their roots in classical sciences these substances are increasingly produced, researched and marketed along modern lines. Companies use modern production and research technology and advertisements appear on television and in glossy, English-language magazines. Large producers like Dabur, Zandu and Hamdard also offer financial incentives to 'encourage' retailers and chemists to raise the sales of their products. At the same time a significant number of recipes come from classical texts and traditional medical concepts are used in the marketing of Indian medicines. Indeed, Indian health products are modern and traditional at the same time. Although, logically speaking, 'traditional' and 'modern' exclude each other, in practice these qualities go together.

Especially large companies like Dabur, Zandu and Hamdard have been instrumental in the reworking of traditional medicines into modern health products. In this chapter I will analyse the way over-the-counter Ayurvedic and Unani pharmaceuticals are projected by the industry. How do these large companies 'manage the paradox of being natural and traditional, while remaining contemporary', as one of Dabur's directors put it. Analysis of promotional material as well as interviews with managers will provide us with insight into the dialectic relationship between tradition and modernity, which marks Indian health traditions and Indian society today. Besides, to sell their products Dabur, Zandu and Hamdard tap into popular Indian notions of health and disease. For example, advertisements target the moral dimensions that are part and parcel of discourses about health and illness in the Indian context.

The commodification of Indian indigenous medicines

In June 1998 India Today, a prominent Indian weekly with 15.9 million readers, contained an advertising special on Ayurvedic medicines. It included five pages with advertisements and small articles about three

companies. Allen Laboratories promoted its capsules for fighting dandruff, hair loss and premature greying by toning up the stomach and liver. Baidyanath, a large north Indian company established in 1918, selected five products out of its range of five hundred : two rasayanas (tonics, vitalisers,) a medicinal tooth powder, a digestive, and a medicine for the treatment of dysmenorrhoea. Dabur restricted itself to a food supplement and 'Pudin Hara', a digestive already mentioned in their therapeutic index of 1930.

Most Ayurvedic and Unani medicines don't find their way to patients and consumers through the prescriptions of traditional healers. I estimate that at the moment 80 to 90 percent of Ayurvedic and Unani pharmaceuticals are sold directly to consumers by retailers such as chemists, small grocers as well as supermarkets and beauty parlours. This reality differs from the image of the scholarly traditional healer who prescribed medicines after carefully having examined his patients. Self-medication seems to be the rule for most Indian indigenous pharmaceuticals. One of the reasons is the fact that a large majority of the students who finish their education at one of the colleges of Ayurveda or Unani begin to practise Western medicine. Rather than promoting the cause of traditional medicine by offering teaching facilities and stimulating confidence in Indian medicine the more than 'hundred badly-funded Ayurvedic and unani colleges' have mainly functioned as 'backdoors', i.e. backdoor entrances, to the practice of Western medicine for those who failed to get access to Western medical training. The larger part of the training in these 'traditional colleges' is usually in Western medicine and allied modern sciences. Following graduation students will make use mainly of Western disease categories and medical prescriptions. Therefore, the practice of institutionally trained Ayurvedic and Unani physicians often does not differ from that of biomedically trained physicians. Indeed, the prestige of modern medicine as well as the lack of proper training in traditional medicine has deprived the traditional pharmaceutical industry of physicians for the prescription of their products. Another reason for the dominance of over-the-counter marketing is the large number of medicines for common diseases like cough and body aches, as well as tonics and cosmetics in the product range that for these products a prescription is not needed.

The profusion of advertisements for Unani and Ayurvedic pharmaceuticals complements the increasing consumerism that marks India in the 1990s. Producers of Indian medicines advertise their products widely. Different

media are used including television, radio, cinema, billboards, neon signs, print media, beauty contests, sales exhibitions and even 'international' scientific conferences. Advertisements for Indian indigenous pharmaceuticals are also seen in the streets of India's cities. A walk through Delhi proves my point. A police boat carries the name of the largest producer of Unani medicines. An Ayurvedic company uses city buses for drawing the public's attention to its 'brain tonic'. Above Chandi Chowk, the famous bazaar in the old city, towers an advertisement for an Ayurvedic hair oil that cools the brain. Along Delhi's Ring Road an Unani company uses the road demarcations to advertise its Ayurvedic health tonic demonstrating the intertwining of Indian medical traditions. Because of the costs involved these advertisements are usually for the most 'fast-moving' products of the companies. For other products an army of salespeople tries to influence retailers to 'counter-push' their products. The retailers get financial incentives and signboards that carry the name of the shop next to images of some medicines made by the company that offers the signboard. Product brochures carry the statement 'For medical practitioners only'. This indicates the importance companies attach to maintaining a medical image for their products although it does not deter them from selling them straight to patients.

Who are the customers to whom these commercial messages must appeal? In contrast to India's more advanced hard liquor industry, producers of indigenous pharmaceuticals have just started collecting statistical data about their customers. It was only recently that the Himalaya Drug Company, a large producer of Ayurvedic medicines that is known for its progressive marketing and production, Ayurvedic medicines that is known for its progressive marketing and production, hired a marketing firm to collect socio-economic data about consumers and evaluate their reactions to advertisements for Ayurvedic Concepts, the company's new over-the-counter product line. Even large companies like Dabur and Hamdard remain largely dependent upon piecemeal data collected by their sales staff when they visit retailers. This fact is illustrated by the assistant manager of Dabur Research Foundation who said 'Occasionally we dispense one of our new products to a sample of around four hundred people and ask them their opinion. However, such systematic studies are still exceptional in the Ayurvedic industry'. Though members of the lower middle class and daily wage earners are certainly important customers for Hamdard, Dabur and Zandu, indigenous brand medicines are increasingly marketed to the more affluent middle classes. Newspaper articles, advertisements and industry statements indicate

that people like office workers, executives and affluent farmers are an important new consumer market for indigenous medicines. This trend is also reflected in the price of some of these products, as a statement of the assistant advertising manager of Hamdard illustrates : 'only more affluent people can afford to buy our brain tonic Rogham Badan Shirin on a regular basis'. The recent release of a CD- ROM entitled 'Ayurveda Authentica' by Dabur also demonstrates that middle-class consumers are an important target for these companies' marketing efforts. In their campaigns companies capitalise on anxieties among the better-off about side-effects caused by Western medicines and offer 'gentle' remedies for chronic ailments such as hypertension and diabetes, health problems that affect the richer strata of Indian society.

'Chyawanprash', a general health tonic produced and marketed by Dabur, Zandu and Hamdard, is the best known Ayurvedic tonic. It is named after a sage who was its first user. The sage obtained the tonic from the Asvins, the physicians of the gods, after losing his eye-sight and vigour due to an overcurious and sexually demanding princess. Though many Ayurvedic and Unani companies sell this product, Dabur is the largest producer of 'Chyawanprash'. Due to heavy advertising on television and in the print media the product has had a great impact upon the popular image of traditional medicine in India. In India Dabur's Chyawanprash is often seen as the symbol of commodification of Indian medicine, as a statement by a manager of Dabur testifies: 'after Dabur turned 'Chyawanprash' into a commodified family tonic the number of buyers rose to 25 million'. The product familiarised the Indian middle class with Ayurveda as a codified tradition. In an advertisement in *India Today*, Dabur emphasises the health benefits of the product by stating :

Modern science has ample evidenced today to prove that the unique immunomodulatory action of Dabur Chyawanprash restores the balance of antibodies. It has powerful anti-oxidants which neutralise the harmful effects of modern living. Protecting you from illness. Making you stronger. From within Based on the 3000-year old Ayurvedic recipe in Charaka Samhita, fortified with 48 herbs, roots, fresh fruits and minerals. Completely natural, free from side effects.

Both Ayurveda and Unani *tibb* attach great importance to enhancing vigour and disease resistance. Emaciation, the wasting away of body constituents, is viewed as the blue print for disease. This explains the large number of tonics marketed by the indigenous industry. The *sarbat* 'Rooh Afza', India's best selling Unani tonic, is a case in point. The tonic

is not mentioned in any of the canons of the Greek-Arabic medical tradition. Instead it was developed in 1907 by Hakim Abdul Majeed, the founder of Hamdard. Though 'Rooh Afza' is not a traditional medicine in the strict sense, according to Hamdard the product combines 'the essence and virtues' of 'traditional syrups'. Nowadays 'Rooh Afza' makes up approximately 40 per cent of Hamdard's profits. Like in the marketing of Dabur 'Chyawanprash' a blend of traditional and modern science is used to legitimise the product:

The unique preparation with herbs, vital elements and natural vitamins. People's favourite for over 86 years with scientifically proven natural goodness that balances natural body processes, and body fluids. Its unique ingredients cleanse the blood and correct deficiencies that lead to tiredness, loss of appetite, anaemia and giddiness. Besides being extremely beneficial during vomiting, dehydration, and heat exhaustion, Rooh Afza increases the calcium level in blood as well. Strengthens bones and muscles function efficiently.

'Rooh Afza' is clothed with many images and ideas like science, art, Muslim hospitality- the product is widely used by north Indian Muslims for breaking the fast during Ramadan- nature and beauty. We find most of these on the 'Rooh Afza' calendar that Hamdard distributed in 1999. Next to pictures of young women who are said to be 'completely natural', 'completely beautiful', 'completely happy' and 'completely fit', glitter the names of prominent modern research institutes that have done research on the product such as the All Indian Institute of Medical Sciences. According to the calendar the product 'can actually cool body, mind and soul', is 'anabolic and 'anti-stress' and 'stimulates cardiovascular and central nervous system activity as well as regulates the balance of electrolytes in the body'. The products's '1992 year heritage' is also emphasised on this calendar.

Along with their medicines the producers of Indian indigenous pharmaceuticals also market their medical systems. For example, a brochure of Zandu that mentions 33 of the company's best-selling products, states :

In the service of ailing humanity Zandu's Effective Ayurvedic medicines are based on time-tested prescriptions by India's ancient physician sages of the Aryan era. Effectively revived with intensive research of the ancient blended with modern know-how..... The essence of Zandu's success lies in the firm belief that Ayurveda propounds no mere technique of herbal or mineral cure, but lays down a whole philosophy of human life

and living with a view to the preservation and building of a positive health and happiness, development of immunity to disease, longevity and preservation of youth.

Apart from evoking traditional culture and modern science Zandu legitimises its products by stating that they belong to a holistic medical tradition.

Indeed, the spectrum of ideas and images evoked by the industry is wide. However, after comparing many advertisements and brochures, of which only a few examples have been given, two themes emerge. The first theme symbolised by the *rishi* (seer) sitting in a test tube is the embracing of both tradition and modernity. It is not too difficult to detect in the printed material as well as in the conversations with managers and other employees of the industry the importance of both concepts. What kind of images and ideas are used by the industry to express that their products are both traditional and modern? How do they argue the authenticity of their products in a context in which Western medicine has the upper hand in terms of prestige and power? The second theme is the naturalness and wholesomeness that producers claim for their products. At first sight this looks obvious. Indeed, everywhere producers of herbal and mineral remedies are capitalising on the fear induced by the side effects of 'chemical' pharmaceuticals. However, in the Indian context at least there is more to this. Underneath an instrumental discourse on the dangers of reductionism and the advantages of holism we can detect a moral discourse about human affinities with, at its centre, the construction of 'naturalness' and 'wholesomeness'.

Tradition and modernity

Religious and historical images are used by the industry to anchor Indian pharmaceuticals in traditional culture. For example, the modern plastic container of Dabur 'Chyawanprash' shows a *rishi* sitting in the Himalayas and a 'free, factfilled booklet' for its promotional claims that 'Chyawanprash' is 'from the oldest living system of health care'. These images appeal to Indian people because everyone is familiar with the *Ramayana*. In this Hindu epic the monkey king Hanuman flies to the Himalayas to collect the herbs to save Laksman, the brother of Lord Rama who is the hero of the epic, from dying. The streets were empty when this epic was shown on television in 1987-8. The Himalayas represent the abode of potent medical herbs while a *rishi* denotes superior knowledge about life. Most certainly these images will be part of the attraction 'Chyawanprash' holds in the eyes of the Indian public.

Zandu associates its products with traditional culture by emphasising its relationship with 'a philanthropic and famous Ayurvedic physician from Jamnagar, a district in Gujarat' who 'was popular by his nickname Zandu'. According to Zandu this physician 'was the Rajvaidya [royal physician] to Raja Jam Vibha, then king of Jamnagar'. Zandu uses a picture of Dhanvantari, the Hindu god of medicine, to link its products to Indian traditional culture. On the back of one of its brochures we see Dhanvantari, 'Zandu's Symbol of Purity and Effectiveness in Medicine', rising out of the ocean with a container holding Amruth, the nectar of immortality. As Zandu tells us, in Hindu mythology Dhanvantari is one of the gifts the gods provided to humanity by churning the ocean. Indeed, Amruth denotes the god given nature of Ayurvedic medicines. The sun and the moon are present in 'The 10 Minute Guide to Ayurveda' that Dabur published around 1995. In Hinduism, the sun and the moon are deities as well as basic semantic opposites. Among many other things they represent heat and coolness that people who have some basic knowledge about Ayurveda will immediately associate with *pitta* (bile) and *kapha* (phlegm), two of the Ayurvedic humours. Gods, *rishis* and the Indian *sastras* (sciences), also play a prominent role in Ayurveda Authentica, a CD-ROM for the promotion of Ayurveda that Dabur released in 1998. The cover of the CD-ROM evokes Indian traditional culture through the phrase 'Discover India's ancient secrets for health and healing.'

The producers of Unani pharmaceuticals also refer to traditional culture. The Koran and the crescent moon decorate the packaging and the promotional materials of the products of the Ajmal Khan Tibbiya (medical) College Dawakhana (pharmacy), a Unani pharmacy that is part of the Unani medical college of Aligarh Muslim University, one of the largest Muslim universities in the world. Though the products of Hamdard do not carry religious symbols, the use of Urdu poetry for the promotion of 'Rooh Afza' links the product to Delhi's pre-independence Muslim culture that suffered greatly in the aftermath of partition. The majority of Delhi's Muslim population left for Pakistan shortly before and after this nation was created in 1947. The absence of religious symbols in the marketing of Hamdard could be due to Hindu sensitivity towards Islam. Instead of Islam Hamdard uses Unani *tibb* to link its products to tradition. The 'centuries old Unani system of medicine' as well as ancient physicians like ibn Sina and Galen feature in the promotional material of the company. Sculptures at the entrance of the head office off Hamdard at Asaf Ali road, just on the border of old and New Delhi, aim at anchoring Hamdard in world medical history. Among the sculptures we find Abdul Majeed,

the founder of Hamdard, in the company of the prominent Unani physician and freedom fighter Ajmal Khan and classical medical authorities such as Hippocrates, Galen and Ibn Sina. These statues denote Unani *tibb's* shared ancestry with Arabic and classical Western medicine.

Do all these images of traditional culture mean that Unani and Ayurvedic medicines are things of the past? Certainly not, for example in an advertisement for a 'brain tonic' the Central Drug Research Institute, a modern research centre based in Lucknow, is mentioned alongside the *Rig Veda*, the oldest of the four Vedas holding the greatest authority within Hinduism. In the introduction to its latest therapeutic index Hamdard promises to open 'the doors of research' and enter 'an expansive world of discovery and research'. Images of modern research and production technology are as important for the marketing of Indian indigenous pharmaceuticals as are references to tradition. Pestles and mortars are placed next to computers. A *rishi* is sitting in a test tube (Figure 11.1). Deified planets are combined with pictures of the latest equipment for chemical laboratory analyses. Company brochures contain pictures of modern factory buildings and halls equipped with modern production machinery such as huge metallic containers, electric ovens and packing machines.

Almost all promotional material from the three companies that are the focus of instance, Dabur's booklet for 'Chyawanprash', the tonic named after the consummated sage, mentions research on the product by the Banaras Hindu University.

Modern medical journals such as the *Journal of the National Integrated Medical Association* and *Indian Practitioner* are referred to in a brochure for 'Livotrit', Zandu's liver tonic. Hamdard too is keen to offer modern scientific data to 'validate' or 'authenticate' its products. To boost the scientific image of its products Hamdard offers monetary rewards to scientists who do research on its best-selling products. Research monographs have been published on its 'super star product' 'Rooh Afza' as well as on its 'star products' 'Cinkara', a herbal tonic containing 'vitamins, minerals and trace elements', and 'safi' (pure, just), Hamdard's 'blood purifier for the treatment of skin diseases'. These studies are published as Hamdard National Foundation Monographs. Since the 1970s Hamdard has been developing a new science called 'elementology' that seeks to provide a modern epistemological base for its products. International conferences devoted to elementology have been organised and occasionally Nobel prize winners have been invited to provide

international glamour. With the profits of its products Hamdard has built its own university in New Delhi. Jamia Hamdard (Hamdard University) is equipped with laboratories and a hospital for conducting research on Unani and Ayurvedic medicines. Zandu and Dabur also have their own laboratories for researching their products. Indeed, to validate their products the producers of Ayurvedic and Unani medicines use modern research. Is this a new phenomenon caused by accelerated globalisation after the opening up of the Indian economy in the late 1980s and early 1990s? The answer should be negative because as early as the nineteenth century it was propagated that if Ayurveda and unani wanted to survive these 'native systems should improve by borrowing from modern medicine, 'the epistemological other'. Consequently dissection and modern pharmacological research became part of these medical traditions. This trend continued after independence with the creation of the Central Council of Research in Indian Medicine by the Indian government in 1970. Also, R.N. Chopra, a modern pharmacologist and the chairman of the first official commission on Indian Systems of Medicine that advised the Indian government in 1747, propagated the use of modern pharmacology because there are sure to be others [indigenous medicines] of little therapeutic value that are given merely because they are mentioned in some old manuscripts, and no one has taken the trouble to confirm the truth of these statements. Attempts must be made to separate the good ones from the useless ones and for this a systematic investigation of these drugs must be undertaken.

How could 'certain spurious and superfluous formulations' creep into what has been called by Hamdard 'the vast treasure house of medicines?'. This could be explained by a theory of decline as part of a revival movement that started in Bengal in the nineteenth century. These revivalists think of India's medical traditions as 'ruins that testified to a glorious past when Ayurveda and Unani Tibb flourished, both communities hold foreign rule responsible for their decline. Apart from justifying modern research for sifting the wheat from the chaff, this theory of decline implies the greatness of Indian medicine. A system that survived so many onslaughts must have a lot to offer', was the comment of the manager product development of Dabur. This theory of decline as well as the past glory that is an integral part of it is still very much alive in the promotional material of the industry. For example, in the inaugural issue of the English version of its magazine *Ayurved Vikas* (Blooming Ayurveda), Dabur explains the present subordinated state of Ayurveda by 'invasions' having 'disastrous effects on various aspects of ancient sciences'. In the same

article the heyday of Ayurveda is located in the Buddhist period which is projected as the period in Indian history in which 'basic human values' and 'the logical sciences' were prominent. Also, Zandu's symbol Dhanvantari, the Hindu god of medicine, refers to a period when Indian civilisation was at zenith. A theory of former greatness is also part of the discourse within Unani *tibb*. 'Unani declined, because the British suppressed educated Muslims culturally, educationally and economically', I was told by the superintendent of the Unani wing of the teaching hospital of jamia Hamdard. Indeed, Unani *tibb* is often linked to the glories of the Indian Mogul empire. By associating their medicines with a glorious past the producers of Indian indigenous pharmaceuticals legitimise their products.

When modern science is the 'arbiter' does this mean that Ayurveda and Unani *tibb* are just adapting to biomedicine? This question has often been answered in the affirmative. For instance, Leslie has argued convincingly that modern Ayurveda, created through the professionalisation of the field in the nineteenth and twentieth century, differs from classical Ayurveda of the first millennium AD, as well as from the 'traditional culture' Ayurveda that marked the second millennium up to the nineteenth century. In his view modern Ayurveda has many things in common with the way biomedicine is taught and practised in India. For instance, modern science dominates Ayurvedic and Unani colleges while the prescription of Western pharmaceuticals and biomedical disease categories are part and parcel of 'indigenous practice'. Likewise, other social scientists like Bala and Banerjee have argued that Indian systems of medicine have become standardised through their interaction with biomedicine and modernity at large. According to Banerjee, Ayurveda has become 'formatted' and 'co-opted' by the 'capitalist enterprise' that she sees as typical of colonial and post-colonial India.

However, at the marketing level adaptation and resistance to biomedicine are paradoxically linked. For example, the slogans 'right effect, no side effect' and 'from deep within' that are used by Dabur represent a critique of Western medicines. Ayurvedic as well as Unani medicines are marketed as natural medicines without harmful side effects. Modern medicines 'have played havoc with the natural power of resistance of the human system', says the marketing brochure on Safi, Hamdard's blood purifier. Modern drugs cause 'unheard of allergies and loss of immunity', because they testify to a 'one-symptom-one-drug-one-action-mindset'. With these slogans the industry addresses the fear of side

effects of modern medicines. According to the marketing manager of Hamdard, using modern medicines is like 'printing money to fight inflation' because 'Western medicines cure on the one hand and make you sick on the other'. Taking Western medicines is like an addiction because it never stops', was the comment of an Ayurvedic physician who runs an outpatient clinic owned by a south Indian manufacturer of Ayurvedic medicines. Next to presenting Indian indigenous medicines as safe alternatives they also claim to be more effective in the long run. While 'Western medicine focuses mainly on the symptoms and not the cause of the illness', Indian indigenous pharmaceuticals are marketed as medicines that fortify the immune system and therefore work 'from deep within'. These medicines have 'the right effect' because by regulating digestion and blood formation they take care of the formation of healthy humours and tissues. Indian medicines 'balance' organs, 'lubricate' tissues and 'clean' canals. Indeed, Indian physiology explains the efficacy of Ayurvedic and unani medicines. They are said to fortify the innate human power for conserving health and fighting disease.

Natural medicines

Ayurvedic and Unani pharmaceuticals are represented as 'completely natural' Natural ingredients such as fruits, flowers, vegetables, leaves, roots and minerals decorate labels, advertisements and promotional material for them. The Dabur company has chosen a tree as its company logo and hamdard's brochures discuss the health benefits of the natural ingredients found in its products. In *Ayurved-Vikas*, Dabur's health magazine, a lot of attention is devoted to the medical properties of 'Indian plant drugs' such as neem, tulsi and amla. A few years ago the firm Zandu added a leaf of its company logo to emphasise the natural quality of its products. As natural medicines Ayurvedic and Unani pharmaceuticals are presented as green alternatives to 'modern curative agents' that are labelled 'synthetic'. The safety and efficacy of these medicines is guaranteed because their 'ingredients are so well balanced that they cancel out possibly harmful effects on one another while bringing out-even boosting-the curative properties of each'. Next to synergy- the joint action of medical ingredients as well as organ systems- immunity and vitality, which are closely connected within modern Ayurveda and Unani *tibb*, are important markers of contemporary Indian health traditions. To communicate the latter two concepts Hamdard uses the slogan '*hamara angrakshak*' (our bodyguard) in its marketing of 'Chyawanprash'. Both immunity-vitality and synergy are argued on technical grounds. In

the case of immunity and vitality, terms such as free radicals, anti-oxidants, *kapha sleshma* (anabolic function) and *ojas* (vital energy) which belong to different knowledge systems, are used simultaneously. But this technical discourse- clothed in biomedical as well as humoral terms- is at the same time, or at a deeper level, a moral discourse about 'wholesomeness' and 'naturalness' in which 'divine intelligence' and the natural order of the universe are important images.

The animated life force is central to the natural philosophy that forms the epistemological base of Indian health traditions. This paradigm offers explicit guidelines for an appropriate way of living marked by 'naturalness', 'appropriateness' and 'wholesomeness'. Indeed, *vaidyas* and *hakims* are naturalists who claim that their cures are based on both the products and the laws of nature. Both are seen as god-given. They are not based upon the mechanism of natural selection of modern science but upon a master plan. Indian health traditions represent the human body as a canopy of the soul and hold its owner responsible for keeping it in good shape. At the same time it is the task of the physician to provide patients with guidelines that seek to bring the body back to its natural state, i.e. health. This places Ayurveda and Unani *tibb* in contrast to biomedicine as a laboratory science which sees illness as a natural object that can be manipulated by positivistic research designs and high-tech medical treatment. To emphasise the philosophical and spiritual status of their medical systems, the producers of Indian pharmaceuticals state that their products embody a 'whole philosophy of life and living' and conquer the evil of disease. For example, in one of its brochures, Zandu phrased it like this :

The God of Science of Ayurveda, Dhanvantari, with a pitcher containing Amruth (nectar of Ambrosia), emerging out of the ocean, has a mythical significance to the great event of Samudra Manthan (Churning of the Oceans), referred to in the Ved, Puranas and ancient Hindu literature. The emergence of Dhanvantari symbolizes the victory of whatever good and noble over evil.

Zandu tells us that health conquers disease because its sacred medicines contain and activate the life force and therefore restore the body's natural order. In natural philosophies such as Ayurveda and Unani *tibb* disease is seen as preternatural, i.e. not part of the 'natural order of things'. Treatment tries to restore the balance between the humours which, during illness, have degenerated from pillars that support the body into substances that undermine it. It is revealing that the Ayurvedic word for

humour is *dosa*, which literally means 'fault' and 'trouble'. Medicines and dietary and behavioural guidelines aim at balancing somatic components such as humours, tissues and organs. When bodily order has been restored the body's self-healing capacity automatically returns. Hence, it is argued that systems such as Ayurveda and Unani *tibb* do not force the body but rather guide it back to 'its natural pace of disintegration'. Likewise the phrase 'He is the healer' on top of Unani prescriptions indicates that medicines are 'only helpers from the outside' for activating the inner healing force. However as I have noted before, this capacity for self-healing only works well in an ordered body which means that the humoral balance and the life force are closely connected. By restoring the individual balance known as *Idhaprakrti* in Ayurveda or *tabiat* in Unani *tibb*, Indian therapeutic agents are said to create the stamina to fight disease. Is this animated life force identical to the biomedical concepts of immunity and disease resistance which are linked to anti-bodies and vitamins? According to the head of the Department of History of Medicine of Hamdard University, the life force transcends these Western concepts because although the working of organ systems such as respiration, digestion and evacuation can be explained in physiological terms, these bodily functions are controlled by a conscious agent which cannot be named, measured or located.

Indeed, according to those involved in Indian health traditions, somatic integration eventually depends upon a life force endowed with volition. This is not in contrast with the idea that natural substances such as herbs and minerals can restore health. On the contrary, as we have seen these 'materials' substances are effective exactly because they are designed according to a master plan and therefore contain the life force that pervades the universe. This is in line with Indian traditional conceptions of the body in which the spiritual and the material are arranged in a hierarchy.

As we have seen Indian medical traditions are based on a natural philosophy that provides guidelines for a healthy life that, by definition, is in harmony with the sacred, natural order. Ayurveda and Unani *tibb* provide a moral code that takes care of individual and social hygiene. Healthy bodies make a 'healthy' society and vice versa. Hence corrupted societies and corrupted bodies are dialectically related. Violation of the 'natural' code will lead to illness as illustrated by an Indian story in which the god Soma, the Moon, is punished for breaking a social rule. Because of an excessive passion for one of his wives Soma neglects

his other spouses. Consequently the deified planet loses his unctuousness, which is closely related to vital energy, and becomes emaciated. Only by promising to behave properly in the future is the Moon restored to health. Indeed, according to Indian health traditions the body wastes away when the 'natural' rules of life which are engraved in the social code of a 'healthy' society, are violated. Ignoring these rules brings a person into the state of *vikrti* (disorder, impairment of health). Because of a close association between somatic and social order, Ayurveda as well as Unani *tibb* are tailored to provide a vehicle to critique contemporary Indian society and Western therapeutic drugs that nowadays have a prominent place in Indian health care. In regard to medical traditions the marketing manager of hamdard, stated: 'Indian medicines do not have the side effects of Western drugs, because our natural products embody traditional Indian values which lead to health'. As I have argued in the previous section of this chapter, Indian medicines refer to the glory of the past when India was not a poor developing country but the epitome of civilisation. In contrast, the present is known as the kali Yuga (the period of darkness), when 'immorality' rules the world. It is a time marked by 'the blurring of categories' and confusion about the right code of conduct. Indeed, a critique of Western medicines easily becomes a critique of modernity and a glorification of Indian traditional culture in which people are said to have followed the 'natural' rules for somatic, mental, spritual and social hygiene.

As a metonym for Westernisation, city life is criticised for providing an environment that denies people the means for a 'natural' life and therefore leads to somatic and mental stress. For example, according to a Zandu publication entitled *Swasth Jivan* (Healthy Life), the environment of contemporary Indian cities undermines the three pillars of health which are: wholesome diet, undisturbed sleep and 'sexual abstinence', i.e. the practice of sexuality according to social rules which usually means marital sexual relations. *Vaidya* Lata, the author of this Hindi work that lists a selection of Zandu's products, states that these three guardians of health conflict with modern life which is marked by 'mental and environmental pollution'. Returning to a 'natural' life-style, of which the consumption of Ayurvedic medicines is just one aspect, is offered as a solution for the ills of modernity. Likewise Dabur claims that 'the answer is now Ayurveda' because its medicines offer the antidote against:

Today's fast and competitive world [in which] stress and strain tell upon our health, our diet has become more synthetic and even the modern

therapeutic agents are synthetic exposing us to toxins, resulting in various disorders.

Apart from a critique of the synthetic character of Western medicines and the modern, artificial lifestyle to which they are said to belong, Dabur propagates the idea that its Ayurvedic preparations fight the venom created by a modern lifestyle. Indeed, Indian indigenous pharmaceuticals provide a vehicle to criticise Westernisation while also offering a solution for the health hazards caused by 'modern things' such as fast food, alcoholic drinks and excessive ambition. In the same line, Dabur's popular magazine, *Ayurved-Vikas*, blames 'the anger of city life' for 'modern' diseases such as hypertension, diabetes and impotence. In the same article the author strongly suggests that the city makes people prone to disease while its unnatural life deprives people of their inner healing force. Because of its 'unnaturalness' the city is called a 'non-environment' where the inhabitants live a 'machine life' that takes away their vitality and vigour. Within Indian health traditions diminishment of both natural forces is closely connected to disease as a brochure for Hamdard's sexual tonic 'Lahmina' illustrates:

..... tiresome, demanding life of modern man can lead to general debility, listlessness, high blood pressure and a weak heart. And naturally, this weakness can drastically affect a man's sex life.

In this fragment weakness and sexual impotence as its most powerful image, is once more tied to modernity. Just as in the examples above. Hamdard's tonic embodies a critique of modernity while at the same time its producers promise relief from its ills. In the same line Dabur promises that its 'Chyawanprash' will provide 'the strength to fight and win the daily battle for survival. Indeed, Indian medicines are offered as antidotes against 'the poison of modernisation'.

Within Indian symbolic contexts the spiritual and the material are not exclusive categories but part of a hierarchy in which matter is potentiated by the metaphysical realm. Nature and its products have both supernatural and physical dimensions. which are not as rigidly separated as they are in the West. When the producers of Indian indigenous pharmaceuticals claim superiority in terms of safety and efficacy world containing their factories and laboratories.

Concluding remarks

Large producers of Indian indigenous pharmaceuticals shape Indian medical systems such as Ayurveda and Unani *tibb*. Their use of modern

product forms such as capsules, pills and syrups as well as sophisticated production and packaging technology have changed the outlook of Indian bioceuticals. This modern image of Indian health products has been reinforced by marketing schemes, heavy advertising in media such as television and glossy magazines as well as laboratory research. By updating their products the three companies which are the focus of this chapter have changed the archaic image of Ayurveda and Unani *tibb* away from the domain of *vaidyas* and *hakims* dealing in outdated ideas and products. They have made these 'traditional' systems contemporary. Hence for many Indians indigenous medicines are no longer substances prepared and prescribed by traditional healers but modern over-the-counter products used for self-medication.

Increasingly the consumption of Indian medicines has become an urban middle-class phenomenon. Consequently the importance of Indian medicines for diseases such as cholera, elephantiasis and goitre-health hazards that mainly affect the poor- has diminished. Nowadays, the industry projects its products as safe and effective remedies for both chronic and common diseases. The rise of chronic diseases among the Indian middle classes as well as the popularity of preventive health products among these groups has created a favourable epidemiological context for Indian indigenous pharmaceuticals. Because many of these new consumers have a modern education, the producers of Indian pharmaceuticals cannot only refer to traditional medical authorities for the marketing of their products.

Therefore, to legitimise their products the industry 'has added science to culture', which means that they are 'reworked' by laboratory and clinical research. The action mechanisms of Indian medicines are both their researched chemical properties as well as their traditional and divine nature. They derive their power from a sacred and glorified past as well as from modern science. Indeed, like contemporary Indian culture indigenous medicine and the medical traditions to which they belong are hybrid phenomena.

In India it is often said that medical traditions such as Ayurveda and Unani Tibb incorporate modern medicine in the sense that Ayurveda is the mother of all medical system and Unani Tibb has adhered to the truths of Hippocrates and Galen which biomedicine has forgotten. This demonstrates that in the Indian arena traditional and modern medical systems are not considered to be exclusive. Indeed, at least at the rhetorical level the modern is enclosed by the traditional. From another

angle it can be argued that Indian medical systems can be pictured as local modernities in the sense that these traditions have been modernised and globalised.⁷⁰ However, this does not mean that all medical options available in India boil down to the same thing. Indian medical traditions provide us with ideas and products that differ from biomedical ones. For instance, because Ayurveda and Unani tibb are based upon a natural philosophy and include prescriptions for a 'wholesome' life, patients are easily held responsible for their illness. Because these modern traditions ascribe illness to a damaged divine life force caused by violating the 'natural' laws of individual and social life, Ayurveda and Unani tibb are tailored for a critique on individual and collective lifestyles. Within such an ethical discourse modern life weakens bodies and makes them susceptible to disease. Ayurvedic and Unani pharmaceuticals are marketed as products that can protect and cure the body from the consequences of an 'unwholesome' way of living marked by the consumption of 'synthetic' food and medicines, competition and environmental pollution.

Indian health traditions and biomedicine are both part of contemporary Indian society and are therefore integrated into 'local symbolic contests', which shape all medical options available in India. Therefore ideas and commodities such as therapeutic drugs are not the exclusive domain of one medical tradition. This is well demonstrated by medical practice in India. For example, Indian biomedical physicians 'have a strong faith in the medical beliefs of their forefathers' which shows itself in prescriptions for Ayurvedic or Unani drugs and the representation of health and disease as a 'moral enterprise'. At the same time, Western drugs and modern medical technology are part and parcel of 'tradition practice. Indeed the traditional is found in the modern and the modern is in the traditional. Medical pluralism exists within rather than between medical systems. Traditional and modern medical forms are creatively rearranged in the Indian context. This should not surprise us as Indian society at large is marked by the entanglement of the modern and the traditional. After all the people of the Indian subcontinent have a long history of integrating Indian and Western Ideas, practices and commodities.

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Notes

- 1 In 1989-90 the Indian central and state government spent Rs. 62.54 crores (US\$ 15.64 million) of Indian Systems of Medicine, See the Ministry of Health and Family Welfare, Indian Systems of Medicine and Homeopathy and India 1990, 1993, p. 297. The turnover of Ayurvedic medicines alone was estimated by the industry to be between Rs. 1,500 crores (US\$ 375 million) and Rs. 2,300 crores (US\$ 575 million) in 1997. (The conversion to US dollars is based on the exchange rate in 1997 which was forty rupees to one US dollar.) These data are based on written enquiries made by the author. For comparison, the sale of Western medicines was estimated to be between US\$ 2,650 million and US\$ 3,000 million in 1997. Though the purchasing power of the Indian rupee went down by 50 per cent between January 1991 and January 1998 there remains a large gap between government expenditure on Indian medical traditions and the public spent on indigenous medicines.
- 2 To my knowledge Charles Leslie was the first scholar who emphasised the importance of research on the indigenous industry for the study of contemporary Indian medical systems. See G. Leslie, 'Indigenous Pharmaceuticals, the capitalist world system, and civilisation', Kroeber Anthropological Society Journal (1988): 23-31. I benefited greatly from the research materials on the indigenous industry that Charles Leslie handed over to me in 1995.
- 3 According to the Ministry of Health and Family Welfare on 31 December 1989 there were 7,648 licensed pharmacies producing indigenous pharmaceuticals, Indian Systems of Medicine and Homeopathy in India 1990, 1993, pp. 266-7.
- 4 These data come from two sources: 1) A personal letter from the General Secretary of the Kerala Drug Manufacturers Association of 18 February 1998, and 2) a speech by the manager of the Dabur Research Foundation delivered on 17 February 1998 at the 'International Conference About Medical Plants For Survival', held in Bangalore. The substantial difference in the two figures can be explained by the non-availability of production data of the majority of the 8,000 firms that produce Indian health products. Moreover, there are no official government data on this. The share of Dabur, Zandu and Hamdard in the total sale of Ayurvedic and Unani products is an educated guess based on the following data: 1) According to the assistant manager of the Dabur Research Foundation, the turnover of Dabur in 1997 was approximately Rs. 700 Crores (US\$ 175

million), of which approximately Rs. 500 *crores* (US\$ 125 million) came from Ayurvedic products while the remaining amount was earned with the sale of products such as 'bulk drugs and chemicals' and 'food stabilisers';²) During an interview held in Delhi on 25 March 1999, the marketing manager of Hamdard told me that in the financial year 1997-8 the turnover of his company approximately amounts to Rs. 110 *crores* (US\$ 37.5 million). In a letter dated 16 March 2000, the managing director of Zandu claimed a turnover of Rs. 110.78 *crores* in the financial year 1998-9 Zandu and Hamdard claim a yearly rise of their sales of around ten per cent, volume-wise, while the rise in the sales figures of Dabur is even bigger. For instance, according to data taken in September 2000 from the internet site (www.Dabur.com), the turnover of Dabur was Rs. 1035.83 *crores* (US\$ 258.96 million) in the financial year 1999-2000. This suggests a substantial rise.

- 5 The translations of Hindi terms in this chapter taken from R.S. McGreggor. *The Oxford Hindi-English Dictionary*, Oxford, Oxford University Press. 1993. In our times the word 'medicine' has largely become a reserved term for substances on which there exists a large body of modern laboratory and clinical research of which the results are laid down in professional journals.
- 6 For studies on the meaning of medicines see: S. van der Gees and S. Whyte (eds), *The Context of Medicines in Developing Countries*, Studies in Pharmaceutical Anthropology, Dordrecht, Kluwer Academic Publishers, 1988; S. van der Gees and S. Whyte, 'the charm of medicines: metaphors and metonyms', *Medical Anthropology Quarterly*, 3.4 (1989): 346-67; and S. van der Geest, S. Whyte and A. Hardon, 'The anthropology of pharmaceuticals. A biographical approach', *Annual Review of Anthropology*, 25 (1996): 153-78.
- 7 See F. Zimmermann, 'The scholar, the wise man, and universals: three aspects of Ayurvedic medicine; in D. Bates (ed.), *Knowledge and the Scholarly Medical Traditions*, Chambridge, Cambridge University Press, 1995, pp. 297-319.
- 8 See Chapter 2 by Arnold and Sarkar in this volume.
- 9 Consult the contribution of Scheid to this volume (Chapter 8).
- 10 Mark Nichter speaks in this context of 'double think', M. Nichter, 'Pharmaceuticals, health commodification, and social relations: ramifications for primary health care' in M. Nichter (ed.), *Anthropology and International Health. South Asian Case Studies* Dordrecht,

Kluwer Academic Publishers, 1989, p. 255.

- 11 G.G. Burman, director, (<www.Dabur.com>), September 2000.
- 12 This estimate is an educated guess based upon written and oral data of the sale of individual products and information about their marketing route. Moreover, in India it is common knowledge that many 'prescription'.
- 13 There are two exceptions to this rule. First, companies belonging to the Kerala tradition such as the Arya Vaidya Shala and Arya Vaidya Pharmacy market their products via franchises. These franchises, as well as the hospitals of these companies, are run by qualified vaidyes holding a degree that is sanctioned by the government. These franchises as well as the company hospitals which resemble the 'Kurorts' of Germany and Austria, are mainly frequented by affluent middle-class people looking for relief from chronic diseases such as arthritis, spondylitis, digestive ailments, depression and sleeplessness. The second exception is the Himalaya Drug Company holding around 7 per cent of the market in Ayurvedic products. The Himalaya Drug Company has around 1200 medical representatives who market their products to physicians who have either a degree in Western medicine (MBBS), Ayurveda (BAMS) or Unani tibb (BUMS). The medicines of the Himalaya Drug Company are mainly adjuvants for mitigating the effects of Western medication as well as herbal alternatives for the treatment of common and chronic diseases. However, recently this company started an over-the-counter line called Ayurvedic Concepts. This confirms the increasing importance of the over-the-counter market for the sale of Indian indigenous pharmaceuticals. In this chapter no attention is paid to part-time traditional healers. Many of them prescribe medicines comprised of fresh herbs. See D. Shankar, 'Indigenous health services. The state of the art', in A. Mukhopadhyaya (ed.), *State of India's Health*, New Delhi, Voluntary Health Association of India, 1992, p. 157. See also many articles on this topic published in the bimonthly *Amruth* of the Bangalore-based Foundation for the Revitalization of Local Health Traditions (FRLHT).
- 14 Interview with the director of a large Indian NGO, Bangalore, 5 January 1997. See also G. Leslie, 'Interpretations of illness. Syncretism in modern Ayurveda', in G. Leslie and A Young (eds), *Paths to Asian Medical Knowledge*, Berkeley, University of California Press, 1992, p. 184.
- 15 For the practice of such and Ayurvedic physician in a government

- Out Patient Clinic, see V. Kamat, 'Reconsidering the popularity of primary health centres in India: a case study from rural Maharashtra', *Social Science and Medicine*, 41, 1 (1995): 87-98. For the biomedical Ayurvedic practice of government-trained Ayurvedic physicians in Sri Lanka see N. Waxler-Morrison, 'Plural medicine in Sri Lanka: Do Ayurvedic and western medical practices differ?' *Social Science and Medicine*, 27, 5 (1998): 531-44.
- 16 For the lack of Ayurvedic education in 'Ayurvedic' colleges, see R. Mnohar and D. Shankar, 'Ayurveda today Ayurveda at the crossroads', in J. v. Alphen and A. Aris (eds), *Oriental Medicine*, London, Serindia Publications, 1995, pp. 102-4.
 - 17 Lecture given by Sanjib Datta Choudury, PhD, entitled: 'Whiskey advertisement in north India', University of Amsterdam, 3 September 1999.
 - 18 The statement has been confirmed during an interview with the marketing manager of Dabur Pharmaceuticals Limited, Delhi, 26 November 1997. However, my consultation in December 2000 of Dabur's internet-site (<www.Dabur.com>) shows that the company has professionalised the marketing of its 'fast moving products'. For example, in the case of its newly launched digestive Pudina Hara G the Company states that 'pre-launch research' and 'post-marketing surveillance' has been conducted.
 - 19 Interview with the general manager for sales and marketing of Dabur, Delhi, 29 November 1997.
 - 20 Interview with the assistant advertising manager of Hamdard, Delhi, 19 February 1999.
 - 21 See S.C. Banerji, *A Companion to Sanskrit Literature*, Delhi, Motilal Banarsidass, 1971, pp. 29-31.
 - 22 According to the company at the end of 1997 Dabur Chyawanprash had 25 million users and a turnover of Rs. 110 crores (US\$ 27.5 million).
 - 23 Interview with the assistant manager of Dabur Research Foundation, Delhi, 21 December 1997.
 - 24 *India Today*, 10 May 1999.
 - 25 In the case of Ayurveda, see F. Zimmermann, *The Jungle and the Aroma of Meats. An Ecological History of Ayurveda*, Zimmermann, 'The love-lorn consumptive: south Asian ethnography and the psychosomatic paradigm', *Curare*, Special issue 7, 91m (1991): 185-95.
 - 26 'The History of Rooh Afza', Hamdard (wakf) Laboratories, 8 pp., no date, probably mid-1980s.

- 27 'Rooh Afza. Deliciously nutritious recipes. From a family favourite', Hamdard (wakf) Laboratories 12 pp., no date, probably 1993.
- 28 A brochure with a rishi in a test tube on the cover issued by Zandu Pharmaceutical Works Ltd. no title, no date, probably from the early 1980s.
- 29 'Think health think Dabur Chyawanprash', Dabur India Limited, 8pp, no date, probable mid-1990s.
- 30 'A dream come true. Indian expertise, global perspective', Zandu Pharmaceutical Works Ltd. 8 pp., no date, probably 1997.
- 31 'Zandu, the company that bears the great name', Zandu Pharmaceutical Works Ltd. 4 pp., no date, probably end 1970s or beginning 1980s.
- 32 'Unani system of medicine. The natural way of healing', Hamdard (wakf) laboratories, 2 pp. no date, probably mid-1990s. See also Hamdard's brochure for the promoting of its blood no date, probably mid-1990s. See also Hamdard's brochure for the promoting of its blood purifier 'Safi, titled 'Authoritative research findings on the inter-linkage of blood impurity and diseases of the skin and blood', Hamdard (wakf) Laboratoires, 24 pp., no date,, probably 1980s.
- 33 'Brento, Memory booster'. Products information of the Zandu Pharmaceutical Works Ltd., no date, probably from mid-1990s.
- 34 'Diseases and treatment. Health with Hamdard'. Therapeutic Index, Hamdard (wkf) Laboratoires, 56 pp., no date, probably from mid-1990s.
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- 36 'Alcohol damages but Livotrit protects', Zandu Pharmaceutical works Ltd., 2 pp, no date, probably from mid-1990s.
- 37 D. Kumar, 'Medical encounters in British India, 1820-1920', *Economic and Political Weekly*, 25 January 1997, p. 168.
- 38 R.N. Chopra et al., *Indigenous Drugs of India*, Culcutta, Dhur and Sons, 1958 [1933] pp. 5-6.
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- 40 G. Leslie, 'The ambiguities of medical revivalism in modern India', In G. Leslie (ed.), *Asian Medical Systems*, Berkeley, University of California Press, 1976, p. 362.
- 41 Interview with the manager product development of Dabur Research Foundation, Ghaziabad, 4 November 1997.

- 42 Ayurved-Vikas. A Complete Health Magazine, Dabur India Publication, 1999 Inaugural Issue. p. 43.
- 43 Interview with the superintendent of the Unani tibb section of the Majeedia hospital, Jamia Hamdard, Delhi, 11 March 1999.
- 44 G. Leslie, 'The ambiguities of medical revivalism in modern India', in G. Leslie (ed.), *Asian Medical Systems*, Berkeley, University of California Press, 1976, pp. 356-67. See also G. Leslie, 'Pluralism and integration in the Indian and Chinese medical systems', in D. Landy (ed.), *Culture, disease and Healing. Studies in Medical Anthropology*, New York, McMillan, 1977, pp. 511-18; and G. Leslie, 'Interpretations of illness. Syncretism in modern Ayurveda', in G. Leslie and A. Young (eds.), *Paths to Asian Medical Knowledge*, Berkeley, University of California Press, 1992, pp. 177-208.
- 45 P. Bala, *Imperialism and Medicine in Bengal. A Socio-Historical Perspective*, New Delhi, Sage, 1991; M. Banerjee, *Power, Culture and Medicine: A Study with Special Reference to Ayurvedic Pharmaceuticals in India*, PhD. Thesis Delhi University, 1995.
- 46 'Authoritative research findings on the inter-linkage of blood impurity and disease of the skin and blood', Hamdard (wakf) Laboratories, 24 pp., no date, probably from mid-1990s; 'The 10 minute guide to Ayurveda', Dabur India Limited, no date, probably from mid-1990s.
- 47 Interview with the marketing manager of Hamdard, Delhi, 25 March 1999.
- 48 Interview with the head physician of the outpatient clinic of the Arya Vaidya Pharmacy, Delhi, 28 October 1997.
- 49 'Unani system of medicine. The natural way of healing', Hamdard (wakf) Laboratories, 2 pp., no date, probably from mid-1990s.
- 50 'Dabur Ayurvedic specialities', Therapeutic index, Dabur India Limited, 206 pp., 1995.
- 51 'Think health think Dabur Chyawanprash', Dabur India Limited, 8pp., no date, probably from mid-1990s.
- 52 According to G. Obeyesekere, 'Science, experimentation, and clinical practice in Ayurveda', in G. Leslie and A. Young (eds), *Paths to Asia Medical Knowledge*, p. 176 ojas is the 'vitality that infuses our body'. In a more religious context ojas is seen as the seat of prana (vital breath) which endows five primordial elements (mahapancabhuta) with life. In the English language version of its magazine Ayurved-Vikas Dabur defines oj. the Hindi equivalent of the Sanskrit ojas, as 'the essence of all dhatus' (bodily tissues) and 'the essence of our energy'.

- 53 See for Ayurveda, F. Meyer, 'Introduction', in J. van Alphen and A. Aris (eds), *Oriental Medicine*, London, Serindia Publications, 1995 pp. 11-15, and for Unanai tibb Chapter 4 of Claudia Liebskind in this volume.
- 54 For an expose about morals in classical and modern medical traditions, consult B.S. Turner, 'Disease and disorder', in his *The Body and Society*, London, etc., Sage Publications, 1996, pp. 197-215. the naturalisation of 'the work of culture' is an important topic of discourse for anthropologists and social historians, and perhaps even more so for those involved in women studies. For example, consult B. Good, 'Semiotics and the study of medical reality', in B. Good, *Medicine, Rationality, and Experience, An Anthropological Perspective*, Cambridge, Cambridge University Press, 1994, p. 114, for the naturalisation of gender differences through the idiom of 'Greco-Islamic' medicine. See also on this topic: B. Good and M. DelVeceho Good, 'The comparative study of Greco-Islamic medicine: the integration of medical knowledge into local symbolic contexts', in C. Leslie and A. Young (eds.) *Paths to Asian Medical Knowledge*, Berkeley, University of California Press, 1992, pp. 267-8. For the way the biomedical discourse in the 18th and 19th centuries did 'intermediate gender differenced consult L. Jordanovea. *Sexual Visions. Images of Gender in Science and Medicine between the Eighteenth and Twentieth Centuries*, Hertfordshire, Harvester Wheatsheaf, 1989, pp. 1-18.
- 55 In Ayurveda the term *suasthya* (health), 'being established in oneself', refers to the fact that health is considered to be the normal state of a human being.
- 56 A brochure featuring a rishi in a test tube on the cover issued by Zandu Pharmaceutical Works Ltd., 6 pp. no title, no date 1980s.
- 57 'A dream come true. Indian expertise, global perspective', Zandu Pharmaceutical Works Ltd., 8 pp. no date, probably 1997.
- 58 For the Ayurvedic humours, *kapha* *vata* and *pitta*, which in disease become the body's troubles (*dosa*), See G. boeyeskere, 'The theory and practice of psychological medicine in the Ayurvedic tradition', *Culture, Medicine and Psychiatry*, 1,2 (1977): 155-81. Leslie qualifies Ayurveda as a 'moral enterprise', C. Leslie, 'Interpretations of illness. Syncretism in modern Ayurveda', in C. Leslie and A Young (eds.) *Paths to Asian Medical Knowledge*, Berkeley, University of California Press, 1992, p. 202.

- 59 Interview Delhi, 5 March 1999. See also 'Unany system of medicine. The natural way of healing'. Hamdard (wakf) Laboratories 2 pp., no date, probably from mid-1990s.
- 60 For the dialectical relationship between corrupt bodies and a corrupt state in the contemporary India, see J. Alter, 'Gandhi's Body, Gandhi's Truth: Nonviolence and the Biomoral Imperative of Public Health', *Journal of Asian Studies*, 55, 2, (1996): 301-22.
- 61 Interview with the marketing manager of Hamdard, Delhi, 19 February 1999.
- 62 W.S. Lata, *Swasth Jiwan (Healthy Life)*, Bomba, Leopard Investments, 1990, p. 2.
- 63 Interview 17 April 1996.
- 64 'Dabur Ayurvedic specialities', *Therapeutic index*, Dabur India Limited, 1995, p.iii.
- 65 Many more examples can be given. For instance, Zandu's liver tonic 'Livotrit' is marketed as a panacea against modern things such as 'potent drugs', 'increased consumption of alcohol' and viruses that stand for 'environmental pollution'.
- 66 M. Bode, 'On the consumption of Ayurvedic pharmaceutical in India. Extracting the poison of modernisation', in A. Gevers (ed.), *Uit de Zevende Faculteit. Fijftig jaar Politieke en Wociaal-Culturele Wetenschappen aan de Universitit van Amsterdam (Form the Seventh Faculty: Fifty Years of Political and Social Sciences in Amsterdam)*, Amsterdam, Het Spinhuis, 1998, pp. 367-78.
- 67 See also the conclusion of Chapter 3 by Arnold and Sarkar in this volume.
- 68 Interview with the assistant manager of Dabur Research foundation, Ghaziabad, 24 March 1999.
- 69 See Chapter 6 by Ria Reis in this volume in which she draws our attention to the hybridisation of traditional and modern medical ideas and practices in Swaziland.
- 70 See also Chapter 8 by Volker Scheid in this volume.

A HISTORIC SEMINAR
ON
STRATEGY FOR DEVELOPMENT OF INDIGENOUS MEDICINE
IN THE TWENTY-FIRST CENTURY
DHAKA
BANGLADESH
19 June 2002

**Address by Professor A Q M Badruduzza Chowdhury,
The Hon'ble President, People's Republic of Bangladesh**

I am delighted to be able to attend this National Seminar of Bangladeshi Unani Medical Association. I noticed that it would continue for two days. Such a big seminar was never organized before. I thank the activists and the patrons who have taken such a bold step. We know that Unani and Ayurvedic systems of medicine have a long history. Some say that these systems have been in existence for the last 10,000 years. Others think they have existed for less than that period of time. In any case it is well known that the ayurvedic systems of medicine had its inception in the Indian sub-continent while the Unani system of medicine originated in Arab-world. Indian sub-continent had been ruled by the Greeks, the Persians and finally the Muslims. The Unani system of medicine entered India with those rulers and later on spread to Bangladesh. When it got mixed with Ayurvedic system it became enriched and became the predominant system of medicine. At one time it was the ruling system of health-care in Bangladesh. But when the British rule came to this part of the world and the Western system of medicine began to spread here it brought evil days for Unani and Ayurvedic systems. Later on in the earlier part of the 20th century when both Ayurvedic and Unani medicine were facing great crisis, through the efforts of Shifaul Mulk Hakim Habibur Rahman the first Unani Medical College was established in Dhaka in 1930 which was called Tibbiya Habibiya College. We pay tribute to the memory of that grand old man of medical profession!

Gentlemen!

Many people think Unani and Ayurvedic systems of medicine have been left behind because these systems have not been able to achieve parity with the Western system of Medicine which is based on modern science and technology. The general impression is that even if medical treatment as per the western medical system is comparatively more expensive it is preferable to Unani and Ayurvedic systems which have not undergone rigorous scientific testing and clinical trials.

So if modern science and technology is not utilized for the validation of indigenous system of medicine their survival will face a serious crisis. This reality must be accepted and the practitioners of indigenous medicine must march forward. From this angle this Seminar on Indigenous Medicine is of great importance. On the other hand already some positive steps had been taken for upgrading indigenous medicine such as

inclusions of these systems in 1982 Government Ordinance about Drugs & Medicines, promulgation of 1983 Govt. Ordinance about Unani & Ayurvedic Medicine and publication of the National Formulary.

I guess you remember that I served as Advisor on health matters in the regime of Shaheed President Ziaur Rahman. He was very keen to enhance the scientific basis of indigenous medicine. To achieve that goal one hospital Ward consisting of 10 beds was established in both the P.G Hospital Dhaka and the Dhaka Medical College Hospital. In these Wards patients suffering from Rheumatic Arthritis were treated side by side through Allopathic system and Unani-Ayurvedic System. We did not get any bad results from such medicines. We have constantly tried to develop indigenous systems of medicine. These are very important therapeutic systems. Our country has plenty of resources for indigenous medicine. If Quality can be ensured, their acceptance would rise many-fold. Nobody would object to their use if their effectiveness is well established. On the other hand the cost of Western drugs and medicines is rising so fast day by day that common people can hardly afford them. Not only in our country but in America too. Common people cannot afford western drugs and medicines. The costs are too high even for their Medical Insurance! Many people say that the medical system of China is ideal and worth following. Let us study and examine the Chinese system too. It has gained some admirers in the West. I have myself seen shops selling Chinese medicines in the UK and USA. Similarly in the developing countries, sale of Herbal and Chinese drugs and medicine is growing day by day. Such growth cannot escape notice. Recently two or three experts have come to Dhaka who are practicing the Chinese System of medicine. They have set up a private hospital too. We can share their knowledge and experience. It must be borne in mind that the essential need for the development of Unani and Ayurvedic Systems is continuous scientific and clinical research. Three points will determine the status and prospects of medicine namely a. Curative power b. Freedom from toxicity and c. Competitive price. A very large number of our fellow countrymen depend on Unani and Ayurvedic Systems of therapy. It would not be enough to cure the sick; you must also acquire the knowledge how to prevent illness!

We must make common people and the sick understand the nutritive value of our traditional food, common fruits and vegetables. We must follow hygiene and sanitation and ensure that everybody maintains cleanliness of body and environment. Finger-nails must be trimmed;

hands must be washed before eating. Such simple steps can prevent much suffering and disease. However now-a-days few physicians mention such basic things. Most of the raw materials or ingredients for Unani & Ayurvedic medicines are easily available in Bangladesh. If for some reason Western drugs and medicines could not be important it would give rise to a serious crisis. However Herbal medicines would have no interruption in supply-chain because most of the raw materials and ingredients are homegrown. Therefore herbs and medicinal plants should be grown on a large-scale under a well-thought-out Plan and an export-market should be developed for the same. The Prime Minister has turned Tree Plantation Campaign into a vigorous movement this year. She has appealed to the masses to plant fruit-bearing trees and medicinal plants extensively. We want to see a scientific and modern technological basis of the Indigenous Systems of Medicine. We want to see that indigenous drug and medicines would be affordable for the common people. We want to move forward with Unani and Ayurvedic Systems of Medicine conforming to scientific advances of the 21st century. In this context I regard this Seminar as highly significant. People hope that you would work hard to develop indigenous systems of medicine and we assure you to give a helping hand. So you must provide health-care which would bring peace and well being of our fellow countryman. I pray for you. I wish this Seminar on Strategy for Development of Indigenous Medicine in the 21st Century great success. May the Almighty help you. Allah Hafez. Bangladesh Zindabad.

**Address by the National Professor (Dr) Nurul Islam,
Founder Vice Chancellor, University of Science & Technology
Chittagong (USTC)**

I think Bangladesh Unani Medical Association has staged a rare event by organizing this seminar in the context of 21st century. By taking stock of Alternative Systems of Medicine in various parts of the world, we are sure to gain a better understanding. It is recognized that there are some good points in every system of medicine. Herbal medicine in modern form is in vogue in many countries. It is spreading in both the developed and developing countries. It is not possible to provide healthcare to the entire population in poor countries through Allopathic system of medicine i.e. using the latest medical discoveries. In such societies, alternative systems of medicine have an important role to play. So we can deliver health-care to the whole population through a well-coordinated effort, utilizing all kinds of medical knowledge. We must admit that no single system of medicine can cure every illness. We should therefore be willing to utilize all known systems of medicine in a well coordinated form to provide sound health-care to our patients of various types. Until recently we did not know the advances made in alternative systems of medicine. We did not know the advances made in alternative medicine at home and abroad and research-work that was in progress. It is not proper to persist in that abhorrent or negative attitude. We owe it to ourselves to acquire maximum knowledge of the alternative systems of medicine. I am sure we should welcome that expertise and make it easily accessible for our fellow-countryman!

Our people must gain a higher level of knowledge. The indigenous system of medicine is not something to be discarded or ignored. The presence of His Excellency the President of the Republic in this Seminar is a historical event. He will be always remembered for this wonderful gesture. I am confident he will make a significant contribution in this regard. We along with all Unani and Ayurvedic physicians are friendly behind him. I hereby greet His Excellency the President of Bangladesh on behalf of all the physicians and thank him for taking the trouble to attend this seminar. In this country many diseases are being cured through Alternative System of Medicine as is happening now a days in America. If our respected Hakeems come forward and undertake more scientific research they shall achieve great success. I end my speech by wishing you unprecedented progress in the days to come.

Welcome Address by the Hakim M. Yusuf Haroon Bhuiyan

Bismilla Hir Rahmanir Rahim. Mr. Chairman of this "Seminar for the Development of Indigenous Medicine in 21st Century", Hon'ble Chief Guest Dr A Q M Badruzza Chowdhury, President of the People's Republic of Bangladesh, respected Special Guest and Gentlemen present,

Assalamo Alaikum Wa Rahmatullah Wa Barokatuhu. We are honoured to have the pleasure of the company of His Excellency the President of Bangladesh. He is esteemed as an extraordinary Physician at home and abroad.

I welcome the President on behalf of Bangladesh Unani Medical Association and also on behalf of the Hamdard Laboratories (Waqf) Bangladesh. Your gracious presence is a proof that as an outstanding Physician who is sincere and dedicated to development of all Systems of Medicine and their proper utilization you have the courage of your conviction!

I welcome Justice Abdur Rouf who is esteemed by the whole nation. I welcome National Prof. Dr Nurul Islam who drafted the National Drug Policy and has been Well-wisher and Guide. I welcome the Hakeems and Kabirajs who are participants in this Seminar. I welcome the invited guests, medical-scientists, pharmacists and teachers. Last but not the least I welcome the journalists who have taken the trouble to come and are going to cover this Seminar for the mass-media.

The remarkable progress Indigenous System of Medicine made was made quite a long time ago in the Indian Sub-continent. But its triumphant march was suddenly halted when British colonial rule overwhelmed this part of the world. At long last when "Swadeshi" i.e. Self-rule Movement commenced a vigorous campaign for the revival of Indigenous System of Medicine by the Founder of HAMDARD Hakim Abdul Majid, his friend Hakim Ajmal Khan and a great son of this soil Shifaul Mulk Hakim Habibur Rahman.

Subsequently world-renowned medical-scientist Hakim Abdul Hamid and Hakim Muhammad Sayeed ensured a scientific basis for the Unani System of Medicine through HAMDARD. As a result of their effort this system of medicine again became popular. Now-a-days it is recognized that Unani and Ayurvedic Systems of Medicine have no side-effects. Their efficacy is well-established and they are gaining world-wide popularity. Especially in our neighbouring status the practice of these

systems of medicine is growing fast. So much so that the Government of those countries are patronizing these traditional systems of medicine and helping in their future development.

In our country these systems have long tradition but their development has not been as expected. Majority of our people is interested in this system of medicine. Due to lack of patronization by the Government it has failed to grow in a big way. Herbal Medicine is surprising because indigenous medicine is part of the culture of Bangladesh and its social fabric.

Honourable President of Bangladesh

We believe that our Government has to give preferential treatment and encouragement to Unani and Ayurvedic systems of medicine for the overall advancement of medical services. We feel that our own resources being rather limited long-term progress of Indigenous Medicine cannot take place without the patronization of the Government.

Recently the Prime Minister has called upon the people to plant medicinal plants as well as fruit-bearing trees to bring about good health. The policy that the present Govt. has adopted for planting of medicinal plants, herbs and its attitude towards herbal medicine are gratifying. If this trend is maintained I am sure Unani and Ayurvedic Systems of Medicine will play a significant role in the service of the nation.

I also believe that the gracious presence of the President of Bangladesh and the of other members of the elite of Bangladesh society is a positive step for the Indigenous system of medicine. The guidance given by the President as a veteran physician will help us attain our goal. Inshallah.

Today Herbal Medicine is marching triumphantly all over the world. Due to the side-effects of synthetic medicines the world is returning to Harbal Medicine. So it can be asserted that Indigenous Medicine will become the major system of medicine in the 21st Century. It is essential to develop traditional medicine, if health-care is to be provided to the teeming millions of Bangladesh. I would like to end my address with an appeal to everybody to extend a helping hand for the attainment of this important goal.

Allah Hafiz. Bangladesh Zinda Bad. Unani & Ayurvedic Systems of Medicine Zinda Bad!

(Hakim M. Yusuf Haroon Bhuiyan is the Managing Director Hamdard Laboratories (Waqf) Bangladesh, Secretary General, Hamdard Foundation Bangladesh, President Bangladesh Unani Shilpa Samity and Sr. Vice President Bangladesh Unani Medical Association)

**Address by the Hakim Hafiz Azizul Islam
Chairman, Bangladesh Unani-Ayurvedic Board**

Bangladesh Unani Medical Association is a representative body of all the registered Unani Physicians. It has an illustrious history. This body is descended from the "Anjumun Atibba" which was formed in 1940 by an outstanding son of Dhaka, namely Shifaul Mulk Hakim Habibur Rahman. We have organized many Seminars before this one. Before Partition and after it, as well as since the liberation of

Bangladesh we have organized several one-day Seminars. However it is the first time we have been able to hold such a big 2-day Seminar. We have been overwhelmed by the wonderful response we have received. There are 397 registered participants in this Seminar. We have invited His Excellency the President of Bangladesh to grace this Seminar because he has played an important role in the promotion of indigenous medicine i.e. Unani & Ayurvedic Systems and especially in the scientific-research thereof. We are delighted to have him with us and feel honoured!

The theme of this National Seminar is to lay down a strategy for the development of Unani & Ayurvedic medicine, a strategy for the promotion of pharmaceutical industry connected with indigenous medicine, educational facilities for Unani & Ayurvedic medicine, extension of health-care, strategy for the development of research-work in Unani & Ayurvedic medicine. Many papers will be presented in this Seminar. Seventy or eighty Papers will be read in eleven sittings of the Seminar by experts and teachers. Scientists and Professors from University of Dhaka, Rajshahi, Jahangir-nagar, and Khulna will address this Seminar on various topics. It is a great honour for us. Tomorrow at 4 PM there will commence the concluding session of this Seminar which is to be presided over by the State Minister for Religious Affairs Mr. Mosharaf Hossain Shahjahan!

We express our gratitude towards all who are attending this Seminar. We hope that towards the end of next year or in the early part of year 2004 we shall be able to hold an International Seminar or a large-scale Regional Seminar on Indigenous Medicine. I thank the younger and energetic Hakeems who have worked hard for this Seminar and others who have helped in holding matter.

I thank the President of Bangladesh once again. We hope we shall continue to get advice and guidance from him in the days to come.

Allah Hafiz!

Some Questions & Answers

THREE SYSTEMS TOGETHER (TST) PROGRAM AT USTC

Question: What are three Systems?

Answer:

- i. Allopathic or Modern Medicine
- ii. Unani / Ayurvedha Medicine
- iii. Homeopathic.

Three systems include above three systems of medicine.

Question: Why do you put three systems together?

Answer: Present health care system consists of Allopathic systems or modern medicine run only by qualified medical graduates whose number till today is 26,000. Evidently the number of qualified doctors necessary for extending health care in a country where the population is one hundred & thirty million shall continue to be a dream from many years. Annual production of doctors at present is around 2000. Number of villages in the country 68,000. We therefore need a bare minimum of 40,000 doctors to cover each village with only one qualified medical graduate. If the present state continues it will take 25 years to produce 25,000 doctors. If diseases, deaths, disabilities departure (Emigration) and retirement are consider it will take another 30 to 35 years for the production of required number of doctors. It is estimated by year 2020 the population will be double. This threatens all calculation, possibilities and framework for health care.

Question: If the modern medicine covers only 30% of the population, what will happen with the rest? Do they remain untreated?

Answer: Yes! Where there are people there must be diseases and medical problems and where there are problems there must be attempt for solving them. As a result by the demand of the populations and the situation several types of healers grow-up. These are call traditional healers.

Question: What the traditional healers do?

Answer: They practice, age-old traditional medicine the know ledge about which they acquire by various means.

Question: What are those means?

Answer: There are various means of acquiring this knowledge and becoming traditional healers. These are through education, experience and assistance.

Question: Please explain – what you mean by heritage?

Answer: I mean the process/practice runs in family. By education I mean there are center (Put) for formal education (Unani & Ayurvedhic

system of made). By experience, I mean getting experience by working qualified with experience traditional healer.

Training in Homeopathy is easier and cheaper as many Homeopathic Institutions (Pvt.) have developed all over the country. As a result there are today 33 Homeopathic Medical Colleges in the country.

Question: What is the status of Unani, Ayurvedic & Homeopathic system of medicine in Bangladesh?

Answer: Unani, Ayurvedic & Homeopathic system of medicine are recognized by the Government of Bangladesh. There are several Governmental and Non-Governmental Institutions or Colleges established in the country, which are as follows:

- i. Six Unani Medical Colleges
- ii. Six Ayurvedic Medical Colleges
- iii. Thirty Three Homeopathic Medical Colleges

In the private sector there are several Homeopathic institutes developed in India & Pakistan with initiative of Hakim Mohammad Abdul Hamid. With the initiative of Hakim Mohammad Hamid a University was established in Delhi. His brother Hakim Mohammad Said came to Pakistan after partition of India and established National **Madinatul Hikma – City of Science, Education & Culture**. Having a college, a medical college for MBBS degree for modern medicine and another similar college for study of Unani system of medicine. Hakim Mohd. Said had a vision and a dream, he wanted to incorporate the two systems of medicine Modern & Unani which he called Islamic Medicine. But for several reasons he established this two Institutions in the same campus almost side by side. He felt than both the systems should work together in close co-operation for wider health care facilities for large number of people. The cruel bullets of a misguided terrorist took away the life of Hakim Mohd. Said but his idea is remains and his eldest daughter Rasheda has taken over the responsibility to fulfill his dream. Madinatul Hikma is a brilliant example of success of truth over falsehood and science over fiction. Hakim Said shall remain immortal and he shall be remembered for ages to come for his magnificent contribution for Islamic medicine vis-a-vis alternative medicine. In Bangladesh Hakim Mohd Said totally ignored the political separation. He loved and respected to the people hard deserving his lifetime. He made several visits, established, gave new life to Hamdard Bangladesh with started with virtually nothing after liberation. But with the untiring zeal, unlimited efforts and enthusiasm Yousuf Haroon Bhuiyan under the guidance, and patriotism of Hakim Mohd Said Saled lovely and effectively through the turbulent see of trouble to reach the shore of success. Consequently Hamdard Bangladesh today is a mighty

organization with around 250 crore Tk. as capital, more than 200 products and approximately 100 crore Tk. yearly sales. It is now planning for a University for which progress has been made and the responsibility for the planning has been entrusted on me.

Question: What is your plan with these three systems?

Answer: These three systems are now recognized in many developed countries in America and in Europe. In India there is a separate council namely Medical Council for Indian Medicine has been established for these three systems and person so qualified are employed in health care system in India. In America a separate directorate for Alternative Medicine has been established in the National Institute of Health where a budget allocation of about 5 crore dollars (50 million US dollar) has been made for education research in alternative medicine. WHO has a section of Alternative Medicine with a Director-in-Charge. In Bangladesh Alternative Medicine and the two systems referred to viz. Ayurvedic and Homeopathic. They are popular among the poor and the rural people have not gained the status and these bad systems in other countries. Misconception exists about this effectiveness of these systems. There are several reasons for these unhappy situations. Ignorance is perhaps more than indifference for these unhappy situations. Our people are not aware of the present status of these systems in the developed way. The old idea of modern medicine is the only scientific medicine system and the traditional medicine bring a scientific still remain. Indifference may be partly two professional and privately and partly due to non-recognition of government. I propose to proof the value of these system scientifically with these in mine have a plan to have three systems side by side in Out Patient Department of my University. Consultant in three systems shall be accommodated in the Out Patient Department side by side in the same floor. Treatment shall be offered to the Out Patient to those the system. Patient attending the OPD shall be guided junior experts to which system they should be effort depending on:

- A. Nature and duration of disease
- B. Previous treatment obtained
- C. Financial resources and status

Full record of the patient shall be maintained for analysis and comparative study of the three systems to find out efficacy, usefulness and affordability and of these three systems which sufficient data it may thus be possible to find the usefulness of other systems. Which may prospect the government to adopt these systems for health care delivery.

Hamdard in Bangladesh

Professor Shiry Farhad

Unani system of medicine has been used for the prevention and treatment of disease for almost 3000 years. Contribution of this system in health care has been very significant and over the ages there has been several improvements. During the British ages, however they were neglected and left ignored. Subsequently, Hakim Azmal Khan and the founder of Hamdard Hakim Abdul Majid, the two world famous Unani specialists, put their tireless efforts, research and perseverance to establish this system in the world of therapy, in general and in this subcontinent. Their efforts and the worldwide recognition of this system influenced the WHO to recognize this and to establish a separate section for traditional medicine, including the Unani system.

Undoubtedly, Hakim Mohammed Said played the leading role and used all his influences and efforts for this system. Hamdard is a symbol of success and the herbal system through this has been playing a significant role for almost half a century in this subcontinent. Illustrious Unani physician Hakim Abdul Majid established Hamdard in 1906 at New Delhi with five following objectives:

1. Improvement, preservation and development of herbal medicine in scientific way.
2. Improvement of basic principles of pharmaceutical sciences.
3. Cooperation in the preparation of herbal medicines.
4. Education in the medical sciences, health and medicine.
5. To be dedicated selflessly for the welfare of the people.

In 1922 with the death of Hakim Abdul Majid, his eldest son Hakim Abdul Hamid took over the charges of Hamdard as managing director and made the organization popular in the field of herbal medicine within a short time. He has the credit of establishing Hamdard University, research center, Galib academy and Hamdard city in Delhi, a unique contribution for the Unani system of medicine.

Hakim Mohammed Said was the youngest son of Hakim Abdul Majid who established Hamdard in Pakistan in 1948. Through his untiring

efforts he succeeded to establish Madinat-Al-Hikmah, a wonderful organization consisting of university, medical college, school, hospital and the largest library of Asia. His herbal garden is the most impressive.

In 1953 Hamdard started functioning in Bangladesh by establishing two sale centres- one in Dhaka and other in Chittagong. Initially medicine was used to be brought from Pakistan to sale in Bangladesh. In 1972, Hamdard was recognized by the ministry and included in the Waqf system. Till 1977 very little success was achieved and there was nothing remarkable in production and distribution.

The present status of Hamdard has been the sole contribution of Hakim Md. Yusuf Harun Bhuiyan, who gave life to this virtually dead organization. Through his untiring effort and zeal, undaunted by challenges, difficulties and perils, he successfully established peace, harmony and enthusiasm among the workers and successfully eliminated corruption, conspiracy and various grievances. When the organization was facing the crisis in 1977, Mr Nurul Absar, a senior officer took over the charges of Motoalli. But he could not do much for some reason and other. Mr Nurul Absar died in 1982, when the Hamdard property was of the value of only Tk. 50,225.00, whereas the liabilities were Tk 2,92,000.00 There were 23 workers and the total monthly salary was 6,500.00 only. This small amount could not be paid regularly. After the death of Mr. Nurul Absar, Hakim Md. Yusuf Harun Bhuiyan took over the responsibilities of Hamdard and gives a new life to the organization. Despite many obstacles, conspiracy and criticisms Hakim Md. Yusuf Harun Bhuiyan brought series of successes and it is to his credit that Hamdard Bangladesh what it is today. It is through his efforts the first trustee board of Hamdard was established in 1986. The members of the first trustee board of Hamdard:

Hakim Mohammed Said

Founder, Donor & Advisory member

Justice AFM Ahasanuddin Chowdhury

Chairman

Former President, PRB

National Professor N Islam

Vice Chairman

Architect of National Drug Policy &

Vice Chancellor, USTC

Dr Humauyan KMA Hai

Member

Member of National Drug Policy Committee &

Former Director, Drug Administration

Alhaj Hakim Azizul Islam

Member

Chairman, Unani Ayurvedic Board

Moulana Mohiuddin Khan

Member

Muslim Scholar

Alhaj Atiqur Rahaman Sarkar

Member

Formar DD, Waqf Administration

Alhaj Mir Kashem Ali

Member

Former Director, Rabeta Alam Islami

Director, Islami Bank

Mr GA Kham

Member

Advocate, Bangladesh Supreme Court

Hakim Md Yusuf Harun Bhuiyan

Member Secretary

Managing Director, Hamdard

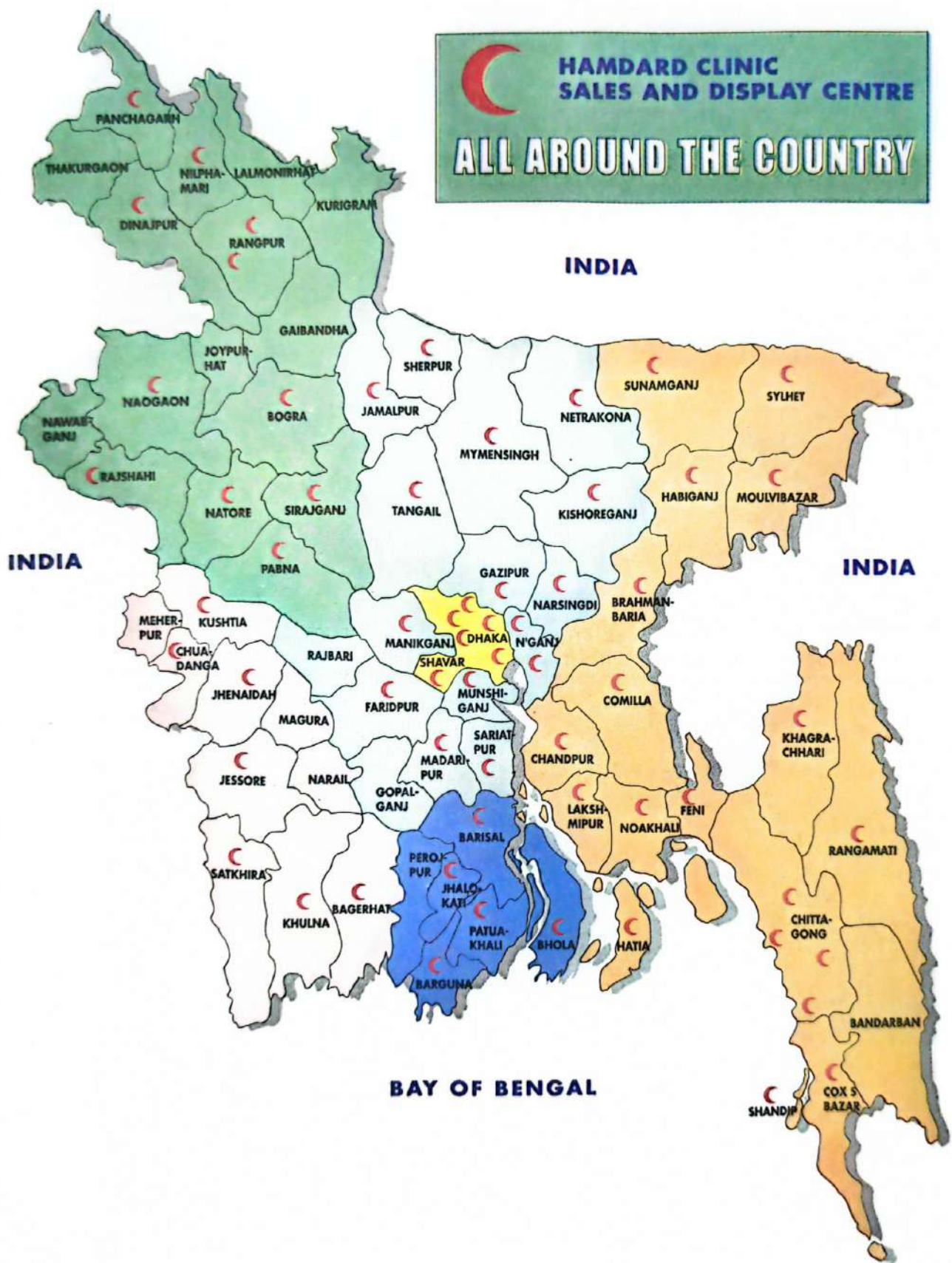
This committee is renewed in every three years and constituted with renowned specialist in various field. With the help and guidance of this committee and wholehearted cooperation of the Waqf administration, the management under the leadership of Hakim Md Yusuf Harun Bhuiyan has been successful in bringing success and glory of

this organization. We are now proud that the organization has achieved success, glory and admiration from many corners.

Success brings success. We have now dream of a university, known as Hamdard University. The proposal has been accepted by the board of trustee on principle and entrusted National Professor N Islam, our Hon'ble Vice Chairman to act as the Chairman of the Sub-committee for the establishment of Hamdard University. The work is in progress and we hopefully wait for the day when the university will be established and the people of the country will get the benefit. It will open up wider opportunities for closer relationship and cooperation between Madinat Al Hikmah of Pakistan and Hamdard University of Bangladesh. The past history of Hamdard and its subsequent success raises hope for our success.

Hamdard is dedicated to the welfare of the people. Our mission is to serve because, "To Serve People is to Serve GOD."

 **HAMDARD CLINIC**
SALES AND DISPLAY CENTRE
ALL AROUND THE COUNTRY



Ictam Conference
Halle, Germany
16-24 August-2002



The Author at a reception with the Mayor of Halle



The Author & his son with the Vice Premier of a State in Russian Federation at a Reception by the Mayor of Halle

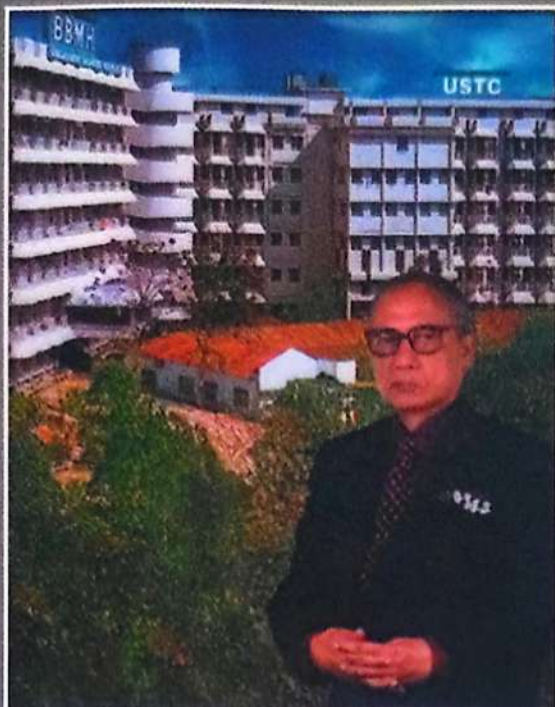
Board of Trustees Hamdard Bangladesh



From Right : Hakim Hafiz Azizul Islam (Member), Hakim Md. Yousuf Haroon Bhuiyan (Secretary), Prof. Dr. Choudhury Mahmood Hasan (Member), M.A. Kashem (Member), National Prof. Dr. Nurul Islam (Vice-Chairman), Justice Mohammed Abdur Rouf (Chairman), Dr. Humayun K.M.A. Hye (Member, Prof. Mohammed Mosihuzzaman (Member), Khandker Abul Basher (Member).



Present Board of Director of "Hamdard Laboratories (waqf) Bangladesh".
(From the Left) Md. Golam Nobi Director Production , Prof. Shiry Farhad Director Administration, Rafiqul Islam Director Marketing, Hakim Md. Yousuf Haroon Bhuiyan Managing Director, Kazi Mansur-ul-haq Director Information And Md. Anisul Huq Director Finance.



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National Professor Dr. Nurul Islam is a successful Physician, Teacher and Research-Scientist. He is an outstanding personality of Bangladesh.

He has been decorated with **The Independence Day Award** in 1997 (the highest national award). He is the Founding Father of the Institute of Post Graduate Medicine & Research (IPGMR) and the Founder Vice Chancellor, University of Science & Technology, Chittagong (USTC). By his hard work, merit and creative powers Prof. Islam has received recognition as a great physician and research-scientist, at home and abroad. Prof. Nurul Islam had been a close associate of 'Father of the Nation' Bangabandhu Sheikh Mujibur Rahman and was proud to be his personal physician. People of Bangladesh have long respect to Prof. Islam for his patriotism, amiable nature and love of fellow-men.

He has published over one hundred research papers in International Medical journals. Prof. Islam received several awards from different Governmental and Non-Governmental organizations, which include-President Gold Medal (1963), National Academy of Sciences Award (1982), WHO Commemorative Medal on Tobacco & Health (1990 & 1992), MK Ghandi Peace Award (1996) etc. He is the Founder of "ADHUNIK" (national anti-tobacco organisation) which is well-known at the international level.

Dr. Nurul Islam is the author of several books. He is the Founder-councilor of Bangladesh College of Physicians and Surgeons, Regional Adviser of Royal College of Physicians, Edinburgh, member of the Editorial Board of the Tropical Doctor published by Royal Society of Medicine. He is also Adviser to the Madinatul Hikmah-City of Education, Science & Culture, Karachi, Pakistan. The titles of his Bengali books are : JIBON SROTAY (In the Stream of Life) PALLI CHIKITSHAI ATTABOSHOKIO AUSHAUD (Essential Medicines for Rural Medical Practice), KICHHU BHABNA (Some Thoughts). His two English books which are most well-known internationally are: Medical Diagnosis & Treatment and Tropical Eosinophilia.

Utilization of religious leaders & primary school teachers for Primary Health Care was a concept organized by him. Essential drugs concept and development of national drug policy by him, in 1982, had led to the significant growth of the pharmaceutical industry enabling it to export many pharmaceutical products. From all considerations Prof. Islam deserves the highest respect and awards of this country.

