This report has covered a broad spectrum of alternative medical therapies and systems of medicine. Some of these medical systems, such as Ayurvedic medicine and traditional oriental medicine, are centuries old and are still in extensive use in other nations and cultures of the world. Others, such as osteopathy and naturopathy, evolved in the United States in the not-too-distant past but were relegated to the fringes of medicine because they differed from conventional biomedicine in the concepts of health and illness they embraced. Still others, such as some of the mind-body and bioelectromagnetic approaches, are on the frontier of scientific knowledge and understanding.

Many alternative practitioners face numerous economic, political, and scientific barriers that block their acceptance by mainstream biomedicine. On the other hand, some alternative medical practitioners do not expect to be brought into the fold. Rather, they just want the opportunity to coexist peacefully with mainstream medical practitioners and to be allowed to offer consumers alternative health care options. Consumers, however, are not waiting for mainstream science to give them a "green light" on many alternative treatments before using them. The fact is that today alternative medicine constitutes a significant and growing portion of the Nation's health care expenditures.

Recent surveys have demonstrated that most people who opt to use alternative treatments or systems of medicine believe that conventional medicine has not adequately addressed their needs, or they want to supplement and thus improve on their conventional treatment. This is especially true of people with chronic, debilitating illnesses such as arthritis, pain, cancer, and AIDS. People often are attracted to alternative medicine practitioners who emphasize the patient's role in the healing process as well as the importance of the patient-practitioner interaction.

Studies also show that individuals who seek out and use alternative medical treatments tend to be the better educated and the more affluent. Thus the stereotype of the alternative medicine consumer as an uneducated, poor person succumbing to the sideshow lures of quacks and charlatans appears to be greatly overblown. The reality is that because patients, in general, are demanding more health care options at a lower cost, a growing number of conventionally trained American physicians have already begun incorporating alternative medical modalities into their everyday medical practices.

The dominant biomedical U.S. health care system has made countless technological discoveries and innovations in the past half century, revolutionizing the way the body, the mind, and the environment are viewed. By all measures, however, it is an extremely expensive system offering limited accessibility. In other words, the patients who have the most money and live nearest the best health care facilities often receive the best care. Increasingly, this situation will dictate that the elderly, the disadvantaged, people with chronic illnesses, and the very young go without adequate health care—the populations that need health care most.

One of the simplest and most effective ways to significantly lower health care costs and thus increase access is through a major focus on preventive medicine. In this clinical arena, many of the alternative health care systems may have much to offer. Homeopathic and naturopathic physicians, for example, strongly advise their patients about diet and other health-promoting lifestyle choices as a matter of routine care. In contrast, many conventional physicians do not routinely give such advice until a patient has already become chronically ill, by which time the patient may need expensive high-tech surgery and face a lifetime of expensive drug therapy.

Another major factor contributing to the skyrocketing health care costs in this country is the amount of time involved in officially certifying a drug or medical intervention as clinically effective and safe. Millions of dollars may be spent, and years may pass, before a potentially lifesaving drug, instrument, or intervention winds its way through the complex Federal approval process. That same process too often ignores or discounts related, potentially valuable Canadian, European, and Asian data that could significantly shorten the assessment process.

In addition, standards of testing drugs and therapies in the United States are inconsistent with standards in many other technologically developed countries. For example, U.S. regulations on testing herbal medicines require a much more circuitous testing process than is required overseas. There, evidence of prior use without adverse side effects may be accepted by medical authorities without data from extensive clinical trials; preliminary clinical trials can therefore focus immediately on the effectiveness of the herbal remedy. In the United States, however, Phase I trials focus solely on safety issues, and effectiveness is not dealt with until much later.
Furthermore, in many European and Asian countries it is completely acceptable to test an herbal extract as a single drug rather than require every potentially active ingredient in the plant to be tested, as is the rule in the United States. Thus in other developed countries significantly less time and cost often are involved in bringing a potentially beneficial herbal or naturally occurring remedy to market.

As U.S. consumers continue to use alternative medicine, the challenge for health care policymakers and Federal regulators is not only to protect the public from unscrupulous medical practitioners but also to ensure the public's access to the most effective treatments available. Certainly, patients should have recourse if it can be shown that their practitioners or the treatments they offer have no clinical or psychological benefit. By the same token, patients with debilitating severe or chronic illnesses should have the right to have access to--as well as insurance to cover--an alternative therapy they believe offers them relief.

Many of the alternative therapies described and discussed in this report--hypnosis, art therapy, music therapy, chiropractic, massage therapy, acupuncture, and many herbal and nutritional supplementations, to name a few--have already received extensive and positive clinical evaluations. However, no critical mass of researchers, clinicians, and policymakers has formed to give them more exposure and recognition. Therefore, many of these therapies should be included in any serious discussions about developing a truly comprehensive health care system. Others, as the report has indicated, need to be quickly and thoroughly evaluated before any judgment can be passed. However, they still may represent a great and largely untapped resource for improving the Nation's health.

**Appendix A: Participants at the Unconventional Medical Practices Workshop**

Westfields International Conference Center  
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Appendix B: Comments of the Panel on Mind-Body Interventions on the National Research Council's Reports on Alternative Medicine

In 1991 the National Research Council (NRC) issued an evaluation of some of the therapies examined herein (Druckman and Bjork, 1991). The NRC in 1988 also reviewed certain human-performance technologies designed to enhance human abilities beyond normal levels, which are also the concern of the Panel on Mind-Body Interventions (Druckman and Swets, 1988). Because the conclusions of the NRC reports differ from our own, and because these reports have been influential in shaping public opinion about the effectiveness and benefits of certain mind-body interventions, we believe it is important to comment on these discrepancies.
We shall focus on the NRC's treatment of meditation, one of the approaches we have closely examined, and parapsychology, an indirectly related area, to illustrate these differences of opinion and describe how they have taken shape.

Meditation

The 1991 NRC report stated, "Overall, our assessment of the scientific research on meditation (primarily, transcendental meditation [TM]) leads to the conclusion that it seems to be no more effective in lowering metabolism than are established relaxation techniques; it is unwarranted to attribute any special effects to meditation alone" (Druckman and Bjork, 1991). The NRC report reached this conclusion by drawing primarily on two previous narrative reviews. One of these, by Holmes, covered less than half the relevant studies on TM available at the time it was prepared (Holmes, 1984). The other, by Brener and Connally (1986), also appears to have ignored much of the available and relevant research.

A meta-analysis by TM researchers Dillbeck and Orme-Johnson on the effects of meditation, published in American Psychologist, came to a different conclusion but was ignored in the NRC report. Their quantitative approach showed that the effect size for TM was more than twice that of resting quietly on basal skin resistance, respiration rate, and plasma lactate (Dillbeck and Orme-Johnson, 1987).

Furthermore, Eppley, Abrams, and Shear, addressing psychological and physiological measures of anxiety, showed that TM typically produces two to three times the reductions in effects of chronic stress compared with other meditation and relaxation techniques (Eppley et al., 1989). Yet the NRC report said "no evidence supports the notion that . . . meditation permits a person to better cope with a stressor."

Meta-analysis allows quantitative analysis of various aspects of the literature. For instance, it allows one to compare the results of studies done by experimenters who are cordial, neutral, and negative toward TM. The Eppley meta-analysis demonstrated that the distribution of effects was normal, indicating that the positive conclusions reached in studies of TM are not the result of selective reporting, and that the NRC's characterization of researchers who are practitioners of meditation as subjectively biased "devotees" is without merit. The Eppley meta-analysis also contradicted the Brener and Connally claim that meditation research suffered from "weak design" by providing quantitative demonstration that the results cannot be accounted for by subject selection, experimenter bias, expectancies, or atmospheric effects.

The NRC report embodies some faulty assumptions about meditation. It expresses the expectation that meditation should "[lower] reactivity to challenge"--that is, to make one less responsive to stressors, perhaps through "distracting a person" or providing a "quiet place." But this is neither the traditional nor the express purpose of TM, which is to achieve "restful alertness, a state of unifying capacity." These misunderstandings may be due to the fact, acknowledged by the NRC, that no one on their committee was personally familiar with the experience of any of the meditation practices they reviewed. The difficulties this created were also acknowledged by the committee: "It seems appropriate to be mindful of the constraints that science, as well as culture, background, and personal life experience, place on how the committee views the field of meditation."

The most glaring omission in the NRC report is a large database (more than 40 published reports) of societal impact studies on what the TM researchers call the consciousness field. The theory underlying this research is that the field, when supported by a sufficient number of meditators, produces the effects and benefits of meditation in the larger population. This is a nonlocal effect, a type of action-at-a-distance, and the TM researchers describe a correspondence to aspects of quantum nonlocality in their efforts to explain the results of these studies.

On the positive side, the NRC report makes a number of very sensible recommendations for research. In a general observation, they state that "learning to relax and enjoy good feelings may prompt a person to make positive changes in his or her work and personal situation. . . [I]t may be that meditation and relaxation . . . effect cognitive change." Their overall conclusion restates a question about relative efficacy and constitutes an implicit recommendation for more incisive research, but they do not dispute the potential therapeutic effects of meditation broadly defined.

Parapsychology
In its 1988 report the NRC is strongly critical of parapsychology, a field that studies, from an independent perspective, the nonlocal events exemplified in prayer and mental-spiritual healing that we have reviewed earlier. The NRC emphasized their belief that more than 130 years of research have failed to find any evidence of parapsychological phenomena. Because of the relevance of this research to issues addressed by the Panel on Mind-Body Interventions, the literature was examined, revealing impressive evidence in clear disagreement with the NRC’s conclusion.

In the December 1989 issue of Foundations of Physics, Radin and Nelson reported the largest meta-analysis of parapsychological findings ever done—a total of 832 studies from 68 investigators, involving the influence of human consciousness on microelectronic systems (Radin and Nelson, 1989). The results: “Radin and Nelson’s meta-analysis demonstrates that the . . . results are robust and repeatable. Unless critics want to allege wholesale collusion among more than 60 experimenters or suggest a methodological artifact common to . . . hundred[s of] experiments conducted over nearly three decades, there is no escaping the conclusion that [these] effects are indeed possible” (Broughton, 1991; Jahn and Dunne, 1987).

Meta-analysis has also been applied to research studies in precognition, which typically involve card-guessing by a subject before the targets are even prepared. Honorton and Ferrari found 309 studies in English-language publications by 62 investigators, involving more than 50,000 subjects who participated in nearly 2 million trials. Their findings were as follows:

* Thirty percent of the studies produced statistically significant results (where 5 percent was expected by chance). The odds of this result happening by chance are approximately 1 in 1,024.

* The results could not be explained by the failure of researchers to report negative studies (the “file drawer” effect).

* Studies with the most rigorous methodology tended to produce better results (exactly the opposite of critics’ claims).

* The effect size remained constant over the more than 50 years under consideration (Honorton and Ferrari, 1989).

An excellent summary of the techniques of meta-analysis applied to several parapsychological databases was published in 1991 by Jessica Utts in Statistical Science (Utts, 1991).

A charge frequently made about parapsychology and the nonlocal therapies we have examined is that the quality of research in these areas is low or substandard. In its 1988 report, the NRC commissioned psychologist Robert Rosenthal of Harvard University to prepare an evaluation of all the controversial areas of interest to the NRC committee. Parapsychology researcher Richard S. Broughton describes this undertaking:

Rosenthal is widely regarded as one of the world’s experts in evaluating controversial research claims in the social sciences and has spent much of his career developing techniques to provide objective assessments of conflicting data. Neither Rosenthal nor his coauthor, Monica Harris, had taken any public position on parapsychology . . . . The report by Harris and Rosenthal determined that the “research quality” of the parapsychology research was the best of all the areas under scrutiny. . . . Incredibly . . . [the] committee chairman . . . asked Rosenthal to withdraw the parapsychology section of his report. Rosenthal refused. In the final document, the Harris and Rosenthal report is cited only in the several sections dealing with nonparapsychological topics; there is no mention of it in the parapsychology section (Broughton, 1991).

The Panel on Mind-Body Interventions believes it is necessary to acknowledge and document our differences of opinion with the NRC reports. At the same time, we do not wish to overemphasize or dwell on these conflicting points of view.

If the field of alternative medicine is to progress, it is vital that any evaluation of mind-body practices be comprehensive, rigorous, and unbiased.

References


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**Appendix C: WHO Guidelines for the Assessment of Herbal Medicines**

**Appendix D: Plant Sources of Modern Drugs**

Species Family Type of Drug/Product

Acacia senegal (L.) Willd. Leguminosae Gum acacia

Agathosma betulina (Berg.) Pillans Rutaceae Buchu leaf

(Syn.: Barosma betulina (Berg.) Bartl. et Wendl. f.)
Ammi majus L. Umbelliferae Xanthotoxin

Ananas comosus (L.) Merr. Bromeliaceae Bromelain

Aralia racemosa L. Araliaceae Aralia extracts

Arctostaphylos uva-ursi (L.) Spreng. Ericaceae Uva ursi

Atropa belladonna L. Solanaceae Belladonna extract

Avena sativa L. Gramineae Oatmeal Concentrate

Berberis vulgaris L. Berberidaceae Berberine

Calendula officinalis L. Compositae Calendula oil

Camellia sinensis L.
(Syn.: Theasinensis L.) Theaceae Caffeine

Capsicum annuum L. Solanaceae Capsicum oleoresin

C. baccatum L. var pendulum (Wild.)
Eshbaugh Capsicum oleoresin

C. chinense Jacquin Capsicum oleoresin

C. frutescens L. Capsicum oleoresin

Capsicum pubescens R. et P. Solanaceae Capsicum extract

Carica papaya L. Caricaceae Papain

Cassia senna L. (Syn.: C. acutifolia Delile senna leaf C. angustifolia Vahl) Leguminosae Sennosides A + B, senna pods

Catharanthus roseus (L.) G. Don Apocynaceae Leurocristine (vincristine) and incaleukoblastine (vinblastine)

Cephaelis ipecacuanha (Brot.) A. Richard Rubiaceae Ipecac fluid extract, ipecac syrup

Chrysanthemum cinerariaefolium (Trev.) Vis. Compositae Pyrethrins

Cinchona calisaya Wedd. Rubiaceae Quinine, quinidine
C. ledgeriana Moens Quinine, quinidine

C. pubescens Vahl Quinine, quinidine

Cinnamomum camphora (L.) J. S. Presl Lauraceae Camphor

Citrus limon (L.) Burm. f. Rutaceae Pectin

Citrus sinensis (L.) Osbeck Rutaceae Citrus bioflavonoids

Colchicum autumnale L. Liliaceae Colchicine

Commiphora abyssinica Engl. Burseraceae Myrrh gum

C. molmol Engl. ex Tschirch Myrrh gum

Digitalis lanata Ehrh. Scrophulariaceae Digoxin lanatoside C, and acetylgitoxin

D. purpurea L. Digitoxin, and digitalis whole leaf

Dioscorea composita Hemsl. Dioscoreaceae Diosgenin


D. deltoidea Wallich Diosgenin

Duboisia myoporoides R. Br. Solanaceae Atropine hyoscyamine scopolamine

Eucalyptus globulus Labill. Myrtaceae Eucalyptol (cineole) eucalyptus oil

Fagopyrum esculentum Moench Polygonaceae Rutin

Frangula alnus P. Miller

(Syn.: Rhamnus frangula L.) Rhamnaceae Frangula bark

Gaultheria procumbens L. Ericaceae Wintergreen oil

Gelsemium sempervirens (L.) St. Hil. Loganiaceae Gelsemium extract

Glycine max (L.) Merr. Leguminosae Sitosterols
Glycyrrhiza glabra L. Leguminosae Licorice extract

Gossypium hirsutum L. Malvaceae Cottonseed oil

Guarea rusbyi (Britton) Rusby Meliaceae Cocillana extract

Hamamelis virginiana L. Hamamelidaceae Witch hazel extract

Lavandula officinalis P. Miller
(Syn.: L. officinalis Chaix) Labiatae Lavender oil

Linum usitatissimum L. Linaceae Linseed oil

Malus sylvestris P. Miller Rosaceae Pectin

Melaleuca leucadendron L. Myrtaceae Cajeput oil

Mentha arvensis L. Labiatae Menthol

M. piperita L. Peppermint oil

M. spicata L. Spearmint oil

Myristica fragrans Houtt. Myristicaceae Nutmeg oil

Myroxylon balsamum (L.) Harms Leguminosae Tolu balsam

M. balsamum var. pareirae (Royle) Harms
(Syn.: M. pareirae (Royle) Klotzsch) Peru balsam

Olea europaea L. Oleaceae Olive oil

Papaver somniferum L. (Paregoric) Papaveraceae Opium extract codeine, morphine, noscapine, and papaverine (33)

Pausinystalia yohimba Pierre ex Beille Rubiaceae Yohimbine

Physostigma venenosum Balf. Leguminosae Physostigmine (eserine)

Pilocarpus jaborandi Holmes Rutaceae Pilocarpine

Pimpinella anisum L. Umbelliferae Anise oil

Piper cubeba L. f. Piperaceae Cubeb oil
Plantago indica L. Plantaginaceae Psyllium husks

P. ovata Forsk. Psyllium husks

P. psyllium L. Psyllium husks

Podophyllum peltatum L. Berberidaceae Podophyllin

Polygala senega L. Polygalaceae Senega fluid extract

Populus balsamifera L.

(Syn.: P. candidans Ait., P. tacamahacca P. Miller) Salicaceae Poplar bud

Prunus domestica L. Rosaceae Prune concentrate

P. virginiana L. Wild cherry bark

Quercus infectoria Olivier Fagaceae Tannic acid

Rauvolfia serpentina (L.) Benth. ex Kurz Apocynaceae Reserpine alseroxylon fraction, powdered whole root

Rauvolfia R. vomitoria Afzel. Deserpidine, reserpine, rescinnamine

Rhamnus purshiana DC. Rhamnaceae Cascara bark, casanthranol, danthron(33)

Rheum emodi Wallich Polygonaceae Rhubarb root

R. officinale Baill. Rhubarb root

R. palmatum L. Rhubarb root

R. rhaponticum L. Rhubarb root

Ricinus communis L. Castor oil, ricinoleic acid

Rosa gallica L. Rosaceae Rose petal infusion

Salix alba L. Salicaceae Saligenin

Sanguinaria canadensis L. Papaveraceae Sanguinaria root
Appendix E: The 20 Most Popular Asian Patent Medicines That Contain Toxic Ingredients

1. Product Name: Ansenpunaw Tablets
   Manufacturer: Chung Lien Drug Works, Hankow, China
   Toxic Ingredients: cinnabar (mercury chloride)

2. Product Name: Bezoar Sedative Pills
   Manufacturer: Lanzhou Fo Ci Pharmaceutical Factory, Lanzhou, China
   Toxic Ingredients: cinnabar 2% or 10%

3. Product Name: Compound Kangweiling
4. Product Name: Dahuo Luodan
Manufacturer: Beijing Tung Jen Tang, Beijing, China
Toxic Ingredients: centipede (scolopendra) 10%

5. Product Name: Danshen Tabletco
Manufacturer: Shanghai Chinese Medicine Works, Shanghai, China
Toxic Ingredients: borneol

6. Product Name: Fructus Persica Compound Pills
Manufacturer: Lanzhou Fo Ci Pharmaceutical Factory, Lanzhou, China
Toxic Ingredients: cannabis indica seed ()

7. Product Name: Fuchingsung-N Cream
Manufacturer: Tianjin Pharmaceuticals Corp., Tianjin, China
Toxic Ingredients: fluocinolone acetonide ()

8. Product Name: Kwei Ling Chi
Manufacturer: Changchun Chinese Medicines & Drugs Manufactory, Chang Chun, China
Toxic Ingredients: cinnabar

9. Product Name: Kyushin Heart Tonic
Manufacturer: Kyushin Seiyaku Co., Ltd., Tokyo, Japan
Toxic Ingredients: toad venom, borneol

10. Product Name: Laryngitis Pills
Manufacturer: China Dzechuan Provincial Pharmaceutical Factory, Chengtu Branch
Toxic Ingredients: borax 30%, toad-cake 10%

11. Product Name: Leung Pui Kee Cough Pills
Manufacturer: Leung Pui Kee Medical Factory, Hong Kong
Toxic Ingredients: dover's powder (opium powder) ()

12. Product Name: Lu-Shen-Wan
Manufacturer: Shanghai Chinese Medicine Works, Shanghai, China
Toxic Ingredients: toad secretion
13. Product Name: Nasalin
Manufacturer: Kwangchow Pharmaceutical Industry Co., Kwangchow, China
Toxic Ingredients: centipede 5%

14. Product Name: Nui Huang Chieh Tu Pien
Manufacturer: Tung Jen Tang, Beijing, China
Toxic Ingredients: borneo camphor

15. Product Name: Niu Huang Xiao Yan Wan
Bezoar Antiphlogistic Pills
Manufacturer: Soochow Chinese Medicine Works, Kiangsu, China
Toxic Ingredients: realgar 19.23%

16. Product Name: Pak Yuen Tong Hou Tsao Powder
Manufacturer: Kwan Tung Pak Yuen Tong Main Factory, Hong Kong
Toxic Ingredients: scorpion 10%

17. Product Name: Po Ying Tan Baby Protector
Manufacturer: Po Che Tong Poon Mo Um, Hong Kong
Toxic Ingredients: camphor 20%

18. Product Name: Superior Tabellae Berberini HCl
Manufacturer: Min-Kang Drug Manufactory, I-Chang, China
Toxic Ingredients: berberini HCl (]

19. Product Name: Watson's Flower Pagoda Cakes
Manufacturer: A.S. Watson & Co., Ltd., Hong Kong
Toxic Ingredients: piperazine phosphate (]

20. Product Name: Xiao Huo Luo Dan
Manufacturer: Lanzhou Fo Ci Pharmaceutical Factory, Lanzhou, China
Toxic Ingredients: aconite 42%


: requires doctor's prescription.
Appendix F: A Guide for the Alternative Researcher

by Claire Cassidy, Ph.D., Barrie Cassileth, Ph.D., Wayne B. Jonas, M.D.,
Richard Pavek, and Linda Silversmith, Ph.D.

The guidelines in this appendix are provided to assist the alternative researcher. The topics presented were selected from a broader array of methodologies and approaches. There is no intention to be all-inclusive. Topics that were omitted may nevertheless be appropriate tools for conducting alternative research.

General Methodological Guidelines

Research studies on alternative medical therapies should be held to the same rigorous scientific and ethical standards that are applied to research on conventional therapies. The guidelines in this appendix represent a summary of major principles for new investigators as they begin to develop research protocols or grant applications. It is recommended that at least one investigator in each study of alternative medicine be experienced in the therapy or research area to be investigated.

It takes as many years to learn how to conduct good research as to become an accomplished practitioner of alternative medicine. Alternative practitioners who wish to do research need to increase their understanding of good research design, but they should also seek out experienced researchers to guide them as collaborators or resources.

Approaches for conducting research must follow a logical sequence for gathering useful data. Typically, research on a given topic is first exploratory, then descriptive and qualitative, then correlative and comparative, and finally experimental and quantitative. Interviews and surveys are examples of descriptive research or possibly correlative/comparative research; best case series fit the correlative/comparative category; and clinical trials are experimental.

Once a decision has been made that a topic is worthy of investigation and not duplicative of previous work, preliminary or pilot studies (exploratory-descriptive) generally are carried out to determine whether there are any promising effects worthy of further investigation and to detect any negative side effects or practical difficulties. These studies may consist of anecdotal case reports, systematic case studies, or uncontrolled single-group studies. Questions are then formulated for use in controlled comparisons (correlative-comparative) using controls such as the best available “other techniques” or a placebo. A large enough group of patients and sufficient time are necessary to provide enough data to suggest whether the treatment is really working and what conditions seem most practical. If effectiveness is reported, then large studies (experimental-quantitative), such as clinical trials, should be organized to find out whether the earlier observations hold true with a more detailed examination using a greater number of participants.

Whatever the research approach, the following procedure generally applies:

1. Identify the paradigm, model, or pattern and explanatory strategies that underlie the intervention under consideration for testing and evaluation.

2. Carefully develop one or two precise research questions to form the basis of the study. The research questions are crucial because they lead directly to the study’s objectives, methods, implications, and so on.

3. Ensure that all components of the research plan relate logically to one another. Research questions, goals, subject groups, therapies (regimens, products, etc.) to be studied, and methodologies must be mutually consistent and appropriate. When conceptualizing study objectives, make them consistent with research questions and assumptions of the intervention; in turn, make the study design (the strategy for conducting the study) consistent with research objectives. For all procedures that are operator dependent, identify the skills training and experience of the operator (e.g., teacher or deliverer of treatment). Clarify the nature of the population to be studied; in particular, identify whether the entry criteria lead the study population to be different from the spectrum of people being treated by practicing clinicians.

4. Conduct a library search and gather a comprehensive collection of previous research in the specific area to be studied.
Because of incomplete archiving and indexing, computer database searches are currently inadequate to capture the information needed. It may be necessary to read published articles in their entirety and to speak with representatives of alternative medical organizations to locate some references and information. Literature reviews should be comprehensive and systematic (see the "Guidelines for Conducting Literature Reviews" section below).

5. Explain explicitly the methods used to obtain the literature. Simple citation of publications is not adequate. Literature obtained through library search serves as the basis for the "Background" section of grant applications or manuscripts. Background sections should incorporate accurate, high-quality summary evaluations of existing literature. If a systematic review (see the "Introduction to Systematic Reviews" section) or meta-analysis (see the "Introduction to Systematic Reviews" section) has been conducted to quantitatively evaluate the literature, this point should be noted.

6. Clearly define (not just label) the intervention to be tested or evaluated.

7. Include in the study any special diagnostic or outcome aspects of the alternative medicine practice that can be reliably measured.

8. Thoroughly and objectively document all procedures and events that occur during the research study, from subject accrual through data collection, data analysis, and reporting of results.

9. In clinical research (studies involving humans), include adequate control groups and provide followup of subjects over time, with appropriate monitoring of both the intervention group and the control group.

10. In clinical research, consider and minimize any potential risks to subjects. Along with other required information, these risks must be explained to potential subjects in an informed consent document, provided by the sponsoring institution's human subjects committee or institutional review board.

11. Before research begins, decide and indicate in the research proposal what will be considered sufficient evidence to recommend inclusion of the intervention in clinical practice (if relevant).

12. Where appropriate, use standard comparative outcome measures that will allow the new data to be compared with previous and future information on the same topic.

13. Obtain expert guidance on computerizing and analyzing research data. Biostatistics and computer programming assistance will ensure proper management and analysis of data.

Guidelines for Conducting Literature Reviews

Summary information about previous work in a given field is necessary for grant applications and publications. In addition, literature reviews in and of themselves often are useful additions to the literature.

Overview of Goals of the Review

The literature review must address a clearly focused question. It should specify the particular population, intervention or treatment, subject or diagnostic group, or the like, on which the review will focus. A summary table of all studies included in the review, along with their data, may be appropriate. The review should address a specific and pragmatic issue.

Literature Search

The process of collecting relevant articles must be comprehensive and thorough. The search should use bibliographic databases such as MEDLINE, Science Citation Index, Social Science Citation Index, references from relevant articles, personal communications with authors, and manual searches of databases such as Index Medicus. Note that currently...
this approach may locate only 25 to 50 percent of articles on alternative medicine because most such articles do not appear in standard medical journals (see the “Research Databases” chapter).

Search methods must be systematic and clearly described. Possible selection bias must be addressed when articles are obtained through personal contact. Negative studies should be described along with others; their exclusion suggests possible bias.

Selection of Articles for the Study

The chosen method for selecting articles must be clear, systematic, and appropriate. Inclusion and exclusion criteria should be preestablished in the form of a protocol to be followed when reviewing articles for inclusion; the selection process should then be followed systematically.

The selection protocol should address major criteria that are relevant to the therapy or system under review, including whether the population is adequately defined, whether the exposure or intervention is clearly described, and whether outcomes are detailed and comparable.

Articles should be reviewed in random order and selected as they meet the preestablished criteria. The reliability of the selection process can be measured by comparing articles collected by at least two independent selectors (expert and nonexpert). The extent of selection disagreement can then be evaluated, and a method can be developed to deal with discordant selections.

Research Quality

The quality of the methodology of each study under review is evaluated according to a single set of standards applied to all studies, whether or not the studies have been published. Literature evaluation must be reproducible. It should be conducted by evaluators who are blind with respect to authors, institutions, and study results. These methods of assessment should be described in the introduction to the literature review.

Combining of Results

Results across studies may be combined only when the studies are adequately similar. Study designs, populations, exposures, outcomes, and direction of effect should be similar enough to warrant combining. If studies are methodologically similar, it is less likely that chance influences their results. Analysis of numerous subgroups matched between studies should be avoided, as spurious statistical significance is likely to result. Comparisons are more likely to be valid if variation in the primary studies is considered when results are combined. Differences in study design and components (e.g., population, exposure or intervention, outcomes) should be addressed. Any nonstatistical criteria used for comparison should be explained.

Meta-Analysis and Systematic Reviews

A statistical review method that combines data from several studies is termed meta-analysis (or statistical meta-analysis). These quantitative analyses, which require similar study samples, interventions, and outcomes, can evaluate the magnitude of treatment effect (percentage risk reduction) and the possibility that the differences were due to chance. Meta-analyses can be used to determine the frequency (i.e., quantity) and the quality of the research method employed in studying a specific factor or issue within a single research field or across several fields of study.

Systematic reviews are another orderly approach to reviewing research literature. Like meta-analysis and other quantitative review methods, systematic reviews use clearly specified methods to avoid the introduction of bias in the selection and interpretation of the research literature being reviewed. Clearly defined criteria for including or excluding specific journals and articles are applied; additional criteria are used to evaluate the quality of the measures applied in the reported research to assess the topic of interest. Systematic reviews differ from meta-analyses in that the studies selected for review need not use strictly similar study samples, interventions, or outcome measures.
Significance of Results

The importance of the results can be determined by calculating an odds ratio (the odds of the effect occurring in the exposure group divided by the odds of the effect occurring in the control or comparison group). The resultant number should be large to have any significance. The results should be reported in a clinically meaningful manner such as the absolute difference or the number needed to treat. The results also should be reproducible and generalizable, with similar effects on different types of subject groups. (The level of significance of results could become a criterion for including studies in an alternative medicine research database; such a database is proposed in the "Research Databases" chapter.)

All clinically important consequences should be considered, including other outcomes from the intervention or treatment; these results should be discussed in the context of those analyzed in the review.

Guidelines for Descriptive and Cross-Cultural Studies Using Qualitative Research Methods

Overview

Many alternative medical systems and practices derive from other cultures or reflect models of health and dysfunction that differ substantively from those current in conventional medicine. As a result, research on alternative medical systems often is in effect, if not explicitly, cross-cultural. The fundamental issue of cross-cultural research is that people who have different views of what constitutes reality also experience reality differently. This means that questions, concepts, diseases, treatments, and research protocols that “make sense” in one setting may not make sense in another.

Before conventional quantitative techniques can be validly applied to the scientific analysis of alternative medical systems, enough must be known of these systems to understand how their beliefs (conscious and unconscious) and behaviors differ from those of conventional systems. These differences can then be taken into account in research design. Failure to know about and account for differences leads to uninterpretable or inaccurate research, raises the potential for misapplying findings to the care of patients, and violates the criterion of model fit.

Methods for cross-cultural research--adjusting for the existence of different models of reality--are most highly developed in the social sciences, especially anthropology and communications, and have been incorporated into medical outcome studies. These methods are mostly categorized as qualitative, but quantitative versions of some techniques are available. In practice, most cross-cultural descriptive research demands the use of qualitative methodologies or a mixture of qualitative and quantitative techniques.

The focus of qualitative research is the individual practitioner or patient, and the community. This form of research is respondent centered, and researchers must take care not to impose their own assumptions or biases on data collection. Qualitative research requires the use of open-ended research techniques or instruments. The research team should include investigators who have had prior experience with qualitative methods and have produced publications that provide evidence of relevant expertise.

Methodological issues of clarity, validity, and the testing of hypotheses are similar in qualitative and quantitative research (see the "Guidelines for Clinical Trials" section for a summary). Correspondingly, in qualitative research as in quantitative research, concepts are detailed, theory is constructed by the testing of hypotheses, data are collected systematically, and criteria of soundness are applied to design, data collection, and interpretation.

Uses of Qualitative Research

Qualitative research is a body of techniques and assumptions concerning how to gather and analyze complex real-world data so that they can be applied to real-world problems (Bernard, 1993; Denzin and Lincoln, 1994; Marshall and Rossman, 1989). All qualitative research shares a set of assumptions or concepts about the research field (Marshall and
To find out about people's behavior, it is best to immerse oneself in the actual setting chosen for study.

The participants in the study have values that researchers must honor.

The researcher's task is to discover these values and perspectives and how they affect the participants' behavior and experience.

Research is an interactive process.

Research relies on people's words, stories, and actions as the primary data.

Accordingly, in qualitative or field research, the investigator has direct contact with research subjects and is directly and personally involved in data collection and analysis, with the aim of generating realistic descriptions and explanations. The choice of data collection methods, sampling procedures, and analytic approaches during the research process evolves into a question-specific research design (Crabtree and Miller, 1992). As data are collected and analyzed, this iterative process affects future decisions for additional sampling, collection, and analysis.

Data collection in field research is accomplished primarily through the use of observation, interviewing, and recordings. The researcher may be required to make relatively "unstructured" observations or "structured" observations that depend on a particular knowledge base. Observation is formalized in many ways, including studying proxemics (how people use space) and kinesics (how people move to communicate), participant observation, and various unobtrusive observational measures in which participants are unaware that they are being observed.

The basic approach for data collection usually consists of interviews with individuals or groups. Focus-group interviews are appropriate in some settings and for some purposes but should not replace individual indepth interviews (McCracken, 1988). Sometimes questionnaires can be administered as interviews. Interviews may be conducted at several levels--unstructured (guided everyday conversation), semistructured (more focused but still open-ended), or structured (like spoken questionnaires). Conversations and events may be recorded with audio or video equipment.

Surveys can be constructed on the basis of interview data and, though not administered in a face-to-face setting, can be personalized by offering respondents opportunities to expand on their answers or to contact the researcher for an interview if they want to say more than the survey form permits.

Qualitative researchers have also developed various projective instruments that elicit respondents' unconscious knowledge and beliefs. For example, anthropologists use card-sort and triad-sort techniques, geographers use "mental map" techniques, and psychologists use various picture-response instruments. Preexisting instruments are rarely appropriate for studies across cultures or medical systems.

Much qualitative research also uses secondary sources, such as films, videotapes, texts, and photos. Historical, proxemic, and content analyses of these materials can reveal the unstated values and assumptions of the producers and participants.

To analyze the data collected, the researcher must develop an organizing system, segment the data accordingly, and then determine connections. If the data do not sort well into the categories first selected, the organizing system must be revised. Connections among the sorted data may be made either statistically or interpretively.

Analytical goals

The goal of any analysis is to bring order to what are often extremely complex data. Qualitative researchers try to discover classes of behavior or responses, themes that guide interpretation of events, and differing patterns of response.
The first step is descriptive—simply to disentangle the data. Researchers then try to generalize, that is, to find and name the rules under which a particular result may be expected and to explain why this should be so. Much qualitative research eventually is applied in efforts to improve the quality of life, for example, by delivering health care in ways that make sense to the target population.

To be considered useful, qualitative research must fulfill certain criteria of soundness. It must be clear under which circumstances a particular finding applies and whether a finding works consistently. Another demand is that this research be objective. Traditional criteria, such as reliability and validity (see the "Guidelines for Clinical Trials" section), are applied (Kirk and Miller, 1986). However, some authors have defined different criteria of soundness for qualitative research (Lincoln and Guba, 1985; Marshall and Rossman, 1989):

* Credibility. The conduct of inquiry must enable the subjects of the research to say, "Yes, that question (or that interpretation) sounds right to me." This demand can be met because qualitative research deals directly with research subjects.

* Transferability. A researcher samples a population and makes generalizations about the whole population. If another researcher thinks this generalization applies to a different population, tests it, and finds it to be true, then the criterion of transferability has been met. Note that the underlying concepts are transferred, not the specific data.

* Dependability. Rather than assume that observed events can be replicated (the reliability assumption in quantitative research), qualitative researchers want to be able to account for events as they arise and change. When they do so successfully, the criterion of dependability has been met.

* Confirmability. This criterion is met when the findings of one researcher can be confirmed by another. Qualitative researchers can easily bias their data collection by becoming subjectively involved with the research field; this criterion helps to ensure that excessive subjectivity is not biasing the data, that is, that the data are objective.

Although analytical procedures in qualitative research are not necessarily statistical (as they are in quantitative research), some distinct statistical methods can be applied to qualitative research (Bernard, 1993; Miles and Huberman, 1994); software programs such as Anthropac, Ethnograph, and NUDIST, are available to apply these analyses.

Qualitative Versus Quantitative Methods

Research design often requires a combination of qualitative and quantitative approaches. Qualitative and quantitative research differ in the underlying assumptions that researchers make (Cassidy, 1994). In quantitative research, scientists are likely to detail (and often count) particularities and therefore focus on strategies that limit the view, even if they must do so artificially. The randomly assigned, blinded, controlled clinical trial is an important example of this approach; it is not like the real world, because patients normally do not choose practitioners or treatments randomly, and both practitioner and patient usually know what is going on.

Quantitative methods are useful for answering the following types of questions: How many? How much? How often? What size? What are the measurable associations? What will happen if . . . ? Does one variable cause the other? Is A more effective than B? The quantitative approach serves to isolate variables so that their influence on outcome can be separated from other factors that might otherwise cloud the interpretation.

In contrast, qualitative researchers are interested in complexity and pattern—the interactions among variables—and purposely avoid approaches (such as the use of controls) that simplify and focus. Qualitative methods are useful for answering the following types of questions: What is going on? What is the nature of the phenomenon? What variations occur? How does it work? How did something happen? What patterns can be identified? Is the original theory or hypothesis correct? Does the original theory fit other circumstances? What difference does this program or intervention make? Why does this intervention work or not work?

In a real-world medical setting, these questions might address the following issues:
* Differences in therapeutic effectiveness when patients are assigned or freely choose their health care.

* How patient and practitioner interact, and how this interaction affects the medical outcome.

* How the design of the health care delivery setting affects patient or practitioner satisfaction.

* How patients compare care in two different medical systems.

* How patients become acclimated in a new (e.g., alternative) system of medical care.

There is another important difference between qualitative and quantitative approaches. Quantitative research depends on an assumption that a certain commonality or unchangingness underlies how materials interact. This assumption translates to a demand that a hypothesis be tested the "same way" and "as planned" in different research settings. Once the research has begun, the protocol cannot be changed, for doing so introduces new variables that would invalidate the work.

Qualitative research depends on the opposite assumption, namely that the real world always involves flux and change. Qualitative research protocols outline the goal and approaches, but they are based on the assumption--indeed, the expectation--that unpredictable events will occur and that the research protocol can be changed as one means of dealing with these events (Marshall and Rossman, 1989). Such changes do not invalidate the qualitative research so long as researchers recognize that change is necessary, document the reasons, and create a logical means to deal with the novel event.

Qualitative methods can explain the real world of alternative health care delivery. The qualitative approach is an ideal way to elucidate outcomes issues (as in cost and clinical effectiveness studies) and can be used in settings where little is known about a practice and its theory, techniques, practitioners, or users. When qualitative and quantitative methods are linked, researchers are able to gather fruitful data suitable for use in improving the delivery of health care.

Guidelines for Screening Best Cases

Introduction

Many practitioners of unconventional therapies for cancer and other illnesses have not documented the effects of their treatments, yet they claim positive results. A process is needed to screen such claims to determine whether each patient, or case, provides enough information to qualify as part of a best case series and then to determine whether there are enough cases to meet criteria for a best case series.

The guidelines summarized below were adapted from a National Cancer Institute publication (NCI, 1991) produced to assist the development and reporting of best case series for unconventional cancer treatments. These guidelines retain references to cancer therapies, but a similar approach could also be applied to some other unconventional treatments. Applying this simple and reliable best case evaluation system should enable many unconventional therapies to be screened for adequate information. If available information were not found to be adequate, further attempts to evaluate the therapy would be postponed until better information could be obtained.

With sufficient information to create a best case series, cases that meet NCI's criteria (or other designated criteria for other health problems) can be determined. Necessary information includes documentation--using standard measures--of the patient's diagnosis, staging (severity of illness), treatment, outcome, and so on. The procedure for determining adequate best case information includes six steps.

Conclusion

NCI's best case criteria represent a specific and reliable means of uncovering therapies worthy of study. This approach
uses a single standard to detail the amount of information available and the response achieved.

This method is used to screen charts for adequate information, estimate clinical response, and evaluate practitioner judgment about clinical response. It provides a systematic method for determining which one or ones of the numerous unconventional approaches to cancer warrant further evaluation through clinical trials. The method is applicable to therapies for other problems besides cancer when appropriate evaluators are available.

Guidelines for Clinical Trials

The following guidelines address major methodological issues relevant to designing and conducting clinical trials. The final guideline addresses how interactions between the subject and the health care practitioner may affect study results.

Model Fit

The basic assumptions about health and disease intrinsic to the system under study should be noted, as should the model for classifying and treating patients by that system. For example, if clinical acupuncture care is under investigation, a description of qi and meridians (see the glossary) and the criteria for patient classification and outcome changes must be presented.

The study population should be selected and classified in a way that reflects the assumptions of the model under consideration. For example, if the study addresses disease outcomes, proper diagnostic categories must be used. If the study involves assumed changes in energy patterns, pulses, or symptoms, patients must be classified according to these criteria from the outset. Outcome measures used must be consistent with these assumptions.

The design and methods to explore the intervention must be selected in a way that is consistent with the model's assumptions and with the objectives of the study. Methodologic goals include efforts to (1) demonstrate any effect, (2) assess relative effects between therapies or therapeutic systems, (3) test the utility of an intervention in actual practice, (4) evaluate a possible mechanism of action, (5) examine an assumption that underlies a practice, (6) examine patient reports of satisfaction and relevant explanatory models, (7) examine practitioner explanations of what happened and why, and (8) examine the character of the practitioner-patient relationship and how it affects the delivery and receipt of care.

The goals of the investigation in relation to the system under study must be clearly delineated in the protocol. The study's title and conclusions should reflect the assumptions of the relevant model and the study goals that were actually investigated.

Hypothesis

Clearly established hypotheses should be contained in the research description or grant application. These should identify or predict the main results so that analyses can test the hypotheses.

Patient Selection Bias

The means by which people are identified and accrued to the study, as well as the numbers of potential subjects who decline participation, must be carefully recorded. For example, did subjects come to the study through advertisements? Were they recruited from clinical practices? By random dialing?

Eligibility and selection (inclusion/exclusion) criteria should be clearly stated. Criteria used to diagnose or classify subjects must be valid and reliable. A reference should be given to document the established reliability of the classification system used. In cancer studies, for example, detailed and specific classifications are established (see the "Guidelines for Screening Best Cases" section).

If no generally accepted classification system exists, the system used in the study must itself be detailed and defended in
Comparison groups are developed through a specific process such as randomization, matching, or stratification. Randomization (or a related procedure) applied to a large enough group should distribute differences in the control and treatment groups in a random fashion. In this way the two groups are “equalized” and made as similar as possible except for the intervention to be studied. The method used to create the comparison group should be clearly described. The method should be balanced at least by age, gender, specific diagnosis and stage of disease, important prognostic factors, and other factors relevant to the particular study.

Control Subjects

To obtain comparative data that will shed light on results found in the treatment (or experimental) group of subjects under study, an appropriate control group is needed. Data from control and treatment group subjects are gathered simultaneously by the researchers. Ideally, the groups are identical except for the treatment or intervention to be studied. However, because no two people are identical in every way that may relate to the illness or therapy to be studied, subjects are randomized or matched.

Blinding

Evaluators of the condition of subjects should be blind with respect to (1) whether subjects receive the intervention or a placebo treatment, (2) how the outcome will be measured, and (3) how results will be analyzed.

Crossover Bias

There should be no dilution or co-intervention, that is, the treatment group should not receive any other therapy or intervention in addition to that evaluated in the study. There should be no contamination, that is, control subjects must not receive the same treatment or one that is similar to the treatment received by the experimental subjects.

Confounding Factors

Possible confounding variables (factors that may influence the study’s results) must be addressed adequately. The study groups should be comparable on important prognostic factors. All funding sources should be disclosed, and reports should indicate whether these sources were independent of potential profit from the type of treatment under study.

Sample Size

Estimates of the required number of subjects must be made before the study begins and must be discussed in the research proposal. The statistical basis for selecting the number should be given, and the calculations that led to that number should be described. The research proposal also should provide information about how the researchers plan to attain the desired sample size.

Outcomes and Measurement Errors

Outcome and measurement criteria must be clearly defined and explicit. The validity of the outcome measurements used should be established by references and by verification within the study (against a "gold standard" or parallel outcome measures). The measurement methods used must be sensitive enough to detect the outcome or change to be investigated. All important outcomes must be reported.

The duration of effects must be considered in evaluating outcomes. For example, if subjects of a treatment are crossed
over to a control group, consideration must be given to whether they were still experiencing effects from their treatment after the crossover. Statistical mechanisms for handling this type of problem exist.

Loss to Followup

At least 80 percent of subjects brought into the study should be shown to remain with the study long enough for necessary followup to occur. Subjects who withdraw from the study must be fully described. For the study results to be acceptable, subject characteristics (including age, gender, diagnosis, stage of disease, and other important factors) must be similar for those who withdrew and those who remain in the study.

Statistical Methods

Descriptive statistics (data) are presented on all prognostic and outcome factors. Inferential and hypothesis-testing statistics (p-values) are calculated and reported for all major treatment-outcome links. Confidence intervals or probability distributions also are reported for primary treatment-outcome links.

Multiple Measures

When more than one measure, variable, or comparison group is assessed, appropriate analyses are applied. Examples of such analyses include analysis of variance with multiple comparison groups, post hoc analyses, subgroup analyses, multiple hypothesis testing with serial t- or z-tests, and serial dependent measures.

Clinical Significance

Clinical (versus statistical) significance indicates whether research effects are important or meaningful. Patient or physician satisfaction with treatment is an example. Results that achieve statistical significance are not meaningful unless they are also clinically important or meaningful in clinical practice. For example, a very small difference in the effectiveness of two treatments would not be likely to change clinical practice or to influence physicians or patients to adopt the new treatment.

The new treatment should have a low risk of causing direct harm in comparison to the risks of not treating the disease. If risks associated with the treatment are low, the treatment is more likely to be used.

Generalizability

Results cannot be generalized beyond the type of illness or patient studied. Any other studies that addressed the same research questions should be discussed in the protocol. If intervention X is shown to work for patients with diabetes, for example, it cannot also be said to work for people with other illnesses. If intervention Y produces good results in breast cancer, it cannot be claimed to work in lung cancer. Broader generalizability is possible only with very large research projects that include adequate numbers of men and women of different age groups, disease severity categories, and stages of the illness.

As a general guideline, there should be at least 40 people in each group for each treatment-outcome link examined.

Disclosure Issues

The sources of funding for the research should be disclosed, as should any additional sources of funding for the participating investigators when these sources have the potential to influence their work. Reports on the research should indicate whether any of these sources might potentially profit from the type of treatment under study or might profit from an alternative treatment if the treatment under study were discredited.
Often in clinical trials, the beliefs of and interactions between investigators and subjects are assumed not to be important, but in alternative medicine these are valid concerns. This guideline addresses such personal considerations.

One consideration is bias, which is not usually intentional in research. The differences that could introduce interference or bias in the conduct of the research should be identified and evaluated. Among these are (1) whether the treatment is delivered in the usual method and style used in health care practice, (2) whether the health care practitioner and patient have expectations about the treatment results, (3) whether the patient has complied with the treatment regimen, and (4) whether interference with normal spontaneity and flexibility in patient-therapist interactions has been avoided or noted.

Utility of the treatment involves the question of whether the treatment, as reported, could be applied by practitioners other than those who participated. The investigators’ belief in the efficacy of the treatment should also be assessed, and any idiosyncratic responses or beliefs should be described.

Study subjects must be adequately prepared for their participation. The view of each subject on the need for treatment should be evaluated. For example, does the subject regard the problem as a major or minor condition?

The possibility of transpersonal phenomena should also be considered. Such phenomena might include cultural or spiritual perceptions of the study's importance; cultural disparities in treatment delivery; events that might affect outcome, such as direct observer and evaluation effects; and possible field—that is, nonlocal—effects.

Introduction to Outcomes Research

Outcomes research evaluates the ultimate effects of treatment systems on patients. This evaluation usually involves a retrospective examination of records or databases accumulated by health care practitioners, hospitals, insurers, and government health programs in order to identify which medical interventions produced the best outcomes (Wennberg, 1990). It is also possible to conduct prospective research by tracking clinical practices concurrently into the future. Outcomes research has been described as the use of natural experiments to find what works in medicine.

The databases under examination in outcomes research may be developed by using various kinds of research methods—descriptive (qualitative), best case (mixed qualitative and quantitative), or quantitative. Clinical case records and insurance claims data are often perused.

Advocates of outcomes research claim that it is potentially cheaper and faster than clinical trials and can provide data on treatments that would not otherwise be evaluated. In fact, retrospective database analysis may be the only way to obtain data on treatments with rare complications. Outcomes research is also useful when dealing with "soft" results such as effects on the quality of life. Consequently, some advocates of alternative medical practices consider outcomes research ideal for examining aspects of alternative medicine.

Outcomes research has other inherent advantages. It does not interfere with the doctor-patient relationship, does not require informed consent or permission from an institutional review board (as do clinical trials), and includes groups (such as the elderly, children, the poor, and minorities) that might not be widely represented in clinical trials.

Critics point out that any research based on retrospective analysis of clinical records is flawed by hidden biases in the data. They claim that researchers cannot correct for the subtle reasons why doctors choose one treatment over another for a given patient (or why patients choose their doctors). Furthermore, the records under examination were made for a different purpose and are likely to be incomplete in describing all relevant conditions that may affect the patients whose records are being analyzed.

Proponents and opponents of outcomes research agree that some aspects of the research are useful—that it is important to learn what doctors are actually doing in clinical practice and that this knowledge can provide a basis for further studies, including clinical trials.
One government agency, the Agency for Health Care Policy and Research (AHCPR), was created in 1989 largely to conduct outcomes research. However, in a recent article in Science, Anderson (1994) reported that "after spending nearly $200 million on outcomes research (about one-third of the agency's budget . . .), AHCPR cannot point to a single case in which its database studies have changed general clinical practice." Anderson further noted that even the agency's most definitive result--a guideline to physicians that "watchful waiting" is more appropriate for some patients than surgery for benign prostate disease (see the "Research Methodologies" chapter)--was accompanied by a recommendation for a clinical trial to confirm these findings.

Increasingly, it appears that AHCPR will use its database analyses of outcomes to supplement and complement other tools, including case control studies, meta-analyses of previous studies, and clinical trials. Two new references are expected to help researchers rank the value of outcomes research: (1) the proceedings of a March 1993 conference sponsored by the New York Academy of Sciences that analyzed the relative merits of outcomes research and clinical trials (Warren and Mosteller, 1994); and (2) the results of an 18-month study by the Office of Technology Assessment (OTA) analyzing AHCPR's outcomes research (publication due September 1994).

Introduction to Meta-Analysis

The term meta-analysis was first coined by G.V. Glass, in a 1976 study of the efficacy of psychotherapy, as "the statistical analysis of a large collection of results from individual literature, for the purpose of integrating the findings." Although meta-analytic procedures have been widely employed in the social sciences since the early 1970s, many did not consider it a valid tool for the natural sciences until numerous retrospective studies accumulated that used meta-analysis to analyze data that had previously been studied with other statistical tools. As these studies illustrated both the statistical power and the increased information provided by meta-analysis, interest in its medical applications began to increase significantly. Since then, meta-analysis has been applied to questions of efficacy (e.g., chemotherapy in breast cancer, patient education interventions in clinical medicine, spinal manipulation); questions of cause and effect (e.g., effect of exercise on serum lipid level); and, increasingly, public health problems. Today meta-analysis is being used in a variety of settings to draw conclusions from results collected from literature or narrative reviews and from data pooled from independent studies (often clinical trials).

In general, meta-analysis is a systematic method that uses statistical analysis for extracting, comparing, and combining results from independent studies to obtain quantifiable outcomes. Meta-analysis also can help detect gaps in knowledge in the published literature and thus can help provide guidance for future research. Although there have been several approaches to meta-analysis, each follows the same basic procedure:

1. Define the problem and criteria for admission of studies.

2. Locate research studies.

3. Classify and code study characteristics.

4. Measure study characteristics quantitatively on a common scale.

5. Aggregate findings to study characteristics (analysis and interpretation).

6. Report the results.

Problem formulation includes explicit definition of outcomes and potentially confounding variables. Carefully done, this step enables the investigator to focus on the relevant measures in the studies under consideration and to specify the relevant methods for classifying and coding study characteristics. The literature search uses a systematic approach to locating studies. First, information is obtained from colleagues in a particular discipline. Second, the various indexes, abstracting services, and electronic databases are searched. Third, references from the primary articles are used to find secondary sources of information. Finally, information is gathered from academic, private, and government sources, including unreferenced reports and unpublished data.
In order to measure results across disparate studies, several methods are used. The most common method is to measure the effect size (i.e., an index of both the direction and the magnitude of the effect of a procedure under study). One estimate of the effect size for quantitative data is the difference between the two group means, divided by the control group standard deviation, \((X_t - X_c)/S_c\), where \(X_c\) is the mean of the control group and \(S_c\) is the standard deviation of the control group. Effect size expresses differences in standard deviation units so that, for example, if a study has an effect of 0.2 standard deviation units, the overall effect size is only half that of another study that has an effect size of 0.4 standard deviation units. The appropriate measure of effect across the research literature varies according to both the nature of the problem being assessed and the availability of published data. Pooling of data from controlled clinical trials, for example, has been more widely used in the medical literature than for other subjects.

Effect size for proportions has been calculated in cohort literature as either a difference, \(P_t - P_c\), or as a ratio, \(P_t/P_c\). The latter has the advantage of considerable change relative to the control percentage; in epidemiological studies, it is equivalent to the concept of risk ratio.

Whatever combination statistic is used, a systematic quantitative procedure to accumulate results across studies should include the following:

2. Calculation of variance of a statistic across studies.
3. Correction of the variance by subtracting sampling error.
4. Correction in the mean and variance for study artifacts other than sampling, such as measurement error.
5. Comparison of the corrected standard deviation to the mean to assess the size of the potential variation across studies.

The value of meta-analysis is that as evidence begins to accumulate, meta-analysis forces systematic thought about methods, outcomes, categorizations, populations, and interventions. In addition, it offers a mechanism for estimating the magnitude of the effect in terms of a statistically significant effect size or pooled odds ratio. Furthermore, the combination of data from several studies increases generalizability and potentially increases statistical power, thus enabling more complete assessment of the impact of a procedure or variable. Quantitative measures across studies also can give insight into the nature of the relationships among variables and can provide a mechanism for detecting and exploring apparent contradictions in research results. Further, because meta-analysis is less subjective than other analytical methods, it has the potential to decrease investigator bias.

However, like the value of all review methods, the value of meta-analysis can be limited by a number of factors. For example, the current use of parametric statistical methods for meta-analysis is the subject of intense theoretical study. Other methodological issues of concern include bias, variability between studies, and the development of models to measure variability across studies. One major concern about qualitative reviews of the literature is that although meta-analysis is more explicit, it may be no more objective than a narrative review. Both critics and advocates of meta-analysis are concerned that an unwarranted sense of scientific validity, rather than true scientific understanding, may result from quantification. More simply stated, use of sophisticated statistics will not improve poor data but could lead analysts to an unwarranted level of comfort with their conclusions.

Introduction to Systematic Reviews

The systematic review is an orderly approach to reviewing research literature that minimizes the problems that can arise with less scientifically rigorous review methods (Larson et al., 1992). To avoid introducing bias in the selection and interpretation of the literature under study, systematic reviews spell out in advance the approach to be taken. Systematic review entails defining criteria for (1) the selection of journals and articles to include and exclude, (2) the quality of the measures used in the selected literature to assess the factor being reviewed, and, (3) the quality of each study's research methodology. The technique also looks at the frequency of assessment of a particular research question, variable, or
Advantages

Systematic reviews, like meta-analyses and unlike standard literature reviews, are replicable from one reviewer to the next. This point is particularly important when a potentially controversial research topic is being evaluated.

Systematic reviews differ from meta-analytical reviews in two major ways. First, the systematic review costs much less—only 10 to 20 percent of the expense of a similarly sized meta-analysis. Second, systematic reviews can consider single factors of interest within an inadequately developed research field. In contrast, meta-analyses require a well-developed research field with a large amount of experimental or quasi-experimental research; they also require that an adequate number of studies address essentially the same research question using comparable study samples.

While systematic reviews can examine the key or central findings in studies, they also permit analysis of noncentral or peripheral factors. Thus systematic reviews are particularly useful in examining an underdeveloped or infrequently studied research issue.

Method

There are five key steps in conducting a systematic review: (1) selecting the factor or factors to be studied; (2) deciding whether to use an exhaustive review or field review approach; (3) assessing the frequency and quality of measurement of the factor of interest; (4) evaluating the studies that contain the factor of interest; and (5) determining and maintaining reviewer reliability.

Selecting the factor or factors to be studied. This first step involves formulating research questions based on the topic the reviewer wishes to study. Each systematic review should address clear research questions. For example, several systematic reviews have focused on whether the quantity or quality of research containing religious variables was substandard in certain clinical scientific literatures (Larson et al., 1986). Another review concerning the effects of pornography asked whether existing research demonstrated harm—or lack of harm—in assessing the associations in each literature report between exposure to pornographic materials and changes in attitudes concerning rape or aggression toward women.

Deciding whether to use an exhaustive review or field review approach. Both types of systematic reviews use research reports that have undergone a peer review process of critique and revision prior to being published. However, criteria for what to include and exclude are defined differently for the two types of reviews.

The exhaustive review method involves identifying every possible peer-reviewed study from every relevant field of study that includes information about the factor of interest. This review is carried out in three steps. (1) First, an initial list of articles is prepared, based on a multiple, overlapping, computerized literature search that uses multiple key-word terms and indexes. (2) Next, other potentially relevant articles are identified in the reference sections of the articles obtained in the initial search, and these new articles are also searched for relevant references. This repeated reference review continues until no new articles can be identified for addition to the master list. (3) The final step is the circulation of the list of articles to identified experts, such as the three to five researchers with the most publications on the research study list; these researchers are asked to identify additional relevant articles.

In contrast, field reviews involve selecting only one field of study, the leading peer-reviewed journals in that field, and the period to be reviewed (usually 5 to 10 years). The leading journals are identified as the ones most frequently cited in a particular research field, by using the Science Citation Index or the Social Science Citation Index as a citation source. (These indexes provide ratings of journals in various research fields based on the frequency with which their articles are cited). If the goal is to define the most accurate and up-to-date research in a specific field, then the field review is the more appropriate type of systematic review to use.

The field reviewer obtains a proper sample by manually searching through every journal issue and every article in the journal to identify studies that include the review factor of interest. Some topics of previous systematic reviews include mental health factors in nursing home studies, AIDS research in general medical journals, and religious factors in...
Assessing the frequency and quality of measurement of the factor of interest. In this step the factor of interest is examined across the reviewed articles to determine whether it is of major or minor importance—that is, whether it is frequently or infrequently assessed. Additional information is tabulated concerning whether the factor is being assessed through use of one or several questions and—if through several questions—whether reliability was reported or demonstrated.

Evaluating the studies that contain the factor of interest. Next the research quality of the studies that include the factors of interest is assessed. If a study is poorly designed, its findings may be questionable.

Assessing the quality of the methods used requires clearly defining each study factor, including such variables as the response rate, size of the study population, use of a control or comparison population, type of sampling method used, and whether study measures demonstrated reliability. For example, defining the response rate might entail grouping rates in categories: low, less than 50 percent; medium, 50 to 69 percent; and high, 70 percent and more. Similarly, other factors require some definition and grouping.

Determining and maintaining reviewer reliability. Reproducibility of systematic reviews depends on training multiple reviewers to appropriately assess the factors of interest. The goal here is statistical reliability, so that reviewers reviewing the same articles achieve the same assessments. Training reviewers has been found to produce replicable results with reliabilities above 0.90 (Larson et al., 1992).

High reliability can be maintained through periodic checks—especially if a large number of studies and a large number of reviewers are involved—and, if necessary, retraining of reviewers.

Usefulness

The kinds of information that systematic reviews can provide about a specific research field or topic include the following:

* Number of studies assessing the factor of interest.
* Statistical reliability of measures assessing the factor of interest.
* Approach most often used for assessing the factor of interest.
* Frequency of assessing the factor as a variable of major versus minor study relevance.
* Quality of the research studies that include the factor of interest.

Selected Bibliography for Researchers


Jonas, W.B. 1992. Evaluation of studies involving non-mainstream medicine. Presented at the 7th Annual Primary Care Research and Statistics Conference, University of Texas Health Science Center, San Antonio.


Information on the National Library of Medicine

The following Fact Sheets on the library and its services are available from the Public Information Office, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; telephone 301-496-6308; E-mail
Assistance for Research Investigators

DIRLINE (Directory of Information Resources)

DOCLINE

Grateful Med7

HISTLINE (History of Medicine Online)

History of Medicine Division

LOANSOME DOC

Medical Subject Headings (MeSH)

The National Library of Medicine

National Network of Libraries of Medicine

NLM Online Databases and Databanks

Online Indexing System

Public Services Division

Grateful Med7 may be ordered from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; 703-321-8547.

Order number PB92-105444/GBB (for IBM PC, includes tutorial) $29.95 plus shipping.

Order number PB93-502433/GBB (for Macintosh, includes tutorial) $29.95 plus shipping.

A list of other NLM Searching Tools (books and software), item number MMS 3/94, is available from NTIS at 703-321-8547, or fax your request to 703-321-8547/9038.

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NIH Guide for Grants and Contracts (a weekly publication)
Contact person:

Myra Brockett (as of 5/94)
Institutional Affairs Office

Phone order: 301-496-5366

Written order:

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Request: Preparing a Research Grant Application to the National Institutes of Health: Selected Articles, revised October 1993.

Sidebar

Some Helpful References for New Investigators*


Sidebar

NCIs Suggested Steps for Screening Best Cases

1. Chart Selection

The practitioner or another individual in the alternative medicine setting reviews clinic charts and selects those that are believed to represent the best examples of successful treatment. These charts are copied and brought or sent to NCI, where an independent evaluator reviews them. Alternatively, the evaluator may visit the clinic and review the best case charts on site.

2. Chart Review

*These references were selected as basic guides. An extensive methodological bibliography is provided at the end of this appendix.
The evaluator judges the charts acceptable if the needed information is present and rejects them if it is lacking. The reason for either decision is documented. The evaluator’s specific criteria for adequacy of information also can guide the practitioner to select best cases.

When a specified proportion of submitted charts contains adequate information, outcome evaluation can be considered. Charts that provide adequate evidence of response or lack of response are then evaluated according to outcome criteria.

3. Inclusion Criteria

Evidence for the diagnosis of cancer (or another illness under treatment) and details of the treatment regimen are documented. Clinical information that demonstrates the status and course of the illness, such as the malignancy and the sites of metastatic disease, must be detailed. Minimum evidence includes the following:

a. The diagnosis of cancer must be documented by one of the following:*  

* A pathology report.

* Radiological, surgical, or blood evaluation, and a specialist’s written report diagnosing cancer or indicating that it has recurred.

* A specialist’s written report that standard treatment is unlikely to be helpful or has failed, or that the disease severity prior to alternative medicine treatment indicated extremely poor prognosis.

b. The patient must have received the unconventional treatment according to the alternative medicine practitioner’s regimen. Information about the treatment must include the following:

* Detailed description of treatment source, doses, method, and delivery frequency.

* Chart documentation of patient compliance, such as pill counts and completion of at least 70 percent of followup visits.

* Complete documentation of any other previous or ongoing therapies, medications, and so on.

4. Exclusion Criteria

The following problems invalidate a chart for inclusion in a best case analysis. If any of these are present, the chart information is inadequate:

* No evidence of the disease under study when the patient began alternative medical treatment.

* No pathology diagnosis or objective evidence of disease recurrence as defined above when alternative medical treatment began.

* Inadequate delivery (insufficient dosage or treatment time) of the therapy under study, or current or recent delivery of another therapy that could affect the disease.

* Followup less than 6 months from the start of therapy, or less than 2 standard deviations beyond the patient’s expected survival, as determined by current estimates of life expectancy for the same diagnosis and stage of the disease when treatment was started.
5. Outcome Criteria

If criteria for adequate information as described above are met, cases can be reviewed according to outcome (clinical response) criteria. If outcome criteria also are met, it can be concluded that the therapy is producing positive results and that further study may be warranted. Outcome criteria consist of complete or partial clinical response as determined by the following standard oncology definitions:

- Complete tumor remission. Complete disappearance of all evidence of tumor (all sites of measurable disease) for a minimum number of weeks.

- Partial tumor response. Fifty percent decrease in the size of the tumor. This is calculated as the sum of the perpendicular diameters of all measured lesions, with no progression of disease at any site and no appearance of new lesions for a specific number of weeks.

- Prolonged quality-of-life expectancy. Evidence that the patient has experienced good quality of life (increased energy, improved appetite, greater mobility, and reduced pain) since the start of treatment for longer than expected by at least 2 standard deviations.

- Complete or partial tumor response. Determined either by a pathology report of a biopsy showing no evidence of disease, or by radiological, surgical, or blood evaluation and a specialist's written opinion that evaluation indicates disease reduction or elimination.

6. Tabulation

Using forms available from NCI, a specific procedure is followed to record all patient data:

a. Information is carefully tabulated on a standard Best Case Series Form.

b. Each chart selected is evaluated and results are recorded on a Score Sheet.

c. All reasons for inclusion or exclusion are noted on the Score Sheet and recorded on a Spread Sheet.

d. If a chart displays adequate information, outcome criteria also are recorded on the Score Sheet and Spread Sheet.

e. The proportion of cases submitted to cases included in the best case series is calculated by dividing the accepted cases by the total number of cases submitted. This calculation provides a "discrepancy index," which is an estimate of the accuracy of practitioners' judgments about the success of their treatment. The amount of discrepancy due to inadequate information or faulty outcome estimation can be determined.

Abbreviations and Glossary

Abbreviations

AA--Alcoholics Anonymous

AC--alternating current

ACS--American Cancer Society
AHCP--Agency for Health Care Policy and Research

AIDS--acquired immunodeficiency syndrome

AMA--American Medical Association

AMTA--American Massage Therapy Association

BEM--bioelectromagnetics

BRM--biological response modifier

CCE--Council of Chiropractic Education

CHD--coronary heart disease

CoQ10--coenzyme Q10

DC--direct current

DMT--dance/movement therapy

D.O.--doctor of osteopathy

DRG--Division of Research Grants

ECT--electroconvulsive therapy

EDTA--ethylene diamine tetraacetic acid

EEG--electroencephalogram

ELF--extremely low frequency

EM--electromagnetic

EMG--electromyographic

EMS--eosinophilia myalgia syndrome

FDA--Food and Drug Administration

FDCA--Food, Drug, and Cosmetic Act
FTC--Federal Trade Commission

G--gauss

GSR--galvanic skin response

HDL--high-density lipoprotein

HIV--human immunodeficiency virus

HPA--hypothalamic-pituitary-adrenocortical

Hz--Hertz, (see hertz)

IgA--immunoglobulin A

IgE--immunoglobulin E

IND--investigational new drug

INF-A--interferon alpha

INF-G--interferon gamma

IU--international units

LDL--low-density lipoprotein

MEDLARS--Medical Literature Analysis and Retrieval System

MEDLINE--MEDLARS on Line

MHz--megahertz

MRI--magnetic resonance imaging

NAMT--National Association for Music Therapy

NCI--National Cancer Institute

NCNM--National College of Naturopathic Medicine

NCSA--Network Chiropractic Spinal Analysis
NHLBI--National Heart, Lung, and Blood Institute

NIOSH--National Institute for Occupational Safety and Health

NLM--National Library of Medicine

NRC--National Research Council

NSAID--nonsteroidal anti-inflammatory drugs

NSF--National Science Foundation

OAM--Office of Alternative Medicine

OTA--Office of Technology Assessment

PEMF--pulsed electromagnetic field

PET--positron emission tomography

PRC--People's Republic of China

RF--radio frequency

RFA--request for applications

SD--standard deviation

SHBG--sex hormone binding globulin

TCES--transcranial electrostimulation

TENS--transcutaneous electrical nerve stimulation

TIMPs--(proteins that are) tissue inhibitors of metalloproteinases

TM--transcendental meditation

TNF--tumor necrosis factor

USAID--United States Agency for International Development

WHO--World Health Organization
Glossary

adiposity: the state of being fat.

adjustment: the chiropractic adjustment is a specific form of direct manipulation of joint (articular) areas, using either long or short leverage techniques with specific contacts. It is characterized by a dynamic thrust of controlled velocity, amplitude, and direction (see thrust). Colloquially referred to as "bone cracking."

adrenergic: activated by, characteristic of, or secreting adrenaline (scientific name, epinephrine) or similar substances that constrict blood vessels and raise blood pressure, preparing the body for "fight or flight."

adrenochrome: a red oxidation product of epinephrine that slows the blood flow because of its effect on capillary permeability. It is currently being tested as a psychomimetic drug (a drug that imitates natural substances that can affect a person psychologically).

allergic rhinitis: hay fever; significant nasal drainage and inflammation of the eyes in susceptible subjects, caused by inhaling allergens (usually pollens).

allopathy: substitutive therapy; a therapeutic system in which a disease is treated by producing a second condition that is incompatible with or antagonistic to the first. May be used to describe Western medicine as currently practiced.

amide: an organic compound in which the hydroxyl (-OH) of a carboxyl group (-COOH) of an acid has been replaced by the nitrogen-containing group-NH2. For example, O=C-NH2.

amine: an organic compound containing nitrogen, equivalent to replacing one or more atoms of hydrogen in ammonia by an organic hydrocarbon. For example, -NH2.

amyotrophic lateral sclerosis: a disease marked by progressive degeneration of the nerve cells that conduct electrical impulses, leading to degeneration of the motor cells of the brain stem and spinal cord and resulting in a deficit of motor skills among other symptoms; it usually ends fatally within 2 to 3 years. Also called Lou Gehrig's disease.

anabolism: constructive metabolic processes in which new substances are built.

anaphylaxis: a major type of allergic reaction to a substance, resulting in difficulty breathing and followed usually by shock and collapse of the blood system.

angina pectoris: a spasm with sudden chest pain, accompanied by a feeling of suffocation and impending death, most often due to lack of oxygen to part of the heart wall, and caused by excitement or activity.

angiography: the study of the cardiovascular system (heart and blood) by radioscopy after the introduction of a contrasting material, such as radioactive iodine, into the body.

anthropology: the study of human beings and their origin in relation to social, cultural, historical, environmental, and developmental aspects.

antipsychotic drug: a substance effective in the treatment of psychosis, a severe type of mental disorder involving total disorganization of the personality.
apoenzyme: the protein portion of an enzyme that can be separated from any cofactor but needs the cofactor present to function properly as an enzyme.

arrhythmia: any variation from the normal rhythm of the heartbeat.

ascorbyl palmitate: a derivative of vitamin C that is being tested as a preventive agent.

autism: a condition characterized by preoccupation with inner thoughts, daydreams, fantasies, delusions, and hallucinations; egocentric, subjective thinking lacking objectivity and connection with reality; a disorder of currently unknown origin characterized by such activities.

benzopyrene: a highly carcinogenic organic chemical that is produced when carbon compounds are incompletely burned.

bind: an increasing resistance to motion in the problem area (in manual therapy the practitioner uses feedback obtained by touching the problem area to guide the medical procedure). See also ease.

bioelectromagnetics: the scientific study of interactions between living organisms and electromagnetic fields, forces, energies, currents, and charges. The range of interactions studied includes atomic, molecular, intracellular up to the entire organism.

biofeedback: the process of furnishing an individual with information, usually in an auditory or visual mode, on the state of one or more physiological variables such as heart rate, blood pressure, or skin temperature; it often enables the individual to gain some voluntary control over the physiological variable being sampled.

biofield: a massless field (not necessarily electromagnetic) that surrounds and permeates living bodies and affects the body. Possibly related to qi. See qi.

bioflavonoid: a generic term for a group of anti-oxidant compounds that are widely distributed in plants and involved in animals in maintaining the walls of small blood vessels in a normal state. See flavonoids.

biogenesis: Thomas Huxley's theory that living matter always arises by the agency of preexisting living matter. The opposing theory is spontaneous generation.

biomechanics: the study of structural, functional, and mechanical aspects of human motion.

biophoton: a small amount of electromagnetic energy emitted by molecules in living organisms. Biophoton emission is associated with processes, such as mitosis (cell division), and possibly with the vibrations of certain large molecules; It may also be used to communicate information over relatively large distances, as the firefly does.

biorhythm: the cyclic occurrence of body processes, such as in daily, or circadian, rhythm. Other rhythms may be monthly or yearly.

biostatistics: the science of applying statistics in biology, medicine, and agriculture.

botanical medicine: another term for herbal medicine.

cardiac catheterization: the passage of a small fluid-gathering tube through a vein in the body into the heart to gather blood samples, to measure internal blood pressure, or to obtain other intracardiac information.
catabolism: destructive metabolic processes in which substances are broken down.

catecholamine: chemical messengers, such as dopamine and norepinephrine, that stimulate various receptors in the sympathetic and central nervous systems in the body.

catechu: an extract from the heartwood of the Acia catechu tree that contains catechin, a crystalline, contraction-causing chemical. Formerly used as an antidiarrheal agent.

cell proliferation: growth by the reproduction of similar cells.

cellular metabolism: the sum of the chemical processes of a cell, including the transformation of sugars into energy and related processes.

cervical dysplasia: deviations in the cells that cover the uterine cervix, which may begin as unusual increased cell growth and progress to the loss of the unique characteristics of a cell; tends to lead to a tumor.

chakra: one of the areas of rotation in the biofield, first elaborated in ancient Indian metaphysics.

chelation: formation of a complex molecule involving a metal ion and two or more polar groupings of a single molecule. Chelation can be used to remove an ion from participation in biological reactions, causing a change in the reaction.

chemopreventive: the attempt to prevent disease through the use of chemicals, drugs, or food factors, such as vitamins.

chemotherapy: treatment of disease by chemical compounds selectively directed against invading organisms or abnormal cells.

chiropractic practice: a discipline of the scientific healing arts concerned with the development, diagnosis, treatment, and preventive care of functional disturbances, disease states, pain syndromes, and neurophysiological effects related to the status and dynamics of the locomotor system, especially of the spine and pelvis.

chiropractic science: the investigation of the relationship between structure (primarily of the spine) and function (primarily of the nervous system) in the human body.

cholecystectomy: surgical removal of the gall bladder.

chronic fatigue syndrome: an illness characterized by long periods of fatigue, often accompanied by headaches, muscle pain and weakness, and elevated antibody titers to some herpesviruses. The cause or causes are unknown.

chronic hepatitis: a persistent inflammation of the liver.

circadian: a phenomenon being, having, characterized by, or occurring in approximately 24-hour periods or cycles (as of biological activity or function).

clairsentience: the ability to use touch to sense subtle variations in the biofield.

clairvoyance: the ability to perceive things that are out of the range of normal human senses.

closed system: a field or system that does not react with other fields or anything outside that system.
cochlear reflex: a contraction of the cochlea—a spirally wound tube that forms part of the inner ear—when a sharp, sudden noise is made near the ear.

cofactor: a non-protein chemical that is not an enzyme in its own right but must be present for an apoenzyme (i.e., the protein component of the enzyme) to function.

collagen: an insoluble, fibrous protein that occurs in bones as the major portion of the connective tissue fibers. Yields gelatin and glue on prolonged heating with water.

complementary medicine: another term for alternative medicine; frequently used in Europe.

congenital: something that exists at, and usually before, birth.

corpus callosum: the mass of white matter in the brain that connects the two hemispheres, linking the "creative" (or left-brained) side with the "raw intelligence" (or right-brained) side.

coumarin: an odorous material found in tonquin beans, sweet clover, and woodruff; used for scenting tobacco and as an anticoagulant to prevent excessive blood clotting.

cryosurgery: the application of extreme cold to destroy tissue.

cyclotron resonance: the resonant coupling of electromagnetic power into a system of charged particles undergoing orbital movement in a uniform magnetic field.

cytokine: a generic term for various small proteins that are released by cells and that act as intercellular communicators to elicit an immune response. Examples include the interferons and the interleukins.

cytokinesis: the contraction of a belt of cytoplasm, bringing about the separation of two daughter cells during cell division in animal tissues.

cytotoxicity: the degree to which a chemical is toxic, or lethal, to a cell, such as how toxic a chemotherapy agent may be to cancer cells.

Delphi method: a consensus procedure in which participating experts are polled individually and anonymously, usually with self-administered questionnaires. The survey is conducted over a series of "rounds." After each round, the results are elicited, tabulated, and reported to the group. The Delphi process is considered complete when there is convergence of opinion or when a point of diminishing return is reached.

diabetes mellitus: a disorder of metabolism in which the lack of available insulin causes an excess of sugar in the blood and urine, as well as excessive thirst and loss of weight. Various long-term problems can result.

diagnosis: the art of distinguishing one disease from another; the use of scientific and skillful methods to establish the cause and nature of a person’s illness.

dietetics: the study and regulation of the diet.

direct technique: any manual medical method or maneuver that engages and passes through and beyond an area of increasing tissue or joint motion resistance, commonly called a "direct barrier." (Physical penetration of the body surface is
dosimetry: the process of measuring doses of radiation (e.g., x rays).

double-blind: a term pertaining to a clinical trial or other experiment in which neither the subject nor the person administering treatment knows which subjects are receiving actual treatment and which are receiving a placebo.

dysfunction: a term used in medicine to describe abnormal, impaired, or incomplete functioning of an organ or part.

dysmenorrhea: a condition characterized by difficult and painful menstruation.

ease: a region of decreasing resistance to movement. In manual therapy the practitioner uses feedback obtained by touching the problem region to guide the medical procedure. See bind.

echocardiography: a method of graphically recording the position and motion of the heart walls or the internal structures of the heart and neighboring tissue by the echo obtained from beams of ultrasonic waves directed through the chest wall.

eczema: an inflammatory skin condition characterized by itching and the secretion of liquids from subdermal pockets of pus and water.

electroencephalogram (EEG): a recording of the electrical potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain.

electromagnetic field: the force or energy associated with electromagnetic interactions, charges, and currents. EM fields include electrostatic, magnetostatic, radiation, induction, vector-potential, and scalar-potential fields, and Hertz and Fitzgerald potentials. The EM field is usually said to comprise two components: an "electric field" and a "magnetic field." However, according to apparently well-established theorems (e.g., Maxwell's equations), these two components are closely coupled and not truly independent of each other.

electromagnetic radiation: one type of EM field, namely, an oscillating EM field that has free motion in space at a distance from its source.

electromagnetism: the magnetism produced by an electric current.

electrophysiology: the study of the mechanisms and consequences of the production of electrical phenomena in the living organism.

electropollution: EM fields produced by sources that may have harmful effects on humans, such as electric power transmission and radio transmission.

electrosurgical excision: surgical removal of an organ or tissue by electrical methods.

embolism: the blocking of a blood vessel, usually by a blood clot or thrombus originating from a remote part of the circulatory system.

emission tomography: a computer-constructed image of the body, created by measuring radioactive presences in the body.

end play: discrete, short-range movements of a joint, independent of the action of voluntary muscles, determined by
springing each vertebra or extremity joint at the limit of its passive range of motion; also called "joint play."

endocrine: a material that is secreted internally in the body, most commonly through the bloodstream rather than through the various ducts; of or pertaining to such a secretion.

endorphin: any of three compounds found naturally in the brain that may have adrenaline-like effects, such as a burst of energy or an analgesic effect.

endoscopy: visual inspection of any cavity of the body by means of an endoscope (an instrument to examine the interior of a hollow cavity inside the body, such as the bladder).

enzymes: proteins that catalyze many biochemical reactions, necessary in all life forms.

epidemiology: the medical study of the incidence, distribution, and control of disease in a population; the conditions controlling the presence or absence of a disease or pathogen.

esophageal motility: the muscular movements of the esophagus, the tube that carries food from the mouth to the stomach. Orderly and rhythmic esophageal motility is necessary for swallowing; any disorder in this process may result in pain and dysfunction.

ethnobotany: the science of plants in relation to ethnic groups of humans.

etiology: the medical study of causes of disease.

faith healing: healing that occurs because of the patient's belief in a supernatural being or the healer.

fascia: a sheet of fibrous tissue that envelops the body beneath the skin; it also encloses muscles and groups of muscles, and separates their several layers or groups.

fibromyalgia: a poorly understood illness characterized by fibrous muscular pain.

fibrositis: an inflammation of fibrous tissue.

flavonoids: a large group of metabolic byproducts of mosses and other plants, based on 2-phenylbenzopyran (a particular type of organic compound with a ring structure); for example, the chemicals that give yellow, red, and blue colors to plants.

forensic: evidence or material gathered for or used in legal proceedings or in public debate.

free radical: a molecule or atom in which the outermost ring of electrons is not complete, making it extremely chemically reactive.

galvanic skin response: a change in the electrical resistance of the skin, recorded by a polygraph; widely used as an index of autonomic (involuntary) nervous system reactions.

gastroenteritis: an inflammation of the mucous membrane of the stomach and the intestines.

gauss: a unit of magnetic flux density. In colloquial terms, the strength of a magnetic field is specified in terms of gauss;
for instance, the strength of a typical household magnet that holds papers on a refrigerator is about 200 G.

glycyrrhetinic acid: a derivative of vitamin A that is being tested for its disease preventive activity.

Hawthorne effect: the observation that experimental subjects who are aware that they are part of an experiment often perform better than totally naive subjects.

heavy metal: a metal of high atomic number; may be used to measure electron density in electron microscopy; high concentrations of heavy metals can harm plant and animal growth.

hematology: the medical specialty that pertains to the anatomy, physiology, pathology, symptomatology, and therapeutics of blood and blood-forming tissues.

Hertz (Hz): the unit of measure used to specify the frequency of complete waves of electromagnetic radiation, such as light, radio waves, and X rays; expressed as cycles per second. These waves take on the property of a sinusoid (see sinusoidal). Table 1 in the "Bioelectromagnetics Applications in Medicine" chapter shows the electromagnetic spectrum ranging from 0 Hz to over 1020 Hz.

heuristic: anything that encourages or promotes investigation; that which is conducive to discovery.

high sense perception: a system of diagnosis based on clairsentience and clairvoyance.

hippocampus: a particular part of the gray matter of the brain; in humans, it extends from the olfactory lobe to the posterior end of the cerebrum.

homeopathy: an alternative medical system that treats the symptoms of a disease with minute doses of a chemical. In larger doses, the compound would produce the same symptoms as the disease or disorder that is being treated.

homeostasis: the maintenance of a static, constant, or balanced condition in the body's internal environment; the level of physiological well-being of an individual.

humoralism, humorism: an ancient theory that health and illness are related to a balance or imbalance of body fluids or "humors."

hydrocortisone: a complex chemical secreted by the human adrenal cortex which has life-maintaining properties and is important to sustaining blood pressure and the balance of fluids and electrolytes in the body.

hydrotherapy: treating a disease with water, externally or internally.

hypercholesterolemia: an excess of cholesterol in the blood.

hyperlipidemia: an excess of lipids (fatty components, such as cholesterol or triglycerides) in the blood.

hypertension: a persistent state of high arterial high blood pressure.

hypothalamic-pituitary-adrenocortical axis: the interaction involving chemical and neuronal signals between the hippocampus, pituitary gland, and the cortex (outer layer) of the adrenal glands, with significant impacts on the body's state of health.
iatrogenic: an illness, injury, disease, or disorder induced inadvertently by physicians or their treatments.

ichthyosis: a group of skin disorders characterized by increased or aberrant development of keratin, resulting in noninflammatory scaling of the skin.

immunocompromising: anything that interferes with the healthy function of the immune system.

impedance: the state of resistance in electrical circuits.

incontinence: the inability to control one or both excretory functions (i.e., defecation and urination).

indirect technique: any manual medical method or maneuver that engages and passes through and beyond an area of decreasing resistance, commonly called an “indirect barrier.” (Physical penetration of the body surface is not involved.)

indole: a type of nitrogen-containing organic compound with a double ring structure; a breakdown product of the amino acid tryptophan and related biologically active compounds.

infrasonic energy: energy waves transmitted at a frequency lower than the frequency at which humans are normally aware of sound.

innate: something that inborn or hereditary.

innate intelligence: the intrinsic biological ability of a healthy organism to react physiologically to the changing conditions of the external and internal environment.

interferon: one of a group of small immune system stimulating proteins produced by viral-infected cells or by noninfected white blood cells; it is used as an anticancer agent in some clinical trials because of its ability to inhibit further viral replication.

interleukin: one of a group of small proteins that are involved in communication among white blood cells and that activate and enhance the immune system's disease-fighting abilities.

internal validity: the certainty that the treatment or regimen under study, rather than something else, is responsible for producing study results.

irritable bowel (spastic colon) syndrome: a condition characterized by sudden, involuntary contractions of the colon.

ki: the Japanese term for qi.

kinesthetic senses: the senses by which movement, weight, and position are perceived; commonly used to refer specifically to the perception of changes in the angles of joints.

L-dopa: the naturally occurring form of the amino acid dopa, which is a precursor of epinephrine and other biologically active compounds. It is used in the treatment of Parkinson's disease.

leukocytes: a group of blood cells that have a nucleus but lack hemoglobin and that are involved in fighting disease; also known as “white blood cells.”
limbus: a general term for describing border structures, such as the limbic region of the brain.

lipids: a generic term for organic compounds based on fatty acids, such as fats, waxes, fat-soluble vitamins, and steroids.

local healing: biofield healing that uses the practitioner's hands on the subject's body.

lymph: a clear, transparent, or yellowish-opaque liquid found in the vessels of the lymphatic system; this liquid returns proteins and other substances from tissues to the blood.

lymphatic system: the system of the lymph, including the lymph nodes, and the vascular channels that transport lymph.

lymphocyte: a white blood cell formed in lymphatic tissue; in normal adults, lymphocytes comprise approximately one-quarter of the white blood cells.

macrophage: a class of white blood cells, found in tissues, that are scavengers. Macrophage can wander the system or migrate to points of infection in the body.

magnetic resonance imaging: the use of nuclear magnetic resonance of protons to produce proton density maps or images of tissues or organs in the human body.

magnetite: a spinel (metal oxide) of iron (Fe3O4); a naturally occurring magnet.

manipulation: a term used in connection with the therapeutic application of manual force. Spinal manipulation, broadly defined, includes all procedures in which the hands are used to mobilize, adjust, manipulate, apply traction, massage, stimulate, or otherwise influence the spine and nearby (paraspinal) tissues with the goal of positively influencing the patient's health.

materia medica: a collection of descriptions of products that are usable medically as drugs. In homeopathy, substances are included that may not be in the official pharmacopoeia (drug registry), as are descriptions of how to physically prepare the substances as drugs.

mental healing: a process whereby one individual endeavors to bring about the healing of another by using conscious intent, without the intervention of any known physical means. The term is often used synonymously with spiritual healing.

meridian: In Asian traditional medicine, the body has a channel with 12 portions, or meridians, which loop through the body in an endless circuit, connecting the principal organs and other body parts. The meridians are said to carry ching qi, which regulates the relationship between, and the functioning of, the various body structures.

meta-analysis: a method for combining the results of several or many studies to see if the combined results provide significant information that was not obtainable by examining individual studies.

metabolism: the sum total of the chemical and physical changes constantly occurring in a living body.

metaphysics: the branch of philosophy that systematically investigates first causes and the ultimate nature of the universe. Such investigations are generally of insubstantial elements and are outside physics, thus difficult to measure.

metastasis: the movement of cancerous cells in the body from a primary site to a distant site, usually through the blood or lymph system, with the subsequent development of secondary cancers.
mobilization: the process of making a fixed part movable; a form of manipulation characterized by nonthrust, passive joint manipulation.

modulation: the change of amplitude or frequency of a carrier signal of given frequency.

molecular biology: the study of the structure and function of macromolecule in living cells.

morbidity: the state or condition of being diseased, for an individual or community.

mortality: the death rate within a given population.

motion palpation: a term used in connection with using touch to diagnose passive and active segmental joint ranges of motion.

motor hand: the hand the practitioner uses to induce passive movement in the subject. See bind.

mucosal: a term for cells of or pertaining to the mucous membrane, a tissue layer that lines various tubular cavities of the body, such as the viscera, uterus, trachea, and nose.

multivariate analysis or multivariate statistical treatment: a method of statistical analysis that employs several measurements of various characteristics on each unit of observation.

musculoskeletal manipulation: a hands-on procedure to physically correct or reset abnormalities of joint muscle and connective tissue function.

mutagenic: an agent that causes change or induces genetic mutation in the DNA of cells.

myocardial infarction: a sudden shortage of arterial or venous blood supply to the heart due to blockage or pressure; it may produce a sizable area of dead cells in the heart.

myofascial: of or relating to the sheets of fibrous tissue (that is, fasciae) that surround and separate muscle tissue.

necrosis: death of cells or groups of cells in a living body.

neurodegenerative disease: a disease that involves deterioration in the function and form of nerves and related structures. Alzheimer’s disease and multiple sclerosis are examples.

neuropeptide: a small chain of linked amino acids with neurological activity.

neurotransmitter: a chemical messenger used by nerves.

neutrophil: a granular white blood cell having a nucleus with three to five lobes connected by slender threads of chromatin and cytoplasm containing fine, inconspicuous granules.

nocebo effects: a toxic or negative placebo event.
noetic: a thought process based on pure intellect or reasoning ability, (e.g., a noetic doctrine).

noninvasive: not involving physical penetration of the skin (e.g., a noninvasive diagnostic or therapeutic technique).

nonlocal: something that occurs at a distance; in physics a nonlocal effect is a form of influence that is unmediated, unmitigated, and immediate. Nonlocal healing is healing that occurs at a distance.

oncology: the study of all aspects of cancer.

open system: a system that interacts with other fields or systems, giving off or receiving energy or materials. The opposite is a closed system.

orthomolecular medicine: a system of medicine aimed at restoring the optimal concentrations and functions at the molecular level of certain substances normally present in the body, such as vitamins.

osteopathic: a system of therapy that emphasizes normal body mechanics and manipulation to correct faulty body structures.

otitis media: inflammation of the middle ear.

oxidation: the addition of oxygen to a compound or the removal of electrons from a compound.

p-value: the probability that the observed outcome of a particular experiment is due to random chance. Also known as uncertainty level.

Paleolithic: of or belonging to the period of human culture beginning with the earliest chipped stone tools, about 750,000 years ago, until the beginning of the Mesolithic period, about 15,000 years ago.

palpation: the physical examination of the body using touch.

paradigm: an explanatory model, especially one of outstanding clarity; a typical example or archetype. See Introduction of this report.

parapsychology: the field of study concerned with the investigation of evidence for paranormal psychological phenomena, such as telepathy, clairvoyance, and psychokinesis.

pathogen: any disease-producing microorganism or substance.

pathogenesis: the cellular events and reactions and other pathologic mechanisms occurring in the development of disease.

pathology: the medical study of the causes and nature of disease and the body changes wrought by disease.

pellagra: a clinical syndrome due to deficiency of niacin, characterized by inflammation of the skin and mucous membrane, diarrhea, and psychic disturbances.

peptide: any of various amides that are derived from two or more amino acids when the amino group of one acid is combined with the carboxyl group of another; peptides are usually obtained by partial breakdown of proteins.
peroxidation: the process by which enzymes activate hydrogen peroxide and induce reactions that hydrogen peroxide alone would not effect.

person-years: a unit of time used in various statistical measurements of the aggregate effects of agents or events on people, as in epidemiology.

phagocyte: a cell (e.g., a white blood cell) that characteristically engulfs foreign material and consumes debris and foreign bodies.

pharmacology: the science that deals with the origin, nature, chemistry, effects, and uses of drugs.

pharmacopeia: a book describing drugs, chemicals, and medical preparations, especially one issued by an officially recognized authority and serving as a standard for the preparation and form of drugs; a collection or stock of drugs.

phenomenology: the study of phenomena; in psychiatry, it is the theory that behavior is determined by the way the person perceives reality rather than by external reality.

physics, classical: the branch of physics that studies mechanics and electromagnetism. It includes kinetics, optics, hydraulics, aerodynamics, and astrophysics.

physics, quantum: the branch of physics that deals with atomic and subatomic particles.

placebo: an inert substance that is given to the control group of patients in a blinded trial. A placebo is used to distinguish between the actual benefits of the medication and the benefits the patients think they are receiving.

platelet: a disk-shaped structure found in the blood of all mammals, chiefly known for its role in blood coagulation.

plethysmography: the recording of the changes in size when an organ or other structure is modified by the circulation of blood through it.

polarity: the differences between portions of a biofield, similar to the polarity or directionality of magnet fields; a form of manual healing that incorporates this feature.

positron emission tomography: a form of diagnostic imaging that makes use of the electromagnetic energy transitions of "excited" molecules to indicate changes in the function of tissues under investigation.

postoperative: something that occurs after a surgical operation.

potentized: in homeopathic pharmacy, a substance that is prepared by dilution while the diluting fluid is being agitated in a standard fashion; widely believed by practitioners to impart additional medical value to higher dilutions.

propranolol: a chemical that decreases heart rate and output, reduces blood pressure, and is effective in the preventive treatment of migraine.

proprioceptive: stimuli produced by movement in body tissues. Proprioceptive nerves are the sensory nerves in muscles and tendons that detect such movements.
prospective study: a scientific study that is planned in advance, as opposed to looking back at previous situations to collect data for analysis.

psoriasis: a chronic disease of the skin in which red scaly papules and patches appear, especially on the outer aspects of the limbs.

psychic healing: a term for biofield and mental healing, used especially in England.

psychogenic: anything that is produced or caused by psychic or mental factors rather than by organic factors.

psychoneuroimmunology: the study of the roles that the mind and nervous system play in various phenomena of immunity, induced sensitivity, and allergy.

psychopathology: the medical study of the causes and nature of mental disease.

psychosomatic medicine: the branch of medicine that stresses the relationship of bodily and mental happenings, and combines physical and psychological techniques of investigation.

pulmonary: anything pertaining to the lungs.

qi (chi, ki): in Eastern philosophies, the energy that connects and animates everything in the universe; includes both individual qi (personal life force) and universal qi, which are coextensive through the practice of mind-body disciplines, such as traditional meditation, aikido, and tai chi.

qigong (qi gong): the art and science of using breath, movement, and meditation to cleanse, strengthen, and circulate the blood and vital life energy.

quantum domain: the atomic and subatomic dimension dealt with in the science of quantum physics.

Raynaud's disease/phenomenon: a disorder characterized by intermittent, bilateral attacks in which a restriction of blood flow occurs in the fingers or toes and sometimes the ears or nose. Severe paleness, a burning sensation, and pain may be brought on by cold or emotional stimulation; these symptoms sometimes are relieved by heat. The condition is due to an underlying disease or anatomical abnormality.

reduction: any chemical process in which an electron is added to an atom or an ion, or an oxygen is removed. The opposite process is oxidation.

retrospective study: a scientific study that collects data for analysis after events, rather than during events.

rheumatoid arthritis: a chronic inflammation of the joints, which may be accompanied by systemic disturbances such as fever, anemia, and enlargement of lymph nodes.

sacrum: the part of the vertebral column (backbones) that is directly connected with or forms a part of the pelvis; in humans it consists of five united vertebrae.

secretory immunoglobulin A (IgA): the predominant immune system protein in body secretions such as oral, nasal, bronchial, urogenital, and intestinal mucous secretions as well as in tears, saliva, and breast milk.

sensing hand: the hand used by the practitioner in manual therapy to detect changes (see bind); the sensing hand is used
to assess the subject's increasing and decreasing resistance to the passive motion demands of the practitioner's motor or operating hand.

serial t-or z-tests: various types of statistical measurements that are used to determine whether data have significance.

serotonin: a naturally occurring body chemical that can cause blood vessels to contract; it is found in various animals, bacteria, and many plants. Serotonin acts as a central neurotransmitter and is thought to be involved in mood and behavior.

short leg: an anatomical, pathological, or functional leg deficiency leading to dysfunction.

sinusitis: the inflammation of any of the air-containing cavities of the skull, which communicate with the nose.

sinusoidal: of, relating to, shaped like, or varying according to a sine curve or sine wave, which is a waveform of single frequency and infinite repetition in relation to time.

sleep latency: the interval before sleep.

sociogenic: anything arising from or imposed by society.

somatic: pertaining to or characteristic of the body; distinct from the mind.

somatic dysfunction: impaired or altered function of related components of the somatic system (the skeleton, joints, and muscles; the structures surrounding them; and the related circulatory and nerve elements).

spiritual energy: energy that comes from a supernatural being or the cosmos.

structural diagnosis (osteopathic): an osteopathic physician's use of hands and eyes to evaluate the somatic system, relating the diagnosis of somatic dysfunction to the state of a patient's total well-being, according to osteopathic philosophy and principles.

subatomic: something pertaining to the constituent parts of an atom.

subluxation: a situation in which two adjacent structures involved in joints have an aberrant relationship, such as a partial dislocation, that can cause problems either in these and related joints or in other body systems that are directly or indirectly affected by them.

symptomatology: the study of symptoms.

syndrome: the signs and symptoms associated with a particular disease or disorder.

synergistic: entities working together or cooperating to produce a positive effect greater than the sum of the contributing individual entities.

systemic review: a method of analyzing a group of scientific studies that may individually be weak, producing results with more significance than the individual studies may have.

theosophy: a doctrine concerning a deity, the cosmos, and the self that relies on mystical insights by unusually perceptive
individuals; it teaches that its practitioners can master nature and guide their own destinies.

thromboembolism: an obstruction of a blood vessel with clotting material carried by the bloodstream from the site of origin to plug another vessel.

thrombus: an aggregation of blood factors that creates an obstruction; more severe than a clot.

thrust: the sudden manual application of a controlled directional force on a suitable part of the patient's body, the delivery of which effects an adjustment (see adjustment).

transcranial electrostimulation: a method of clinical treatment involving electrical stimulation of the brain through the skull.

transcutaneous electrical nerve stimulation: a clinical treatment modality involving electrical stimulation of nerves through the skin.

trigger points: specific points in the muscular and fascial tissues that produce a sharp pain when pressed; may also correspond to certain types of traditional acupuncture points.

triplet states: a state in which there are two unpaired electrons.

turnover: the movement of a substance into, through, and out of a place; the rate at which a material is depleted and replaced.

vascular system: the system formed by the blood vessels.

visceral: pertaining to the soft interior organs in the cavities of the body.

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The data show that the TM-trained body operates at a lower baseline level of activity and has more adaptive reserves; hence, the meditator may respond more powerfully and recover more rapidly when challenged by stressors.

The above observations on the NRC report on meditation are based on Orme-Johnson and Alexander's "Critique of the National Research Council's Report on Meditation" (1992).

The subsequent sections of this appendix present several types of research in the same sequence in which they are usually applied, providing guidelines to literature reviews, descriptive and cross-cultural studies, "best case" screening, clinical trials, and outcomes research. These are followed first by introductions to two sophisticated approaches to analyzing research--meta-analysis and systematic reviews--and then by a selected bibliography, information on the National Library of Medicine, and useful contact information.

Descriptive research is sometimes called "qualitative research," but descriptive research actually uses a mixture of qualitative and quantitative techniques.

The design and methods chosen for conducting research must be consistent with the assumptions of the model used in generating the hypothesis under study. Model fit is explained more fully in the "Guidelines for Clinical Trials" section.

Since preparing the best case screening guidelines in response to a request from Congress, NCI has reviewed three series of best cases--for nutritional therapy (Nicholas Gonzales), antineoplastons (Stanislaw Burzynski), and insulin potentiation therapy (Steven Ayre). As a result of these reviews, NCI determined that antineoplastic therapy is a suitable candidate for clinical trials (see also the "Pharmacological and Biological Treatments" chapter); clinical trials began in winter 1993-94.

An example is the Hawthorne effect, the observation that experimental subjects who are aware that they are part of an experiment often perform better than totally naive subjects.

The working title of the OTA report is Searching for Evidence: The Effort to Identify Health Care Technologies That Work.

The diagnosis of any other illness must be similarly documented with measures appropriate to that illness.