

Perceptions about Complementary Therapies Relative to Conventional Therapies among Adults Who Use Both: Results from a National Survey

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Background: Little is known about perceptions of complementary and alternative medical (CAM) therapy relative to conventional therapy among patients who use both.

Objective: To document perceptions about CAM therapies among persons who use CAM and conventional therapies.

Design: Nationally representative, random-household telephone survey.

Setting: The 48 contiguous U.S. states.

Participants: 831 adults who saw a medical doctor and used CAM therapies in 1997.

Measurements: Perceptions about helpfulness and patterns of CAM therapy use relative to conventional therapy use and reasons for nondisclosure of CAM therapies.

Results: Of 831 respondents who saw a medical doctor and used CAM therapies in the previous 12 months, 79% perceived the combination to be superior to either one alone. Of 411 respondents who reported seeing both a medical doctor and a CAM provider, 70% typically saw a medical doctor before or concurrent with their visits to a CAM provider; 15% typically saw a CAM provider before seeing a medical doctor. Perceived confidence in CAM providers was not substantially different from confidence in medical doctors. Among the 831 respondents who in the past year

had used a CAM therapy and seen a medical doctor, 63% to 72% did not disclose at least one type of CAM therapy to the medical doctor. Among 507 respondents who reported their reasons for nondisclosure of use of 726 alternative therapies, common reasons for nondisclosure were "It wasn't important for the doctor to know" (61%), "The doctor never asked" (60%), "It was none of the doctor's business" (31%), and "The doctor would not understand" (20%). Fewer respondents (14%) thought their doctor would disapprove of or discourage CAM use, and 2% thought their doctor might not continue as their provider. Respondents judged CAM therapies to be more helpful than conventional care for the treatment of headache and neck and back conditions but considered conventional care to be more helpful than CAM therapy for treatment of hypertension.

Conclusions: National survey data do not support the view that use of CAM therapy in the United States primarily reflects dissatisfaction with conventional care. Adults who use both appear to value both and tend to be less concerned about their medical doctor's disapproval than about their doctor's inability to understand or incorporate CAM therapy use within the context of their medical management.

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Complementary and alternative medical (CAM) therapies (also known as integrative or unconventional therapies) have been defined as "those interventions neither taught widely at U.S. medical schools nor generally available in U.S. hospitals" (1, 2). While imperfect, this definition has been used to identify representative CAM therapies, which have been studied for prevalence of use in two national random-household telephone surveys (1, 2). Data from these surveys indicate that CAM therapy use and expenditures increased substantially in the United States between 1990 and 1997 (1). Overall prevalence of use increased by 25%; total visits by an estimated 47%, from 427 to 629 million; and expenditures for CAM services by an estimated 45%, which totaled \$21 billion (1).

National surveys performed in other countries have suggested similar rates of CAM use throughout the industrialized world (3-7). Less well documented, however, are the reasons that adults typically use (and pay out of pocket for) these therapies, most of which have not been satisfactorily evaluated for relative effectiveness, safety, or mechanisms of action. Only one U.S. national survey published in a peer-reviewed journal has explored reasons for CAM use (8). Astin's survey, conducted in 1994 on a convenience sample of 1035 adults, found that reasons for CAM use included "a holistic orientation to health; having had a transformational experience that changed the person's world view; . . . and classification in a cultural group identifiable by their commitment to environmentalism, commitment to feminism,

and interest in spirituality and personal growth psychology" (8).

National surveys in the United States of CAM use in 1990 and 1997 revealed that adults typically do not disclose their use of CAM therapies to their medical doctors (1, 2). In 1997, as in 1990 (1), fewer than 40% of CAM therapies used in the previous 12 months were discussed with a medical doctor. A recent analysis of data on U.S. national medical expenditures corroborated these findings and suggested that the percentage of CAM users who disclose their CAM visits to their medical doctors may be as low as 20% (9).

This paper summarizes 1997 national survey data on respondents' perceptions about use and nondisclosure of CAM therapies relative to conventional medical care.

METHODS

Sample

We conducted a nationally representative telephone survey between November 1997 and February 1998. Survey methods were approved by the Beth Israel Deaconess Committee on Clinical Investigations, Boston, Massachusetts. The survey used random-digit dialing techniques to select households and random selection of one resident per household, age 18 years or older, as the respondent. Eligibility was limited to English-language speakers for whom cognitive or physical impairment did not prevent completion of the interview. The survey sample and weighting methods have been previously described (1).

Interview

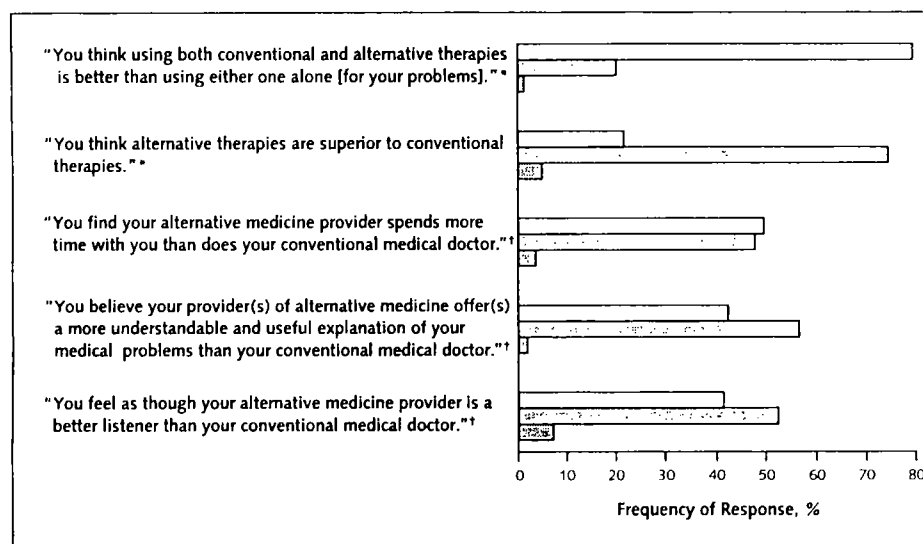
The interview was presented as a survey by investigators from Harvard Medical School about the health care practices of persons in the United States. No mention was made of "alternative," "integrative," "unproven," or "complementary" therapies in the introductory comments. The first substantive questions addressed perceived health, health worries, days spent in bed, and functional impairment due to health conditions. Next, respondents were asked about their interactions with a "medical doctor," defined as "a medical doctor, MD, or an osteopath, DO—not a chiropractor or other non-medical doctor." The term "medical doctor" was used throughout the remainder of the interview.

Respondents were asked if they had experienced any of a list of specified common medical conditions in the previous 12 months. Those who reported experiencing more than three conditions were asked to identify the three "most bothersome or serious" medical conditions. Respondents were then asked about seeing a medical doctor for these "principal medical conditions" and about perceptions of confidence in the medical doctor and the helpfulness and efficacy of their interactions. Next, respondents were asked about use of CAM therapies in the past 12 months and over their lifetime and whether each of these therapies was used for each of their principal medical conditions. We distinguished between use under the supervision of a professional (a provider of CAM therapy) and personal use without such supervision. Persons who reported having supervised use were asked about the number of visits during the past 12 months to providers of each therapy, perceptions of helpfulness and efficacy, and confidence in their CAM therapy providers. Respondents were asked whether they typically see a CAM provider before, after, or concurrent with their visits to a medical doctor. In addition, respondents were asked whether they agreed or disagreed with a list of "thoughts about the use of alternative therapies" (Figure 1). Each question was intended to elucidate perceptions about CAM therapy use relative to conventional care. All users of CAM therapies who had seen their medical doctor in the past year were asked if they had discussed use of each therapy with their medical doctor and if not, why they had not. They were then provided a list of possible reasons why people might not discuss certain therapies with a medical doctor and were asked to say "yes" to any number of items on the list that explained their own reasons for nondisclosure and "no" to items that did not. Additional details of the survey instrument are described elsewhere (1).

Statistical Analysis

As previously described (1), we calculated sampling weights for each respondent to reflect the probability of selection and to parallel the aggregate distribution of demographic characteristics of the U.S. population. We used SUDAAN software (10) to compute weighted estimates of the proportion of respondents giving specific answers to study questions. We applied the McNemar test to compare respondents' evaluations of the helpful-

Figure 1. Perceptions about complementary and alternative medical (CAM) therapy relative to conventional therapy.



Shown for each statement is the frequency of responses—agree (white bars), disagree (shaded bars), neither agree nor disagree (darkly shaded bars). * Asked of respondents who had seen a medical doctor and used any CAM therapies (excluding use of self-prayer alone) in the past 12 months ($n = 831$). † Asked of respondents who had seen both CAM therapy providers and medical doctors within the past 12 months ($n = 411$).

ness of CAM therapies and conventional care among respondents who used both for the same medical condition.

Role of the Funding Sources

This research was funded by grants from the National Institutes of Health, the John E. Ferzer Institute, and the American Society of Actuaries. Additional support for the completion of analyses and manuscript preparation was provided by unrestricted gifts from the Friends of Beth Israel Deaconess Medical Center, the Kenneth J. Germeshausen Foundation, the J.E. and Z.B. Butler Foundation, and The American Specialties Health Plan. None of the sponsors had access to the primary data, nor did they review the manuscript before submission.

RESULTS

Characteristics of the Respondents

The weighted survey response rate was 60% (1). The sociodemographic characteristics of the survey sample ($n = 2055$) were similar to the population distributions published by the U.S. Bureau of the Census (1). Among the 2055 survey participants, 1802 (87% weighted) reported seeing a medical doctor in the previous 12 months. Of these, 831 (45% weighted) reported

using CAM therapy (excluding use of self-prayer alone) in the past 12 months, and 411 (23% weighted) reported seeing a CAM provider in the past 12 months (1).

Perceptions of CAM Relative to Conventional Therapy Use

Figure 1 summarizes responses among respondents who used conventional care and CAM therapies in the past 12 months. As a preface to these questions, the interview script read,

I am going to read you some thoughts people have about their use of alternative therapies, like chiropractic, massage, acupuncture and the others I mentioned earlier. For each statement, please tell me if you agree or disagree.

As shown in Figure 1, fewer than 1 in 4 (21%) CAM therapy users ($n = 831$) agreed with the statement, "Alternative therapies are superior to conventional therapies," and roughly 4 of 5 (79%) respondents agreed that "Using both conventional and alternative therapies is better than using either one alone [for your problems]." For respondents who saw a CAM therapy provider and a medical doctor ($n = 411$), we asked

whether they agreed or disagreed that their CAM provider did a better job of “listening” or “explaining their medical problems” than their medical doctor. Forty-one percent agreed that their CAM provider was a better listener, and 52% disagreed; 42% agreed that their CAM provider did a better job of explaining their medical conditions, and 56% disagreed.

Sequence of Seeking Care from CAM Providers and Medical Doctors

We asked respondents who reported seeing both a medical doctor and a CAM provider during the past 12 months ($n = 411$) the following:

The next questions are about your use of alternative therapies in general. People generally fall into one of three groups regarding their use of alternative medicine. Some people see an alternative provider before they consult a medical doctor; some see both alternative providers and conventional doctors at the same time; and some see an alternative provider after they have seen a medical doctor. Which of these best describes your pattern of seeing alternative providers?

As summarized in Figure 2, 7 of 10 respondents

reported typically seeking the services of a CAM provider after or concurrent with their visit to a medical doctor. Fewer than 1 in 6 (15%) said they saw a CAM therapy provider before seeing a medical doctor.

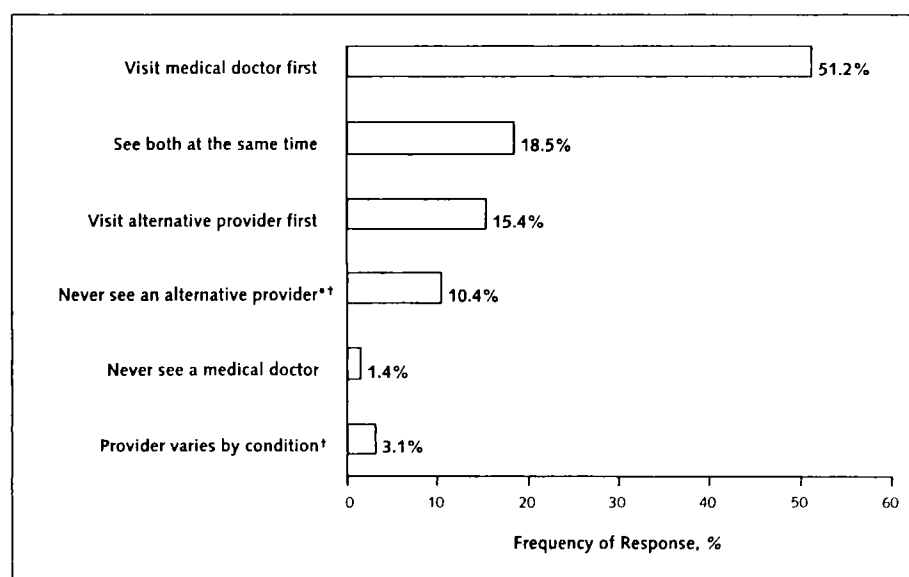
Overall Helpfulness of Therapies

The Table summarizes perceived relative helpfulness for 10 of the most commonly reported principal medical conditions identified in the 1997 national survey among respondents who used both conventional care and CAM therapies for each condition. The CAM therapies were judged more helpful than conventional care for treatment of headache and neck and back conditions; conventional care was considered more helpful for treatment of hypertension. Trends suggesting a perceived difference in helpfulness for other common conditions were observed, but we cannot confirm this because of sample-size limitations for most condition-specific groups.

Confidence in CAM Providers Relative to Medical Doctors

Respondents who reported seeing conventional and CAM providers in the past year ($n = 411$) were asked

Figure 2. Sequence of seeking care from complementary and alternative medical (CAM) providers and medical doctors.



Data are for the respondents who saw a medical doctor and a CAM provider during the past year ($n = 411$). *On further evaluation, this category was found to predominantly represent respondents who sought CAM therapies from a medical doctor. †These response choices were not read but were volunteered by respondents.

Table. Relative Helpfulness of Complementary and Alternative Medical Therapies Compared with Conventional Medical Care among Respondents Who Used Both for Specific Medical Conditions*

Medical Condition	Total Weighted Sample, <i>nt</i>	Respondents' Perception, %†		<i>P</i> Value§
		Conventional Care Was Better	CAM Therapy Was Better	
Back conditions	158.3	12.4	46.1	<0.001
Allergies	48.4	22.7	29.9	>0.2
Fatigue	14.6	9.4	41.3	0.09
Arthritis	72.1	25.9	44.8	0.06
Headaches	71.6	19.0	39.1	0.03
Neck conditions	87.9	6.4	61.0	<0.001
High blood pressure	14.9	57.0	0	0.004
Strains or sprains	17.4	7.8	22.5	>0.2
Lung conditions	36.1	25.9	23.5	>0.2
Digestive conditions	42.7	34.5	25.9	>0.2

* CAM = complementary and alternative medical.

† Values represent the sum of standardized sampling weights for the respondents with the condition.

‡ The remainder of respondents found their physician's care and CAM therapy to be equally helpful.

§ Based on a two-sided McNemar test.

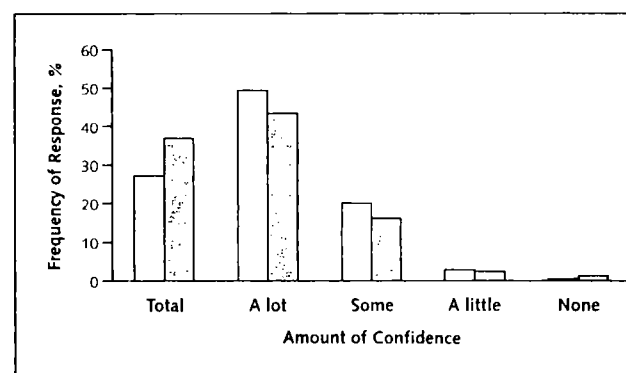
about confidence in their medical doctors and CAM providers (Figure 3). The question regarding confidence in one's CAM providers was asked only of respondents who had seen the provider in the past 12 months, whereas the question about confidence in one's medical doctors was asked of respondents who had ever seen a medical doctor. Furthermore, the question on CAM providers was repeated for each type of CAM provider seen. Therefore, responses in these categories are not ideally suited for formal statistical comparisons. However, the percentage of respondents who perceived "to-

tal" or "a lot of" confidence in their CAM provider was similar to the percentage of respondents who perceived "total" or "a lot of" confidence in their medical doctor (81% and 77%, respectively).

Reasons for Nondisclosure of CAM Therapy Use to Medical Doctors

Among the 831 respondents who saw a medical doctor and used CAM therapies in the past year, 63.0% (*n* = 536) did not disclose use of at least one of their CAM therapies, and 28.1% (*n* = 225) disclosed all of their three or fewer CAM therapies. Information on the remaining 8.8% (*n* = 70) of respondents is incomplete because these individuals used more than three CAM therapies but were asked only about their disclosure of a random three therapies. These 70 respondents reported disclosing the three CAM therapies about which they were asked, but disclosure on use of their other CAM therapies is unknown. Consequently, nondisclosure of at least one type of CAM therapy to a medical doctor was at least 63%, possibly as high as 72%, of these 831 CAM therapy users.

Figure 4 summarizes responses to the following instructions, which were asked of all respondents who used CAM therapy in the past 12 months but did not disclose this use to their medical doctor. The instructions were read for each of the 726 total alternative therapies that these respondents reported as nondisclosed.

Figure 3. The amount of confidence patients reported having in complementary and alternative medical (CAM) providers (shaded bars) and conventional medical doctors (white bars).

Data are for respondents who saw both a medical doctor and a CAM provider in the past year. Overall, these 411 respondents reported using a total of 538 CAM therapies.

Here are some reasons people have for not discussing certain therapies with a medical doctor. As I read each statement, please say "yes" if it applies to your not discussing your therapy with your doctor and "no" if it does not apply.

As shown in Figure 4, for three fifths of the CAM therapies that were reported to have been used but not disclosed, respondents agreed with each of the following two statements: "It was not important for the doctor to know" and "The doctor never asked." For nearly one in three therapies (31%) used, respondents considered their CAM therapy use "None of the doctor's business," and for 20% to 34%, depending on the therapy and condition, respondents agreed that "The doctor would not understand." For 14% of all nondisclosed therapies, respondents acknowledged being concerned that their medical doctor would "disapprove" of or "discourage" their CAM use. For 2% of all nondisclosed therapies used, respondents agreed with the statement, "You thought your doctor might not continue as your provider."

DISCUSSION

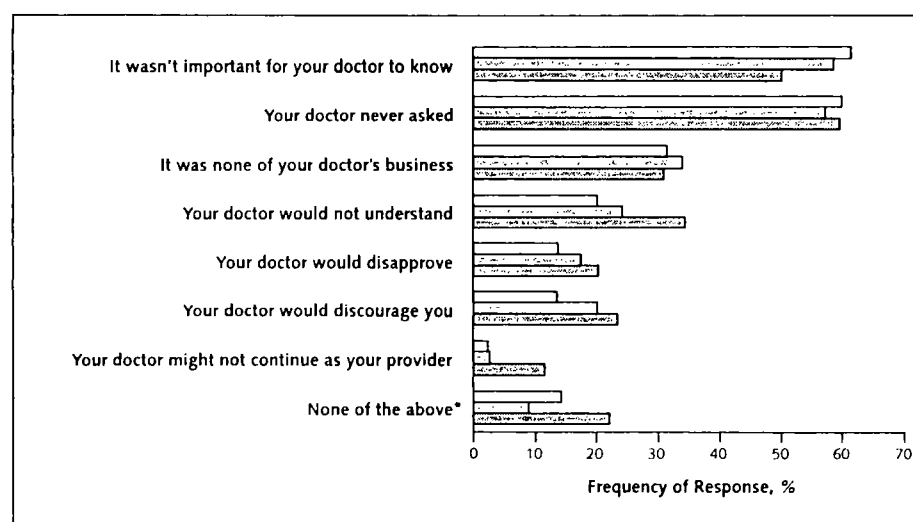
The methodologic limitations of our 1997 national survey, which were previously described (1), include the

sampling restriction to persons who spoke English and lived in households with telephones, the modest response rate, and the use of a financial incentive. Furthermore, we have no data on the accuracy of self-reports concerning recollections of CAM or conventional therapy use. Recall bias is a possibility, and the degree of bias may be related to the time lapsed since the most recent visit to a provider.

Within the context of these caveats, the results of this national survey suggest that the use of CAM therapies cannot be attributed primarily to perceived dissatisfaction with conventional medical care or caregivers. Many adults seek, explore, and experience benefits from both conventional and CAM therapies. These survey data are consistent with the findings of Astin (8), as well as those of Druss and Rosenheck (9), and contrast with previous editorials suggesting that the high prevalence of CAM therapy use in the United States largely represents a societal rejection of orthodox and conventional medical care (11–15).

Regarding CAM therapies for specific medical conditions, we found that CAM therapies were perceived to be more helpful than conventional medical care for chronic, debilitating conditions such as headaches and

Figure 4. Reasons for nondisclosure of complementary and alternative medical (CAM) therapy use.



*This response choice was not read but was volunteered by respondents. White bars represent reasons for nondisclosure of any therapy included in the survey ($n = 726$); the lightly shaded bars depict reasons for nondisclosure of therapies with a recognized potential risk for adverse events—namely, herbal remedies, chiropractic, naturopathy, megavitamins, and chelation therapy ($n = 188$). Our analysis also considered whether reasons for nondisclosure were associated with the severity of the medical condition; the darkly shaded bars summarize reasons for nondisclosure among respondents who reported having a relatively "severe" medical condition—cancer, coronary artery disease, or diabetes mellitus—in the past 12 months ($n = 33$).

neck and back conditions. These findings corroborate the reports of Astin (8) and others who have investigated the reasons for CAM therapy use (16–21). As for the sequence of seeking the services of medical doctors and CAM providers among adults, our data, consistent with other (population-specific) studies, show that adults typically seek the services of their medical doctor before seeing a CAM provider, or they see both concurrently (16, 20). Only a minority of individuals seek the professional services of a CAM practitioner before seeking conventional medical care. As such, medical doctors and other conventional caregivers who are knowledgeable about CAM practices and the evidence to support or refute their application have a unique opportunity to advise patients on the use or avoidance of individual CAM therapies on a case-by-case basis.

Wolpe has suggested that as a society, adults are not abdicating the role of modern biomedicine but rather are redefining biomedicine's responsibility within the larger model of health care delivery (Wolpe PR. *Alternative medicine in the social and historical context*. Presented at Retreat on the Role of Alternative Medicine in the Academic Medical Center, 24 March 1999, Philadelphia, Pennsylvania). The popularity of CAM therapies cannot be attributed solely to a dissatisfaction with or lack of attraction to high-tech, scientifically validated orthodox care.

Our survey data show an interesting split between participants agreeing and disagreeing with the view that CAM therapy providers 1) spend more time with patients, 2) offer more understandable explanations, and 3) are better listeners. Like a Rorschach test, these data offer multiple interpretations. On one hand, 47%, 56%, and 52%, respectively, disagreed with each of these statements. On the other hand, more than 40% agreed with each. Other population-specific studies have reported patients' perceived differences when comparing CAM providers with medical doctors. For example, some studies have found that patients value the counseling aspects of care exhibited by CAM providers compared with the care provided by conventional medical doctors. These aspects of care include an improved explanation of illness (16, 17, 22) and a willingness to discuss emotional factors (16), a better understanding of their problems (17, 20, 22), and the therapist's personal attention and expenditure of time (17, 18, 22). Each of these perceptions warrants further qualitative study.

Clearly, many adults believe that their medical doctor will not understand their use of complementary and alternative therapies, and that "it is not important for the doctor to know" or "it is none of the doctor's business." These findings are consistent with those of other investigators (23–26). Similarly, our observation that fewer than one in five respondents feared disapproval from their physician is consistent with comparable surveys of rheumatology patients (23, 24). Collectively, these data suggest that many patients, in their capacity as consumers of care, view medical doctors as members of a larger, patient-selected health care team. Increasingly, medical doctors are being viewed as one of several professionals whom the average adult seeks for advice or treatment of health-related matters. This is consistent with societal trends toward increased autonomy and personal responsibility for one's health. A deeper understanding of the extent to which these perceptions are affecting CAM use and disclosure will require additional qualitative and quantitative investigation.

Ideally, we should develop an evidence-based approach to CAM therapies that incorporates our patients' perceptions and their right to choose their own therapy and therapist. David Sackett, in an editorial titled "Evidence-Based Medicine: What It Is and What It Isn't" (27), argued that

Evidence-based medicine is not 'cookbook' medicine. Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in slavish, cookbook approaches to individual patient care. . . . Similarly, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament, and preferences, and thus, whether it should be applied.

As an evidence-based evaluation of CAM therapies materializes, let us be reminded that many adults currently choose to use CAM therapies to treat their most serious medical problems and appear to value both conventional and CAM approaches. Moreover, when patients choose not to tell their physicians that they use CAM therapies, they appear to be less concerned about their physician's disapproval than their physician's per-

ceived inability to understand or incorporate CAM therapy into their overall medical management.

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Alternative Medicine: A “Mirror Image” for Scientific Reasoning in Conventional Medicine

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A reflection on the scientific behavior of adherents of conventional medicine toward one form of alternative medicine—homeopathy—teaches us that physicians do reject seemingly solid evidence because it is not compatible with theory. Further reflection, however, shows that physicians do the same within conventional medical science: Sometimes they discard a theory because of new facts, but at other times they cling to a theory despite the facts. This essay highlights the seeming contradiction and discusses whether it still permits the building of rational medical science. We propose that rational science is compatible with physicians’

behavior, provided that physicians acknowledge the subjective element in the evaluation of science, as exemplified in the cross-word analogy by the philosopher Haack. This type of thinking fits very well with the Bayesian approach to decision making that has been advocated for decades in clinical medicine. It does not lead to complete and uncontrollable subjectivity because discernment between rivaling explanations is still possible through argument and counterargument.

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Discussions about the scientific value of alternative medicine quickly touch the raw nerve of conventional medical reasoning and medical wisdom. As such, alternative medicine is a useful “mirror” for conventional medicine (the idea that alternative medicine, in particular homeopathy, acts as a “forbidden mirror-image” for conventional medicine was described by Wiersma [1]): How one looks at the “other” may reveal more about oneself. Physicians’ response to the “other” may clarify neglected or hidden aspects of the scientific process in conventional medicine. This article examines aspects of the process of weighing scientific evidence in modern medicine. It is not primarily concerned with alternative medicine; rather, we reflect on scientific reasoning within medicine as a whole. Nevertheless, our train of thought in this article was triggered by examining our response to claims of scientific proof of the effectiveness of alternative medicine. We use homeopathy as the main example to discuss the scientific evaluation of alternative medicine because homeopathy has a long and extensive history of evaluation by randomized, controlled trials, and because the debate surrounding homeopathy makes the contradictions between seemingly solid evidence and scientific judgment most clearly visible.

HOMEOPATHY AND SCIENTIFIC EVIDENCE OF ITS EFFICACY

Homeopathy was devised in Germany by Samuel Hahnemann (1755–1843). It espouses the belief that whatever symptoms a substance causes in a healthy per-

son, a disease with a similar symptom configuration can be cured by small amounts of the same substance: *Similia similibus curentur* (“like cures like”), a principle that is already controversial in itself. Even more controversially, homeopathy claims that the more dilute a substance (if prepared by a series of shakings called “succussion”), the more “spiritual vital essence” is released and therefore the more potent the medicine that is created: Less becomes more (2). Remedies are often diluted up to or beyond Avogadro’s number (10^{23}), with a chance that not a single active molecule is left in the vial (2, 3).

Homeopathy has been debated for more than a century and a half. The debate has entered the modern medical era: Randomized trials have been performed and then summarized in meta-analyses. A recent meta-analysis (4), which built on previous ones (3, 5), found 89 trials that were described as adequate. The authors of the meta-analysis conclude that the data are “not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo” (4). The combined odds ratio showed a twofold benefit in favor of homeopathy, even after statistical correction for publication bias.

The future of homeopathy now seems bright: A meta-analysis of randomized trials concluded that homeopathic effects can no longer be seen as placebo effects and that the positive reported effects are not due to publication bias. Yet, most physicians working in conventional medicine vehemently dismiss this conclusion and find all kinds of counterarguments: The trials might

have been too small; there is only an overall effect, which might be due to the accumulation of several small biases (the position of one of us [6]); a repeatedly proven consistent effect has never been shown for a single indication with a particular regimen (7). In short, we want to find good reasons to discard the randomized trials.

Why? What is our ultimate reason for discarding the evidence from the meta-analysis of randomized trials on homeopathy? The authors of the meta-analysis showed that even the very best trials (as judged by the authors' methodologic standards) that used the highest dilutions (approaching or surpassing Avogadro's number) still showed a beneficial effect. That is materially impossible. The highest dilutions in homeopathic medicines are so high that it is not possible to determine by ordinary chemical principles which vial contains an "active product" and which one "placebo" (2, 3). Microbiologists know for sure that infinite dilutions of an antibiotic will never show any effect on bacterial growth. No physician will use an antihypertensive medication in a dilution that surpasses Avogadro's number. No oncologist would propose to dilute cytotoxic drugs beyond the limit of chemical detectability. Because of the impossibility of chemical effects, adherents of conventional medicine disbelieve the evidence from the randomized trials on homeopathy.

This leads to ever more intricate reanalyses of this meta-analysis. A novel proposition is to apply meta-regression analysis of measures of the quality of randomized trials (8). Through a meta-regression, one tries to estimate the effect of all individual quality elements that matter in particular trials (for example, size and blinding). This approach differs from that of the authors of the meta-analysis on homeopathy, who used an overall quality score. A new meta-regression analysis of the homeopathy trials found that "inadequate blinding" and "small sample size" strongly determined the overall positive effect of homeopathy (9). The two largest, adequately blinded trials on homeopathy showed no effect, a finding that is consistent with the intercept of the meta-regression that stood for "large blinded trials." However, the authors are quick to point out that their results do not *prove* that the apparent benefits of homeopathy are due to bias. Nevertheless, those of us who think that the homeopathy results are impossible will see this meta-regression as a strong confirmation of our position.

DO TRIALS OVERTURN THEORY?

Once we recognize the tendency not to accept the evidence if it is incompatible with theory and to accept this reasoning as valid, we should analyze it: It might teach us a lot about how we actually reason in conventional medicine. When reflecting on our behavior in several controversies, we recognize that sometimes we accept the evidence from the randomized trial and overturn a theory—however beautiful it was—but that at other times we stick with the theory and dismiss the evidence.

Examples of both behaviors can be found in conventional medicine. One of the more fashionable and popular recent theories in immunology and infectious disease medicine concerned the immunologic mechanism of septic shock. Gram-negative septic shock was ascribed to circulating endotoxins produced by the bacteria; endotoxins would elicit a powerful cytokine response that harmed the organism itself. Animal research showed that gram-negative shock could be prevented if the blood was immediately cleared of circulating endotoxin and cytokines. This was done by using antibodies tailor-made by the stock-raising stars of the biotech industry. The first randomized trial, which studied antibodies against endotoxin, was reported as a success (10). However, doubts were expressed upon discovery that the positive findings concerned the subgroup of patients with gram-negative sepsis only. This discovery gave way to a lengthy discussion that is pertinent to our reflection on how we interpret "evidence."

The problem was that at admission to an intensive care unit, the patient's infection cannot be identified as gram-negative or gram-positive (or as another type of infection), nor can one determine whether the infection led to bacteremia. Thus, in the trial, all patients with clinical suspicion of sepsis were randomly assigned. However, the type of infection was only known after 24 or 72 hours. The analysis was then restricted to patients with gram-negative bacteremia and clinical sepsis; these results showed a clear beneficial effect, supporting the immunologic theory and the animal experiments. Yet, the original report already indicated that the benefit almost disappeared when all randomly assigned patients were considered. The only logical conclusion was that the intervention had more untoward outcomes in the patients without gram-negative sepsis. Regardless of the

ensuing discussions (which also frowned on other subgroup analyses [11]), we can imagine that the investigators, as well as the journal's peer reviewers, originally found the restriction justified: Theory predicted that the intervention should work only in patients with gram-negative sepsis. Any untoward outcome in the remaining patients must have appeared to be a "freak accident." Subsequently, however, additional trials studied tailor-made antibodies against mediators of sepsis. Another picture emerged: no benefit, and sometimes even a small effect to the contrary (12).

Immunologists and infectious disease physicians recognized that the relationship among septic shock, endotoxins, and the cytokine response might have been more complex. It was not just a strong immunologic response to high levels of endotoxin that might be detrimental; the timing of the response might have an effect as well. An initial strong response to endotoxin might be beneficial, while an initial weak response might lead to dissemination of the infection. That dissemination, in turn, might lead to higher levels of endotoxin only at a later stage of the disease. Even some old animal experiments were seen in a new light (13, 14). Thus, in the end, the consistently negative findings of the randomized trials overturned the immunologic theory.

The inverse also happens. Recurrent vasovagal syncope is an annoying and sometimes dangerous condition. During the later phases of a syncope, profound bradycardia can develop. It is believed that this bradycardia might augment or prolong the symptoms. Therefore, some physicians have proposed the implantation of demand pacemakers to people with recurrent vasovagal syncope. Such pacemakers would not prevent the onset of syncope but might prevent its full development. A randomized trial of implantation of demand pacemakers had such positive results that the investigators stopped it prematurely (15). However, researchers who had studied the physiology of vasovagal syncope by using a tilt table to elicit syncope in healthy volunteers and patients had proven that syncope is due to vasodilatation and reductions in blood pressure and that cardiac pacing does not alleviate those symptoms (16).

This places us fully in the realm of the "homeopathy" dilemma: Physiologic theory, based on small-scale experiments, holds that pacing cannot work. Yet a randomized trial was overwhelmingly positive. The ensuing discussion (Wieling W. Personal communication) is

illuminating. Trial enthusiasts dismiss the physiologic studies as "small uncontrolled observations," while to physiologists these observations proved that pacing could not possibly work in any mechanistic sense. Consequently, the physiologically inclined physicians posed many a critical objection to the trial: Patients had not been selected because of profound bradycardia (on the contrary, tachycardia-producing isoprenaline was often used to elicit syncope during diagnosis, and only "relative bradycardia" was observed); the trial was open and unblinded (each cardiologist assessed his or her own patient by telephone); and during the average 1-week waiting time before implantation, no patient in the intervention group experienced syncope, whereas six in the placebo group did (suggesting a placebo effect or an overall randomization imbalance). In contrast, cardiologists point to the large effect of the pacemaker intervention, and they have electrophysiologic arguments of their own: New "dual pacing" would have a better influence on blood pressure than older "right-heart pacing" does. The discussion might go on for some time. It will certainly lead to new investigations, new randomized trials, and new electrophysiologic experiments.

EVIDENCE AND SPONSORSHIP

The example of homeopathy concerns a "class" of trials, while in the examples of conventional medicine we discussed specific instances and specific theories. However, some instances in conventional medicine also concern a "class" of trials. A recent review of hematology trials sponsored by the pharmaceutical industry found that most such trials had a positive result for the new product; this finding indicates that these trials could not have started under "equipoise," the genuine uncertainty that is necessary at the onset of a randomized trial (17). In contrast, publicly funded trials favored the investigated drug half of the time, as expected under equipoise. The authors of the review discuss many reasons for this difference, including the possibility that the designing of sponsored trials may lead to conditions favoring the success of the new product.

Another outstanding example is that of sponsored randomized trials on nonsteroid anti-inflammatory drugs (NSAIDs). A review of such trials found that all sponsored studies favored the new product (most of the time because of superior efficacy or lesser toxicity) or found the new product to be at least as good as the

competitor product (18, 19). This review reported that the competitor product was often administered in rather low dosages. Because many of the newer and older NSAIDs resemble each other pharmacologically, the finding that sponsored trials of NSAIDs give predominantly positive results for the sponsor's product is, *a priori*, as impossible as the predominantly positive results of trials on homeopathy. Therefore, we suspect that the same mechanisms are at play: a departure from "equipoise" due to the accumulation of larger or smaller biases in design, analysis, or reporting.

THE CROSSWORD ANALOGY

Our overall conclusion from the preceding examples and others, alternative and conventional (20), is that in conventional medicine we sometimes accept the randomized trial evidence and discard the theory but at other times we stick to the theory and dismiss the "facts."

What is the basis of such reasoning, and can it be justified? The U.S. philosopher of science, Susan Haack, tries to steer a middle course between "naïve" hypothetical-deductive dogmatism (that is, one immediately discards a theory upon experimental falsification, which in reality never happens), and a postmodern "anything goes" approach (that is, truth is just another commodity that we negotiate about, a matter of societal convention and silent pacts, that is completely dependent on time, place, and person). How can we on the one hand acknowledge that a scientific experiment might be set up in a spirit of "conjecture and refutation" yet believe that its interpretation might be colored by theoretical preconceptions? Haack proposed the "crossword analogy." In her words (21):

The clues [of the crossword] are the analogue of experiential evidence, already-completed entries the analogue of background information. How reasonable an entry in a crossword is depends upon how well it is supported by the clue and any other already intersecting entries; how reasonable, independently of the entry in question, those other entries are; and how much of the crossword has been completed. An empirical proposition is more or less warranted depending on how well it is supported by experiential evidence and background beliefs; how secure the relevant background beliefs are, independently of the proposition in question; and how much of the relevant evidence the evidence

includes. How well evidence supports a proposition depends on how much the addition of the proposition in question improves its explanatory integration. There is such a thing as supportive-but-less-than-conclusive evidence, even if there is no formalizable inductive logic.

Thus, when the randomized trials on antiendotoxin repeatedly did not fit with the previous entry about the theory of septic shock, that previous entry was removed. Inversely, we do not want to remove the notion that "infinite dilutions cannot possibly work." While the former reaction might seem reasonable to most observers, why is the latter acceptable? Can we dismiss "evidence" because it does not fit with an already existing theory?

A BAYESIAN OUTLOOK

As a matter of fact, physicians are pretty well used to discarding "facts" because of theory. This is called the Bayesian outlook in diagnostic thinking. When confronted with a middle-aged woman who has vague chest symptoms and a host of psychosocial problems, the physician might still order electrocardiography, just for certainty. However, if the echocardiogram shows a slight ST-segment elevation, the physician will shrug his shoulders and mention it as an aside in his report. His reasoning is that many persons have ST-segment elevations without consequence and that the patient's symptoms do not fit with a truly cardiac abnormality. However, if the same electrocardiogram belongs to an elderly man with a history of typical angina, the physician will exclaim, "Ha! You can see it on the cardiogram." The same fact gets a different meaning according to diagnostic suspicion.

This Bayesian outlook has been formalized in medical decision making, but it has also been shown to apply to the interpretation of clinical trial evidence (22, 23). Results of randomized trials can be seen as results from the "statistical lab" that come in just like electrocardiogram results come in. Depending on our prior belief, we will accept them or not. If our prior belief is strong, as with, for example, homeopathy, we will shrug our shoulders when confronted with randomized trial evidence: There are so many reasons why trials can turn out positive. Inversely, when we still believed in the original endotoxin-septic shock paradigm, we believed the results from the first randomized trials. And when

we are confronted with positive results from industry-sponsored trials, our a priori suspicion about a lack of "equipoise" will make us dismiss such trials more easily.

One of the great theoreticians of epidemiology, Jerome Cornfield (the inventor of both the odds ratio and logistic regression), who had a firm Bayesian outlook in his statistical thinking, recognized the problem when he wrote about the problems of interpreting the results from randomized trials: "good scientific practice . . . places the emphasis on reasonable scientific judgment and the accumulation of evidence and not on dogmatic insistence of the unique validity of a certain procedure" (24).

This quote looks like a foreshadowing of Haack's crossword analogy. Cornfield's idea was initiated by his reflection on the status of randomization in study design, and therefore also has bearing on debates on the relative merit of randomized and nonrandomized evidence (25–27).

ARGUMENTS AND COUNTERARGUMENTS

This brings us to the status of arguments about evidence: What arguments count? In a personal communication, Gerard de Vries, professor of the philosophy of science in Amsterdam, the Netherlands, taught one of us about the "U.S.–Japanese electron argument." It runs as follows: A physics experiment is carried out in Japan, and the same experiment is carried out in the United States. Suppose that the outcomes differ. One of the investigators might then propose, "Well, perhaps electrons in the United States and in Japan are different." Most people with some knowledge about science will tend to dismiss this argument immediately and will suspect that something went wrong in one of the experiments. This reaction would occur because most people expect that explanations on the atomic level are the same, wherever on earth. However, the investigator might remain stubborn and maintain that people who stick to such a position are no longer true scientists: They dismiss the very experiments showing that Japanese and U.S. electrons are different!

The answer is that the position of that investigator is "too easy": It is too easy to bend the theory to the experiment each time that one sees a reason to do so. If we leave the position that explanations on the atomic scale should be the same on all places on earth, we leave

meaningful physics; from that moment onward, anything goes. Therefore, we prefer to take a second look at the Japanese and U.S. experiments. We want to determine whether they differed in their execution in a way that might explain the different results. The same goes for homeopathy and infinite dilutions. Accepting that infinite dilutions work would subvert more than conventional medicine; it wrecks a whole edifice of chemistry and physics. That price is too high: Too much knowledge that really works in our day-to-day world is built on existing chemistry and physics. We do not want to discard this because of a few randomized trials. Therefore, we prefer to take a hard look at this type of "evidence."

While the discussions about alternative medicine do highlight the nature of our reasoning and put its strengths and weaknesses under a stark spotlight, we should not forget that we do continuously apply these rules—without knowing it—when discussing the merits of a new therapy or a new theory in conventional medicine.

SCIENCE VS. BELIEF

Our position is a difficult one: Highlighting the judgmental nature of our theoretical positions inevitably leads to the suspicion that we cannot "prove" these positions, that some positions might ultimately be amenable to change, and that other persons have an equal right to cling to their positions.

Of course, in principle, all positions are amenable to change. It remains possible that out of the blue, from the observation of a single patient, from local folklore, or even from alternative medicine, some principle that is of value emerges. After all, that is how medicine started with "willow bark" and "foxglove"; we ended with salicylates and digitalis.

Nevertheless, science is not just another belief system that can be replaced by any other belief at will. Science is a construct of arguments and counterarguments that we try to fit together in a mental crossword puzzle. Certain propositions are simply not acceptable because they are just unproven flights of imagination. For example, in discussions about epidemiologic case-control studies, one can always dream up potential bias and confounding, but that does not mean that they exist. Other arguments might be valuable in themselves

but can be dismissed; arguments about potential bias and confounding in epidemiologic studies can often be verified by stratification or replication.

To further scientific arguments and counterarguments, we continuously produce new experiments and new observations—and have new rounds of discussion around them, to examine how they fit. In day-to-day science, we see this most clearly in the midst of a controversy still lacking sufficient evidence—that is, when the crossword is far from completed and large blank areas surround the few entries. Decisions about the next correct entry, and about how to obtain the next entry, will retain a subjective element. When a theory is still developing, different scientists will cling to different opinions, and that is legitimate. However, all strive to a common end point, according the word of Sir Dominic Corrigan, Irish physician and statesman (1802–1880), one who never ran away from a controversy: “Whether my observations and opinions be disproved or supported, I shall be equally satisfied. Truth is the prize aimed for; and, in the contest, there is at least this consolation, that all the competitors may share equally the good attained” (28).

An important proof for the value of this process is that science “works,” from its ancient forms in the construction of temples or cathedrals to telecommunication and experimental gene therapy. In an illuminating essay on the “science wars,” Stephen Gould accepts that science is socially constructed and that it is therefore uncertain whether humanity should by necessity have arrived at its present state of knowledge (29). If science had taken another detour, part of our scientific world might be different, but it would always reflect a reality “out there.” In his own words: “The true, insightful and fundamental statement that science, as a quintessentially human activity, must reflect a surrounding social context, does not imply either that no accessible external reality exists, or that science, as a socially embedded and constructed institution, cannot achieve progressively more adequate understanding of nature’s facts and mechanisms” (29).

THE MIRROR

Our purpose in this article was to show that the confrontation concerning the results of randomized trials in alternative medicine teaches us a lot about our way

of reasoning in conventional medicine. The extreme challenge presented by alternative medicine is that some trials have positive findings when that is impossible; this situation leads us to reflect that the same happens in conventional medicine. We surmise that the same mechanisms that lead to positive trials in alternative medicine may lead to false-positive trials in conventional medicine. In conventional medicine, however, this is much more difficult to see because we tend to believe in the pathophysiologic mechanisms that are proposed to explain the trial results. Where strong prior beliefs operate (for example, in alternative medicine trials or in industry-sponsored trials), we will want to maximize guarantees that scientific research has been done properly. For example, we should be especially careful to determine whether equipoise was guaranteed in the design of a trial and whether all results of all trials have been reported (17). The realization of the difficulties that confront medical research in this area will stimulate the development of new tools to identify which randomized trials are credible and which ones are not. Nevertheless, in the ultimate judgment, reasoning—and thus subjectivity—will remain unescapable.

We should be grateful for debates about alternative medicine: They open our eyes to the nature of our reasoning in conventional medicine. We should forever keep an open mind, but, according to the late Petr Skrabanek, not so open that our brain falls out (30).

Note added in proof: A recent randomized trial of dual pacemaking in patients with syncope selected participants according to cardiac response on tilt-table testing (31). The benefit of pacemaking was as high as seen in the previous study discussed above (15). After pacemaker implantation, however, susceptibility to elicited tilt-table syncope (the entry criterion) was unaltered. This finding will lead to continued debate between physicians who predominantly stress pathophysiologic reasoning and those who adhere to trial results.

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Groft, Stephen (WHCCAMP)

From: George DeVries [GEORGED@ashn.com]
Sent: Wednesday, August 15, 2001 6:00 PM
To: Kaczmarczyk, Joseph (WHCCAMP)
Cc: Groft, Stephen (WHCCAMP)
Subject: Provider Licensure Report



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Exhibit 6.xls



Exhibit 7.xls

Attached is the report on Provider Licensure. It has been updated to reflect the appropriate references in the terms of source of data. The General Accounting Office is authorized to utilize this Provider Licensure Report in reports currently being prepared on Complementary Healthcare.

Thanks,
George DeVries

Summary Overview of Complementary & Alternative Medicine Licensing by State and Specialty

August 13, 2001

Chiropractic

Reference and Data Collection Methods

The baseline data used to calculate the number of chiropractic providers was derived from three primary sources.

1) *Federation of Chiropractic Licensing Boards (FCLB). Official Directory – Chiropractic Licensure and Practice Statistics. Greeley: FCLB, 2001.*

2) *Personal communication with individual State Chiropractic Licensing Boards and*

3) *Research via State Board websites.*

Exhibits

Chiropractors are licensed in all 50 states and Washington, D.C. (**Exhibit 1, Column 1**).

Exhibit 2 (Column 1) Data concerning licensure can be reported in two different manners. “*Resident*” licenses account for chiropractors living in the State in which they practice. “*Active*” licenses include chiropractors that hold a license for a State that they may or may not be practicing in or living within the boundaries of the State. There were 81,011 total “*active*” licenses within the United States in the year 2000 as reported by the FCLB Official Directory 2001-2002. Data reported in **Exhibit 2, Column 1** (Total = 70,604) predominantly represents “*resident*” licenses as compared to “*active*” licenses. There were thirteen (13) States where “*resident*” license information was not available, consequently “*active*” license data was reported. These thirteen States are identified in Exhibit 2 using (*). “*Resident*” licenses were selected for publication as this statistic more closely reflects the number of chiropractors in that State likely to be involved in patient care.

Exhibit 3 documents the ratio of licenses for chiropractors to population in the United States. This data represents the State population, the ratio of chiropractors to population, and the number of active licenses annually from 1996-1999. 1990 Census data was used as the data for the State population against which active license years 1996-1999 were compared.

Exhibit 4 documents the ratio of licenses for chiropractors to population in the United States. This data represents the State population (based on census data for the year 2000), the ratio of chiropractors to population, and the number of active licenses by State for year 2000.

Acupuncture

Reference and Data Collection Methods

The baseline data used to calculate the number of acupuncture providers was derived from three primary sources.

1) *Mitchell, Barbara B. Acupuncture and Oriental Medicine Laws. Gig Harbor: National Acupuncture Foundation, 2001*

2) *Personal communication with individual State Acupuncture Licensing Boards and*

3) *Research via State Board websites.*

Exhibits

Acupuncturists are licensed in 39 States and Washington, D.C. (**Exhibit 1, Column 2**).

Exhibit 5 reflects the growth of the acceptance of acupuncture over the past 28 years as reflected by the increasing number of States that license acupuncturists.

Massage Therapy

Reference and Data Collection Methods

The baseline data used to calculate the number of massage therapy providers was derived from two primary sources.

1) *Personal communication with individual State Massage Therapy Licensing Boards and*

2) *Research via State Board websites.*

Exhibits

Massage Therapists are licensed in 29 States and Washington, D.C. (**Exhibit 1, Column 3**).

Exhibit 6 reflects the number of hours of education required by states that have educational qualifying factors for licensure.

Naturopathy

Reference and Data Collection Methods

The baseline data used to calculate the number of naturopathy providers was derived from two primary sources.

- 1) *Personal communication with individual State Naturopathy Licensing Boards and*
- 2) *Research via State Board websites.*

Exhibits

Naturopaths are licensed in 11 States. **(Exhibit 1, Column 4)**

Based upon data collected from the Naturopathy licensing boards, a comparison was made to identify growth in the number of providers licensed on a state by state basis. **(Exhibit 7)**

Dietetics

Reference and Data Collection Methods

This baseline data used to calculate the number of dietetic providers was primarily derived from:

American Specialty Health, Inc. market research.

Exhibits

Dietitians are licensed/certified in 41 states. **(Exhibit 1, Column 5)**

Exhibit 2 (Column 5) contains the number of Registered Dietitians (R.D.s) who in addition may also hold a state license.

RATIO OF LICENSES FOR CHIROPRACTORS TO POPULATION BY U.S. STATE

State	*Population (1,000) 1990	Active Licenses 1996	Ratio Chiropractors to population	Active Licenses 1997	Ratio Chiropractors to population	Active Licenses 1998	Ratio Chiropractors to population	Active Licenses 1999	Ratio Chiropractors to population
Alabama	4,041	712	1/5,676	749	1/5,395	764	1/5,289	764	1/5,289
Alaska	550	163	1/3,374	179	1/3,073	166	1/3,313	166	1/3,313
Arizona	3,665	2,404	1/1,525	2,490	1/1,472	2,514	1/1,458	2,476	1/1,480
Arkansas	2,351	525	1/4,478	532	1/4,419	542	1/4,338	541	1/4,345
California	29,760	11,339	1/2,625	11,332	1/2,626	12,732	1/2,337	12,192	1/2,440
Colorado	3,294	1,870	1/1,761	1,970	1/1,672	1,916	1/1,719	1,831	1/1,799
Connecticut	3,287	855	1/3,844	869	1/3,783	884	1/3,718	894	1/3,676
Delaware	666	191	1/3,487	212	1/3,142	195	1/3,415	219	1/3,041
Dist. Of Columbia	607	46	1/13,196	42	1/14,452	45	1/13,489	49	1/12,387
Florida	12,938	4,115	1/3,144	4,224	1/3,063	4,153	1/3,115	4,153	1/3,115
Georgia	6,478	2,003	1/3,234	2,474	1/2,618	3,482	1/1,860	3,482	1/1,860
Hawaii	1,108	454	1/2,441	502	1/2,207	522	1/2,123	522	1/2,123
Idaho	1,007	327	1/3,080	328	1/3,070	339	1/2,971	363	1/2,774
Illinois	11,431	2,610	1/4,380	2,835	1/4,032	3,260	1/3,506	2,925	1/3,908
Indiana	5,544	866	1/6,402	905	1/6,126	964	1/5,751	928	1/5,974
Iowa	2,777	1,258	1/2,207	1,363	1/2,037	1,367	1/2,031	1,409	1/1,970
Kansas	2,478	678	1/3,655	623	1/3,978	675	1/3,671	675	1/3,671
Kentucky	3,685	1,034	1/3,564	1,037	1/3,554	1,090	1/3,381	1,085	1/3,396
Louisiana	4,220	587	1/7,189	559	1/7,549	515	1/8,194	533	1/7,917
Maine	1,228	360	1/3,411	367	1/3,346	360	1/3,411	360	1/3,411
Maryland	4,781	520	1/9,194	518	1/9,230	602	1/7,942	679	1/7,041
Massachusetts	6,016	1,574	1/3,822	1,663	1/3,618	1,813	1/3,318	1,813	1/3,318
Michigan	9,295	2,435	1/3,817	2,527	1/3,678	2,568	1/3,620	2,676	1/3,473
Minnesota	4,375	1,702	1/2,571	1,622	1/2,697	1,823	1/2,400	1,863	1/2,348
Mississippi	2,573	330	1/7,797	335	1/7,681	311	1/8,273	334	1/7,703
Missouri	5,117	1,875	1/2,729	1,827	1/2,801	1,871	1/2,735	1,877	1/2,726
Montana	799	245	1/3,261	256	1/3,121	277	1/2,884	277	1/2,884
Nebraska	1,578	273	1/5,780	296	1/5,331	310	1/5,090	338	1/4,668
Nevada	1,202	342	1/3,515	356	1/3,376	385	1/3,122	414	1/2,903
New Hampshire	1,109	450	1/2,464	497	1/2,231	435	1/2,549	423	1/2,621
New Jersey	7,730	2,881	1/2,683	3,160	1/2,446	3,387	1/2,282	3,255	1/2,374
New Mexico	1,515	580	1/2,612	590	1/2,568	553	1/2,740	493	1/3,073
New York	17,990	5,127	1/3,509	5,909	1/3,045	5,524	1/3,257	5,757	1/3,124
North Carolina	6,629	1,356	1/4,889	1,399	1/4,738	1,490	1/4,449	1,490	1/4,449
North Dakota	639	230	1/2,778	201	1/3,179	252	1/2,536	224	1/2,852
Ohio	10,847	1,774	1/6,114	1,944	1/5,580	1,877	1/5,779	1,877	1/5,779
Oklahoma	3,146	1,073	1/2,932	1,013	1/3,106	1,062	1/2,962	1,062	1/2,962
Oregon	2,842	886	1/3,208	1,370	1/2,074	1,410	1/2,016	1,394	1/2,038
Pennsylvania	11,882	3,174	1/3,744	3,490	1/3,405	3,434	1/3,460	3,727	1/3,188
Rhode Island	1,003	169	1/5,935	171	1/5,865	170	1/5,900	201	1/4,990
South Carolina	3,487	1,140	1/3,059	1,139	1/3,061	1,165	1/2,993	1,263	1/2,760
South Dakota	696	201	1/3,463	324	1/2,148	317	1/2,196	350	1/1,988
Tennessee	4,877	758	1/6,434	778	1/6,269	802	1/6,081	802	1/6,081
Texas	16,987	3,828	1/4,438	3,960	1/4,290	4,240	1/4,006	4,341	1/3,913
Utah	1,723	544	1/3,167	575	1/2,997	639	1/2,696	700	1/2,461
Vermont	563	223	1/2,525	246	1/2,289	206	1/2,733	235	1/2,395
Virginia	6,187	1,300	1/4,759	1,462	1/4,232	2,308	1/2,681	2,185	1/2,831
Washington	4,867	1,669	1/2,916	1,803	1/2,699	1,809	1/2,690	1,993	1/2,442
West Virginia	1,793	244	1/7,348	273	1/6,568	262	1/6,844	267	1/6,715
Wisconsin	4,892	1,677	1/2,917	1,804	1/2,712	1,710	1/2,861	1,875	1/2,609
Wyoming	454	185	1/2,454	182	1/2,495	177	1/2,565	176	1/2,579
U. S. Total	248,710	71,162	1/3,495	75,282	1/3,304	79,674	1/3,122	79,928	1/3,111

*Population statistics taken from 1990 U.S. Census

RATIO OF LICENSES FOR CHIROPRACTORS TO POPULATION BY U.S. STATE

State	*Population (1,000) 2000	Active Licenses 2000	Ratio Chiropractors to population
Alabama	4,447	759	1/5,859
Alaska	627	175	1/3,582
Arizona	5,131	2,488	1/2,062
Arkansas	2,673	557	1/4,800
California	33,872	12,600	1/2,688
Colorado	4,301	2,063	1/2,085
Connecticut	3,405	893	1/3,814
Delaware	784	242	1/3,238
Dist. of Columbia	572	35	1/16,344
Florida	15,982	4,335	1/3,687
Georgia	8,186	3,552	1/2,305
Hawaii	1,211	521	1/2,325
Idaho	1,294	363	1/3,565
Illinois	12,419	2,925	1/4,246
Indiana	6,080	964	1/6,307
Iowa	2,926	1,309	1/2,235
Kansas	2,688	932	1/2,884
Kentucky	4,042	1,121	1/3,605
Louisiana	4,469	1,289	1/3,467
Maine	1,275	355	1/3,591
Maryland	5,296	587	1/9,023
Massachusetts	6,349	1,934	1/3,283
Michigan	9,934	2,755	1/3,606
Minnesota	4,919	1,960	1/2,510
Mississippi	2,845	339	1/8,391
Missouri	5,595	1,917	1/2,919
Montana	902	302	1/2,987
Nebraska	1,711	324	1/5,282
Nevada	1,998	427	1/4,680
New Hampshire	1,236	449	1/2,752
New Jersey	8,414	3,383	1/2,487
New Mexico	1,819	493	1/3,690
New York	18,976	5,885	1/3,224
North Carolina	8,049	1,628	1/4,944
North Dakota	642	240	1/2,676
Ohio	11,353	2,015	1/5,634
Oklahoma	3,451	867	1/3,980
Oregon	3,421	1,396	1/2,451
Pennsylvania	12,281	3,704	1/3,316
Rhode Island	1,048		
South Carolina	4,012	1,263	1/3,176
South Dakota	754	346	1/2,182
Tennessee	5,689	802	1/7,094
Texas	20,852	4,268	1/4,886
Utah	2,233	754	1/2,962
Vermont	609	215	1/2,832
Virginia	7,078	1,311	1/5,399
Washington	5,894	1,938	1/3,041
West Virginia	1,808	276	1/6,552
Wisconsin	5,364	1,584	1/3,386
Wyoming	494	171	1/2,888
U.S. Total	281,421,906	81,011	

*Active Status Information Not Given

Population statistics taken from 2000 U.S. Census

PROVIDER LICENSING BY STATE AND SPECIALTY, AUGUST 6, 2001

STATE	CHIRO- PRACTORS	ACUPUNCTURISTS				MASSAGE THERAPISTS			NATURO- PATHS	DIETITIANS			
	Licensing Laws	Licensing Laws	Access Requires MD Referral and/or Prior Diagnosis	MD Supervision Required	May dispense TCHS	MD Supervision Required	Licensing Laws	Regulated	Licensing Laws Pending	Licensing Laws	Registration Laws	Licensing Laws	Certification Laws
Alabama	0						0				0	0	
Alaska	0	0						0		0	0	0	
Arizona	0	0			0			0		0	0	0	
Arkansas	0	0			0		0				0	0	
California	0	0			0			0			0		
Colorado	0	0			0			0			0		
Connecticut	0	0					0			0	0		0
Delaware	0						0				0		0
Florida	0	0			0		0				0	0	
Georgia	0	0			0			0			0	0	
Hawaii	0	0			0		0			0	0	0	
Idaho	0	0			0			0			0	0	
Illinois	0	0	0					0			0	0	
Indiana	0	0	0					0			0		0
Iowa	0	0					0				0	0	
Kansas	0							0			0	0	
Kentucky	0							0			0	0	
Louisiana	0	0		0		0	0				0	0	
Maine	0	0					0			0	0	0	
Maryland	0	0					0				0	0	
Massachusetts	0	0			0			0			0	0	
Michigan	0							0			0		
Minnesota	0	0			0			0			0	0	
Mississippi	0							0	0		0	0	
Missouri	0	0					0				0	0	
Montana	0	0			0			0		0	0	0	
Nebraska	0						0				0	0	
Nevada	0	0			0			0			0		
New Hampshire	0	0			0		0			0	0	0	
New Jersey	0	0	0		0		0				0		
New Mexico	0	0			0		0				0	0	
New York	0	0					0				0		0
North Carolina	0	0			0		0				0	0	
North Dakota	0						0				0	0	
Ohio	0	0	0	0		0	0				0	0	
Oklahoma	0							0			0	0	
Oregon	0	0			0		0			0	0	0	
Pennsylvania	0	0		0		0		0			0		
Rhode Island	0	0					0				0	0	
South Carolina	0	0	0	0		0	0			0	0		
South Dakota	0							0			0	0	
Tennessee	0	0					0				0	0	
Texas	0	0	0		0		0				0	0	
Utah	0	0					0			0	0		0
Vermont	0	0			0			0		0	0		0
Virginia	0	0					0				0		
Washington	0	0					0			0	0		0
Washington, DC	0	0					0				0	0	
West Virginia	0	0			0		0				0	0	
Wisconsin	0	0					0				0		0
Wyoming	0							0			0		
Count	51	40	6	4	20	4	30	20	1	11	50	33	8

PROVIDER LICENSING BY STATE AND SPECIALTY, AUGUST 6, 2001

STATE	CHIRO- PRACTORS	ACUPUNCTURISTS				MASSAGE THERAPISTS				NATURO- PATHS	DIETITIANS		
	Licensing Laws	Licensing Laws	Access Requires MD Referral and/or Prior Diagnosis	MD Supervision Required	May dispense TCHS	MD Supervision Required	Licensing Laws	Regulated	Licensing Laws Pending	Licensing Laws	Registration Laws	Licensing Laws	Certification Laws
Alabama	0						0				0	0	
Alaska	0	0						0		0	0	0	
Arizona	0	0			0			0		0	0		
Arkansas	0	0			0		0				0	0	
California	0	0			0			0			0		
Colorado	0	0			0			0			0		
Connecticut	0	0					0			0	0		0
Delaware	0						0				0		0
Florida	0	0			0		0				0	0	
Georgia	0	0			0			0			0	0	
Hawaii	0	0			0		0			0	0	0	
Idaho	0	0			0			0			0	0	
Illinois	0	0	0					0			0	0	
Indiana	0	0	0					0			0		0
Iowa	0	0					0				0	0	
Kansas	0							0			0	0	
Kentucky	0							0			0	0	
Louisiana	0	0		0		0	0				0	0	
Maine	0	0					0			0	0	0	
Maryland	0	0					0				0	0	
Massachusetts	0	0			0			0			0	0	
Michigan	0							0			0		
Minnesota	0	0			0			0			0	0	
Mississippi	0							0	0		0	0	
Missouri	0	0					0				0	0	
Montana	0	0			0			0		0	0	0	
Nebraska	0						0				0	0	
Nevada	0	0			0			0			0		
New Hampshire	0	0			0		0			0	0	0	
New Jersey	0	0	0		0		0				0		
New Mexico	0	0			0		0				0	0	
New York	0	0									0		0
North Carolina	0	0			0		0				0	0	
North Dakota	0						0				0	0	
Ohio	0	0	0	0		0	0				0	0	
Oklahoma	0							0			0	0	
Oregon	0	0			0		0			0	0	0	
Pennsylvania	0	0		0		0		0			0		
Rhode Island	0	0					0				0	0	
South Carolina	0	0	0	0		0	0				0		
South Dakota	0							0			0	0	
Tennessee	0	0					0				0	0	
Texas	0	0	0		0		0				0	0	
Utah	0	0					0			0	0		0
Vermont	0	0			0			0		0	0		0
Virginia	0	0					0				0		
Washington	0	0					0			0	0		0
Washington, DC	0	0									0	0	
West Virginia	0	0			0		0				0	0	
Wisconsin	0	0					0				0		0
Wyoming	0							0			0		
Count	51	40	6	4	20	4	30	20	1	11	50	33	8

NUMBER OF COMPLEMENTARY HEALTH CARE PROVIDERS IN STATES WITH LICENSURE LAWS
August 14, 2001

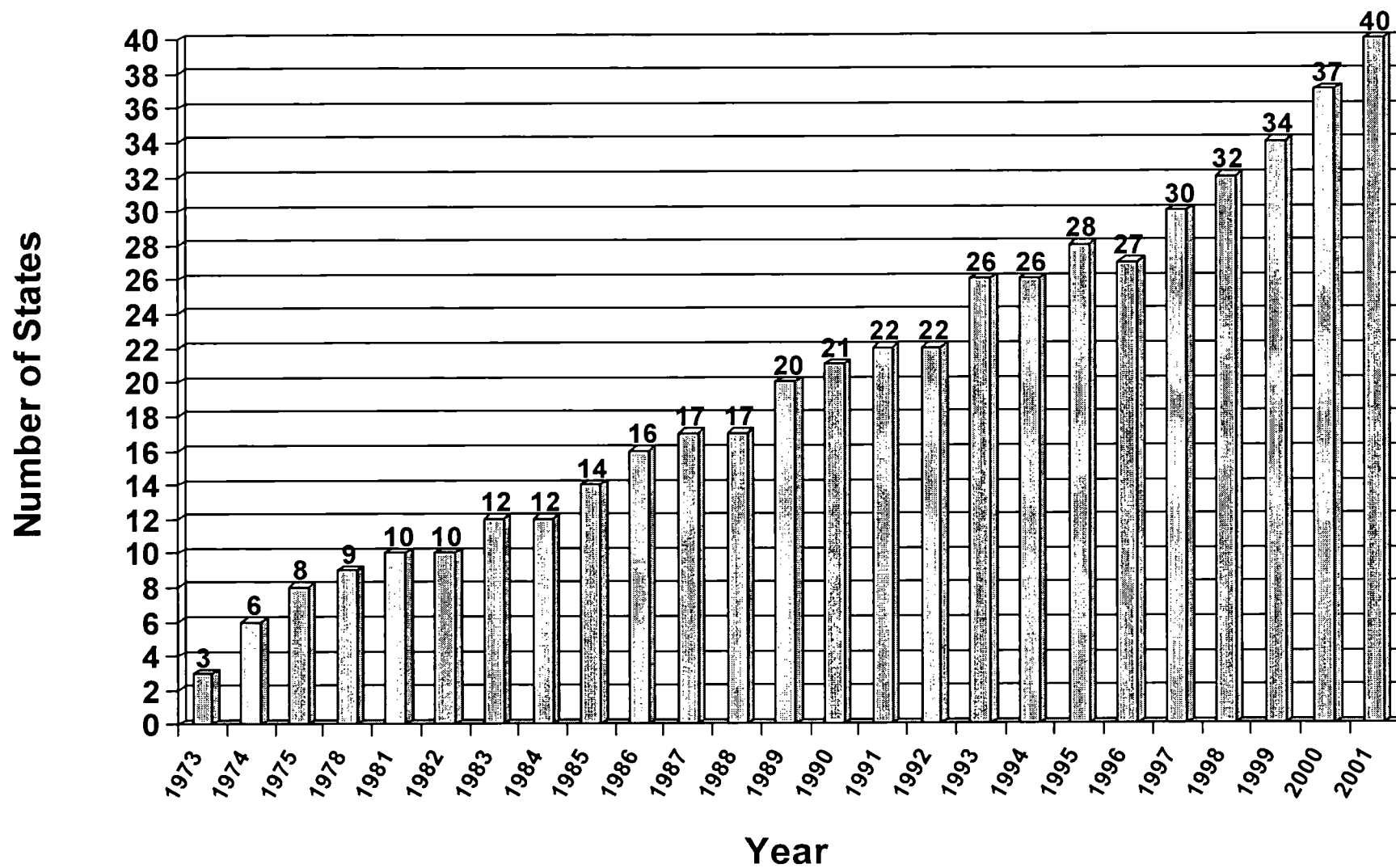
State	Chiropractic	Acupuncture	Massage Therapy	Naturopathy	Dietetics
Alabama	582	0	1,166	0	1,639
Alaska	160	47	0	25	179
Arizona	1,625	142	0	200	0
Arkansas	451	17	1,340	0	831
California	11,528	5,321	0	0	0
Colorado*	2,063	386	0	0	0
Connecticut	710	163	Data not available	120	0
Delaware	129	0	167	0	0
Florida*	4,335	1,029	17,490	0	4,490
Georgia*	3,552	8	0	0	2,449
Hawaii*	521	405	3,620	58	477
Idaho	316	45	0	0	510
Illinois	2,555	224	0	0	5,791
Indiana*	964	0	0	0	0
Iowa	1,057	19	1,085	0	1,308
Kansas*	680	0	0	0	1,246
Kentucky	661	0	0	0	1,514
Louisiana	470	3	1,405	0	9
Maine*	355	79	1,020	11	1,912
Maryland	587	720	1,570	0	2,507
Massachusetts*	1,934	805	0	0	3,347
Michigan	2,008	0	0	0	0
Minnesota	1,873	119	0	0	2,836
Mississippi	239	0	0	0	958
Missouri	1,589	0	703	0	2,337
Montana	266	117	0	25	370
Nebraska	319	0	727	0	1,114
Nevada	428	29	0	0	0
New Hampshire	294	0	1,123	18	640
New Jersey*	3,383	180	1,527	0	0
New Mexico	375	498	2,100	0	571
New York	4,819	11,200	8,450	0	0
North Carolina	1,169	146	2,493	0	2,838
North Dakota	212	0	441	0	461
Ohio	1,885	11	5,607	0	6,634
Oklahoma	667	0	0	0	1,343
Oregon	983	326	3,256	411	1,301
Pennsylvania*	3,704	545	0	0	0
Rhode Island	200	99	494	0	561
South Carolina	736	73	1,343	0	0
South Dakota	241	0	0	0	310
Tennessee	682	0	1,531	0	2,140
Texas	3,719	409	Data not available	0	6,877
Utah*	754	37	3,500	14	0
Vermont	138	76	0	22	0
Virginia*	1,311	80	1,218	0	0
Washington	1,775	535	8,125	471	0
Washington, DC*	35	128	Data not available	0	314
West Virginia	198	40	Data not available	0	439
Wisconsin	1,272	133	1,311	0	0
Wyoming	95	0	0	0	0
Total	70,604	14,194	72,812	1,375	60,253

* denotes States where "resident" license data was not available. "Active" license data was reported.
This only applies to Chiropractic license information

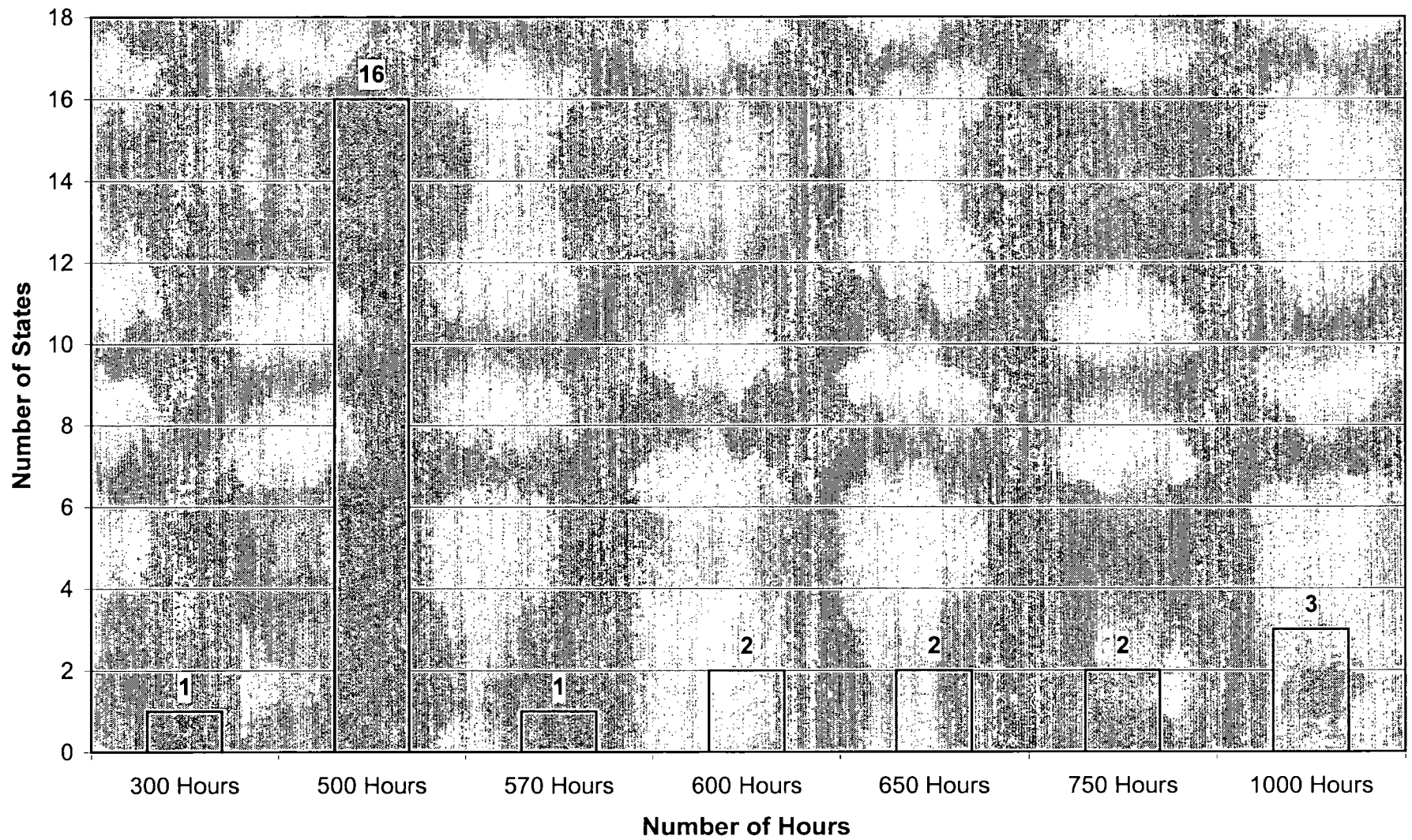
Information obtained from:

- 1) State Licensing Boards
- 2) Federation of Chiropractic Licensing Boards (FCLB). Official Directory – Chiropractic Licensure and Practice Statistics. Greeley: FCLB, 2001.
- 3) State Licensing Board websites.

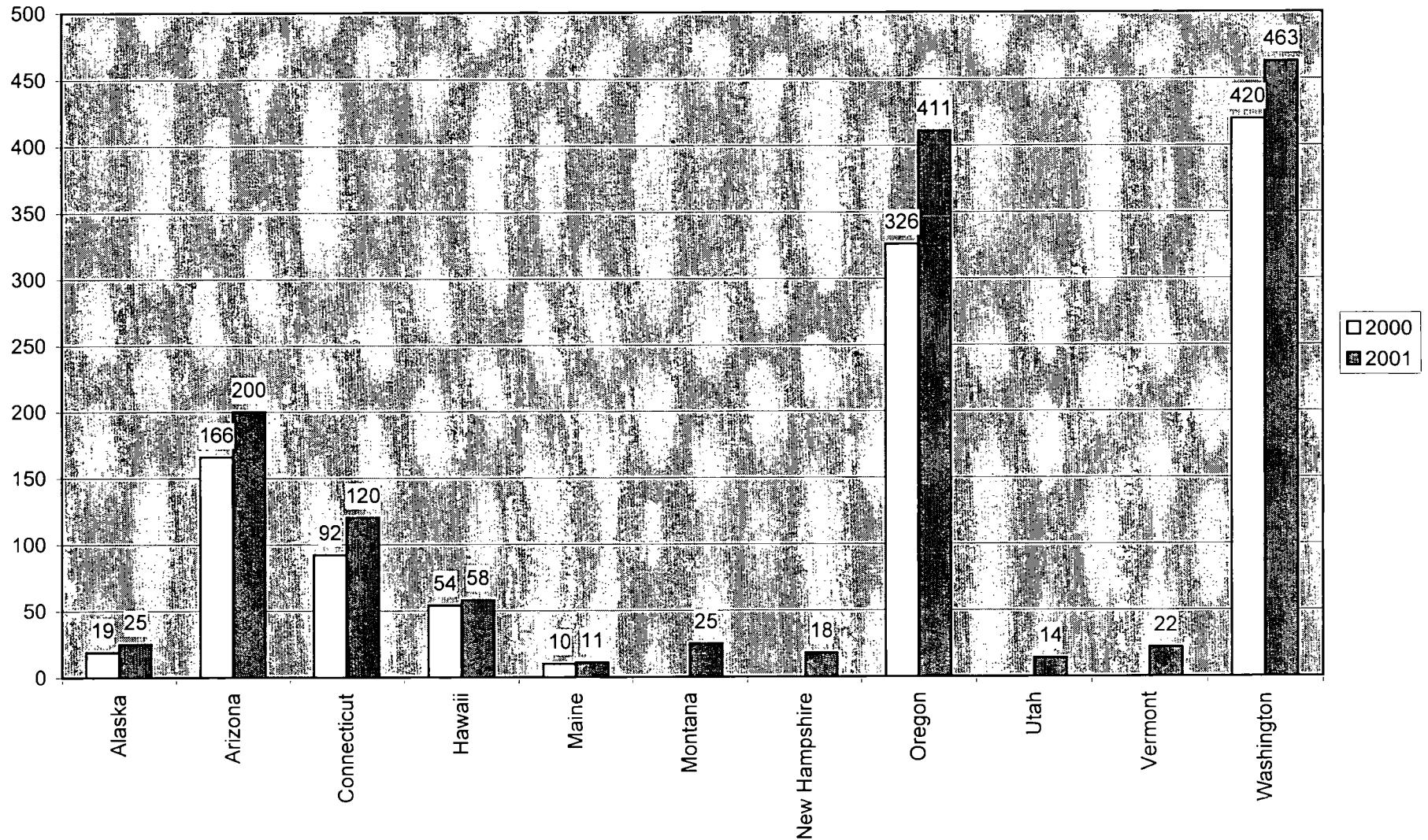
Number of States Licensing Acupuncture, 1973 - 2001



Education Requirements for Massage Therapists by Number of Hours



Comparison of Number of Naturopaths in States with Licensure Laws, 2000 - 2001



Present at Public

Hearings on 12/20/04

1. Hearings - 1 town 1 July

Get feedback to town
meeting to express

needs & issues

Consistent - become

Bill Duncan

Barkeley Phone #

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Appendices

- A: Health Freedom Working Group papers, April 25, 1997.
- B. "Why Patients Use Alternative Medicine," *The Journal of the American Medical Association*, May 20, 1998.
- C. "Alternative Medicine and the Conventional Practitioner", *Pulse*, March 4, 1998.
- D. "Introduction: History of Medicine in the United States," by Larry Dossey, M.D. and James P. Swyers, M.A.; *Alternative Medicine: Expanding Medical Horizons; A Report to the National Institutes of Health on Alternative Medical Systems and Practices in the United States*, September 14-16, 1992.
- E. "A Fixed Star in Health Care Reform: The Emerging Paradigm of Holistic Healing," by Michael H. Cohen, J.D.; *Arizona State Law Journal*, 27:79, 1995.
- F. "Are Clinical trials Really the Answer?", by Gladys Block; *American Journal of Clinical Nutrition*, 1995:62.
- G. "Who's Absurd?", Editorial; *Natural Health Magazine*, March/April 1995.

Executive Summary

National Plan to Advance Integrated Health Care

We have prepared the following *National Plan to Advance Integrated Health Care*, in order to help focus the health care debate in the coming millennium. As representatives of consumers and practitioners, educational institutions and industry, we are dedicated to promoting national policies that will facilitate research, appropriate standards for professions as well as products, and increased consumer access to complementary and alternative therapies. We believe that a coordinated national effort, initiated at the highest levels of the federal government, is needed to ensure that the American public benefits from advancements in the science and understanding of all health care systems, disciplines and modalities.

The public health is best served by removing barriers to access, either via legislation, regulation, peer pressure, administrative law, or other means. The public will be well served by the objective and open examination of all health care systems, disciplines, and modalities, and the restoration of health care decision-making authority to consumers. In addition to eliminating barriers to access, we believe research must be done by as many public and private agencies as possible; integrated-care pilot projects must be developed to observe and analyze results; training and practice standards must be identified or developed for individual disciplines; open lines of communication must be maintained between policy makers, practitioners and patients; and the right to make their own health care decisions must be guaranteed for all Americans.

Our goal is for Americans to have equal access to all qualified practitioner types and for practitioners to have an equal opportunity to participate in all federal programs, and should they so chose, to participate in an integrated health care system free from bias and discrimination. We hope to help create a health care environment in which practitioners can practice in good conscience, with the well being of patients foremost in their minds and without fear of censure or recrimination for the use of complementary and alternative therapies. Consumers need to have confidence in the quality and safety of the products and therapies available to them; and confidence in the abilities and expertise of the practitioners they choose to see. For all of this to occur, the following issues need to be addressed in a coordinated manner:

I. Increased Research

Opportunities must be created to fund research for appropriate scientific and evidence-based models and databases for complementary and alternative medicine (CAM) and integrated health care (IHC).

II. Accountability and Education

Standards of accountability and education in CAM systems and disciplines must be recognized, researched and addressed. These standards must be further developed for those in emerging professions, for practitioners incorporating CAM therapies in conventional practices, and for licensed practitioners in established professions

III. Under served and Special Needs Populations

Greater access to CAM can benefit the American public at large, and can particularly benefit certain special needs populations.

IV. Regulation and Access to CAM Products and Devices

Opportunities *must* be created and barriers to access removed so that practitioners have more freedom to use and integrate CAM therapies into their practices, and so that consumers have access to the full range of health promotion and disease treatment approaches.

V. Federal Benefits Discrimination Against CAM

CAM providers and therapies should be included in all federal health care initiatives as a matter of policy. This would result in a dramatic increase in individuals' health care freedom, individuals' access to a broader array of therapies, significant cost savings, improved health, and a more egalitarian health care system.

VI. Clinical Practice, Quality of Care, Delivery Systems

The diversity of treatment options for patients *must* be increased; in addition, we must ensure that the practitioners have met educational and/or credentialing criteria and that adequate consumer protections are in place. A combination of solid practitioner training, appropriate standards of practice, increased research, and consumer education will result in better, safer, more equitable health care for all Americans.



We would like to emphasize that if only *one* of the proposed policy changes we have proposed was enacted -- a new and focused federal effort on disease prevention -- millions of Americans could experience longer, healthier lives. The ten leading causes of death, which affect 82 percent of all Americans, are highly preventable yet not easily addressed if we limit ourselves to conventional therapies. As such, we believe there is a moral imperative to create a health care environment in which the full range of therapies and full complement of practitioners is accessible to every American; and in which research concentrates not just on disease but on disease prevention. Without these changes, health care costs will continue to skyrocket; a two tiered system of health care will become firmly entrenched; and the health and quality of life for millions of Americans will suffer from a system of inequality mandated and maintained by federal policies.

The following report elaborates on these proposals. It is designed to spur national debate and to focus attention on the very timely need to revamp our national health care policies, and on the costs of failing to do so. It is our hope that policy makers as well as stakeholders will respond by joining together in taking the steps necessary to move this discussion forward.

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National Plan to Advance Integrated Health Care

I. RESEARCH ISSUES AND GOALS

Goal Statement: Opportunities must be created to fund research for appropriate scientific and evidence-based models and databases, and to assess public health and economic impact for Complementary and Alternative Medicine (CAM) and Integrated Health Care (IHC). The new NIH Center for Complementary and Alternative Medicine (NCCAM), with its increased funding and broader research mission, should be structured to participate as fully as possible (both directly and collaboratively with other agencies) in a comprehensive CAM research agenda.

Background: The NIH research mandate, which supports primarily large-scale controlled clinical trials of single therapeutic agents in placebo-controlled designs (and some basic sciences research) has generally been inadequate to measure the efficacy and value of CAM. With the creation of the new NCCAM, we expect the following issues will be addressed:

- Most CAM systems and modalities involve the use of multiple agents and rely to some undetermined extent on synergistic therapeutic interactions. Single-agent research does not adequately evaluate the effectiveness of multifactorial, integrated treatment plans.
- Placebo-controlled research poses an ethical problem for many CAM providers because its structure requires withholding a treatment believed to be effective from an ill patient.
- A major strength of many CAM systems is the ability to individualize treatment plans to accommodate each patient's unique presentation of health and illness. Health outcomes using these systems cannot be measured by the current NIH mandate and model.
- CAM systems of diagnosis, treatment, prevention and case management impact safety and efficacy, and direct the use of substances, methods and individualization of care. Systems must be studied, as well as substances and methods, and the effects on pathology and health status must be analyzed.
- Integrated Health Care (IHC) systems are developing; the effect of these systems on health and cost of delivery does not currently fall within the NIH operation, except under the new NCCAM.

Many of these research issues also exist in conventional medicine. Due to CAM systems approaches, however, they become essential priorities for validating effectiveness of CAM methods and systems.

A. Many appropriate and effective models are available to do credible research into CAM efficacy, cost effectiveness and safety. Outcomes and health services research needs to be done on public impact, costs, standards and effectiveness of CAM and Integrated Health Care (IHC).

1. Clinical epidemiological studies can be done to collect and analyze data on utilization patterns within CAM services.
2. Outcomes research includes a variety of possible targets and structures:
 - a. Western diagnosis- and symptom-related clinical outcomes (verified by objective laboratory and assessment tools) can be evaluated and compared to CAM treatment methods. (Non-western diagnostic and wellness approaches may be addressed in future strategic planning.)

- b. Quality of life and wellness measures can be obtained prior to and subsequent to treatment. Functionality and patient/provider perceptions of functionality should be measured, as should health performance indicators (Healthy People 2010 initiative).
 - c. Cost comparison outcomes across certain diagnoses or health conditions can be measured and then correlated with measures of effectiveness and patient satisfaction.
 - d. Systems of case management must be correlated with measures of clinical effectiveness and patient satisfaction.
 - e. Clinical results in integrated care models can be compared to those from conventional and alternative providers working in non-integrated settings.
3. Randomized clinical trials can and should be done in the accepted NIH model to test the individual efficacy of single agents on specific conditions. They should be one part of a multifaceted research agenda.
4. Basic science research should be funded to a much greater extent to do *in vitro* and bench research on mechanisms of action.
5. Systematic literature reviews summarizing research already published in the peer reviewed literature should be funded. CAM and IHC research and practice literature must be collected, organized, evaluated and made accessible to the scientific community at large and to the public.
6. Meta analyses can be done to evaluate groups of randomized clinical trials; such major overviews of past research can be of critical importance in choosing directions for future research and in guiding the development of education and policy.
7. Demonstration and pilot projects often provide ideal environments in which to perform some of the research described above; they can be efficiently structured to collect data assessing clinical outcomes, patient satisfaction, cost effectiveness, provider skills and competence. Many IHCs and health systems are currently piloting diverse CAM initiatives without necessary funds for proper study design, both for prospective and retrospective analysis. Federal support can rapidly enhance data gathering from these current integration sites.
8. The success of CAM interventions in diminishing the need for, or use of, conventional medications or procedures can be readily tracked, particularly in pilot or demonstration project settings, or in existing integrated care settings. (Three studies -- Landmark 1997, Alternare/Group Health Cooperative-Premiera Blue Cross 1997, and Stanford/ASHP 1998 -- all found that a significant percentage of CAM users [30% to 62%] believe that CAM has diminished use of conventional services [office calls and/or prescription drugs]. Perception of diminished use of conventional services was highest in the most controlled environment. This significant pattern of perceptions demands analysis, particularly in a time when health costs are once again soaring.)
9. Federal agencies can work with insurers and HMOs to analyze "add-on versus replacement" data for CAM interventions. This requires analysis of both patient perceptions and of claims data for significant populations, preferably both retrospectively and prospectively.

10. There needs to be a new emphasis on disease prevention research, and bench science needs to be translated into outcomes. The present system rewards physicians for treatment, not prevention, yet the ten leading causes of death, affecting 82% of all Americans, are highly preventable.

B. There are many federal agencies in addition to the new Center for Complementary and Alternative Medicine where research such as that described above can and should be funded:

1. **Clinical Epidemiological Research (including Meta Analyses)**
Centers for Disease Control and Prevention (CDCP)
Practice Investigation Unit
CDCP Surveys of Health Trends and Practices
CDCP Practice Based Research Network
2. **Outcomes Assessment, Including Cost Effectiveness**
Agency for Health Care Policy and Research (AHCPR)
CAM and IHC funding for Evidence-Based Practice Centers
AHCPR: Program on CAM effectiveness
AHCPR-IOM (Institute of Medicine)
Outcomes and Effectiveness Research
Technology Assessment Guidelines
CDCP Field Investigation Activities and Surveys of Health Trends and Practices
Practice Effects and Safety Surveillance Research
Health Care Financing Administration
CAM and IHC Benefits
3. **Randomized Clinical Trials and Basic Science Research**
NIH-NCCAM:
Supporting centers of CAM research
Supporting clinical research development
Supporting research training for CAM -licensed and medical researchers
NIH Centers and Institutes:
Supporting clinical trials in their areas
4. **Basic Science Research**
National Institutes of General Medical Science (NIGMS)
5. **Systematic Literature Reviews of CAM and IHC Research**
Obtaining Literature
National Library of Medicine (MEDLINE)
National Center of Complementary and Alternative Medicine
Worldwide database of CAM and IHC research and practice
Evaluating Literature
Agency for Health Care Policy and Research
Cochrane Collaboration
IHC Services Task Force Report (e.g., US Preventive Services Task Force for Prevention) with shared representation among CAM and conventional providers

6. **Demonstration and Pilot Projects**

Health Resources and Services Administration (HRSA): Bureau of Primary Health Care

Education demonstration project: IHC/CAM residency exchange program involving CAM and conventional medical schools

Demonstration projects for minority and under served

Department of Defense Demonstration and Grant Programs

Chiropractic Demonstration Project

Breast Cancer CAM Grants

State and County Health Department Project

King County Natural Medicine Clinic

Community health centers and integrated health care projects

Veterans Administration

Demonstration Project for Veterans

AHCPR

Multi center clinical demonstration projects using combined CAM and IHC delivery systems

C. **Barriers to funding such research include:**

- In general, authorizing legislation for federal agencies is not inclusive of CAM fields or IHC.
Rules and regulations do not include CAM fields, nor do they identify pathways for integration; independent funding approval may be needed for CAM/conventional and IHC collaboration.
- The management of a complex, multi-agency plan such as the one proposed herein may be very unwieldy unless coordinated at a higher level.
- Current research infrastructure is completely dominated by conventional medicine; there is a considerable risk of having CAM systems and disciplines conventionalized or co-opted if forced to operate solely on territory which is already ruled by a huge, powerful, biased vested interest. (NIH-NCCAM is an example. Stephen Barrett - a famed "quack buster" who is unalterably opposed to advancing alternative medicine - was placed on the scientific review panel for the only Center grant renewal application from a CAM credentialed Center!)
- Licensed, credentialed CAM providers need to be adequately represented on Advisory Board and Scientific Review Panels, as mandated for the new NIH-NCCAM.
- Investigational New Drug (IND) applications are required for nonpharmaceutical research (clinical trials). This process for low- or no-toxicity CAM products is prohibitive and unnecessary.
- Pre and post-doctoral research fellowship qualifications do not specify CAM providers in list of authorized degrees.
- Requiring the CAM professions to interface with the huge, complex governmental research bureaucracy as though these professions had well-developed and well-resourced institutional infrastructures for such purposes belies reality.
- Implementing these research goals may require a broader mission than some agencies currently subscribe to (or perhaps are legislatively authorized for).

D. **Action Steps**

- Establish an office on CAM and IHC at the Department of Health and Human Services with authority to coordinate and direct all federal CAM activities.

- Establish a commission on CAM and Integrated Health Care, as mandated in the NCCAM bill language.
- Establish a nondiscrimination policy affecting all funding at the federal level, requiring even-handed treatment of all systems, disciplines and modalities.
- Research legislation and rules which control the listed agencies, and propose amendments and rule changes as necessary to support inclusion of CAM and IHC.
- Ensure that licensed CAM providers from all CAM fields, and credentialed IHC proponents, are represented on Advisory Boards and Scientific Review Panels at NIH-NCCAM and other agencies as appropriate, including Office on CAM and IHC at HHS.
- Fund basic sciences and clinical trials research centers at CAM institutions to help support the necessary development of a research infrastructure.
- Establish pre- and post-doctoral research fellowships in CAM institutions.
- Support CAM and conventional research collaborations.
- Establish "Blue Ribbon" Panels to direct the Office and Congress (see above) on CAM and IHC policy and legislative requirements and to increase communication and education and collaboration among legislators, regulators, federal agency personnel, third party payers; CAM educators, licensed CAM providers, researchers and practitioners; and conventionally trained Integrated Health Care proponents. It is essential that the make-up of all such panels be cross disciplinary.
- Direct the federal commission to identify the most effective use of federal dollars to support and enhance CAM research opportunities currently underway or intended in the not-for-profit and for-profit hospital, HMO, insurance, IHC, and CAM provider networks.

F. Priorities

- Provide funding support for development and operation of individual or consortium research centers funded by NIH-NCCAM, to include accredited complementary and alternative medicine research and education facilities.
- Fund outcomes research (see above).
- Fund demonstration project via HRSA on education and cross-disciplinary training involving CAM colleges and conventional medical schools, as well as projects to increase CAM access for minority and under served populations.
- Fund collaborative CAN/conventional residency exchange programs and residential programs in CAM institutions.
- Fund research on institutional, provider and patient outcomes, including co-management team outcomes.
- AHCPR: Establish a competitive bid process to support and research one dozen clinics in US in various sectors, selection to be made with IHC and CAM accredited institutions. Produce data and reports, including longitudinal data. Needs 5 years funding minimum.
- Encourage research in disease prevention.

II. ACCOUNTABILITY AND EDUCATION

Goal Statement: The established standards of accountability and education in CAM systems and disciplines must be recognized, researched and addressed. Further standard development must be supported for emerging professions, for practitioners incorporating CAM therapies in conventional practices, and for licensed practitioners in established professions.

Background: Recent estimates of CAM use in the United States range from 40% of the populace (Astin, J: Why patients use alternative medicine; JAMA, May 20, 1998;279:1548-1553) to as high as 69% (Stanford University/American Specialty Health Plan national consumer survey, reported 9/18/98). A growing number of community health centers, private clinics and hospitals are slowly integrating CAM with existing services. Such a high level of use demands a responsible evaluation of public accountability in the education of CAM providers and the use of CAM systems and modalities. Such an evaluation must be made in the context of knowledge about emerging professions, including understanding recognizable stages and markers of development. The goal must be to recognize, articulate and help strengthen the education and standards of emerging and established CAM professions in order to improve public accountability in research, clinical practice, and developing integration models. (Significant differences exist in scope of practice from jurisdiction to jurisdiction, making delivery of covered services more problematic, particularly for national purchasers.) Many CAM standards have already been well developed. These standards must be integrated into mainstream delivery systems to insure accountable access.

Broad state practice acts for medical doctors are outdated in today's health care environment. Safety and efficacy in health care are at least partially dependent on credentialing providers in an accountable way to the highest available education and training standards to support scope of practice in various disciplines. The broad practice act ironically may put the consumer at increased risk of ineffective, costly or hazardous practices by MDs who are poorly trained in CAM systems or modalities and have not had their competency in those disciplines or modalities assessed before practicing. High standards have been developed and sanctioned and are being used by public agencies for many CAM providers, but the standards are not applied to M.D.s and other conventionally-trained providers.

A. Differentiate Among CAM Systems, Modalities And Disciplines; Identify Providers

1. Systems/Disciplines

- Ayurvedic Medicine
- Chiropractic Medicine
- Homeopathic Medicine
- Midwifery
- Naturopathic Medicine
- Oriental Medicine/Traditional Chinese Medicine
- Tibetan Medicine
- Traditional and indigenous health care systems

2. Modalities

- Acupuncture
- Botanical Medicine

Chelation
 Health Psychology
 Hydrotherapy
 Lifestyle and Wellness Counseling (including dietary changes and exercise planning)
 Massage
 Nutritional Medicine
 Physical Medicine (i.e., Physiotherapy, Physical Therapy, and Manipulation)
 Spiritual Healing
 Natural Hygiene

3. Providers using at least one of the systems/disciplines and modalities shown above:

Licensed

Acupuncturists (CA, LAc)
 Chiropractors (DC)
 Massage therapists (LMP, LMT)
 Medical doctors (MD)
 Midwives (LM)
 Naturopathic doctors (ND)
 Nurses/ Nurse Practitioners (RN, NP)
 Nutritionists, Registered Dieticians
 Osteopathic doctors (DO)
 Others

Other professional credentialing (may be progressing toward licensure in some states)

Certified nutritionists (CNS)
 Oriental medical doctors (OMD)
 Professional homeopaths
 Professional hygienists

Unregulated (although some non governmental certifications may be available)

Bodywork specialists (Feldenkrais, Rolfers, etc.)
 Fitness/Spa professionals and personal trainers
 Herbalists
 Hydrotherapists
 Lay homeopaths
 Lay midwives
 Lifestyle counselors/health advisors
 Spiritual healers
 Tibetan/Ayurvedic/Yunani practitioners
 Yoga, Tai Chi, Qi Gong instructors

B. Identify and evaluate types of public accountability for CAM education and clinical practice in use today: regulation, recognition or other activities which address public accountability issues.

Accreditation of colleges, curricula and programs
 Board exams for national certification
 Board exams for state licensure
 Continuing education
 Disciplinary guidelines

Educational standards
Licensure and scope of practice
Peer review
Practice guidelines
Research
Quality improvement and quality assurance plans

C. Articulate patterns of emerging professions which may need to be understood and nurtured through transitional phases in public accountability.

1. Report on the general process, criteria and steps involved in a profession's emergence; know the history and stages of emergence which today's well-established professions passed through.
2. Report on status today of all emergent and emerging CAM professions with respect to categories shown above; fund projects for strengthening key standards where necessary.
3. Recommend public agency support to assist in nurturing, accrediting, and facilitating emerging professions as they establish standards for public accountability.

D. Address Conventional Provider Access Issues for CAM

1. Presence or lack of standardized or accredited education for conventional providers using CAM modalities and disciplines should be addressed.
 - a. Articulate and support standards of credentialed CAM training (where available) for non-CAM providers.
 - b. Articulate CAM, conventional and IHC resources for cross-training; support the development of such resources, and fund and replicate existing credentialed training programs.
 - c. Articulate standards of professional accreditation, continuing education, credentialing for reimbursement, and licensure models as they relate to non CAM providers and their scope of practice in CAM modalities and disciplines.
2. Address safety and efficacy issues which the current situation may give rise to.

E. Facilitate Integration of Standards into Mainstream Health Care Systems

1. Identify and describe integration models now in use; disseminate this information. Three such models are integration within single provider (i.e., naturopathic physicians); co-management team; cross-referral and cooperation between institutions and networks.
2. Assess effectiveness of integration and delivery of CAM activities into mainstream systems and into conventional medicine (see Research section above).
3. Support interprofessional association and accreditation (CAM and conventional) coordination.
4. Identify standards gaps and fund consensus projects to recommend improvements.
5. Fund National Congress for CAM and IHC leadership to define consensus recommendations for credentialing standards in White Paper for federal and state guidance.

F. Action Steps

- Research and report on emerging and established accountability standards in health care professions; summarize and compare standards in CAM and non-CAM fields.
- Identify pathways and provide funding for the inclusion of existing CAM standards into established health care systems.
- Fund joint conferencing -- use existing federal agencies and CAM and conventional organizations to coordinate joint offerings in key areas of mutual interest (education, regulation, standards, research).
- HRSA: Bureau of Primary Care and Bureau of Health Professions
- Approve professionally accredited CAM colleges and professions as eligible for grants, for residency and for cross-disciplinary programs.
- Fund Blue Ribbon Panel to investigate issues related to non-CAM providers using CAM methods and make recommendations to Commission (see above) on Action Steps.

G. Priorities

- Hold joint interagency meetings with NIH, FDA, HHS.
- HRSA Bureau of Health Professions and Bureau of Primary Care: Approve accredited CAM colleges and professions for grant eligibility.
- Fund National Congress on Standards/Accountability/Practice/Education/ Reimbursement Systems/Research with Blue Ribbon task force representing accredited colleges of licensed alternative health professions, national associations for licensed CAM professions, and emerging professions. Include organizations and task forces involved with standard setting in CAM education from within conventional medical education.

III. ADDRESS CAM NEEDS IN UNDER SERVED AND SPECIAL NEEDS POPULATIONS

Goal Statement: Greater access to CAM can benefit the American public at large, and can particularly benefit certain special needs populations.

Background: Certain under served or special needs populations now have very limited (or no) access to CAM providers, and therapeutic agents and products used by CAM providers have not previously been covered by Medicare/Medicaid or third party payers. Low income, veterans, tribal people, rural areas, the underinsured, and the disabled are among those groups which could benefit by having greater access and more diversity in health care options. Evaluation of CAM and IHC access is needed to facilitate delivery in these special populations.

A. Identify special needs which CAM providers can help meet.

1. National health shortage areas (HSAs)
2. Public Health Service positions
3. State and county health needs in special populations
4. Community education and support for lifestyle factors
5. Respect for and working with traditional medicines and providers in special populations

B. Identify barriers to implementation.

1. National Health Corps Program includes licensed acupuncturists but does not provide inclusion for licensed CAM providers to fill health care gaps in under served areas. Outreach programs are needed but not funded.
2. Public Health Service authorizing legislation and regulations do not name CAM providers.
3. State and County Health Department boards have no mandate to include CAM representatives.
4. Medicare and Medicaid services and reimbursement for products (Rx) are mostly unavailable, and many government entities use the Medicare authorization language for their own guidelines.
5. Veterans Administration has no mandate to cover CAM and IHC.

C. Action Steps

- Include licensed CAM professions in Medicare/Medicaid regulations.
- Include licensed CAM professions and IHC experts in Public Health facilities, State and County Health Boards and clinics, and National Health Corps Programs.
- Authorize CAM participation in a funded Veterans Administration Demonstration Project.
- Health Resources and Services Administration
 1. Bureau of Primary Health Care Services funding for a demonstration project for under served and minority populations receiving CAM services
 2. Bureau of Health Professions funding for a CAM Residency Training Program in under served/special populations
- Facilitate the integration of co-management teams into state and county health department clinics (with training) using successful models such as the King County Natural Medicine Clinic. Fund training programs (Level 1-4) in CAM disciplines for health care providers in these clinics and systems.

- Fund conference on methods for utilizing CAM health care in under served or special needs population.
- Allow HMOs and provider groups which accept risk on capitated Medicare or Medicaid clients to utilize CAM providers and therapies and to implement integrated health services.
- Create dialog and fund pilot project bringing CAM providers and traditional healers (Native American, Hawaiian, etc.) to a common strategy for their populations.

D. Priorities

- Revise statutes and regulations to provide access to National Health Corps Program for CAM providers.
- Allow access to licensed CAM professions in Medicare/Medicaid and other federal health care programs.
- Fund pilot projects to facilitate the development of integrated care services for under served populations, including co-management training in community health centers.

IV. REGULATION AND ACCESS TO CAM PRODUCTS AND SERVICES

Goal Statement: Opportunities must be created and barriers to access removed so that practitioners have more freedom to use and integrate complementary and alternative therapies (CAM) into their practices, and so that consumers have access to the full range of health promotion and disease treatment approaches.

Background: The general public is turning in ever-increasing numbers to CAM, yet the present system of laws and regulations does not easily accommodate development of integrated health care practices or emerging professions; nor does it allow for advancements in health care to easily reach the public, regardless of whether that care is alternative or conventional. Restrictions on access to information for consumers is analogous to antitrust in business (refer, for example, to the recently proposed and highly inappropriate FDA regulations regarding the use of health-related information on natural products).

- A. **There is a widespread belief that CAM therapies and an increased emphasis on prevention would result in significant cost savings to both individuals and the federal government.** A number of small studies have supported this belief, but much larger ones need to be done.
- B. **Increased access to such therapies would foster the increasing desire of the public to take responsibility for their own health and health care,** a movement that, by itself, will lower costs and improve health.
- C. **Many patients want and deserve both increased access and more information** about the options available to them.
- D. **CAM therapies, as a rule, are safer and less toxic than allopathic therapies** so they can often be tried first, thereby reducing or even eliminating the need for more expensive, invasive and toxic procedures.
- E. **There is a growing science base in support of the safety and efficacy of CAM therapies,** and an increasing willingness to accept the science and experience of consumers and practitioners in other countries who have had decades, even centuries of experience with CAM therapies, thereby reducing or even eliminating the need to duplicate research.
- F. **Barriers to increased access include:**
 - 1. One of the barriers is opposition to CAM by pharmaceutical companies because of the perceived competition from such practices.
 - 2. The Federation of State Medical Boards, and its members believe that increased access will open the door to quackery, exposing vulnerable patients to unnecessary risks and even life-threatening therapies, or failure to use conventional treatments. FSMB members would benefit from guidance in understanding CAM; in properly integrating CAM therapies and practitioners into conventional practices; and in the off-label uses of drugs.
 - 3. There is a perception that CAM presents an economic threat to the allopathic medical industry.

4. Patient-driven health care is a new idea that requires education and changing attitudes among third-party payers, policy makers and mainstream providers.
5. The medical community tends to be unwilling to relinquish control/authority.
6. Competition and rivalries within the CAM community undermine the ability to effect change. Diverse agendas dilute efforts to achieve major changes in the health care environment.
7. Poor science and demagoguery undermine the credibility of valid CAM therapies and make substantiation more difficult.
8. The CAM science base is incomplete and conflicting, primarily because of limited research funding and the ineffectiveness of the Office of Alternative Medicine. It should be noted that CAM research is being measured against a 75-year history of conventional research which was overwhelmingly funded by the Federal Government and pharmaceutical houses, not by the practitioners themselves. The additional funding provided to the new NCCAM should help to remedy this situation, but it will take time.
9. It's difficult to organize and maintain a grassroots effort in support of federal legislation because systemic change is required. Systemic change is difficult to simplify and package; lacks emotional appeal; is expensive to address; and takes a long time to achieve.
10. Insurance coverage of CAM therapies and systems is generally lacking, which is creating a two-tiered system of limited access. Only the best educated or wealthiest Americans now have access to a wide range of therapies. Creation and acceptance of insurance codes is an important step in facilitating this equal access.
11. Lack of access to credentialing, and contracting for CAM providers by plans, creates artificial barriers to what should be a comprehensive, patient-focused health care system.
12. Among policy makers there is a lack of understanding of CAM, which creates barriers to integration.
13. As in any area, there tends to be a reluctance to change the status quo. The American people and especially the American Government want the United States to have the best health care system in the world. Changes in that system are perceived as a negative commentary on the medical community.

G. Action Steps

- Amend administrative laws at the state level to eliminate the unconstitutional, undemocratic behavior of licensing boards, which continue to harass and censure practitioners for the use of CAM products and therapies.
- Promote insurance equality for CAM providers and therapies.
- Change federal laws and regulations so as to create a regulatory system that allows access to non-FDA approved therapies by consumers, within certain guidelines, to prevent the growth of an unregulated black market in CAM therapies, and to eliminate the two-tiered system of access

promoted by the present system.

- Establish a system to collect and disseminate information about promising CAM therapies.
- Promote and fund research on CAM by as many public and private agencies as possible. (See Section I)
- Support, as a matter of national policy, the standards of practice inherent in state licensing laws.
- Support funding by AHCPR for CAM practice guideline projects involving the CAM professions.

H. Priorities

- Eliminate the regulatory, administrative and legal barriers to access for both providers and consumers.
- Maintain open lines of communication between policy makers, practitioners and patients.
- Guarantee the right of all Americans to make their own health care decisions, regardless of race, sex, education, income or eligibility for Medicare.
- Eliminate the barriers to access and information caused by the present drug-approval process and eliminate FDA constraints on the dissemination of truthful, scientific information about natural medicine products such as dietary supplements. The FDA should be relieved of its responsibility to ensure the efficacy of CAM products that are safe.

V. FEDERAL BENEFITS DISCRIMINATION AGAINST CAM

Goal Statement: CAM providers and therapies should be included in all federal health care initiatives as a matter of policy. Agencies which may be affected include the Health Care Financing Administration (Medicare and Medicaid), Congress and Federal Agencies (Federal Employee Health Plans), the Department of Defense, the Veterans Administration, the Indian Health Service, the Substance Abuse and Mental Health Agency, the Food and Drug Administration, the National Institutes of Health, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Agency for Toxic Substances and Disease Registry, the Agency for Health Care Policy and Research, the Public Health Service, the Centers for Disease Control and Prevention, and the Office of Public Health and Science.

Background: The inclusion of CAM in the many health care programs and research initiatives of the Federal Government would result in the widespread and rapid incorporation of CAM therapies in the health care of millions of Americans, resulting in a dramatic increase in health care freedom, individual access to a broader array of therapies, significant cost savings, improved health, and a more egalitarian health care system.

A. There is a tremendous need to reduce health care costs, both on the part of individuals and the Federal Government. The incorporation of CAM therapies and an increasing focus on prevention would result in savings of billions of dollars almost immediately. Diabetes alone consumes nearly 30% of the Medicare budget and it has been demonstrated that a combination of patient education and nutritional approaches could dramatically decrease the costs of patient care. (See Appendix A.)

B. Patients and their families want access to a wider range of therapies and providers. (See attached articles, Appendix B.)

C. Practitioners want to be able to offer a wider range of therapies to their patients than they are currently allowed or reimbursed for.

D. Many licensed providers are not allowed to fully participate in federal health insurance programs (acupuncturists, naturopathic doctors).

E. There is an increasing desire on the part of consumers for freedom and individual choice in health care.

F. Barriers

1. There is often a lack of understanding on the part of policy makers about CAM products and services in general; therefore, they are reluctant to increase access by providing coverage of such products and services in federal health care programs.
2. CAM is perceived as an "add-on" to existing coverage and, therefore, seen as costing the federal government more money instead of the opposite. (See Appendix A.)
- Not all CAM therapies have been researched via the Western scientific method so there is a perception that the therapies are unproved and therefore should not be covered or provided in federal insurance programs.
4. Providers and insurers are afraid that more choice will cause costs to skyrocket.
5. The biomedical model is geared to using a medical doctor as gatekeeper. This gatekeeper has limited knowledge of CAM therapies and is unlikely to either refer or coordinate health care services with CAM providers.

6. The strength of the conventional medical community's desire to protect its turf slows or severely limits the incorporation of CAM products and therapies.
7. The FDA has an institutional bias against CAM. It is not designed to accommodate nonpatentable substances or a holistic approach to health care. Nevertheless, it has complete authority over the use of drugs, devices and foods, and the dissemination of information about drugs, devices and foods. This has resulted in a bottleneck for the dissemination of scientific information, and a roadblock in the advancement of health care for the American public.

G. Action Steps

- Pass legislation to prohibit discrimination against CAM providers, products and services in all appropriate federal programs and initiatives.
- Request a GAO report and mandate research on the cost savings possible through the incorporation of CAM products and services.
- Create an Office of CAM at the Department of Health and Human Services, Office of Public Health and Safety to oversee and direct the incorporation of CAM in all federal health care programs and initiatives.

H. Priorities

- Eliminate federal discrimination against CAM products, therapies and practitioners.
- Educate policy makers about the safety, efficacy and cost savings possible through CAM products and therapies.
- Develop methods to incorporate CAM providers, products and therapies in the existing health care system.
- Provide CAM therapies and products in all of the appropriate federal health care programs and initiatives.

VI. CLINICAL PRACTICE, QUALITY OF CARE, AND DELIVERY SYSTEMS

Goal Statement: To increase the diversity of treatment options for patients while, at the same time, insuring that the practitioners have met educational and/or credentialing criteria and that adequate consumer protections are in place.

Background: CAM practitioners and therapies cannot be integrated with the conventional medical setting without first laying the groundwork. This runs the gamut from standard-setting and credentialing to fostering changes in the attitudes, perceptions and understanding of CAM by state licensing boards and state attorneys general.

- A. **At present, there is considerable variation in the quality of care, level of education, availability of credentialing and reliable science to support CAM therapies and evaluate CAM practitioners.** This means there is no clear or simple way for consumers to evaluate either the practitioners or the therapies.
- B. **Emerging professions present unique challenges,** most notably that of credentialing, which should be developed and monitored by the professions themselves. The Federal Government, however, can and should provide grants to help support the development of uniform standards; policy initiatives can provide support for the expansion of state licensure which provides public oversight.
- C. **The failure to integrate CAM into the existing health care system is resulting in a lack of patient care coordination.** While it appears that the medical community would like to become the gatekeeper, that approach may not be the most fair or effective.
- D. **The integration of CAM into clinical settings is also a women's issue because:**
 - Women are affected disproportionately by chronic conditions.
 - Women are interested in self-care and prevention.
 - Women make the majority of health care decisions in the U.S. for themselves and their families.
 - Women are the largest consumers of health care in the U.S.
 - Women are the major beneficiaries of CAM therapies.

E. Barriers

1. Lack of insurance reimbursement, due to several factors, is hampering the incorporation of CAM.
 - Lack of FDA approval
 - Lack of credentialing/licensing of practitioners
 - Incomplete science base for some therapies
2. Internecine warfare among practitioner types is slowing the credentialing and licensing processes, as well as the incorporation of CAM into clinical settings.
3. The policies and scope of practice guidelines enforced by medical licensing boards do not permit the incorporation of CAM services in standard medical practices.
4. Reprisals, censure and harassment prevent progress in this direction.
5. Potential turf and control issues resulting from the interaction between CAM practitioners, conventional practitioners and those in emerging professions could slow or prevent true integration.

F. Action Steps

6. The National Commission for Quality Assurance, the accreditation body, must be encouraged to work appropriately with emerging professions to establish credentialing procedures, educational requirements, and supportable standards of practice. It will need to work closely with experienced professionals in each field to develop quality measures for CAM. NCQA should be brought into the loop as soon as possible.
7. A nationwide study should be funded to examine the impact of licensure on costs, health care practices, consumer protection, standards and credentials.

G. Priorities

8. The licensing boards, HMO boards, hospital boards -- all of the enforcement bodies now in place to regulate the practice of medicine -- will need to be restructured to allow for the incorporation of CAM.
9. Emerging professions will have to set standards of education, scope of practice guidelines, and continuing education requirements, as well as monitor compliance. Resources are needed to help these processes develop and mature.
- It will be important to educate practitioners, policy makers and patients about CAM to encourage its acceptance and use.

OVERALL PRIORITIES

1. Pass legislation that prohibits discrimination in participation and funding in all appropriate federal programs. Patients must have equal access to all licensed or accredited provider types, and providers must have equal opportunity to participate in federal programs.
2. Establish an office at the assistant secretary level at the U.S. Department of Health and Human Services to:
 11. coordinate and direct all federal CAM activities;
 12. open structured and ongoing communication pathways among legislators, regulators, the research community and CAM providers, researchers, educators and organizational representatives;
 13. increase and coordinate federally-funded research

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July 13, 2000

Stephen Graft, Pharm.D.

Executive Director

White House Commission on

Complementary and Alternative Medicine

6701 Rockledge Drive

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Bethesda, Maryland 20892

Dear Dr. Graft:

Congratulations on your appointment as Executive Director of the White House Commission on Complementary and Alternative Medicine. I'm sure you are overwhelmed at the moment and, no doubt, will continue to be so for quite some time. There is a tremendous amount of pent up energy in the CAM community – we have been waiting two years for this Commission to jell, and many more years than that for the federal government to enter this discussion. All of that energy is now going to be directed at you and the Commission members. A good sense of humor and large doses of kava kava will probably be necessary to get you through.

At this early point in your new position, I just wanted to introduce myself and the American Preventive Medical Association. We led the effort to create the White House Policy Commission, as well as the National Center for Complementary and Alternative Medicine at NIH. We were also plaintiffs in the landmark *Pearson v. Shalala* First Amendment suit regarding health claims for dietary supplements. Our primary mission is to lobby at the federal level for legislation and regulations that increase both research on and access to CAM. Our members are practitioners from many different disciplines; consumers; as well as CAM-related companies.

We obviously believe there is a need for the federal government to take a comprehensive look at how, when, and if CAM should be integrated into the conventional health care system, and we are looking forward to the final report of the Commission. We stand ready to assist you in any way possible, be that identifying potential resources and experts, disseminating information to the CAM community, or helping to organize field hearings. Just let me know how we can be of assistance and we will do what we can to make your job easier.

I would also like to share with you the initial draft of a National Plan to Advance Integrated Health Care. It was prepared at the request of Senator Tom Daschle who felt that Congressional legislative efforts would be more effective if they were based on a review of the perceived roadblocks and shortcomings of the present health care system as it relates to CAM. I expect the Commission will be looking at many of the same issues, and thought it would be helpful for you to have the benefit of our first pass at these subjects. Since our initial discussion with Senator Daschle, of course, the NCCAM legislation passed, the White House Commission was created, and NCCAM published its proposed strategic plan. We have also begun circulating the National Plan to various stakeholder organizations and are planning to organize a national summit meeting to be held next year, which will give the community an opportunity to identify mutual policy goals.

I expect that you will be pleasantly surprised by the degree of interest in the Commission's mandate, and in the number of individuals and organizations who will be willing participants in your work. We stand at an important threshold in health care, driven by consumer demand and advances in science. I hope that we can all work together, with open minds and a willingness to consider new ideas, to help determine the direction health care will take in this country in this new Millennium. We have a tremendous opportunity to get it right; only time will tell the measure of our success.

Sincerely,

Candace Campbell
Executive Director

Enclosure



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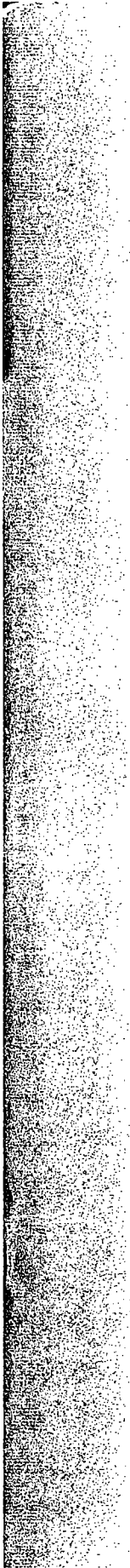
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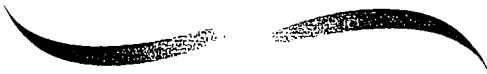
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Notes:



Integrated Healthcare



**A Way Forward for the
Next Five Years?**

A Discussion Document

**Published by The Foundation for Integrated Medicine
on behalf of the Steering Committee for The Prince of Wales's
Initiative on Integrated Medicine**

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Introduction

This report summarises the conclusions of four Working Groups, under the guidance of a Steering Committee, set up at the suggestion of the Prince of Wales to consider the current positions of orthodox, complementary and alternative medicine in the United Kingdom (UK) and how far it would be appropriate and possible for them to work more closely together.

Complementary and Alternative Medicine (abbreviated in the rest of this report to CAM) covers a very broad spectrum of non-conventional therapies, ranging from the manipulative skills of osteopathy and chiropractic to various forms of self-care and, as the recent Scottish Office report "Complementary Medicine and the National Health Service"¹ suggests, may be loosely defined as referring to treatment systems other than those employed in conventional ("allopathic") medicine.* The CAM therapies most widely used in the UK are listed at Annex C. A wider discussion of what the term covers can be found in the British Medical Association's report "Complementary Medicine: New Approaches to Good Practice".² The BMA report draws attention to the fact that there is no common principle linking the different non-conventional therapies and to the great diversity of philosophy and practice they embody.

This diversity needs to be borne in mind in reading the rest of this report, which makes proposals for further action in the fields of:

- research
- regulation
- education and training
- the delivery of integrated care.

Some of the proposals will be more relevant to particular therapies than to others and their differing nature will need to be reflected in the way the proposals are applied.

The Working Groups purposely involved many people drawn from different healthcare backgrounds and representing a wide variety of views (see Annex A). The proposals reflect a general consensus emerging from the workshops and discussions, but it should not be assumed that all the participants agree with everything in the report; some of the views expressed are provisional.

* The Scottish Office report adds: "even this definition is not wholly accurate since the dividing line between conventional medicine and complementary medicine is, in some areas, difficult to determine. In practice it refers to a wide range of health interventions originating from different cultures across thousands of years of history."

Integrated Healthcare: A Way Forward for the Next Five Years?

This document was also circulated to a wider group of some 125 individuals and organisations involved in the provision of healthcare, to invite comments. Some 85% replied. The objectives received widespread support, from both orthodox and CAM organisations. The comments made on the proposals made by the Working Groups have been carefully considered in revising the document for publication.

* The title of the report is "Integrated Healthcare". This does not mean, however, that it is proposing the integration or merging of the various healthcare professions: that could risk losing the advantages of the diversity and choice that now exist. The needs and safety of patients must come first. The aim was to explore how the public could have access to a wider range of effective and safe forms of treatment; the contributions that research, education, training and regulation could make; and how the different healthcare professions could work more effectively together towards this end.

The Growth in Use of CAM...

In recent years there has been rapid growth in the provision of CAM in the UK and elsewhere. The levels of expenditure by private individuals are considerable. Figures from both the United States of America (USA)³ and Australia suggest that expenditure in the US is \$15 billion per annum and over Aus\$1 billion per annum in Australia, where it is estimated that people spend twice as much on alternative medicine as they do on orthodox pharmaceuticals.⁴ Information about public use within the UK is limited. Nevertheless, complementary medicine is increasingly being provided from within the NHS; it is estimated that three quarters of a million consultations per annum occur in the NHS primary care environment and that nearly 40% of GP partnerships in England provide access to CAM for NHS patients.⁵ The Office of Health Economics in 1991 recorded an NHS expenditure of £1 billion per annum with respect to the treatment of chronic and undifferentiated disease – conditions for which patients often seek help from CAM. This figure will almost certainly be exceeded in 1997.

....and possible reasons for it.

This rapid growth in CAM in many Western countries suggests a degree of public dissatisfaction with what people see as the limitations of orthodox medicine and concern over the side effects of ever more potent drugs. Biotechnical approaches – pharmaceuticals and surgery – often have a limited amount to offer those with chronic, degenerative or stress-related diseases, mental disorders or addiction. In all developed countries there is a widespread recognition of the growing financial, social and personal cost involved, and of the need for a less fragmented, and more participative and humane, approach. This view is reflected in both the Report "Tomorrow's Doctors" by the General Medical Council (GMC)⁶ and the BMA's Report: "Complementary Medicine: New Approaches to Good Practice".² It is consistent with the current emphasis in the NHS on basing treatment on proven effectiveness and value for money.

The potential benefits

If healthcare in the UK is to be comprehensive and effective, assumptions about patient needs and the priorities for service delivery have to be re-examined. Although resources of all kinds are limited, and likely to remain so for the foreseeable future, provision needs to evolve to reflect changing needs so that a wider range of **effective** forms of treatment are made available to doctors and patients. CAM may have the potential to play a significant role in improving clinical outcomes and cost-effectiveness in the NHS alongside conventional therapies.

What is wrong with the present situation

The present state of affairs is not satisfactory; both patients seeking treatment and doctors wishing to provide the most appropriate care for their patients face confusing information about CAM. Over the past few years efforts have been made to introduce some co-ordination to the conduct of research, to set up bodies representing the CAM therapies and to provide better information, but overall the position leaves much to be desired:

- There is, as yet, too little high quality and appropriate research (and research capacity) into the **safety, efficacy and effectiveness** of CAM; a lack of research into underlying mechanisms (creating scepticism over biological plausibility); and uncertainty about the most effective patterns of provision. The public have no ready way of knowing what different therapies can offer, what qualifications and levels of skills individual therapists possess and whether the therapies are safe and appropriate in the circumstances of their particular condition.
- Although many professional bodies are increasingly introducing more thorough systems of regulation, the overall picture is uneven – with a proliferation of different representative bodies.
- Most medical and nursing schools and other healthcare training institutions in the UK provide little, if any, familiarisation in CAM; and although there are a small (and growing) number of excellent specialist courses, the overall picture is patchy.
- Some colleges providing training in CAM therapies may provide little grounding in the basis of orthodox Western medicine or the principles of orthodox clinical diagnosis.
- The introduction of CAM courses and research at university level could lead to a significant improvement, but it is of concern that some courses are not properly accredited by the relevant professional body.
- There are few instances where CAM and orthodox medical practice are integrated at the levels of either primary or secondary health care.

How matters might be improved

The rest of this document sets out the Working Groups' proposals on how these deficiencies might be remedied. A full list of proposals is on pages [46 to 50]. They include

- **assessing the needs of the public and patients** for CAM
- deciding on the **priorities for research and development**
- establishing research **centres with the capacity to conduct high quality research in CAM** and linked in **collaborative networks** with individual researchers, CAM hospitals, primary care centres and other institutions
- ensuring that medical and other orthodox healthcare students receive some **familiarisation in CAM** and that CAM practitioners receive appropriate education in the **principles and practice of Western medicine**
- encouraging the development of **common core elements in the curriculum** for all forms of healthcare training
- providing **better information** for patients, healthcare professionals and policy makers
- encouraging **appropriate forms of self-regulation**, both voluntary and statutory
- surveying **existing practice in integrated healthcare provision** and developing best practice guidance.

The Way Forward

It is important to emphasise that this is a discussion document, not a blueprint. It is being published in order to seek views and to stimulate and inform a wider public debate about:

- the future development of complementary and alternative therapies in the UK;
- their relationship to orthodox healthcare;
- how the objectives set out in this report can best be achieved; and, in particular
- what specific, practical steps should now be taken to carry the initiative forward – and by whom.

In particular, organisations and individuals already active in any aspect of healthcare are invited to consider what contribution they can make to finding practical ways of taking things forward.

In a number of places the report makes a specific suggestion about objectives or targets. But the path towards them and the precise shape of the final outcome will depend on a collaborative effort between all the interests concerned. Changes in policy and practice will

need to be introduced gradually and only after careful preparation and discussion. An early task must therefore be to establish processes by means of which a spirit of collaboration can be fostered. This is likely to require:

- broad support for the objectives;
- close collaboration; thorough discussion; and agreement on the means of achieving the objectives;
- a step-by-step approach, building on successful joint initiatives in practice, research and education.

Progress will be more likely if both CAM and orthodox healthcare practitioners are willing to be more open to one another's approaches and values and to learn from their respective strengths. In particular, CAM practitioners, teachers and researchers need to understand the advantages of more systematic audit and rigorous research; while orthodox practitioners and researchers need to understand the potential benefits of an approach that places more emphasis on the personal contribution individuals can make to their own wellbeing, rather than reliance on surgery or drugs.

Research and Development

INTRODUCTION

1. The main questions considered were:

- What are the **priorities** for research into CAM in order to evaluate, in particular, efficacy, safety, biological plausibility and any other factors specially relevant to the provision of CAM treatments.
- What might be the **most appropriate methods** of accomplishing such research, while respecting the individual nature of each therapy?
- How might this be **co-ordinated** and **supported**?

2. There was broad agreement on a number of general principles:

- If CAM and conventional medicine are to be more closely integrated, they must both be subject to rigorous scrutiny. The methods employed should be appropriate to the task and should embrace a wide spectrum, both quantitative and qualitative.
- CAM research will frequently involve expert researchers from outside CAM practice, but CAM practitioners should be actively involved or consulted in the design and execution of a study.
- Collaboration between patients, practitioners and researchers is required.
- Priorities need to be set. They should include, for example, systematic literature reviews of published studies, further investigation where there is some evidence of effectiveness, where the wide use of a therapy indicates that further investigation is warranted, where the nature of the health problem is of importance, and where there are major potential benefits (either health and/or economic).
- The perspectives of different groups will need to be taken into account. In particular, while a substantial amount of research will necessarily follow tried and tested methods, there is a need to develop innovative approaches appropriate to CAM. This might lead to new methods of value also to orthodox medical research.

PRIORITIES

3. Over the last two decades the process of defining research priorities within CAM has been progressing in a haphazard manner and has been conducted by many disparate groups in isolation from both other CAM researchers and the research of more orthodox therapies.

4. The Working Group did not propose to establish a set of priorities itself: rather it seemed more important to set up a **process** to establish priorities **that will command the support of all those involved**. Since 1991 the aim of the NHS R & D strategy has been to create a research and evidence-based health service in which reliable and relevant information is used to make decisions on health policy, clinical practice and the management of services. There needs to be a similar process of collaboration and discussion to develop research priorities within the CAM field. This might involve the following:

(a) **Gathering more information** in the UK, through surveys, expert papers, calls for written evidence, informal workshops, etc., in order to define:

- the perceived public need, current use, and availability of CAM
- the perceived need among practitioners, purchasers and providers
- the capacity for CAM (and orthodox) practitioners to participate in research studies.

(b) **Discussing and filtering the results**, through a series of specialist working groups, covering aspects collectively agreed to be appropriate to CAM practice and perhaps including the six overlapping perspectives used in the NHS review.* This would involve consumers, doctors, nurses and other CAM professions, so as to establish priorities in the light of evidence. The consultation process should help create the perspectives required to evaluate CAM therapies and facilitate change towards good practice. The resulting criteria should define the therapies most fruitful to investigate further, include a range of CAM therapies (given the lack of research in most of them) and should consider the circumstances in which these therapies can be most effectively applied.

* (1) disease related problems, (2) management and organisational issues, (3) problems related to specific client groups, (4) consumer issues, (5) health technologies and (6) research methodology.

METHODOLOGY

5. Whether assessing efficacy, effectiveness, safety or mechanisms of action, research into CAM has tended to be carried out as a collection of isolated studies, partly due to lack of adequate infra-structures and funding for research, but also because of a paucity of research methods and a lack of input from 'professional researchers', who have hitherto mainly operated in more conventional therapeutic areas. As interest grows and funding sources are identified, it is important to encourage the development of research within a strategic framework. For example randomised controlled trials (RCTs) are mainly appropriate if well designed observational studies have been completed to identify the most appropriate and relevant outcome measures.*

6. There has been considerable debate about the need for RCTs, their design in relation to CAM therapies and the appropriateness of other research methods. In fact there is no shortage of appropriate and rigorous research methods by which to evaluate CAM, including RCTs. Annex B describes in more detail some of the issues arising in applying RCTs and other methods of evaluation to CAM research.

7. It is by no means the case that RCT will always be the appropriate choice. This will depend on:

- the kind of question being asked;
- who wants to know the answer and why;
- and, in some cases, the nature of the therapy.

Table 1 lists some examples of different types of research question and the appropriate methods to apply. Each CAM profession needs to be involved in decisions on the choice of methods appropriate to its field.

8. Although various reports⁷ have set out guidelines for CAM research methodology in some detail, there is still widespread ignorance on the subject, among both practitioners and researchers. There are also some clear indications that the 'gatekeepers' to funding for research are not fully aware

*In the USA, an Office of Complementary and Alternative Medicine (OCAM) has been established. One part of its brief is to promote and fund research on unconventional forms of healthcare. It has produced a report on appropriate research methods and strategies, which identifies the following common failures when a strategic approach is not adopted:

- using untested interventions of definitive trials
- researching the mechanisms of action of a non-pharmacological therapy before establishing whether it is of clinical benefit
- developing outcome measures at the same time as evaluating a therapy
- unnecessary replication of negative research

Table 1: Some examples of research questions	Some appropriate methods/designs
Proving (controlled studies)	
'Is there a specific beneficial effect?' (efficacy)	• explanatory RCT
'How well does it work in practice?' (effectiveness)	• pragmatic RCT • outcome studies
'Is it safe, do benefits outweigh risks?' (safety)	• pragmatic RCT • outcome studies • epidemiological studies
'Is it value for money?' (cost effectiveness)	• pragmatic RCT • cohort studies (prospective and retrospective) • case-control studies
Improving (developmental studies)	
'Can I improve my results by changing the treatment?' (treatment variation and clinical outcomes)	• clinical case studies • audit • reflective practice
'Is this a useful diagnostic test?' (diagnostic accuracy)	• comparative studies
'How can we improve the organisation of our CAM service?' (organisational effectiveness)	• quasi-experimental designs • multi-factorial studies • action research • audit
'How can we make the referral system between GPs and CAM more effective?' (service delivery models)	• organisational case studies e.g. co-operative inquiry
'How can I better understand and develop the relationship with the patient and facilitate their motivation and commitment to change?' (personal and inter-personal effects)	• qualitative case studies • focus groups and interviews • audit
Picturing (snapshots)	
'Who uses which therapies and why?' (attitudes/ current use/provision/consumer demand/ purchaser demand)	• population surveys • purchaser and provider surveys • focus groups and interviews
Understanding (basic clinical research)	
'How does the therapy work?' (underlying processes and mechanisms of action)	• laboratory research • explanatory RCT • case studies
'Can different 'systems of medicine' be understood within a common framework?' (relationships between theory and practice)	• transcultural research • discourse analysis
Developing research tools	
How do we assess the full consequence of processes activated as a result of a therapeutic intervention? (outcome measures, instrumentation)	• development and validation of measures and instruments • cohort studies

of the current debate on research methods.* Background information and agreed guidelines on current issues in research into CAM therefore need to be prepared, and communicated to all 'gatekeeper' organisations and to researchers. When funding organisations consult with referees they should ensure that they are appropriately experienced and informed.

9. There is a need for further work in the development of suitable outcome measures by which to evaluate the full benefit experienced by users of complementary therapies. These should include outcome measures reflecting symptomatic as well as curative treatments and their development should involve close consultation with practitioners, researchers and users.

CAPACITY AND SUPPORT

10. In order to move the CAM research agenda forward in the UK, it is essential to identify both the priority areas for research and the human capacity to conduct it. This means both identifying existing centres which have the necessary facilities and capabilities, and either establishing schemes to attract well qualified individuals into the field or developing schemes to train and provide such researchers. As with the NHS R & D programme, every effort should be made to promote an appropriate "evaluative culture" in those practising CAM.

11. CAM Research requires an understanding of research methodology including clinical trial methodology and the difficulties unique to a particular therapy. Generally very few individuals with clinical research experience have any knowledge or experience of CAM; and most CAM therapists lack a background in research. Some CAM organisations have been addressing this by developing their own research agendas though lack of funding for dedicated research units outside higher education institutions has constrained development. Education in research issues is now being included in some training courses.

12. There are a number of different settings in the UK in which CAM research is conducted. They vary widely in structure, and in the personnel involved, from university-based institutions to centres within departments of medicine, dedicated hospital sites to centres within primary care, and from centres which sit between the NHS and the universities to totally private institutions funded by research charity money.

*These 'gatekeepers' include members of medical research ethics committees and grant giving bodies. It is important that research protocols are submitted for the approval of ethics committees, although currently there is no requirement to do so if the study does not involve NHS patients.

13. Excellent work has been done in a small number of centres, but this needs to be further developed and supported if it is to have any chance of meeting current needs. CAM practitioners working in research need an adequate training in literature review, methodology, statistical analysis, and other disciplines required to construct high quality proposals if there is to be a major increase in the amount of robust, high quality work within the CAM field. Moreover, much of the research carried out in CAM is published only in journals with a limited or specialist circulation and therefore has not impinged significantly on mainstream healthcare practice.

14. At present there is an extensive network of CAM practitioners in the UK ranging from the non-medically qualified, single-handed, private practitioners utilising a single form of therapy to groups of practitioners offering a wide range of different therapies. Generally speaking, such centres are doing relatively little teaching and research. As a result, there is a large untapped resource of therapies, therapists and clinical material not being used for clinical and scientific evaluation or teaching purposes.

15. The recent trend towards CAM therapies being taught at universities is welcome, as university environments are well placed to provide a culture of enquiry and adequate research tools such as library facilities, well-equipped laboratories, statistical capacity, computation facilities and an interface with other research environments. There is an urgent need to expand intellectual capacity in order to build up such groups. Many of the existing centres run on very limited resources and infrastructure support. A lack of funding to aid the development of research capacity has been one of the key factors inhibiting the generation of quality research proposals from such centres.

16. The potential advantages and disadvantages of different organisational approaches to supporting CAM research are summarised in Table 2. A constructive way forward would be through the development of multi-disciplinary teams to encourage collaboration between experienced researchers and CAM practitioners. There is a need to build up a critical mass of CAM research in a number of institutions and/or practices which can also provide support for individual research talent. Without this, CAM will continue to fare badly in competition for funds and potential researchers will become discouraged.

17. It would seem appropriate to concentrate resources on **establishing a number of research centres** linked with higher education institutes with the capacity to conduct high quality research into CAM. Such a centre may

Table 2: Potential Advantages and Disadvantages of Different Approaches to Supporting Research in CAM		
Approach	Advantages	Disadvantages
1. Development of self-contained units dedicated to CAM research	Promote and foster i. independence and autonomy ii. stimulating environment for education and training	Potential for: a) low research capacity b) isolation c) insufficient critical mass
2. Collaborations within established research units, e.g.: • collaborations with existing units • project staff within existing units • core staff within an existing unit • independent group/unit within existing structures	Promote and facilitate: i. access to varied skills and experience ii. access to resources and information iii. access to project and educationally based funds/grants iv. enhanced NHS credibility	Potential for: a) erosion of intellectual and functional autonomy b) loss of inherent CAM principles by conforming to orthodox paradigms
3. Researcher-led applications to existing, dedicated funding bodies	Enhanced kudos and credibility: i) within orthodox science circles ii) within the NHS	Extreme competition for limited funds/grants; so success rates will be low
4. Targeted research projects , e.g.: a) within the NHS health technology assessment programme b) commissioned by, or independent of, standard funding agencies c) dedicated CAM programmes	Enhanced kudos and credibility: i) within orthodox science circles ii) within the NHS Potential for: iii) higher application success rate iv) improved CAM research morale v) attracting new researchers, both established and new to field	In the case of (a) and (b), large number of competing priorities may compromise success rates from standard funding agencies
5. Specified CAM training studentships and fellowships	Potential to increase: a) the pool of future researchers b) the prestige and credibility of the subject	Possible shortage of appropriate and suitable training environments

take one of several forms; it could be self-contained, in the sense that the institution concerned would itself include individuals with all the skills and experience required, even though they currently work in different fields; or

it could act as a focal point to co-ordinate a collaborative network of researchers drawn from several institutions within a region. A third, more expansive, model would be a large network of clinical practices with research and training co-ordinated by a director and staff operating from a single site – not dissimilar to the MRC's General Practitioner Network.

18. In addition to having critical mass, research centres would benefit from having close links with:

- undergraduate and post-graduate education and training institutions, which should offer a range of training and research courses and degrees for physicians, scientists and healthcare professionals
- clinical practice in the CAM therapies covered by the research, at either primary or secondary care centres, including individual practitioners who wish to gain research experience
- professional CAM bodies.

19. The choice of centres should be decided in open competition, based on: the range of existing research capacity for the evaluation of CAM; the available personnel; and the potential for academic development and collaboration and existing or potential links with clinical practice. Table 3 summarises the facilities required. The process should be sufficiently flexible to accommodate a 'bottom up' approach to create proposals for research

Table 3: Guidelines for the types of facility to be provided by a research centre

1. Adequate library facilities and access to a variety of databases in CAM
2. Individuals with an active research interest in CAM able and willing to provide a support network
3. Individuals capable of supervising student and research projects and who can advise local ethics committees on the specific problems in CAM research
4. Facilities to audit the various schemes and training programmes
5. An obligation to make use of local ethical committees
6. Ability to address issues of safety in addition to efficacy
7. A track record of developing high quality research protocols and attracting funding from charitable trusts
8. A track record of (or potential for) publication of CAM research in high quality, peer-reviewed, journals
9. Access to patient populations and networks of therapists
10. Ability to give CAM practitioners academic training in research methods

originating from CAM practitioners and their interaction with patients, which can be developed and refined into proposals, which are capable of being researched and generally applied, by involving input from research institutions.

FUNDING

20. Funding for medical research, including CAM, is available from a variety of sources:

- the NHS R&D Programme (within both the Health Technology Assessment Programme and Regional Programmes)
- the Research Councils
- Medical Research Charities – some with a specific interest in CAM
- commercial and industrial sources.

21. At present CAM research is probably at a disadvantage in competing successfully for general research funds, largely due to insufficient interest and inadequate infrastructure to enable competitive applications to be submitted. Funding is required on several fronts:

- to initiate the research centres proposed in paragraph 17;
- to support the CAM research priorities emerging from the process suggested in paragraph 4;
- for responsive funds for good individual projects.

22. Funding for CAM research must be able to compete on equal terms with other medical research projects. The prime need is to generate bids of high quality that will enable CAM projects to gain access to the research agendas of funding bodies and therefore compete on equal terms with other projects; and, where necessary, to encourage greater willingness among these bodies to be sufficiently broad-minded to examine CAM proposals on their merits.

23. In the short term there may be a need for some 'pump-priming' to train CAM researchers and to enable more CAM research to achieve a standard comparable to that in other health-related disciplines. This could take the form of dedicated funds to help set up the research centres proposed in paragraph 17 and the funding of designated research fellowships in CAM research.

24. Further consideration should also be given to the encouragement and development of specific CAM charities, if this could tap additional charitable funds, rather than simply divert them from existing medical research.

DISSEMINATION

25. A certain amount of information already exists on the efficacy, safety and provision of CAM. It includes material from government supported enquiries, Health Authority enquiries and reports by the National Association of Health Authorities and Trusts (NAHAT)*. However, this database is far from comprehensive and contains material which has not been systematically collected, organised or disseminated. A major part of the effort must therefore be to co-ordinate and standardise. Dissemination will need to use many avenues to reach the necessary audiences. These include patients, their families; orthodox and complementary practitioners; researchers; purchasers of healthcare; funding bodies, peer reviewers; politicians and the public generally. It must cover not only the results of clinical trials but also the full range of "research", including audit of primary care results and sociological and conceptual analyses.

26. Dissemination could be improved by:

developing existing resources in CAM

- a major initiative to network CAM databases nationally and internationally
- peer-reviewed international journals in the CAM field
- national enquiry centres developing at institutions with an established track record in research, teaching and practice
- audit at all levels from care provision to policy development and planning through CAM training centres

using existing orthodox models and resources

- e.g.: the NHS Centre for Reviews and Dissemination (CRD) in York
- the UK Cochrane Centre (part of the international Cochrane Collaboration), the National Centre for Clinical Audit; and other centres

*now renamed the NHS Confederation.

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- reporting in established peer-reviewed medical health-related journals
- the media
- undergraduate and postgraduate medical schools
- issuing guidelines for healthcare practitioners to help encourage and direct evidence-based and good clinical practice. Such guidelines need to be developed by careful evaluation of available evidence with input from practitioners. Outcome measures should be identified to enable their effectiveness to be audited.

developing new methods

- through experimental clinics, bringing different disciplines into contact with each other
- establishing a mechanism in the UK, and more broadly in Europe, similar to the Office of Complementary and Alternative Medicine (OCAM) in the USA. Its brief would need to be carefully established by conventional and CAM collaboration
- through courses for undergraduates and post-graduates
- through the Internet
- through a devolved research process, involving practitioners in the conduct of research, which will itself help to spread information and research skills.

Education and Training

INTRODUCTION

27. This chapter summarises the outcome of three workshops devoted to education and training in CAM. The questions considered were how best to encourage and support:

- the development of a core curriculum providing a common foundation for all healthcare training, both orthodox and complementary
- specialist CAM training
- continuing professional training for all healthcare practitioners
- better information on CAM for both patients and healthcare practitioners.

THE CURRENT SITUATION

28. In response to the growing demand for complementary and alternative therapies, there has been a rapid growth in the number of courses provided by universities. In the USA, one third of medical schools now offer some education in the holistic approach and a general familiarisation with CAM. A recent survey in the UK showed that more than 60% of medical students surveyed in one UK medical school think that this would be helpful here.⁸ The survey found that only three medical schools were providing such education in 1995. A recent (as yet unpublished) BMA survey carried out in the Summer of 1996 indicated that six medical schools were then providing some education in CAM and three more were planning to introduce it; the remaining 17 schools were not planning to do so.

29. The BMA also surveyed all university science and healthcare departments and faculties of nursing, and other organisations approved for nurse education in the UK (see Annex F). These unpublished data indicate that over 100 courses in CAM are currently available, ranging from university access courses to higher research degrees. Most course providers are new to this field. CAM content ranges from a few hours to a full module forming part of a BSc/Dip HE, or may be the specialist subject for a diploma or degree course. In addition to these courses at mainstream healthcare

Higher Education Institutes, there are, of course, also specialist courses in particular CAM therapies provided by CAM colleges.

30. The present, rapidly changing, situation gives rise to several grounds for concern:

(a) doctors trained in mainstream medicine are generally unfamiliar with what CAM can and cannot provide. Even where they have received some familiarisation as part of their undergraduate or continuing education, they have no ready means of knowing what qualifications, training or experience CAM practitioners have. There is also inadequate information on the effectiveness, safety and value for money of CAM treatments, for many of which there is at best inadequate research;

(b) nurses are increasingly aware of CAM and may have experience and training in particular CAM therapies, which they use alongside their mainstream nursing qualifications. But there appears to be insufficient information on the level of training received, the competence achieved and the circumstances in which it is appropriate for nurses to apply it;

(c) some doctors have attended specialist courses in particular CAM therapies, but the length and thoroughness of these courses varies widely, as do the levels of competence to practice acquired by those who attend them;

(d) for their part, some of those specialising in CAM therapies may have received little formal instruction in the basis of orthodox medicine, the principles of clinical diagnosis and when they should refer a patient to his or her GP or to another practitioner;

(e) a high proportion of university courses leading to the practice of CAM therapies are not properly accredited by an independent regulatory body for the profession concerned;

(f) healthcare practitioners from different backgrounds find difficulty in communicating with one another in a common language;

(g) patients can neither rely on being able to obtain guidance from their GP about CAM, nor obtain clear and reliable information elsewhere on either the CAM disciplines or their practitioners.

WHAT NEEDS TO BE DONE?

31. The measures taken to overcome these deficiencies need to be set in the context of the changes already taking place in orthodox healthcare. (See the reports by the GMC⁶ and the BMA² referred to in the Introduction) There is some evidence of a growing willingness among both orthodox physicians and CAM practitioners to examine critically the received wisdom within their own fields and to consider multiple potential explanations for ill-health, although these hypotheses need to be tested by carefully designed research and outcome studies.

32. All healthcare professions, orthodox and CAM, are in their various ways and to different degrees, seeking to put more emphasis on human, social and spiritual factors. The educational challenge is to build and strengthen the bridges between the seemingly 'reductionist' approach of scientific, high technology healthcare (which focuses on the disease per se) and the inclusive approach favoured by many CAM disciplines (which focus on the individual patient and the personal and social situation in which his or her illness develops rather than the disease process alone). The Group therefore identified a need to introduce a holistic approach into the basic professional education of **all** healthcare practitioners.

33. There is also a common body of knowledge and skills which **all** healthcare practitioners need. There appears to be no reason why these could not also be incorporated into a common component in the undergraduate curriculum of **all** healthcare education and training institutions.

34. This is not to suggest that all healthcare professionals should be trained to be competent in a range of CAM and orthodox treatments and so become 'jacks of all trades'. The suggestion is rather that common elements in the curriculum should provide a basic grounding in the general principles, values and skills that are common to all healthcare. Individuals would, as now, train for a particular healthcare profession, for example nursing, medicine, physiotherapy, osteopathy, herbal medicine or some other discipline.

UNDERGRADUATE EDUCATION FOR ORTHODOX AND CAM PRACTITIONERS

35. The common elements in the curriculum would thus cover:

- Basic anatomy physiology and pathology
- Fundamentals of orthodox medical diagnosis and guidelines for patient referral
- CAM therapies and their potential uses, including the principles of diagnosis and practice
- Holistic models of healthcare*
- Professional ethics
- The therapeutic relationship
- Impact of social, cultural, economic, employment and environmental factors on health
- Counselling skills
- Principles of quality management and audit
- Organisational skills, including record keeping
- Technical skills: ranging from prevention of cross-infection to information management (including data security to protect the privacy of medical records; use of IT to access information, research and current best practice).

36. CAM teaching at undergraduate level for orthodox practitioners would most appropriately be undertaken by those with relevant clinical experience in CAM so as to ensure a sufficiently deep understanding of the concepts and systems being described and their application to practice. Practical familiarisation experiences could include optional modules in one or more of all five major discrete CAM disciplines (acupuncture, homoeopathy, herbal medicine, chiropractic and osteopathy) and if possible a range of other therapies. Wherever possible, students need to have 'hands on' experience under accredited supervision.

*This includes (a) the relationship of individuals to themselves and their health; (b) the role they can have in their own health, happiness and fulfilment; (c) self-help approaches, including relaxation, exercise and fitness; (d) nutrition; (e) self-help groups; (f) the role of creativity, self-expression and self-development.

37. Similarly, all CAM students should receive instruction on the non-CAM parts of the curriculum from those with clinical experience in the relevant field.

38. Some of these core courses might be attended jointly by people studying for different healthcare professions. This would have the advantage of 'rubbing shoulders' and breaking down interdisciplinary barriers. It is not suggested, however, that joint courses should be the norm. CAM and orthodox students often begin their studies with very different backgrounds and experience; CAM students are often more mature, but may not have the A-level qualifications in science that make it easier to understand the scientific content of Western medicine; orthodox medical students are normally younger and thus may have less experience of life and of social and emotional problems. Although the ground to be covered in the common core would therefore be the same for all, the time spent on particular aspects and the amount of detail covered, would be likely to vary from group to group.

39. Work should be commissioned to develop more detailed proposals; to identify the common elements to be covered in the curriculum and the particular additions that need to be made to the current education and training curriculum for each profession. As a first step, a review of current practice, style and content of undergraduate teaching would help to map this area and identify best practice and those educational establishments (there are several) where the knowledge, skills and enthusiasm are already in place. What is required is not a rigid or detailed blueprint which rules out diversity of approach, but rather a common understanding of the core principles to be covered; the differences in values between different traditions and how these should be taught; and the level of skills and competence to be obtained (which may vary according to the main qualification being sought).

40. Meanwhile the relevant bodies including the GMC, the Council of Deans of the UK medical schools, the UK Central Council for Nursing, Midwifery and Health Visiting, the Council for the Professions Allied to Medicine and the relevant CAM professional bodies, might consider making the inclusion of such a core curriculum a requirement for the recognition and accreditation of courses. The opportunity could be taken of the GMC's current visits to medical schools to try to identify modules which could be commended to other schools.

SPECIALIST TRAINING IN CAM

41. As already noted above, CAM courses are proliferating in response to a genuine demand that is not met by mainstream courses. They are not always well designed and in some cases appear to be 'cash cows' for educational institutions competing for students and funds. This problem needs to be addressed. It is vital that for each CAM discipline a professional regulatory body should accredit courses that lead to a licence to practise. It is extremely disturbing that the BMA survey quoted in para 29 shows that university courses designed to train CAM therapists for practice are often validated only by the university and not accredited by a professional body. Where there is a diversity of approach within a discipline, agreement must be reached on a common set of principles which those running CAM courses can apply. The courses followed at these institutes of higher education should also be validated by the educational institution. Accreditation and validation, though separate processes, need to be closely co-ordinated.

42. In some cases it will be appropriate to license practitioners at different levels of competence, corresponding to the scope of their therapy, the degree of supervision under which they work and whether the therapy is supportive or offered as an alternative to medical treatment. The level of training should be geared to the level of practice to be licensed and the limits of competence of successful candidates made clear. A consensus needs to be reached on the principles that should apply; each profession should then be asked to develop more detailed arrangements for its own members. Several CAM professions (e.g.: osteopathy, acupuncture, homoeopathy) have already made considerable progress towards this.

43. Care must be taken not to be too prescriptive about what can or cannot be practised after different levels of training. In the case of both doctors and nurses, the current regulations leave to the judgement of the individual practitioner what can safely be applied in the best interests of the patient. Some statutory control may be needed for **all** healthcare practitioners using CAM techniques, including doctors and nurses. From the point of view of education and training, the important issue is to ensure that all practitioners are not only well trained but also have regular up-dating of their skills and knowledge.

CONTINUING PROFESSIONAL TRAINING

44. Whatever the level of initial education and training, all practitioners should be required to follow a programme of continuing professional development (CPD) validated by an appropriate professional or statutory body. Courses should be offered to all **existing** healthcare practitioners to develop their awareness of holistic approaches and the potential contribution of CAM treatments to patient care. A wider appreciation of the different types and scope of CAM training and qualifications would help practitioners to assess the relevance of CAM treatments for individual patients and to decide whether to refer or delegate care to competent practitioners. Some accredited postgraduate courses for GP's do include a session on CAM, but it is not systematically taught. It would be helpful to give guidance to postgraduate tutors on what to include and to make similar courses available to other doctors and healthcare practitioners. Funds also need to be provided to enable existing CAM practitioners to be released to attend conferences and courses in self-directed learning, audit and outcomes research and the promotion of evidence-based practice.

45. In both primary and secondary care, forums could be established between conventional and complementary practitioners to develop collaboration and a multi-disciplinary approach to professional education and the management of healthcare problems. This already happens in some places on an informal basis and thought should be given to how these arrangements could be formalised. As a first step a symposium could be funded to bring people together to exchange experience and to explore the factors that constrain or support such arrangements.

BETTER INFORMATION

46. There is an urgent need for patients and orthodox healthcare professionals (particularly GPs) to have access to better information on the therapeutic scope of each CAM discipline, the qualifications of practitioners and the levels of skill to which they are trained for practice. Some reviews have already been carried out (e.g. by the West Yorkshire Health Authority and the National Back Pain Association).⁹ But the current plethora of organisations and initials following certification is confusing and difficult not only for the general public but also for healthcare professionals to understand. The Department of Health or the NHS Confederation might commission the preparation of a more easily accessible reference work for GPs, other healthcare professionals and patients. This may be difficult in

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those areas where there is resistance to self-regulation or different qualifications are awarded by several bodies, but large numbers of people are voting with their feet and making use of CAM therapies without much guidance on effectiveness, safety or qualifications apart from what they obtain by way of personal recommendations. Although preparing guidance will not be straightforward, a start must be made. The survey described in the next Chapter should provide much helpful material.

47. There is also a need to educate the public more generally by providing material on the holistic approach to health and illness. This might form part of a wider consultation with the public on what they expect from CAM and medical care generally. Most of the information available at present to the general public comes to them through the media. Although some newspaper and magazine articles are well informed, others present CAM as offering a 'magical cure'. A balanced message needs to be put across, based increasingly on an evidence-based consensus of best clinical practice and guidance on healthier lifestyles. The Department of Health might commission the Health Education Authority to develop and distribute such material.

Regulation

BACKGROUND

48. This chapter summarises the outcome of four meetings of the Group, discussions with the Department of Health and numerous discussions with CAM organisations. It also sets out the general conclusions of a survey of registering bodies within the field of complementary and alternative medicine.

49. In the UK, non-medically qualified practitioners of CAM are free to practise under common law, irrespective of their levels of training or clinical competence. Such practitioners are subject only to the relevant provisions of such statutes as the Medical, Dental, Professions Supplementary to Medicine, and Medicines Acts. Under other legislation practitioners must not make claims or advertise the treatment of certain diseases such as cancer, tuberculosis, glaucoma, diabetes, venereal disease and epilepsy.

50. Since 1985 politicians of both major parties have opposed the imposition of restrictions on CAM practitioners or measures to curtail the freedom of individuals to seek and receive the treatment of their choice; but they have supported more effective self-regulation to protect the public (see Annex D).

THE SURVEY

51. Given the lack of substantive information about the majority of regulatory and professional registering bodies operating in the CAM area, it was decided to conduct a national survey of all such bodies in this field. Recognising the potential importance of such a survey to future policy making in this area, the Department of Health commissioned the Centre of Complementary Health Studies at the University of Exeter to undertake the project, which was carried out between May and August 1997.

52. The study sought to identify the status, activities, responsibilities and aspirations of the various and diverse groups within CAM. The report¹⁰ of the survey provides a snapshot of the current situation and highlights main areas of development and structure within the CAM field.

53. The data obtained provide an invaluable resource not only for policy makers but also for the individual CAM organisations who responded. Future developments in the field of CAM can now be monitored from an established baseline.

SURVEY OUTCOMES

54. In total 322 organisations were identified and contacted. Of these 166 returned completed questionnaires. The vast majority of the different CAM professions and therapies were represented by these organisations. Some organisations believed that they should not be included as they did not represent a therapy or organisation. Complete non-response from an organisation, despite up to four reminders, was assumed to be because: the organisation was no longer active; the organisation chose not to co-operate; or the organisation's administration could not deal with the survey.

55. The survey elicited the following information from organisations:

- Name and contact address
- Year of establishment
- Corporate/charitable status
- Affiliations to other professional groups and training establishments
- Extent of professional codes of practice, disciplinary and appeals procedures, complaints mechanisms and professional indemnity insurance cover
- Categories of membership, members in each group, rate of growth in membership and degree of joint membership with other organisations
- Registration and educational requirements
- Subscription rates
- Services to members/registrants (e.g. publications, continuing professional development programmes, representation, etc.)
- Policy on statutory regulation and working practices in relation to orthodox medical healthcare professions.

56. Given the fragmentation and diversity within the CAM field, a major objective of the survey was to engage the relevant organisations in a process, which has now begun, to chart the whole CAM territory. The list of registering bodies contained in an annex to the report represents the most comprehensive resource of active organisations within CAM in the UK.

57. The survey highlighted a number of impressive developments in the CAM field, most notably within the osteopathic and chiropractic professions, which have now attained statutory self-regulation enshrined within two separate Acts of Parliament. A number of other bodies, particularly within the field of acupuncture, demonstrated significant progress towards professional self-regulation.

58. The survey revealed a wide spectrum of organisational and administrative development. The variation in responses showed that in terms of development, educational provision, administration, aspiration and clinical practice, the various professions and therapies within CAM are too disparate to be considered as a single group. Indeed, to do so would be misleading and could hinder future development.

59. However, despite this diversity, within many of the organisations the replies revealed considerable enthusiasm and willingness to pursue high standards of training, regulation and clinical practice. A number of organisations expressed a degree of frustration that there was no single body or central resource which could offer emerging, registering or regulatory bodies support and assistance to develop appropriate structures and procedures. Some groups also expressed dissatisfaction with their affiliation to one or other of the 'umbrella' organisations operating in the CAM area and felt that such bodies had not matched up to original expectations.

60. A clear pattern emerged. Where professional organisations within an individual therapy or profession had joined forces or worked closely together, impressive developments in terms of self-regulatory structures, improved standards of training and greater public recognition had ensued. Examples of high levels of intra-professional co-operation were demonstrated in the fields of acupuncture, aromatherapy, chiropractic, healing, herbal medicine, homoeopathy and osteopathy.

61. On the other hand, groups representing therapies such as reflexology, hypnotherapy and massage therapy appeared to be more fragmented. This in part may reflect the fact that within many therapies individual training

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schools tend to have their own professional organisation to represent and register graduates.

62. Most of the responding organisations, however, had in place at least the basic characteristics normally associated with a self-regulatory body. An elected governing council featured in the great majority and almost all organisations had a register of members funded by registration fees. Sectors where the administrative and regulatory infrastructure appeared generally less well developed included organisations involved with hypnotherapy, massage therapy, nutritional therapy, reflexology, colour therapy, crystal healing, iridology, radionics and a number of the 'bodywork' therapies.

63. The survey demonstrated that, while CAM organisations are generally beginning to establish appropriate regulatory structures, there are a number of important areas that remain to be addressed, including:

a) Educational Standards. While there was evidence that most organisations accredited **their own** training establishments, very few bodies sought **external** accreditation or validation for their courses. This raises questions relating to quality control, the consistency of the educational process and the monitoring of the clinical competence of graduates.

b) Fitness to practice. Although the majority of respondents claimed to have codes of conduct and disciplinary procedures, only a few organisations provided evidence of such publications, as requested. If codes of practice exist, they should be available in the public domain and be subject to external review.

c) Public information. There is a paucity of information available to the public about the scope, limitations and potential hazards of the different CAM therapies. There was also little evidence that consumers had access to information on the standards of training or clinical competence of practitioners, which they need to make informed choices.

CONSULTATION PROCESS

64. The Consultation process undertaken during the preparation of this report demonstrated strong support for the development of practical initiatives for systems of self-regulation of CAM therapies and professions that would take account of, and reflect, the diversity of clinical practice and professional aspirations.

65. There was strong support from both CAM and orthodox medical organisations for the proposal to issue guidelines and recommendations on the elements of best practice of self-regulation. The suggestion that a central resource to facilitate the development of effective systems of self-regulation within the CAM field should be established was also welcomed and supported by the large majority of those consulted.

CONCLUSIONS

66. In any healthcare profession or therapy group the quality of care, treatment and patient safety must be the highest priority. The establishment and maintenance of systems of regulation are essential for the provision of high quality care and patient safeguards.

67. While it is not within the scope or remit of this report to rehearse in detail the relative merits of different models of regulation, it is clear that, given the diversity within the CAM field, no single, over-arching system of regulation is appropriate for all the different professions and therapies.

68. As the different CAM professions and therapies aspire to widely differing roles within healthcare and involve very different levels of intervention, the level and scope of regulation for each particular practice must reflect the potential risks to and the needs of patients. For example there is a persuasive argument that where a practice involves invasive therapeutic techniques such as spinal manipulation, the insertion of needles, or the prescribing of medicinal products, regulation may require the force of law, if it is to be effective. On this basis it could be argued that acupuncture and herbal medicine should follow the precedent set by the Osteopaths Act and seek statutory regulation for their professions.

69. The potential advantages of statutory regulation over voluntary regulation are:

- a) provision for the protection of title so that only practitioners registered with the statutory regulating body can legally practice under a particular professional title.
- b) the establishment of a single definitive register of practitioners, established by law.

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c) legal underpinning of disciplinary procedures and sanctions. Thus a practitioner whose name is struck off the statutory register is prevented from practising under that professional title.

70. Statutory self-regulation is not a realistic option for the majority of the CAM therapies in the foreseeable future, as Parliament is likely to be reluctant to accord many therapies the status of statutory recognition – certainly without the support of the medical profession. The costs involved in the establishment and administration of a system of statutory regulation are also considerable and it is doubtful whether the smaller CAM professions and therapy groups would be able to fund such a scheme. It could also be argued that before achieving statutory regulation the professions or therapies would need to demonstrate a sound record of effective voluntary self-regulation.

71. While voluntary self-regulation cannot protect a professional title, such a system can, if properly structured and administered, provide patients with real safeguards. Indeed if a voluntary regulatory scheme can establish a single, high profile, lead registering body which inspires the confidence of the public as well as practitioners, then the threat of removing a practitioner from the register can provide a significant deterrent to unethical conduct.

72. There appears little doubt that for the majority of CAM professions and therapy groups the establishment of a credible and effective system of voluntary self-regulation provides a practical, achievable and highly desirable way forward. The challenge now to all the practitioners and organisations within the CAM field is to ensure that appropriate safeguards and mechanisms of redress for the public are established without delay. In many cases this may require groups within a single profession or therapy to put aside past differences and unite behind agreed standards of training, clinical competence and ethical practice.

RECOMMENDATIONS

73. It is recommended that:

a) Consideration be given to the establishment of statutory self-regulatory bodies for those professions whose practice might put patients at risk of harm from inadequately trained practitioners. The professions of acupuncture and herbal medicine should be a priority. Such statutory systems should be based upon an established system of voluntary regulation within each profession.

b) A single, lead, voluntary, self-regulatory body should be established for each of the CAM professions and therapies. Such a system of voluntary self-regulation should have the following features:

- i. A single independent registering body funded by registration fees.
- ii. A governing council made up of a balance between members of the profession democratically elected by their peers and appointed non CAM or lay members to supplement the skills of the professional members and represent the views and needs of consumers. The lay members should comprise at least one third of total membership.
- iii. Agreed standards of training and minimum levels of clinical competence.
- iv. The independent external academic accreditation of all training courses together with the professional validation of clinical competence of graduates by the regulating body.
- v. Evidence of continuing professional education and development as a prerequisite for continued retention on the register.
- vi. Evidence of adequate levels of professional indemnity insurance should be required for maintaining annual renewal of registered status.
- vii. Publication, dissemination and enforcement of an appropriate code of practice and ethical guidelines which set out a practitioner's responsibilities and duty of care to patients.
- viii. Publication and dissemination of disciplinary procedures and establishment of appropriate fitness to practice mechanisms including investigation, professional conduct, health and appeals jurisdictions.
- ix. Provisions for professional conduct committee hearings normally to be held in public.
- x. An accessible, supportive and published mechanism for dealing sympathetically and effectively with complaints about practitioners from members of the public.

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- xi. Provision of effective enforceable disciplinary sanctions and publication of the findings of professional conduct committees.
 - xii. The publication of patient information leaflets explaining the scope, and limitations of the particular treatments or therapies together with an explanation of what standards of care patients should expect from practitioners.
 - xiii. Publication of an annual report setting out the organisation's main activities and audited accounts.
- (c) All healthcare practitioners (including registered medical practitioners and the professions supplementary to medicine) who practise CAM treatments or therapies should be trained to levels of competence agreed by the appropriate CAM regulatory body and, where appropriate, be registered with that body.
- (d) A central information resource should be established to assist, advise and monitor the development of emerging regulatory structures within CAM and to disseminate information to the public relating to the practice of CAM professions and therapies.
- (e) Consideration should be given to the future establishment by Act of Parliament or Royal Charter of an independent Standards Commission for CAM.

Delivery Mechanisms

INTRODUCTION

74. This chapter summarises the outcome of three meetings of the working group, which considered ways of integrating a broader range of appropriate therapies with mainstream healthcare, having regard to the current patterns of delivering primary and secondary healthcare and existing models for integrating CAM and conventional medicine. Integration, in the wider sense of bringing psychological and social aspects of healthcare together with treatment of bodily ailments, informed the discussions but was not the main remit.

75. The next section (paras 77–78) offers as background an overview of the current demand for CAM, levels of professional support and some suggestions as to what its popularity indicates. The following section looks at different models of integrated care. Detailed guidance on best practice will however require a more comprehensive study to provide the information needed to shape appropriate decisions by practitioners, consumers and NHS purchasing groups.

76. The case that has to be fully explored is whether substantial clinical needs exist that are at present poorly met and which CAM could meet in ways that are acceptable and cost-beneficial. Such an undertaking would explore more fully the likely needs of the public and of health professionals in the decades ahead; whether the NHS can realistically be expected to meet them; and the contribution that CAM therapies can make. This should be set in the context of the wider changes taking place in the NHS; and how the strengths, and scope for diversity and innovation, inherent in general practice, can be married with a greater reliance on clinical evidence and guidance and the need to ensure value for money.

CURRENT PATTERNS AND METHODS OF DELIVERY

77. An independent study carried out for the DOH⁵ reported in 1995 that almost 40% of GP partnerships in England provide access to complementary medicine for NHS patients: 21.4% via a primary care team member and 6.1% through an ‘independent practitioner’. An estimated 24.6% make NHS referrals for complementary medicine. Acupuncture and homoeopathy are the most commonly provided, though the most frequently

employed practitioners were osteopaths. The reasons for the growth in use of CAM within the NHS are not clear, but it may be that rapidly rising health expenditure and calls for managed care have encouraged the hope that non-conventional therapies could be effective and cost-beneficial.

78. Possible priorities for an integrated service would be improved management of stress-related diseases, functional conditions, musculo-skeletal disorders and persistent pain. Conventional medicine finds these common problems difficult to manage, but they are the ones patients most often take to complementary practitioners. About 25% of the public surveyed say they have experienced complementary therapies and some 74% would do so if they were available in the NHS (see Box 1).

Box 1: Changing Attitudes to Complementary Medicine

Public

- An estimated 4–5 million people a year in the UK go to complementary practitioners (CPs)¹¹
- Approximately 14–20% of patients with chronic disease have consulted CPs¹¹
- About 75% of the public support NHS access to complementary medicine¹¹
- Continuing public scepticism about drugs and side-effects
- Continuing media optimism and support for complementary therapies
- Increased public wish to take more responsibility for health choices

Professional

- Greater emphasis on consumer choice and patient care
- BMA's positive attitude to CAM; supports good practice in co-operation, education and research²
- GMC has clarified that doctors may delegate treatment to non-medical complementary practitioners (CPs) if satisfied of their competence and if the GP maintains overall clinical responsibility
- BMA GMSC (1991) survey showed that 20–30% of UK GPs would like to provide main forms of CAM through their practice
- Rising levels of CAM medical research and outcome study publication in mainstream peer-reviewed journals
- Recent establishment of General Osteopathic Council and General Chiropractic Council as statutory bodies to regulate these professions
- Strongly expressed interest among some CAM practitioners in developing an NHS focus for their work

MODELS FOR INTEGRATING CONVENTIONAL MEDICINE AND CAM

79. The working group commissioned a survey by members of the group of over 20 existing examples of primary and secondary care settings where CAM is provided alongside conventional healthcare. The aim was to identify particular factors common to those cases where more effective integration has been achieved. This information should be helpful to healthcare practitioners and managers seeking to achieve greater integration of conventional medicine and CAM.

80. Given the limited resources and time available, a pragmatic approach was adopted to the selection of examples to be studied. The 22 cases analysed covered a wide range of types of provision, which have been categorised in Box 2. Some pros and cons of the various models are indicated.

81. The information about a number of the projects is incomplete and further work will be needed. Nevertheless, using the data provided it has been possible to identify thematic areas of good practice which are expanded on in Annex E within a quality assurance framework¹², looking at three factors:

- **structural criteria:** resources needed to achieve the standard
- **process criteria:** activities needed to achieve the standard
- **outcome measures:** to evaluate the changes introduced.

Collaboration between conventional and complementary practitioners is seen as central to integration. Box 3 sets out the consequences of delivering CAM either in collaboration with mainstream services or without it. This framework uses the same three factors alongside six criteria seen as defining an integrated service.¹³

82. Although the analysis summarised in Annex E may be helpful to healthcare professionals and managers contemplating change, **a more comprehensive national survey and analysis of existing examples of integrated healthcare provision is needed.** Accurate data on treatments and outcomes is required for the management of resources and the development of best practice models. Improved communication between projects, possibly through the development of a national data-base linking them would allow the necessary information gathering.

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Box 2: Current ways of delivering CAM			
Model	Approach	Pros	Cons
General Practice GP non fund-holding practices	1. GP's or nursing staff using CAM 2. Independent CAM practitioners on NHS premises but privately or charitably funded 3. Referral to specialist CAM centres (see below) (NHS or otherwise funded) 4. Private referral to independent CAM practitioners (Referral by conventional specialists to whom GPs have referred may be reimbursed by private medical insurance for some CAM therapies)	Access++ Access++	Expertise? Cost to patient Access Liaison w GP? Cost, liaison?
GP fund-holding (GPFH) practices	1. Any of the above can apply in GPFH practices 2. CAM practitioners working as part of the multi-professional primary care team 3. Referral to independent CAM practitioners's premises: individually or via block contract	Access++ Liaison++ Access Liaison	
GPs and networks	1. Many GPs provide basic CAM treatments, having attended courses 2. Currently a training model giving GPs in primary care competencies in homoeopathy has attracted 10% of Scottish GPs. A network of specialist homoeopathic doctors provides support under agreed terms of service	Access++ Access++ Expertise Integrated	Expertise?
CAM centres NHS Acute Trusts	1. Main homoeopathic hospitals in London and Glasgow are national referral centres for homoeopathy, acupuncture, manipulative and nutritional therapies Mainly outpatients but also some in-patient provision 2. Increasing use of osteopaths in physiotherapy departments, but generally haphazard implementation of this and other main CAM therapies in secondary care 3. Most palliative care units and hospices (>90%) use some form of touch-based CAM therapies, usually by nursing staff or volunteers 4. Pilot projects funded by and implemented on hospital premises a) out patient care e.g.: pain clinic b) in patient care e.g.: massage on cardiac ICU c) dedicated unit e.g.: Lewisham CAM centre, Royal Marsden Rehabilitation Centre d) nurse-led initiatives, e.g. Oxford Institute of Nursing: aromatherapy Macmillan Practice Development Unit: massage	Therapy packages Access Access QA++ QA++	Stable funding? Integrated/QA? Integrated Liaison w GP Integrated? Integrated? Integrated?
Independent units	Independent provider organisations contracted by District Health Authorities (DHAs) to offer CAM services for specified conditions: e.g.: Southampton Centre for Study of Complementary Medicine	GP liaison+ 'Therapy packages'	
DHA initiatives	1. DHA funding via NHS Community Trust for units based in community e.g.: Liverpool Centre for Health 2. DHA funding to independent CAM practitioners in pilot initiatives e.g.: Calderdale & Kirklees project 3. Mental Health initiative, e.g.: Camden Street project		Stable funding? Liaison w GP Stable funding? QA? Integrated?
Charitable projects	Offering subsidised or free treatment, usually to specific client groups e.g.: Bristol Cancer Help Centre, Lighthouse (AIDS), Pathways (drug addiction) (Referrals via GPs, other primary health and community care workers; also self-referral)		Stable funding? Liaison w GP Integrated? Integrated?
CAM training clinics	CAM treatment at low cost by supervised trainees e.g.: British School of Osteopathy, London School of Acupuncture and Trad. Chinese Medicine		Centralised Liaison w GP Integrated?
Corporate services	1. Via occupational health, e.g. M&S osteopathy service 2. Via occupational counselling services, e.g.: massage		Liaison w GP Liaison w GP

Box 3: Defining a 'Quality' Integrated Therapy Service

APPROPRIATENESS
ACCESSIBILITY
ACCEPTABILITY
EQUITY
EFFECTIVENESS
EFFICIENCY

APPROPRIATENESS

	with collaboration	without collaboration
structure	1. The complementary practitioners are supervised managerially in the practice. 2. The complementary practitioner has training funding to develop services 3. The complementary therapist is appointed with the necessary skills in place to deliver the proposed service. 4. The practice has a clear idea of what they want and make sure they get it	1. The complementary practitioner has no contact and no identifiable manager. 2. The practice accepts no responsibility for professional development. 3. The complementary practitioner is appointed with no job description and is inadequately trained to deliver the planned service 4. The GPs don't know what the complementary practitioner is doing except that they ask for a review once a year.

APPROPRIATENESS

	with collaboration	without collaboration
process	1. Complementary practitioners and GP have agreed to target patient groups – e.g. high utilisers and then GP and complementary practitioners work together to identify and share management.	1. The GP refers patients to the complementary practitioner and expects 'magic' to occur for a range of problem areas without discussion of the aims of the service

APPROPRIATENESS

	with collaboration	without collaboration
outcome	1. Complementary practitioners correctly identify patients for complementary therapy using agreed protocols and guidelines. 2. Complementary practitioners are able to assess patients' suitability for complementary therapy and refer back those that are unsuitable and measure outcome	1. Complementary practitioner expected to accept all patients referred and feels that they must cope – who else will otherwise? 2. GPs expect all patients referred to be seen and looked after by the complementary practitioner. No review of service requested.

APPROPRIATENESS

Structure	Process	Outcome
Are the providers of complementary health appropriately trained, supervised and supported?	Do complementary therapists appropriately allocate complementary practitioner treatments to meet patient needs?	Do GPs successfully identify patients' appropriate for complementary therapy treatment?

ACCESSIBILITY

Structure	Process	Outcome
Are the complementary therapy services suitably located and available to all who might be in need of them?	Are waiting times for complementary therapies within the guidelines of the practice's Patient's Charter?	Do GPs enhance accessibility through detailed patient feedback to GPs?

ACCEPTABILITY

Structure	Process	Outcome
Do the complementary services available reflect local care health needs?	Are patients satisfied with the procedures of intake into complementary therapy?	Are patients satisfied with the results of complementary therapy?

EQUITY

Structure	Process	Outcome
Are minority groups catered for in terms of resources?	Are procedures applicable to all minority groups?	Are treatment outcomes equitable with other complementary therapy services?

EFFECTIVENESS

Structure	Process	Outcome
Do intake procedures make maximal use of resources?	Are complementary practitioners establishing and maintaining 'allied' relationships within the field of complementary therapy?	Are the results of complementary therapy considered clinically effective?

EFFICIENCY

Structure	Process	Outcome
Are resources allocated to monitoring and reducing non-attendance rates?	Are complementary therapies given to optimally balance treatment with need?	Is the amount of complementary therapy treatment within evidence-based clinical guidelines?

Acknowledgement: Counselling in Primary Care Trust

INTEGRATING COMPLEMENTARY THERAPIES: KEY ISSUES

83. Complementary medicine is a relative newcomer to the NHS. Rather like counselling and palliative care – relatively recent innovations that have been increasingly integrated into mainstream practice – their effective implementation depends on practitioners' knowledge and skills; and in both instances this has occurred in response to public and professional need rather than on the basis of research evidence of effectiveness. In both cases integration has also taken time, partly because of the need for changes in the attitudes of all those involved, including managers, healthcare professionals and other staff, and of patients and their families. This will no doubt be true also of the further integration of appropriate CAM services.

84. CAM will thrive in the mainstream in the way counselling and palliative care have done, where it satisfies otherwise poorly met need and when conventional practitioners are able to use services appropriately. An optimum service will always depend on organisational factors, including adequate resources and appropriate processes of delivery.

85. Successful integration will need to address a number of issues (See Annex E):

- **Attitudes**, including the natural desire by conventional practitioners to maintain the status quo; worries about competence; fear of litigation; lack of understanding; concern among CAM practitioners about losing autonomy or authority and perceived threats to professional integrity; the concerns of patients and managers.
- **Evidence of effectiveness and safety.** Purchasers and patients need more reliable evidence if they are to be able to make informed choices. More research and audit is required, but it would also be helpful if health professionals and managers could be persuaded to value qualitative evidence of patients' experience more highly.
- **Ensuring adequate training.** There are concerns that the increasing demand from patients for CAM will sometimes lead to practitioners providing treatments without having the full training required.
- **Funding.** The three main sources of funding for CAM therapies (public, private and charitable) do not lead to an equal level of provision across the country; most provision is in the independent sector outside the NHS and in response to demand coming largely from the more prosperous sections of the community. Where funding has been identified to support

the integration of CAM and conventional therapies it has often proved to be short-term, and units have closed despite their usefulness and popularity with patients.

86. Box 4 lists a variety of ways in which CAM services have been funded. The establishment in recent years of GP fundholding practices provided

Box 4: Options for funding	
GP fund-holding	Inevitably raises two-tier service issues, though in some areas provision of CAM services in-house by GP fund holders (GPFHs) has become the norm
Commissioning	Co-operation between GPs to provide equitable access demands a clear sense of cost-benefit and likely health-gain. Local commissioning should be based on identified local needs, available evidence of effectiveness and provision of quality assured delivery systems
Ancillary staff reimbursement funds	DoH ruling in 1991 established that GPs could apply for reimbursement of CAM therapist salaries: at discretion of individual DHAs but no additional funds were made available
Service contracts	Through extra-contractual referrals (which are becoming rarer), or via mainstream contracts with providers: e.g. acupuncture in a pain clinic; hypnotherapy via psychological services. Some DHAs and GPFHs have established contracts with major CAM providers (e.g. homoeopathic hospitals or independent sector organisations e.g. Southampton Centre for the Study of Complementary Medicine (CSCM) for individual patients or for specified conditions. Financial constraints are restricting this type of access. This and other CAM initiatives reliant on public sector funding tend to be targeted in the early phase of cut-backs
Research & development funds	Funds for research initiatives can help expand primary or secondary clinical resources. e.g. primary care development funds
Charitable funding	May support in part or total cost of specific (usually condition-focused) services: e.g. HIV/AIDS (Lighthouse) or cancer (Bristol Cancer Help Centre). Long-term support may be difficult to sustain
Dedicated initiatives	Waiting list reduction initiatives can fund specific therapy provision: e.g. for back pain, chronic pain
Private Medical Insurance	There is an increased willingness by some companies to include a limited list of CAM therapies and/or practitioners. Many companies allow virtually any referral if it is recommended by a consultant. There is "limited specialist" recognition for approved practitioners of certain therapies (notably osteopaths and medical homoeopaths) for referrals directly from GPs.

opportunities for greater integration of CAM within primary care. It is difficult to foresee the impact of any further changes to the structure of NHS financing, though restructuring the commissioning process around larger agencies would not advance the cause of integration if it made it harder for GP's to make use of CAM. It is also clear that integration would require changes in present NHS structures and procedures and this will inevitably take time.

87. Difficult, chronic and complex cases are commonly referred to the CAM units surveyed. There is a risk that this might lead to unpredictable, potentially expensive and inappropriate patterns of referral. Limits may therefore need to be set to ensure that forms of contracting do not disadvantage either purchasers or providers. Otherwise it may be increasingly difficult to obtain NHS Trust and DHA funding for local initiatives or referral to specialist centres. Contracting must include approaches that allow management to evaluate outcomes so that the organisations can learn and adapt even while they are delivering the service.

INTEGRATING COMPLEMENTARY THERAPIES: FURTHER STUDIES

88. The delivery of any new approach to healthcare (including CAM) within conventional settings will raise a variety of questions: some clinical and inter-professional, others financial and managerial. Because of this, it would be unwise at this early stage to separate the study of service delivery from related issues of educational need and research: to address the problems of whether and how best to use CAM an intertwining of all three is required. The health service research needed is currently hampered by a lack of centres (or networks) where this would be feasible. Yet in the absence of such models and the evidence they would generate, the case for establishing integrated care will be more difficult to demonstrate. **The creation of a number of well-resourced units (or networks) competent both to study, teach and provide relevant CAM services would help to overcome this difficulty.**

89. The growing public demand for CAM in the independent sector implies that the current methods of public provision fall short of meeting perceived needs. **Any proposals for integrating CAM should therefore be based on a systematic assessment of healthcare needs, especially the identification of those that are poorly met. A linked project could seek international evidence on the relevance of CAM to**

meeting such needs. Although these two exercises would require sensitivity – for example, when dealing with cultural minorities, ethnic groups or deprived communities – they would enable the relevance of integration to be addressed while avoiding the risk of creating expectations for CAM which could not be satisfied.

90. Current evidence suggest that CAM is often used to supplement conventional care, rather than as an alternative to it. Although evidence for effectiveness and cost-effectiveness is still inconclusive and more high quality research is needed (see the Research & Development chapter) early indications are that certain CAM therapies are particularly valuable in certain types of illness.

91. Commissioning guidelines should therefore be explored, and developed further as evidence grows from clinical research and audit. They should focus on:

- conditions where conventional care has failed to meet patients' needs and complementary medicine can be reasonably expected to improve outcome (see box 5)
- conditions for which there is substantial evidence for successful application of CAM (see box 6)
- defining appropriate outcome measures for CAM therapies in these two categories.

This task would require a collaboration between GP's, CAM practitioners and consultants and their professional bodies.

92. Greater communication with, and involvement of, patients has undoubtedly been a factor in the increasing use of CAM; patients are themselves selecting the CAM practitioners they believe (sometimes on the recommendation of friends) best able to help with their particular problems. However, although self-help can be satisfactory for some individuals, for others the lack of readily available, and user-friendly, information about therapies and therapists is a major obstacle. **If there is to be real progress in integration, the availability and the quality of information for patients and other potential users, about the options, must improve significantly.** Material should be simple and clear, and help in interpreting it should also be available (see the Education and Training Chapter, para 46).

Box 5: Current clinical interest and possible relevance of complementary therapies

- Complaints with little or no tissue damage, such as headache, chronic fatigue, and pre-menstrual syndrome.
- Disorders that require long-term use of conventional drugs, such as chronic inflammatory disorders, and digestive problems
- Diseases for which elective surgery has been proposed, but immediate attention is unnecessary, such as fibroid tumours, gallstones, and haemorrhoids
- Problems that have not been cured by conventional treatments, either because of the inappropriateness of the medication, the determined nature of the disease, or patient's non-compliance.
- Conditions for which no effective conventional treatment is available, such as viral illnesses, traumatic injuries, surgical wounds, multiple sclerosis, AIDS¹⁴

Box 6: Summary of evidence base

therapy	acupunc- ture	homoeo- pathy	osteol/ chiro	nutri- tional medicine	mind-body medicine hypno- therapy	herbal medicine
condition						
asthma	4	4	2	3	4	
chronic fatigue syndrome	2	2		3	3	
cancer	5 [chemo therapy nausea]	3 [scarcity]		3 [prevention]	3*	
eczema	2	3		4	4	5
inflammatory bowel syndrome	2	2		4	2	
IBS	3	3		3	4	4
back/neck pain	4		5		4	
headache/migraine	4	4	3		4	5
osteoarthritis	3	3	3		3	4
glue ear		3		3		4
pre-menstrual syndrome	2	2	3	3	3	4
rhinitis/hay fever	2	5	3		3	
rheumatoid arthritis	4	4		4	3	

* Improved quality of life and survival times in breast cancer
 5 = evidence from sound randomised controlled trials
 4 = some randomised or controlled trials: positive trend but more research needed
 3 = descriptive and/or non-randomised or uncontrolled studies
 2 = clinical evidence but no properly controlled research

This is an incomplete picture, intended only to give an impression of research already available, drawing on a series of very recent overviews.^{15, and also 16, 17, 18}

CONCLUSIONS AND RECOMMENDATIONS

93. Healthcare systems are likely to change radically over the next two decades in response to changes in demography, morbidity and rising costs.¹⁹ Policy will determine what is included in public sector provision, and debate about need – particularly the NHS Review – will depend on how need is defined²⁰. Current evidence shows that most successful organisations and projects are founded on a sure understanding of customers' needs.²¹ The growing emphasis on the importance of the 'informed consumer' suggests that planners will increasingly have to take qualitative measures into account as indicators of need and good practice.

94. The development of delivery systems for integrated healthcare will depend on how information and resources are managed; on the assessment of quality of care; and on appropriate measures of quality of life and health gain. Such measures should be developed collaboratively between those who deliver and those who 'consume' healthcare²². Effective use of CAM could be hindered as much by inappropriate expectations as by blinkered scepticism. Treatment in an integrated system would be pluralistic, centred around primary care, and with an emphasis on prevention. Developing such a system will require a long term strategy – ideally one co-ordinating healthcare data on a large scale.

95. The need for integration and the ways available to deliver such a service have not, however, been adequately defined. A national appraisal of need, and a detailed survey of how and why CAM is being delivered in mainstream practice are now called for.

Summary of Proposals

96. The main proposals emerging from the discussions of the Working Groups can be summarised as follows:

RESEARCH AND DEVELOPMENT

Priorities

(1) Gather more information in the UK, through surveys, expert papers, calls for written evidence, informal workshops, etc., in order to define:

- the perceived public need and current use and availability of CAM
- the perceived need among practitioners and purchasers. **para 4**

(2) Discuss and filter the results, through a series of specialist working groups, so as to establish priorities in the light of evidence. This would involve consumers, doctors, nurses and other CAM professions. The resulting criteria should define the therapies most fruitful to investigate further and the circumstances in which these therapies can be most effectively applied. **para 4**

Methodology

(3) Seek to improve the understanding of the need for research and of appropriate techniques among CAM practitioners and those teaching CAM by:

- preparing background information and guidelines on 'Current issues in research into CAM';
- working in collaboration with professional bodies and
- actively supporting the development of research environments in the Colleges that train therapists. **para 8**

(4) Similarly help 'gateholders' (especially research funders, but also purchasers, medical ethics committees, and orthodox medical practitioners more generally) to understand the current issues in CAM research by disseminating the above guidance and through other means such as seminars. (When funding organisations consult with referees they should ensure that they are appropriately experienced and informed.) **para 8**

(5) Develop outcome measures that can reflect the full benefit experienced by users of complementary therapies. These should include outcome measures reflecting symptomatic as well as curative treatments and their development should involve close consultation with practitioners as well as researchers. **para 9**

Capacity and Support

(6) Concentrate resources on establishing a number of research centres linked with higher education institutes with the capacity to conduct high quality research into CAM either as a self-contained unit, or as a focal point, co-ordinating a network of researchers drawn from different institutions or a network of clinical practices. These centres would benefit from close links with:

- undergraduate and post-graduate education
- clinical practice in CAM
- CAM professional bodies.

paras 17 & 18

(7) The choice should be decided in open competition, based on: the range of existing research capacity for the evaluation of CAM; the available personnel; the potential for academic development and collaboration; and existing or potential links with clinical practice. **para 19**

Funding

(8) Funding is required on several fronts:

- to initiate the research centres proposed in paragraph 17;
- to support the CAM research priorities emerging from the process suggested in paragraph 4;
- responsive funds for good individual projects.

para 21

(9) Further consideration should also be given to the encouragement and development of specific CAM charities, if this could tap additional charitable funds, rather than simply divert them from existing medical research. **para 24**

Dissemination

(10) Improve dissemination of research results by:

- strengthening existing resources in CAM
- using existing orthodox models and resources
- new methods

para 26

EDUCATION AND TRAINING

(11) There should be common elements in the core curriculum of all healthcare workers, both orthodox and CAM, covering:

- Basic anatomy physiology and pathology
- Fundamentals of orthodox medical diagnosis and guidelines for patient referral
- CAM therapies and their potential uses, including the principles of diagnosis and practice
- Holistic models of healthcare
- Professional ethics
- The therapeutic relationship
- Impact of social, cultural, economic, employment and environmental factors on health
- Counselling skills
- Principles of quality management and audit
- Organisational skills, including record keeping
- Technical skills: ranging from prevention of cross-infection to information management.

para 35

(12) Work is needed to develop more detailed proposals for the common core elements and the particular changes required in the curriculum of each healthcare profession. The regulatory bodies for each profession should be closely involved with this and probably take the lead. As a first step there should be a review of current practice in undergraduate and first level education.

para 39

(13) The relevant professional bodies should consider making the inclusion of the common core a requirement for the accreditation of courses.

para 40

(14) CAM practitioners should be trained at courses properly accredited by a professional body representing their discipline.

para 41

(15) Levels of CAM training need to be related to the level of practice to be licensed. Agreement is needed on the principles to be applied; each profession should then be asked to develop more detailed arrangements for its own members.

para 42

(16) All practitioners (both orthodox and CAM) should be required to follow a programme of continuing professional development. All existing practitioners should be offered the opportunity of similar courses in skills development and the holistic approach to practice. **para 44**

(17) The Department of Health should sponsor the preparation of a simple and easily accessible guide to CAM services and the qualifications of practitioners. **para 46**

REGULATION

(18) Consideration should be given to the establishment of statutory self-regulatory bodies for those professions whose practice might put patients at risk of harm from inadequately trained practitioners. Such statutory systems should be based upon an established system of voluntary regulation within each profession. **para 73(a)**

(19) A single lead voluntary self-regulatory body should be established for each of the CAM professions and therapies. Voluntary systems of self-regulation should have the features listed in para 73(b). **para 73(b)**

(20) All healthcare practitioners (including registered medical practitioners and the professions supplementary to medicine) who practise CAM treatments or therapies should be trained to levels of competence agreed by the appropriate CAM regulatory body and, where appropriate, be registered with that body. **para 73(c)**

(21) A central information resource should be established to assist, advise and monitor the development of emerging regulatory structures within CAM and to disseminate information to the public relating to the practice of CAM professions and therapies. **para 73(d)**

(22) Consideration should be given to the future establishment by Act of Parliament or Royal Charter of an independent Standards Commission for CAM. **para 73(e)**

DELIVERY MECHANISMS

(23) Carry out a comprehensive survey of integrated healthcare provision, including an assessment of the needs of professionals seeking integration. **para 82**

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(24) Undertake an assessment of health needs which are currently being poorly met by conventional medicine and nursing. **para 89**

(25) In the light of the above surveys prepare comprehensive advice on best practice for healthcare practitioners and managers. **para 92**

(26) Develop commissioning guidelines. **para 91**

(27) Encourage the development of a number of well-resourced pilot units and networks, competent both to study, teach and provide relevant CAM services. **para 88**

(28) Undertake a review of international initiatives in integrated service provision, including an in-depth survey of models and management practices. **para 89**

Membership of the Steering Committee and the Working Groups

STEERING COMMITTEE

Chairman

Dr Manon Williams	Assistant Private Secretary to H.R.H. The Prince of Wales
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Members

Mr Simon Fielding	Co-Chairman of the Regulation Steering Group
Dr Fleur Fisher	Co-Chairman of the Education & Training Working Group
Professor Stephen Holgate	Chairman of the Research & Development Working Group
Dr Kim Jobst	Hon Research Fellow, Glasgow Western Infirmary
Dr George Lewith	Member of the Research & Development Working Group
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Mr Simon Mills	Co-Chairman of the Regulation Steering Group
Mr Jonathan Monckton	Director, the Research Council for Complementary Medicine
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Professor Lesley Rees	Co-Chairman of the Education & Training Working Group
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RESEARCH AND DEVELOPMENT

Chairman

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EDUCATION AND TRAINING

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Mr Stephen Gordon	Director, Society of Homoeopaths
Mrs Valerie Hopwood	Education Officer, Acupuncture Association of Chartered Physiotherapists
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REGULATION

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Mr Simon Mills	Director of Centre for Complementary Health Studies, Exeter University

Members

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Mr Stephen Gordon	Director, Society of Homoeopaths

Membership of the Steering Committee and the Working Groups: Annex A

Mrs Denise Rankin-Box	Chair of the Royal College of Nursing Complementary Medicine Forum; head of Management of Change Initiatives
Mr Ken Shifrin	Vice-Chairman Designate, British Acupuncture Council; Vice-Chairman, British Acupuncture Accreditation Board
Ms Julie Stone	Lecturer in Ethics and Law, Birmingham

DELIVERY MECHANISMS

Chairman

Dr David Peters	Director, Complementary Therapy Studies Scheme, Centre for Community Care and Primary Health, University of Westminster
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Members

Ms Angela Avis	Chair, RCN Forum on Complementary Therapies
Dr Craig Brown	General Practitioner; President of the National Federation of Spiritual Healers
Ms Val Buxton	RCN Health Visitor Forum; Dept of Primary Care & Population Sciences, University College, London
Mr Leon Chaitow	Naturopath and Osteopath, Marylebone Health Centre
Mr Andrew Chevallier	Chairman, CCAM; medical herbalist
Professor Jessica Corner	The Institute of Cancer Research, Royal Marsden Hospital
Dr Graham Curtis Jenkins	Counselling in Primary Care Trust
Dr Rosy Daniel	Centre Director, Bristol Cancer Help Centre
Dr Peter Dunlop	South Cleveland Hospital
Dr Sarah Eagger	Imperial College School of Medicine; Chair, British Holistic Medical Association
Dr Steven Ersser	School of Health Care Studies, Oxford Brookes University
Ms Deborah Glover	Nursing development programme, the King's Fund
Ms Gerry Harris	Staff and Curriculum Development Officer, St Bartholomew's and the Royal London School of Medicine and Dentistry; teacher at the London School of Acupuncture and Traditional Chinese Medicine
Ms Dione Hills	Evaluation, Development and Review Unit, the Tavistock Institute of Human Relations
Dr Richard James	Centre for Natural Health and Counselling, All Hallows House
Mr A. J. Keighley	Chief Executive, Calderdale & Kirklees Health Authority
Dr David McGavin	Blackthorn Medical Centre
Dr David Morgan	Head of Scientific Affairs, British Medical Association
Ms Yvonne Mouncer	The NHS Confederation
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Dr Peter Reason	School of Management, University of Bath
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Professor Michael Schofield	Chairman, Dorset Community NHS Trust
Ms Caroline Stevensen	The Royal London Homoeopathic Hospital NHS Trust
The Rev David Stoter	Chaplaincy Department, Queen's Medical Centre, Nottingham
Dr John Toby	The Royal College of General Practitioners
Mr Christopher Turner	British Chiropractic Association; Maidenhead Chiropractic Clinic
Dr Martin Twine	Bounds Green Group Practice
Mr Andrew Ward	Society of Homoeopaths; St Margaret's Surgery, Bradford on Avon
Dr Ian Wiles	Fundholding GP; Consultant Psychiatrist
Dr Chris Worth	Director of Public Health, Calderdale & Kirklees Health Authority
Professor Steve Wright	TENDA/The Didsbury Trust

A Note on Research Methods and their Application to Complementary and Alternative Medicine

RANDOMISED CONTROLLED TRIALS (RCTs): EXPLANATORY vs. PRAGMATIC

1. There has been considerable debate about the need for RCTs. There has been a 'myth' that RCTs need to include double blinding, placebo control and 'hard' physical outcome measures. This is not so, but the belief seems to have arisen because of a lack of clear understanding of the distinction between 'explanatory' and 'pragmatic' RCTs.²³

2. The explanatory RCT under controlled conditions is appropriate for determining the efficacy of a single 'active intervention'. For example, one may want to know if a specific herbal remedy or an acupuncture treatment is more effective than a 'placebo' treatment for a particular clinical condition. The methodology also requires blinding of evaluator, patient and practitioner, where possible, to minimise the likelihood of factors other than the component under test having a causative effect on outcome.

3. The pragmatic RCT takes place under 'everyday' conditions to aid decision making. It is used to evaluate the efficacy, safety, cost effectiveness and acceptability of treatments or services. For example, it may be used to compare a 'new' therapy (e.g. chiropractic) with the current conventional treatment of choice (e.g. physiotherapy)²⁴. All RCTs involve randomisation of patients some of which incorporate patient preferences²⁵. Because the aim of pragmatic trials is to mimic 'normal' treatment and allow practitioners to individualise treatment as required, blinding of patient or practitioner may not be required but evaluator blinding is still recommended.

NON-EXPERIMENTAL METHODS

4. Although the advantages of using the RCT are clear, other research methods are also valuable and, for some research questions and situations, more appropriate. This is not specific to the field of complementary medicine. For example, Black²⁶ has identified the circumstances in which observational studies would be the methodology of choice for evaluating the effectiveness of healthcare – situations in which experimentation is unnecessary, in which it is

inappropriate, in which it may be impossible, and in which it may be inadequate. In such situations, a considerable repertoire of methods are available, many deriving from research by clinical professionals other than doctors (e.g. nursing and psychology) or from social science research.

5. Some important research questions that require qualitative research methods inquire about the most effective ways of organising CAM services within the context of the NHS, about patients' experiences of CAM and descriptive work to identify significant variables operating during CAM treatments. For example, there is much discussion on how general practitioners and CAM practitioners can best work together for the benefit of patients. Such questions need to be addressed using practice audit organisational case studies and focus groups.

BASIC CLINICAL RESEARCH

6. Since there is a range of views in CAM as to what constitutes cause and process (mechanism), there is a need for research which investigates the theoretical constructs and biological plausibility of CAM. Some CAM therapies derive from traditions unfamiliar in the west, or from folk traditions that have largely disappeared from view. Therefore, such research needs to start from, and be rooted in, an understanding of the historical development the 'system of medicine or healing' underlying a therapy and to identify points of contact and possible integration within the theoretical basis of orthodox medicine and scientific principles. Of necessity therefore, this will be multidisciplinary and transcultural research, without which some therapeutic modalities may be dismissed by funders and policy makers as lacking biological plausibility and a foundation in the laws of science.

OUTCOME MEASURES

7. To answer questions on the effectiveness of a therapy (such as 'Does it work?') requires clarity about the change that is expected as a result of an intervention and by whom; patient, therapist, relative, policy maker, etc.. This can be particularly problematic in CAM if the desired outcome is not to 'cure' or 'fix' a problem (in the sense of symptom relief per se), but is to enable a condition to be better managed or coped with by a patient and/or their carers, or for the patient to 'heal' in a 'deeper' sense and 'come to terms' with their circumstances, or to enhance their 'quality of life'. At the beginning of therapy, it may not be possible (or desirable) to specify clearly the planned endpoint of treatment. It is important to ask patients about the changes they are experiencing, or which they hope to achieve, before deciding on any specific outcome measures. These concerns are by no means exclusive to research into CAM.

8. In drawing together these principles, the OCAM report (see page 10) identifies some basic assumptions that underpin a research strategy for assessing CAM:

- There is an incomplete understanding of the world: knowledge evolves and develops.

Research Methods and their Application to CAM: Annex B

- Research methods may evolve and change as we continue to learn about the world.
- Research is always feasible – and essential – regardless of the therapy under consideration.
- Research rarely provides definitively unequivocal answers: there is often room for reasonable people to disagree – within limits – about the interpretation of evidence.
- Some statements made about health are incorrect and some practices are not in the best interests of patients.
- Good research aims to minimise the effects of bias, chance variation and confounding.

Our priority is research which investigates whether treatments do more good than harm.

Annex C

Complementary and Alternative Medicine Therapies most widely practised in the United Kingdom

Acupuncture
Alexander Technique
Aromatherapy
Chiropractic
Healing
Herbal Medicine
Homoeopathy
Hypnotherapy
Massage and bodywork therapies
Naturopathy and nutrition
Osteopathy
Reflexology
Shiatsu
Yoga

All of these have been incorporated in one or more models of integrated healthcare, as have the following: counselling and psychotherapeutic care (e.g.: group support), creative therapies, exercise therapy and self-help skills (e.g.: meditation and visualisation).

Recent Political Statements on the Regulation of Complementary and Alternative Medicine

1. In 1987 the then under Secretary of State For Health, Lord Skelmersdale, explained during a debate on complementary medicine in the House of Lords that any proposals or statutory recognition should,

"...be soundly based on independent criteria which clearly safeguard the public interest and are acceptable to all practitioners".

He went on to say that,

"...The view of the medical profession would also be important."

The Minister also highlighted the fact that it was open to any therapy group to decide that it was in their interests and those of their patients to pursue tighter regulations of their affairs.

2. By 1990 the Government had refined its policy still further, largely influenced by the progress towards statutory recognition which had been made by the osteopaths. Speaking in a debate in the House of Lords junior Health Minister Baroness Hooper said.

"The Government have no wish to place any restrictions on natural therapy practitioners or to curtail in any way the freedom of the individual to seek the benefits of the natural therapy. We do however, believe that, members of the public using those therapists have a right to be safeguarded in the same way as those using the NHS professions. That is the challenge to the natural therapy professions and one which in the Government's view needs to be addressed by each profession acting independently rather than action by associations seeking to represent all or most of the natural therapy professions".

3. The Minister went on to say,

"At one time, we were of the view that there might be advantages if all the natural therapies came together in mutual understanding. But given the diversity of practice and aspirations of those professions...we now believe very firmly that it must be for each therapy to determine its own future development."

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4. In January 1992 during the second reading of the Osteopaths Bill, Baroness Hooper, again speaking on behalf of the Government, told the House,

"We have long said that the regulation of the complementary therapy professions should be by way of private members legislation, so that Parliament can make up its own mind on this important issue without political interference."

5. Since 1992 Parliament has supported and successfully steered two separate regulatory bills onto the statute book – namely the Osteopaths Act 1993 and the Chiropractors Act 1994.

6. In 1994 the Labour Party published a policy document "Facilitation not Prescription." The main thrust of the paper focused on the need to encourage developments already taking place within CAM. The paper also suggested that a Labour Government might co-ordinate the implementation of policy on Complementary Medicine through the Department of Health and consider statutory self regulation for the professions of acupuncture, herbal medicine and homoeopathy.

An Analysis of Factors identified as promoting Integrated Healthcare

Structural factors

1 Resources

- A broad range of relevant CAM and psychological therapies potentially available to the public or charitable sectors
- Sufficient funding to allow access to integrated care for all patients who could benefit. Where private funding is the norm the presence of mechanisms allowing access to patients who do not have funds of their own.
- Available State or charitable funding to support R&D in well-organised pilot projects
- Adequate premises for conventional NHS staff and CAM practitioners to work together
- Management that provides leadership within the framework of a learning organisation staffed by competent peers
- Sufficient resources to permit meetings between conventional and CAM staff
- Funding for time and facilities to support educational and research activities

2 Attitudes and values

- Integrated healthcare is more than the incorporation of CAM techniques into mainstream practice. It is facilitated by certain attitudes and values
- A commitment to holistic healthcare combining the best of conventional health and social care with relevant CAM approaches
- Enabling people to be active participants in their own healing processes
- Recognising the relevance of the physical and social environment to health promotion
- An openness to a spiritual dimension to healthcare, concerned with the search for meaning
- Acknowledging the importance of fostering good practitioner-client relationships
- Valuing collaborative working between professions, patients and those supporting or caring for them
- Encouraging high quality training and research. The importance of being 'reflective practitioners'
- Striving to ensure that new methods are safe, effective and acceptable to patients
- Recognising that patients prefer local rapid access to high quality patient-centred services
- Wanting to develop the project as a 'learning organisation' able to recognise and adapt to changing needs

Process factors

1 Maximise supportive processes

- **Referral systems/responding to need**

Use of protocols (ideally evidence based), rigorous referral systems and care plans
Clarity, explicitness about the (organisational, professional and client) needs and expectations involved
Early recognition of relevance of non-conventional approaches

- **Inter-professional working**

Regular relevant communication, inter-professional reflection, supervision for learning/development

- **Education**

Doctors and complementary practitioners require knowledge, skills, attitudes relevant to integration.
Innovative organisations demand internal feedback and learning cycles to stay on track
Service delivery, education and research intertwined

- **Patient-centredness**

Base the service on accurate needs assessment conducted in ways that allow patient voice to be heard
Involve clients in service development processes
Improve avenues for patient education and participation: groups and classes, literature

- **Quality assurance systems**

Systematic data collection and outcome monitoring. Develop databases to track referrals and outcomes
Monitor patients' and practitioners' satisfaction with service

- **Networking**

Processes to disseminate good practice and outcomes through networks and publication

2 Minimise constraining factors

- **Recognising limitations of service**

Establishing clear guidelines for inclusion/exclusion and protocols for discharge
Anticipate that some patients will move inappropriately between practitioners. Take steps to minimise.
Monitor and minimise the inevitable disparity of access that will tend to occur, including waiting lists

- **Recognising limitations of practitioners**

Anticipate and explore communication problems, issues around power and inter-professional conflict
Staff development to develop congruence in data recording

Outcome factors

1 Types of patient/health service outcome

measures which demonstrate that the service produces the following outcomes

- a response to otherwise poorly met clinical need
- enhanced access to a variety of services shown to be culturally relevant
- increased choice of services shown to be appropriate to community needs
- alleviation of physical, psychological or social effects of chronic ill-health
- enhanced health and well-being
- alleviation of somatic distress
- alleviation of relapsing dysfunction
- improved comfort: alleviation of pain or other distressing symptoms e.g. breathlessness
- improved functioning
- alleviation of suffering
- clients being enabled to understand and manage their own healthcare
- clients being empowered to influence factors undermining their health
- client/patient satisfaction

2 Types of staff outcome

measures which demonstrate that the service produces the following outcomes

- delivery of a service consistent with staff beliefs and values
- enhanced work satisfaction
- implementation of a wider range of therapeutic options
- development of new therapeutic skills
- greater opportunity to be involved in inter-professional education
- more opportunities to develop roles in education and research
- improved opportunities for staff support

3 Types of research and development outcome

measures which demonstrate that the service produces the following outcomes

- provision of new models of research
- provision of research data/evidence of treatment effectiveness
- provision of information relevant to policy development

Annex F

Education and Training in Complementary and Alternative Medicine: a postal survey of UK universities, medical schools, and faculties of nurse education

Objectives: To determine the provision of education and training in complementary and alternative medicine (CAM) in UK higher education.

Design: National postal survey using self assessment questionnaire.

Setting: All UK universities: medical schools, faculties/colleges of nurse education and science/health studies departments (1996).

Main outcome measures:

1. Type and number of courses/modules in CAM.
2. Qualification awarded.
3. Details of individual courses/modules: length/content/validation and accreditation status/clinical training.
4. Details of the teachers/trainers.
5. Ongoing and planned research.

Results:

Of 99 universities sent the questionnaire, 88 (89%) responded from one or more departments. Overall, responses were received from 26 (100%) medical schools, 52 (65%) faculties/colleges of nurse education and 51 (51.5%) university science/health studies departments. From all 3 sources, 108 courses/modules in CAM were available. 6 medical schools were providing a very basic introduction through short lectures or special study modules with no clinical training in CAM.

The majority of nursing institutions (37; 71%) provided awareness education in CAM but produced few CAM practitioners from their 68 different courses/modules. 16 university science/health studies departments offered 34 courses, 29 (85%) of which provided specialist

education or training in such therapies as osteopathy, acupuncture, massage therapy etc. 3 medical schools, 30 faculties of nursing and 14 science/health studies departments indicated that were planning future CAM courses.

Conclusion:

Many UK nursing students are likely to receive an introduction to CAM during their training, whereas at present only a minority of medical students receive CAM awareness education during their medical training. Some universities also offer a range of academic and specialist CAM training courses outside the medical/nursing faculties, the majority for intending CAM practitioners. These departments have the potential to become major providers of CAM therapists or researchers. However, few courses are run in conjunction with an external CAM organisation or are validated by a CAM professional body. A national review of CAM education and research is desirable, to establish standards for a core curriculum, and guidelines for validation of courses and assessment of practitioner competence, particularly in acupuncture, herbal medicine and homocopathy. Lay practitioners, doctors, other health care professionals and academics should have an important role in developing agreed guidelines.

A clinical audit of university graduates practising CAM may be continually important if safe and effective integration of CAM within the NHS is to be achieved and if both patients and the medical profession are to be reassured.

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