

Americans' Views on the Use and Regulation of Dietary Supplements

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This article presents the views of Americans on what the government's future role should be in regulating or overseeing the growing sales of dietary supplements for health purposes. Based on results of multiple national opinion surveys, including the views of both users and nonusers of supplements, we found that a substantial percentage of Americans surveyed reported that they regularly take dietary supplements as a part of their routine health regimen. However, they reported that they do not discuss the use of dietary supplements with their physicians because they believe that the physicians know little or nothing about these products and may be biased against them. Many users felt so strongly about the potential health benefits of some of these products that they reported that they would continue to take them even if they were shown to be ineffective in scientifically conducted clinical studies. However, there also was broad public support for increased government regulation of these products. We found that a majority of Americans surveyed supported the following: to require that the Food and Drug Administration review the safety of new dietary supplements prior to their sale; to provide increased authority to remove from sale those products shown to be unsafe; and to increase government regulation to ensure that advertising claims about the health benefits of dietary supplements are true.

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One of the most striking changes in Americans' health behaviors in the 1990s was the widespread and growing use of dietary supplements for health reasons. Since 1994, dietary supplement sales have grown by nearly 80%, from \$8.8 billion to an estimated \$15.7 billion for 2000. Sales of specific herbal remedies, such as echinacea, ginseng, *Ginkgo biloba*, and St John's wort, exceeded \$200 million per product per year, and these supplements are taken routinely by millions of Americans.¹

The sharp rise in the use of these supplements has raised concerns in the medical community and the media about the potentially serious health risks of the mostly untested and unregulated products. Various reports^{2,3} from poison con-

trol centers and practicing physicians have indicated examples of individuals being harmed by taking these supplements. Others⁴ have raised the concern that the use of these products may be leading some to forgo proven conventional medical treatment when they are seriously ill.

Furthermore, the issue has been raised that as these products are increasingly advertised in the media and sold in drug stores and supermarkets the public may be given a false sense of security about their safety. They may believe that supplements are subject to existing government regulations similar to those applicable to over-the-counter medications sold to the public without a prescription. In fact, dietary supplements are subject to a less stringent government standard of safety testing than other over-the-counter medications.^{1,3,5}

After receiving thousands of letters from supplement users in a heated advocacy campaign, Congress passed the Di-

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etary Supplement Health and Education Act⁶ of 1994, which freed dietary supplement manufacturers from many existing Food and Drug Administration (FDA) regulations. In the Nutrition Labeling and Education Act⁷ of 1990, Congress gave the FDA the authority to require manufacturers of dietary supplements to provide evidence that their products were safe prior to sale and to approve the health claims made about these products before they could be used in marketing. After the 1994 legislation was enacted, the burden of proof concerning the safety of dietary supplements shifted. Instead of the manufacturer having to show that a supplement was safe, the FDA had to prove that it was unsafe. Also, as a result of the legislation, manufacturers have been able to make general health claims about products as long as they do not contain references to preventing or curing specific diseases. These supplements are now sold under the same oversight standard as vitamins and are categorized under a separate FDA category as "foods."^{8,9}

Recently, the question of the need for stricter regulation of these products has been raised in editorials, medical journals, and articles in the media, particularly on the issue of safety and the specific health claims that can be made by the manufacturers.^{2,10,11} What has been missing in this growing debate over what the government's role should be in regulating dietary supplements are the views of the American public, both users and nonusers of these products.

In this article, we seek to fill this void by summarizing the available public opinion survey data on the dietary supplement issue. We used national opinion survey data to answer the following questions: (1) What are the characteristics of people who use dietary supplements regularly, and how are users different from nonusers? (2) How are regular users' attitudes about dietary supplements and their usefulness different from those of nonusers? (3) What are Americans' attitudes toward government regulation, and are there differences between the attitudes of regular users and nonusers? (4) What are the policy impli-

cations of these differences, and how might they affect the debate on the national level?

DATA AND METHODS

Relatively few polls investigating Americans' views of dietary supplement use and regulation have been conducted. The data presented herein came primarily from 2 sources.

The first source consisted of specific results drawn from 4 national opinion surveys conducted from 1996 to 1999. These surveys did not differentiate between the views of regular users and nonusers of dietary supplements. These data were compiled from the public opinion database at the Roper Center for Public Opinion Research in Storrs, Conn.¹²⁻¹⁵

The second source consisted of 2 surveys that differentiated the views of users and nonusers of dietary supplements. One survey was designed by researchers at National Public Radio, the Henry J. Kaiser Family Foundation, and the John F. Kennedy School of Government. Telephone interviews were conducted with 1200 randomly selected US adults by Princeton Survey Research Associates between February 19 and 25, 1999.¹⁶ The second survey was designed by researchers at the Henry J. Kaiser Family Foundation and the Harvard School of Public Health. International Communications Research conducted interviews via telephone with 1013 randomly selected US adults between December 16 and 21, 1999.¹⁷

In the analysis of data from these latter 2 surveys, *regular users* were defined as respondents who reported that they regularly use products, such as echinacea, ginseng, over-the-counter hormones, or amino acids. Respondents who reported using dietary supplements sometimes were classified as *sometimes users*. Lastly, *nonusers* were defined as those respondents who reported that they never use these products. We compared the views of both sometimes users and nonusers with regular users. Differences between these groups were tested using a χ^2 test, and significance is noted in the individual tables.

All surveys were subject to sampling and nonsampling errors. Results may have differed from what would have been obtained if the whole population of adults had been interviewed. The size of this error varied with the number surveyed and the magnitude of difference in the responses to each question. These surveys had sample sizes of approximately 1000 to 1200 persons. With a sample this size, the results, with a 95% degree of confidence, have a statistical precision of ± 3 to 3.5 percentage points compared with what would have been obtained if the entire population had been interviewed. Possible sources of nonsampling error include nonresponse bias and question wording and ordering effects.

RESULTS

DEMOGRAPHIC CHARACTERISTICS

A review of the findings of these surveys showed that approximately half (48%) of all American adults surveyed reported taking some type of nonprescription vitamin, dietary, or mineral supplements regularly.¹¹ One in six (16%-18%) reported regularly using dietary supplements, like echinacea, ginseng, amino acids, or over-the-counter hormones.^{16,17}

Table 1 displays the differences between demographic groups in terms of the frequency of dietary supplement use. American respondents with higher levels of education reported greater use than those with less education. Regular users were also more likely to be white (non-Hispanic). Americans older than 45 years were more likely to use supplements regularly than those who were younger (24% vs 14%, respectively).¹⁶

Also, uninsured American respondents were significantly more likely than those with insurance to use dietary supplements (21% vs 15%, respectively).¹⁷ Of note, 1 (18%) of 6 parents reported giving dietary supplements to their children.¹⁶

BELIEFS ABOUT DIETARY SUPPLEMENTS

The surveys found that a substantial percentage of the Americans sur-

veyed held positive views of the health benefits derived from taking dietary supplements. A 1997 survey found that one third (36%) of the American adults thought that there was a dietary supplement that could help them live longer.¹² Overall, 85% of regular users reported that dietary supplements are good for people's health and well-being. The figure was lower for those who were not regular users.¹⁶

Regular users differed significantly from nonusers in their belief that dietary supplements could help with the treatment of a wide range of medical conditions (**Table 2**). About half of the American respondents believed that supplements are helpful for people with colds (61%), arthritis (53%), depression (52%), and influenza (49%). Respondents viewed dietary supplements as helpful in the treatment of cancer (35%) and acquired immunodeficiency syndrome (16%).¹⁶ Not surprisingly, regular users were significantly more likely than nonusers to believe that supplements could help people with all the conditions the survey asked about; however, rates were also high among the nonusers. Another study¹⁴ found that 82% of the Americans surveyed said that they would seriously consider trying alternative treatments, such as herbal medicines, if they were terminally ill.

The surveys also found that those who were regular users believed strongly in the usefulness of various dietary supplements irrespective of the scientific evidence. When asked what they would do if a government agency said that the supplement they use most often was ineffective, 71% of regular users reported that they would continue to use it (**Table 3**).¹⁶ In the follow-up survey, respondents were asked what they would do if the FDA specifically said that the supplement they use most often was ineffective to see if using the FDA's name vs an unknown government agency would alter the result. The addition of the FDA did not lead to different responses (Table 3). Once again, two thirds (67%) of regular and sometimes users said that they would continue to take the supplement.¹⁷

Given how beneficial most regular users believed dietary supple-

Table 1. Demographics of US Respondents*

	Total (N = 1196)	Frequency of Dietary Supplement Use			P
		Regular (n = 235)	Sometimes (n = 381)	Never (n = 580)	
National		18	15	66	
Income, \$†					
<20 000	19	20	30	50	
20 000-29 999	15	20	27	53	
30 000-50 000	18	16	37	48	
>50 000	25	17	34	49	
Education					
Less than high school graduate	17	16	28	56	<.001
High school graduate	34	15	28	57	
Some college	27	22	36	42	
College or more	23	22	33	45	
Race or ethnicity					
White, non-Hispanic	80	20	30	50	.03
Black, non-Hispanic	10	8	33	60	
Hispanic	7	14	34	53	
Other	3	24	45	31	
Insurance status					
Insured	83	15	10	74	.05
Uninsured	16	21	16	64	
Age, y					
18-34	33	16	34	50	<.001
35-44	22	14	32	54	
45-64	28	24	31	45	
≥65	17	22	26	52	
Sex					
Male	48	18	30	52	
Female	52	19	32	49	

* Data are expressed as percentages unless indicated otherwise. Percentages may not equal 100% because of rounding. The values sum horizontally. National indicates the percentage of the national population in each group, ellipses, not applicable. Data are from a survey conducted by Princeton Survey Research Associates.¹⁶
† Percentages do not equal 100% because of missing data.

Table 2. Dietary Supplements' Effect on Health and Well-being According to US Respondents*

	Total (N = 1196)	Frequency of Dietary Supplement Use		
		Regular (n = 235)	Sometimes (n = 381)	Never (n = 580)
Supplements are good for health and well-being				
Yes	52	85	62†	34†
No	17	3	10	27
Some are, some are not†	17	9	18	20
Do not know	14	3	9	19
Supplements are helpful for people with				
Influenza	49	64	56§	40†
Colds	61	77	73	48†
Cancer	35	54	41†	24†
Acquired immunodeficiency syndrome	16	21	20	12†
Arthritis	53	71	61†	42†
Depression	52	72	58†	42†
How important is access to supplements?				
Very important	35	73	40†	19†
Somewhat important	24	18	32	22
Not too important	17	7	18	21
Not at all important	22	2	9	37

* Data are expressed as percentages. Percentages may not equal 100% because of rounding. Data are from a survey conducted by International Communications Research.¹⁷

† Significantly different from regular users (P < .001).

‡ Respondents volunteered answer; it was not given as an option in the survey.

§ Significantly different from regular users (P = .02).

Table 3. US Respondents' Use of Dietary Supplements Considered Unsafe by Government Agencies*

	Total (N = 1196)	Frequency of Dietary Supplement Use	
		Regular (n = 235)	Sometimes (n = 381)
If a government agency said that the dietary supplement is ineffective, what would you do?			
Stop using the supplement	25	24	25
Keep using the supplement	72	71	72
Do not know	4	4	3
If the FDA said that the dietary supplement you use most often is ineffective, what would you do?			
Stop using the supplement	33	32	33
Keep using the supplement	66	67	65
Do not know	1	1	1

*Data are expressed as percentages. Percentages may not equal 100% because of rounding. The first question was from a survey conducted by Princeton Survey Research Associates.¹⁶ The second question was from a survey conducted by International Communications Research.¹⁷ FDA indicates Food and Drug Administration.

Table 4. US Respondents' Opinions on the Safety of Dietary Supplements*

	Total (N = 1196)	Frequency of Dietary Supplement Use		
		Regular (n = 235)	Sometimes (n = 381)	Never (n = 580)
Supplements are adequately tested				
Yes	37	49	38†	33†
No	48	39	47	53
Do not know	15	12	15	14
Advertising for supplements is				
Not true	49	29	43†	60†
Generally true	37	57	45	25
Do not know	15	14	12	16
How often are people harmed by supplements?				
Often or sometimes	47	38	46	51†
Rarely or never	44	53	48	38
Do not know	10	9	6	11

*Data are expressed as percentages. Percentages may not equal 100% because of rounding. Data are from a survey conducted by Princeton Survey Research Associates.¹⁶

†Significantly different from regular users (P < .001).

ments to be, it is not surprising that access to them is very important for regular users. Of those who reported that they regularly use dietary supplements, 91% said that access to them is "very" or "somewhat" important. Of note, 72% of sometimes users and 41% of nonusers felt this way (Table 2).¹⁶

CONFIDENCE IN PHYSICIANS' OPENNESS TOWARD AND KNOWLEDGE OF DIETARY SUPPLEMENTS

The respondents who reported regular use of dietary supplements were divided in their assessment of their physician's level of knowledge

of and openness toward these products. More than two thirds (70%) of those who reported taking supplements regularly said that they had shared this information with their regular physician. However, the survey did not provide a measure of the extent of information shared between patients and physicians, and many regular users were skeptical of their physician's knowledge of and attitudes toward supplements. Nearly half (49%) of regular users believed that physicians are prejudiced against supplement use and 44% believed that their own physician knows only a little or not much at all about these products.¹⁷

SAFETY OF DIETARY SUPPLEMENTS

Regular users of dietary supplements had much more confidence in the safety of these products than nonusers. As shown in **Table 4**, only 37% of the respondents believed that dietary supplements are adequately tested. However, regular users were more likely (49%) than nonusers (33%) to believe that there is adequate testing of these products. Also, the majority of regular users (53%) believed that people are "rarely or never" harmed by taking dietary supplements. In contrast, 51% of nonusers reported that people are "often or sometimes" harmed by these supplements.¹⁶

ROLE OF ADVERTISING INFORMATION

Commercial advertising has been shown to be an important source of information about over-the-counter medications.¹⁸ One recent survey¹⁵ found that 39% of the respondents reported that television commercials are the most influential source of information in their decision about which cold medicine to buy. In the area of dietary supplements, data are not available on the frequency of use of commercials as an important information source. However, a majority (57%) of regular users thought that the claims made by supplement manufacturers in the advertisements are generally true (Table 4). Those who were not regular users were less likely to believe the claims made by these advertisements.¹⁶

ATTITUDES TOWARD GOVERNMENT REGULATION OF DIETARY SUPPLEMENTS

A substantial percentage of the respondents were confused about the role that the government currently plays in regulating dietary supplements. Slightly more than half (53%) of the respondents were aware that supplements are not regulated by the government (**Table 5**). One third (35%) of the respondents believed that supplements are currently regulated, and 12% reported that they did not know. The results were similar for regular users.¹⁶

However, even with this level of public confusion, a majority of respondents expressed support for increased government regulatory efforts to ensure that dietary supplements are not harmful and are pure, that doses are consistent, and that advertising claims are true (**Table 6**).¹⁶ As shown in Table 5, 81% of the respondents supported giving the FDA the authority to allow new supplements to be sold only if the safety of the supplements has been tested by the FDA; 80% supported giving the FDA the authority to remove dietary supplements from the market if they are proved unsafe. Similar levels of support were found among regular users.¹⁷

CONCLUSIONS

It is clear from the rapid growth in sales that dietary supplements have become a big business. Millions of Americans now regularly take these products as part of their routine health regimen. This phenomenon is being driven by a widespread belief that these untested products contain substances that can lead to better health. Many users feel so strongly about the potential health benefits of some of these products that they reported that they would continue to take them even if they were shown to be ineffective in scientifically conducted clinical studies.

Although only 16% to 18% of the respondents were regular users, the majority of the respondents thought that access to these products is important. This finding suggests that Americans want to be able to use supplements if needed. It also may be due to a belief that there are therapeutic or beneficial substances that the medical community is not aware of.

However, the growing enthusiasm for dietary supplements does not mean that there is not support for stronger regulation that would require FDA review of the safety of new dietary supplements prior to their sale and that would give the FDA ample authority to remove from the market those products shown to be unsafe. Broad support also exists for increased government regulation to ensure that advertising claims about the health benefits are true, that the

Table 5. US Respondents' Attitudes Toward FDA Regulation of Supplements*

	Frequency of Dietary Supplement Use			
	Total (N = 1196)	Regular (n = 235)	Sometimes (n = 381)	Never (n = 580)
Does the government regulate dietary supplements?				
Yes	35	32	42†	33
No	53	58	49	54
Do not know	12	11	9	13
Allow new dietary supplements to be sold only if they have been tested by the FDA				
Favor	81	70	80	84
Oppose	14	24	17	10
Do not know	5	6	3	6
Remove dietary supplements from the market if the FDA shows that they are unsafe				
Favor	80	78	79	80
Oppose	16	18	19	14
Do not know	5	3	1	6

* FDA indicates Food and Drug Administration. Data are expressed as percentages. Percentages may not equal 100% because of rounding. Data are from a survey conducted by Princeton Survey Research Associates.¹⁶

†P = .003 compared with regular users.

Table 6. US Respondents' Attitudes Toward Levels of Regulation*

Level of Regulation	Frequency of Dietary Supplement Use			
	Total (N = 1196)	Regular (n = 235)	Sometimes (n = 381)	Never (n = 580)
To make sure that supplements are not harmful				
Too much	7	9	7	5†
Not enough	59	55	59	62
Right amount	24	27	26	22
Do not know or refused to answer	10	9	8	11
To make sure that supplements are pure and doses are consistent				
Too much	6	9	4‡	6§
Not enough	60	55	61	62
Right amount	23	25	25	21
Do not know or refused to answer	11	10	10	12
To make sure that advertising claims are true				
Too much	7	10	6	5
Not enough	64	62	65	64
Right amount	20	19	21	20
Do not know or refused to answer	10	9	7	11
Supports more regulation for children's supplements	77	78	77	77

* Data are expressed as percentages. Percentages may not equal 100% because of rounding. Data are from a survey conducted by Princeton Survey Research Associates.¹⁶

†Significantly different from regular users (P = .005).

‡P = .002 compared with regular users.

§P = .007 compared with regular users.

||P = .004 compared with regular users.

ingredients in the products are pure, and that dose levels are consistent with the labeling.

The caveat is that a substantial number of the respondents were not prepared to be denied access to existing dietary supplements that have not been previously tested for safety.

Many respondents held skeptical views about physicians' and most likely scientists' motivations and knowledge about dietary supplement issues and will likely want clear evidence of a safety hazard before supporting the removal of supplements from the market.

Thus, efforts to increase FDA oversight may not gain support from a critical segment of the public if there is not a clear understanding that any proposed expanded FDA authority is narrowly focused on the testing of either new products or those in use in which there is evidence of potential hazards or untruthful health claims.

These findings also point to the importance for physicians of becoming both more involved with patients in discussing their use of dietary supplements and more knowledgeable about them, particularly in regard to safety issues. The fact that 1 of 6 parents reported giving these supplements to their children should prompt physicians to devote more attention to discussing this practice with parents as they seek health care for their children.

Finally, although the question was not asked directly in the surveys, the findings suggested that there is considerable support for increased research efforts by the government and industry to test and evaluate dietary supplements, particularly for safety purposes. Given how quickly these products are moving into mainstream use, more research seems warranted.

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Herbal Medicines and Perioperative Care

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THERE IS ENORMOUS PUBLIC ENTHUSIASM for herbal medications. Two recent surveys have found widespread use among the presurgical population.^{1,2} Morbidity and mortality associated with herbal medications may be more likely in the perioperative period because of the polypharmacy and physiological alterations that occur.³ Such complications include myocardial infarction, stroke, bleeding, inadequate oral anticoagulation, prolonged or inadequate anesthesia, organ transplant rejection, and interference with medications indispensable for patient care.

Of the herbal medications that clinicians are likely to encounter, we have identified 8 of the herbs that potentially pose the greatest impact to the care of patients undergoing surgery. These herbs account for more than 50% of all single herb preparations among the 1500 to 1800 herbal medications sold in the United States.^{4,5} Nonherbal dietary supplements, such as vitamins, minerals, amino acids, and hormones, are beyond the scope of this review. Some of these nonherbal dietary supplements that patients undergoing surgery are most likely to take, such as glucosamine and chondroitin for osteoarthritis,^{6,7} appear to be safe. Limited information is available, however, on the use of these supplements in the presurgical population.

In this article, we consider safety and US regulatory issues for herbal medications; review the literature on the identified 8 commonly used herbal

Context Widespread use of herbal medications among the presurgical population may have a negative impact on perioperative patient care.

Objectives To review the literature on commonly used herbal medications in the context of the perioperative period and provide rational strategies for managing their preoperative use.

Data Sources The MEDLINE and Cochrane Collaboration databases were searched for articles published between January 1966 and December 2000 using the search terms *herbal medicine*, *phytotherapy*, and *alternative medicine* and the names of the 16 most commonly used herbal medications. Additional data sources were obtained from manual searches of recent journal articles and textbooks.

Study Selection We selected studies, case reports, and reviews addressing the safety and pharmacology of 8 commonly used herbal medications for which safety information pertinent to the perioperative period was available.

Data Extraction We extracted safety, pharmacodynamic, and pharmacokinetic information from the selected literature and reached consensus about any discrepancies.

Data Synthesis Echinacea, ephedra, garlic, ginkgo, ginseng, kava, St John's wort, and valerian are commonly used herbal medications that may pose a concern during the perioperative period. Complications can arise from these herbs' direct and pharmacodynamic or pharmacokinetic effects. Direct effects include bleeding from garlic, ginkgo, and ginseng; cardiovascular instability from ephedra; and hypoglycemia from ginseng. Pharmacodynamic herb-drug interactions include potentiation of the sedative effect of anesthetics by kava and valerian. Pharmacokinetic herb-drug interactions include increased metabolism of many drugs used in the perioperative period by St John's wort.

Conclusions During the preoperative evaluation, physicians should explicitly elicit and document a history of herbal medication use. Physicians should be familiar with the potential perioperative effects of the commonly used herbal medications to prevent, recognize, and treat potentially serious problems associated with their use and discontinuation.

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medications as they affect perioperative care; and propose rational strategies for managing the preoperative use of these agents. The prevention, recognition, and treatment of complications begin with explicitly eliciting and documenting a history of herbal medicine use. Familiarity with the scientific literature on herbal medications is necessary because the current US regulatory mechanism for commercial herbal preparations sold in the United States does not necessarily protect the population against unpredictable or un-

desirable effects. Our goal is to provide a framework for physicians practicing in the contemporary environment where widespread herbal medicine use occurs.

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Preoperative Use of Herbal Medications

The most extensive surveys on the use of complementary and alternative medicine use in the United States revealed that approximately 12% of the population used herbal medications in 1997,^{8,9} representing a 380% increase from 1990. Patients undergoing surgery appear to use herbal medications significantly more frequently than the general population. For instance, Tsen et al¹ reported that 22% of patients who underwent evaluation in their preoperative clinic took herbal medications. Also, Kaye et al² found that 32% of patients in an ambulatory surgery setting admitted to using herbal medications.

More than 70% of the patients in the study by Kaye et al² failed to disclose their herbal medicine use during routine preoperative assessment. Explanations for this lack of disclosure include patient-held beliefs that physicians are not knowledgeable about herbal medications or are prejudiced against their use.¹⁰ Some patients may fear admitting to their physicians their use of unconventional therapies.¹¹ Others may neglect to mention that they are taking herbal medications when they are using them for reasons perceived as unrelated to their medical care.¹² Still other patients would not consider these substances to be medications, and they may neglect to report them during routine preoperative questioning. For these reasons, it is necessary for physicians to specifically seek out a history of herbal medicine use in presurgical patients.

Regulation and Safety of Herbal Medications

Herbal medications were classified as dietary supplements in the Dietary Supplement Health and Education Act of 1994.¹³ This law exempts herbal medications from the safety and efficacy requirements and regulations that prescription and over-the-counter drugs must fulfill (ie, preclinical animal studies, premarketing controlled clinical trials, or postmarketing surveillance). The burden is shifted to the US Food and

Drug Administration to show that a product is unsafe before it can be removed from the market.¹⁴ In addition, the inability to patent herbal medications discourages the manufacturers from performing the costly research required for conventional drugs.¹⁵

The current US regulatory mechanism provides little assurance that commercial herbal preparations have predictable pharmacological effects and that product labels provide accurate information. The potency of herbal medications can vary from manufacturer to manufacturer and from lot to lot within a manufacturer.¹⁶⁻¹⁸ Plants may be misidentified or deliberately replaced with cheaper or more readily available alternatives.¹⁹⁻²² Moreover, herbal medications, especially those of Eastern origin, can be adulterated with heavy metals, pesticides, and even conventional drugs.²³⁻²⁵ Some herbal manufacturers have tried to standardize their herbal products to fixed concentrations of selected chemical constituents.²⁶ The benefit of this effort is uncertain, however, because many products achieve their effects through the combined or synergistic actions of different compounds.²⁷ Even when advertised and labeled as standardized, potency can still vary considerably.²⁸

Because there is no mechanism for postmarketing surveillance, the incidence and exact nature of adverse events is unknown. Empirical evidence gained from a long history of herbal medication use supports the notion that most are safe.²⁹ Nevertheless, some of these medications have been associated with serious harm.^{30,31} More than 5000 suspected herb-related adverse reactions were reported to the World Health Organization before 1996.³² Between January 1993 and October 1998, 2621 adverse events, including 101 deaths, associated with dietary supplements were reported to the US Food and Drug Administration.³³ However, adverse events are underreported because there is no central mechanism for mandatory reporting as there is for conventional medications. Other factors that contribute to underreporting are that physi-

cians do not always recognize adverse events associated with herbal medication use³⁴ and that patients are reluctant to report and seek treatment for the adverse reactions.³⁵ This reluctance has been attributed to the belief that physicians cannot be consulted in the use of unconventional therapies and that patients are unwilling to admit the use of these remedies to physicians. The deficiencies in monitoring adverse events for herbal medicines mean that safety profiles are usually limited to animal studies, case reports, or predictions derived from known pharmacological results.

METHODS

We identified the most commonly used herbal medications by 1999 sales data and surveys in the literature.^{1,2,4} The MEDLINE and Cochrane Collaboration databases were searched for articles published between January 1966 and December 2000, using the search terms *herbal medicine*, *phytotherapy*, *alternative medicine*, and the names of the most commonly used herbal medications (*aloe*, *bilberry*, *cascara*, *cranberry*, *echinacea*, *ephedra*, *garlic*, *ginseng*, *ginkgo*, *goldenseal*, *kava*, *milk thistle*, *saw palmetto*, *soy*, *St John's wort*, and *valerian*). Additional sources included manual searches of textbooks and recent surgery, anesthesiology, and alternative medicine journals.

Although we found no randomized controlled trials that evaluated the effects of prior herbal medicine use on the perioperative period, we identified, based on our judgments, those studies, case reports, and reviews addressing the safety, pharmacokinetics, and pharmacodynamics of the commonly used herbs that may affect the care of these patients.

RESULTS

Eight Commonly Used Herbal Medications

Despite many uncertainties in commercial preparations, herbal medications adhere to modern pharmacological principles. A single herbal medication may adversely affect the patient during the perioperative period

through a number of different mechanisms. These effects are direct (intrinsic pharmacological effects), pharmacodynamic interactions (alteration of the action of conventional drugs at effector sites), and pharmacokinetic interactions (alteration of the absorption, distribution, metabolism, and elimination of conventional drugs).

Echinacea

Three species of echinacea, a member of the daisy family, are used for the prophylaxis and treatment of viral, bacterial, and fungal infections, particularly those of the upper respiratory tract.³⁶ Pharmacological activity cannot be attributed to a single compound, although the lipophilic fraction, which contains the alkylamides, polyacetylenes, and essential oils, appears to be more active than the hydrophilic fraction.

Preclinical studies of echinacea have shown a number of immunostimulatory effects.³⁷⁻³⁹ While no studies specifically addressing interactions between echinacea and immunosuppressive drugs have been conducted, expert opinion generally warns against the concomitant use of echinacea and these drugs because of the probability of diminished effectiveness.^{37,40,41} Therefore, patients who may require perioperative immunosuppression, such as those awaiting organ transplantation, should be counseled to avoid taking echinacea. In contrast to the immunostimulatory effects with short-term use, long-term use of longer than 8 weeks is accompanied by the potential for immunosuppression⁴¹ and a theoretically increased risk of certain postsurgical complications, such as poor wound healing and opportunistic infections.

Echinacea also has been associated with allergic reactions, including 1 reported case of anaphylaxis.⁴² Thus, echinacea should be used with caution in patients with asthma, atopy, or allergic rhinitis. In addition, concerns of potential hepatotoxicity have been raised, although documented cases are lacking.¹⁷ Because of the absence of definitive information, patients with preex-

isting liver dysfunction should be cautious when taking echinacea. Furthermore, since the pharmacokinetics of echinacea have not been studied, it may be prudent for patients to discontinue taking echinacea as far in advance of surgery as possible when compromises in hepatic function or blood flow are anticipated. These situations often occur secondary to concomitant anesthetic drug administration or as an effect of surgical manipulation.

Ephedra

Ephedra, known as ma huang in Chinese medicine, is a shrub native to central Asia. It is used to promote weight loss, increase energy, and treat respiratory tract conditions, such as asthma and bronchitis. Ephedra contains alkaloids, including ephedrine, pseudoephedrine, norephedrine, methylephedrine, and norpseudoephedrine.⁴³ Commercial preparations may be standardized to a fixed ephedrine content.

Ephedra causes dose-dependent increases in blood pressure and heart rate. Ephedrine, the predominant active compound, is a noncatecholamine sympathomimetic agent that exhibits α_1 , β_1 , and β_2 activity by acting directly at adrenergic receptors and by indirectly releasing endogenous norepinephrine. These sympathomimetic effects have been associated with more than 1070 reported adverse events, including fatal cardiac and central nervous system complications.⁴⁴

Although ephedrine is widely used as first-line therapy for intraoperative hypotension and bradycardia, the unsupervised preoperative use of ephedra raises certain concerns. Vasoconstriction and, in some cases, vasospasm of coronary and cerebral arteries may cause myocardial infarction and thrombotic stroke.⁴⁵ Patients who have consumed ephedra and are later anesthetized with halothane may be at risk of developing intraoperative ventricular arrhythmias because halothane sensitizes the myocardium to ventricular arrhythmias caused by exogenous catecholamines.⁴⁶ Ephedra also may affect cardiovascular function by causing

hypersensitivity myocarditis, characterized by cardiomyopathy with myocardial lymphocyte and eosinophil infiltration.⁴⁷ Long-term use results in tachyphylaxis from depletion of endogenous catecholamine stores and may contribute to perioperative hemodynamic instability. In these situations, direct-acting sympathomimetic agents may be preferred as first-line therapy for intraoperative hypotension and bradycardia. Concomitant use of ephedra and monoamine oxidase inhibitors can result in life-threatening hyperpyrexia, hypertension, and coma. Finally, heavy use of ephedra has been documented as a very rare cause of radiolucent kidney stones.^{48,49}

The pharmacokinetics of ephedrine have been studied in humans.^{50,51} Ephedrine has an elimination half-life of 5.2 hours with 70% to 80% of the compound excreted unchanged in urine. Based on the pharmacokinetic data and the known cardiovascular risks of ephedra, including myocardial infarction, stroke, and cardiovascular collapse from catecholamine depletion, patients taking this herb should discontinue use at least 24 hours prior to surgery.

Garlic

Garlic is one of the most extensively researched medicinal plants. It has the potential to modify the risk of developing atherosclerosis by reducing blood pressure and thrombus formation and lowering serum lipid and cholesterol levels.⁵² These effects are primarily attributed to the sulfur-containing compounds, particularly allicin and its transformation products. Commercial garlic preparations may be standardized to a fixed alliin and allicin content.

Garlic inhibits platelet aggregation in a dose-dependent fashion. The effect of 1 of its constituents, ajoene, appears to be irreversible and may potentiate the effect of other platelet inhibitors, such as prostacyclin, forskolin, indomethacin, and dipyridamole.^{53,54} Although these effects have not been consistently demonstrated in volunteers, there

is one case in the literature of an octogenarian who developed a spontaneous epidural hematoma that was attributed to heavy use of garlic.⁵⁵ In addition to concerns about bleeding, garlic has the potential to lower blood pressure. In laboratory animals, allicin decreased systemic and pulmonary vascular resistance⁵⁶ and lowered blood pressure.⁵⁷ In humans, however, the antihypertensive effect of garlic is marginal.⁵⁸

Although there are insufficient pharmacokinetic data of the constituents of garlic, the potential for irreversible inhibition of platelet function may warrant patients to discontinue use of garlic at least 7 days prior to surgery, especially if postoperative bleeding is a particular concern or other platelet inhibitors are given.

Ginkgo

Ginkgo is derived from the leaf of *Ginkgo biloba*. It has been used for cognitive disorders, peripheral vascular disease, age-related macular degeneration, vertigo, tinnitus, erectile dysfunction, and altitude sickness. Studies suggest that ginkgo may stabilize or improve cognitive performance in patients with Alzheimer disease and multi-infarct dementia.^{59,60} The compounds believed to be responsible for its pharmacological effects are the terpenoids and flavonoids. The 2 ginkgo extracts used in clinical trials are standardized to ginkgo-flavone glycosides and terpenoids.

Ginkgo appears to alter vasoregulation,⁶¹ act as an antioxidant,⁶² modulate neurotransmitter and receptor activity,⁶³ and inhibit platelet-activating factor.⁶⁴ Of these effects, the inhibition of platelet-activating factor raises the greatest concern for the perioperative period since platelet function may be altered. Clinical trials with small numbers of patients have not demonstrated complications from bleeding, but 4 cases of spontaneous intracranial bleeding,⁶⁵⁻⁶⁸ 1 case of spontaneous hyphema,⁶⁹ and 1 case of postoperative bleeding following laparoscopic cholecystectomy⁷⁰ have been attributed to ginkgo use.

Terpenoids are highly bioavailable when administered orally. Glucuronidation appears to be part of the metabolism of the flavonoids.⁷¹ The elimination half-lives of the terpenoids after oral administration are between 3 and 10 hours.⁷² Based on the pharmacokinetic data and the risk of bleeding, particularly in the surgical population, patients should discontinue taking ginkgo at least 36 hours prior to surgery.

Ginseng

Among the several species used for pharmacologic effects, Asian ginseng and American ginseng are the most commonly described. Ginseng has been labeled as an "adaptogen," since it reputedly protects the body against stress and restores homeostasis.⁷³ Most pharmacological actions are attributed to the ginsenosides that belong to a group of compounds known as *steroidal saponins*. Commercially available ginseng preparations may be standardized to ginsenoside content.

Ginseng has a broad but incompletely understood pharmacological profile because of the many heterogeneous and sometimes opposing effects of different ginsenosides.⁷⁴ The underlying mechanism appears to be similar to that classically described for steroid hormones. A potential therapeutic use for this herb has to do with its ability to lower postprandial blood glucose in both patients with type 2 diabetes mellitus and without diabetes,⁷⁵ but this effect may create unintended hypoglycemia, particularly in patients who have fasted before surgery. There is a concern about the effect of ginseng on coagulation pathways. Ginsenosides inhibit platelet aggregation *in vitro*^{76,77} and in laboratory rats, prolong both coagulation time of thrombin and activated partial thromboplastin.⁷⁸ One early study suggests that the antiplatelet activity of panaxynol, a constituent of ginseng, may be irreversible in humans.⁷⁹ These findings await further confirmation. Although ginseng may inhibit the coagulation cascade, ginseng use was associated with a significant decrease in warfarin anticoagulation in 1 reported case.⁸⁰

The pharmacokinetics of ginsenosides Rg₁, Re, and Rb₂ have been investigated in rabbits, with elimination half-lives between 0.8 and 7.4 hours.⁸¹ These data suggest that patients should discontinue ginseng use at least 24 hours prior to surgery. However, because platelet inhibition caused by ginseng may be irreversible, it is probably prudent to recommend that patients discontinue ginseng use at least 7 days prior to surgery.

Kava

Kava is derived from the dried root of the pepper plant *Piper methysticum*. Kava has gained widespread popularity as an anxiolytic and sedative. Results from clinical trials suggest that kava has a therapeutic potential in the symptomatic treatment of anxiety.⁸² The kavalactones appear to be the source of the pharmacological activity of kava.⁸³

Because of its psychomotor effects, kava was one of the first herbal medications expected to interact with anesthetics. The kavalactones have dose-dependent effects on the central nervous system, including antiepileptic,⁸⁴ neuroprotective,⁸⁵ and local anesthetic properties.⁸⁴ Kava may act as a sedative-hypnotic by potentiating γ -aminobutyric acid (GABA) inhibitory neurotransmission. The kavalactones increased barbiturate-induced sleep time in laboratory animals.⁸⁶ This effect may explain the mechanism underlying the report of a case of coma attributed to an alprazolam-kava interaction.⁸⁷ Although kava has abuse potential, whether long-term use can result in addiction, tolerance, and acute withdrawal after abstinence has not been satisfactorily investigated. With heavy use, kava produces a condition called *kava dermatopathy*, characterized by reversible scaly cutaneous eruptions.⁸⁸

Peak plasma levels occur 1.8 hours after an oral dose, and the elimination half-life of kavalactones is 9 hours.⁸³ Unchanged kavalactones and their metabolites are eliminated through urine and feces.⁸⁹ The pharmacokinetic data and possibility for the potentiation of the sedative effects of anesthetics sug-

gest that patients taking kava should discontinue use at least 24 hours prior to surgery.

St John's Wort

St John's wort is the common name for *Hypericum perforatum*. A number of clinical trials have reported efficacy in the short-term treatment of mild-to-moderate depression.⁹⁰ However, a recent multicenter clinical trial concluded that St John's wort is not effective in the treatment of major depression.⁹¹ The compounds believed to be responsible for pharmacological activity are hypericin and hyperforin.⁹² Commercial preparations are often standardized to a fixed hypericin content of 0.3%.

St John's wort exerts its effects by inhibiting serotonin, norepinephrine, and dopamine reuptake by neurons.^{93,94} Concomitant use of this herb with or without serotonin-reuptake inhibitors may create a syndrome of central serotonin excess.^{95,96} Although early in vitro data implicated monoamine oxidase inhibition as a possible mechanism of action,⁹⁷ a number of further investigations have demonstrated that monoamine oxidase inhibition is insignificant in vivo.^{98,99}

The use of St John's wort can significantly increase the metabolism of many concomitantly administered drugs, some of which are vital to the perioperative care of certain patients. For example, the cytochrome isoform P4503A4 is induced, approximately doubling its metabolic activity.^{100,101} Interactions with substrates of the P4503A4 isoform, including indinavir sulfate,¹⁰² ethinyl estradiol,¹⁰³ and cyclosporin, have been documented. In 1 series of 45 organ transplant recipients, St John's wort was associated with a mean decrease of 49% in blood cyclosporine levels.¹⁰⁴ Another study reported 2 cases of acute heart transplant rejection associated with this particular pharmacokinetic interaction.¹⁰⁵ Other P4503A4 substrates commonly used in the perioperative period include alfentanil, midazolam hydrochloride, lidocaine, calcium channel blockers, and serotonin receptor

antagonists. In addition to the P4503A4 isoform, the cytochrome isoform P4502C9 also may be induced. In 7 reported cases, the anticoagulant effect of warfarin, a substrate of the P4502C9 isoform, was reduced.¹⁰³ Other P4502C9 substrates include the nonsteroidal anti-inflammatory drugs. Furthermore, the enzyme induction caused by St John's wort may be more pronounced when other enzyme inducers, which could include other herbal medications, are taken concomitantly. St John's wort also affects digoxin pharmacokinetics, possibly by inducing the P-glycoprotein transporter.¹⁰⁶

In humans, the single-dose and steady-state pharmacokinetics of hypericin, pseudohypericin, and hyperforin have been determined.^{107,108} After oral administration, peak plasma levels of hypericin and hyperforin were obtained in 6.0 and 3.5 hours, and their median elimination half-lives were 43.1 and 9.0 hours, respectively. The long half-life and alterations in the metabolism of many drugs make concomitant use of St John's wort a particular risk in the perioperative setting. The pharmacokinetic data suggest that patients taking this herbal medication should discontinue use at least 5 days prior to surgery. This discontinuation is especially important for patients waiting for organ transplantation or in those who may require oral anticoagulation postoperatively; thus, these patients should be counseled to avoid taking St John's wort postoperatively.

Valerian

Valerian is an herb native to the temperate areas of the Americas, Europe, and Asia. It is used as a sedative, particularly in the treatment of insomnia, and virtually all herbal sleep aids contain valerian.¹⁰⁹ Valerian contains many compounds acting synergistically, but the sesquiterpenes are the primary source of the pharmacological effects of valerian. Commercially available preparations may be standardized to valerenic acid.

Valerian produces dose-dependent sedation and hypnosis.¹¹⁰ These effects ap-

pear to be mediated through modulation of GABA neurotransmission and receptor function.^{111,112} In experimental animals, valerian increases barbiturate-induced sleep time.¹¹³ In 1 patient, valerian withdrawal appeared to mimic an acute benzodiazepine withdrawal syndrome after the patient presented with delirium and cardiac complications following surgery and the patient's symptoms were attenuated by benzodiazepine administration.¹¹⁴ Based on these findings, valerian should be expected to potentiate the sedative effects of anesthetics and adjuvants, such as midazolam, that act at the GABA receptor.

The pharmacokinetics of the constituents of valerian have not been studied, although their effects are thought to be short-lived. Caution should be taken with abrupt discontinuation of use in patients who may be physically dependent on valerian because of the risk of benzodiazepine-like withdrawal. In these individuals, with close medical supervision, it may be prudent to taper the dose of valerian during several weeks before surgery. If this is not feasible, physicians can advise patients to continue taking valerian up until the day of surgery. Based on the mechanism of action and a reported case of efficacy,¹¹⁴ benzodiazepines can be used to treat withdrawal symptoms should they develop during the postoperative period.

COMMENT

Because most patients may not volunteer that they are taking herbal medications in the preoperative evaluation,² physicians should specifically elicit and document a history of herbal medication use. Obtaining such a history may be difficult. Written questionnaires for information on herbal medication use have not shown to be beneficial in identifying patients taking these remedies, since half of patients who use alternate therapies fail to report this information during an evaluation unless they are questioned in person.¹¹⁵ An oral history, however, also has been shown to be inadequate. Unless this information is directly so-

licited, patients may not be forthcoming. Even when a history of herbal medication use is obtained, 1 of 5 patients is unable to properly identify the preparation they are taking.¹¹⁶ Therefore, patients should be asked to bring their herbal medications and other dietary supplements with them to their preoperative evaluation.

Patients who use herbal medications may be more likely than those who do not to avoid seeking conventional diagnosis and therapy.¹¹⁷ Hence, a history of herbal medicine use should prompt physicians to suspect the presence of undiagnosed disorders causing symptoms that may lead to self-medication using herbal remedies. These recommendations also apply to pediatric patients be-

cause caretakers may treat children with herbal medications without medical supervision.¹¹⁸ In 1 survey, 1 in 6 parents reported giving dietary supplements to their children.¹⁰

Although the American Society of Anesthesiologists has no official standards or guidelines on the preoperative use of herbal medications, public and professional educational information released by this organization suggest that patients discontinue their herbal medications at least 2 to 3 weeks before surgery.^{119,120} Our review of the literature favors a more targeted approach. Pharmacokinetic data on selected active constituents indicate that some herbal medications are eliminated quickly and may be discontinued closer to the time of sur-

gery. Tailoring recommendations for preoperative discontinuation of herbal medications may be necessary since evaluating patients 2 to 3 weeks before elective surgery may be impossible in practice. Moreover, some patients require nonelective surgery or are non-compliant with instructions to discontinue herbal medications preoperatively. These factors and the high frequency of herbal medicine use may mean that many patients will take herbal medications until the time of surgery. Therefore, clinicians should be familiar with commonly used herbal medications to recognize and treat complications that may arise. TABLE 1 summarizes the clinically important effects, perioperative concerns, and recommendations for dis-

Table 1. Clinically Important Effects and Perioperative Concerns of 8 Herbal Medicines and Recommendations for Discontinuation of Use Before Surgery*

Herb: Common Name(s)	Relevant Pharmacological Effects	Perioperative Concerns	Preoperative Discontinuation
Echinacea: purple coneflower root	Activation of cell-mediated immunity	Allergic reactions; decreased effectiveness of immunosuppressants; potential for immunosuppression with long-term use	No data
Ephedra: ma huang	Increased heart rate and blood pressure through direct and indirect sympathomimetic effects	Risk of myocardial ischemia and stroke from tachycardia and hypertension; ventricular arrhythmias with halothane; long-term use depletes endogenous catecholamines and may cause intraoperative hemodynamic instability; life-threatening interaction with monoamine oxidase inhibitors	At least 24 hours before surgery
Garlic: ajo	Inhibition of platelet aggregation (may be irreversible); increased fibrinolysis; equivocal antihypertensive activity	Potential to increase risk of bleeding, especially when combined with other medications that inhibit platelet aggregation	At least 7 days before surgery
Ginkgo: duck foot tree, maidenhair tree, silver apricot	Inhibition of platelet-activating factor	Potential to increase risk of bleeding, especially when combined with other medications that inhibit platelet aggregation	At least 36 hours before surgery
Ginseng: American ginseng, Asian ginseng, Chinese ginseng, Korean ginseng	Lowers blood glucose; inhibition of platelet aggregation (may be irreversible); increased PT-PTT in animals; many other diverse effects	Hypoglycemia; potential to increase risk of bleeding; potential to decrease anticoagulation effect of warfarin	At least 7 days before surgery
Kava: awa, intoxicating pepper, kawa	Sedation, anxiolysis	Potential to increase sedative effect of anesthetics; potential for addiction, tolerance, and withdrawal after abstinence unstudied	At least 24 hours before surgery
St John's wort: amber, goat weed, hardhay, Hypericum, klamathweed	Inhibition of neurotransmitter reuptake, monoamine oxidase inhibition is unlikely	Induction of cytochrome P450 enzymes, affecting cyclosporine, warfarin, steroids, protease inhibitors, and possibly benzodiazepines, calcium channel blockers, and many other drugs; decreased serum digoxin levels	At least 5 days before surgery
Valerian: all heal, garden heliotrope, vandal root	Sedation	Potential to increase sedative effect of anesthetics; benzodiazepine-like acute withdrawal; potential to increase anesthetic requirements with long-term use	No data

*PT-PTT indicates prothrombin time-partial thromboplastin time.

Table 2. Herbal Medicine and Other Dietary Supplement–Related Sites on the World Wide Web

Organization	Web Address	Site Information
Center for Food Safety and Applied Nutrition, Food and Drug Administration	http://vm.cfsan.fda.gov/~dms/supplmnt.html	Clinicians should use this site to report adverse events associated with herbal medicines and other dietary supplements. Sections also contain safety, industry, and regulatory information.
National Center for Complementary and Alternative Medicine, National Institutes of Health	http://nccam.nih.gov	This site contains factsheets about alternative therapies, consensus reports, and databases.
Agricultural Research Service, United States Department of Agriculture	http://www.ars-grn.gov/duke	The site contains an extensive phytochemical database with search capabilities.
Quackwatch	http://www.quackwatch.com	Although this site addresses all aspects of health care, there is a considerable amount of information covering complementary and herbal therapies.
National Council Against Health Fraud	http://www.ncahf.org	This site focuses on health fraud with a position paper on over-the-counter herbal remedies.
HerbMed	http://www.herbmed.org	This site contains information on more than 120 herbal medications, with evidence for activity, warnings, preparations, mixtures, and mechanisms of action. There are short summaries of important research publications with MEDLINE links.
ConsumerLab	http://www.consumerlab.com	This site is maintained by a corporation that conducts independent laboratory investigations of dietary supplements and other health products.

continuation of the 8 herbal medications before surgery.

Clinicians also should recognize that discontinuation of all herbal medications before surgery may not free a patient from risks related to their use. Since withdrawal of conventional medications is associated with increased morbidity and mortality after surgery, it is conceivable that withdrawal of herbal medications may be similarly detrimental.¹²¹ In patients with alcoholism, preoperative abstinence of alcohol use may result in poorer postoperative outcome than continued preoperative drinking.¹²² The danger of abstinence after long-term use may be similar with herbal medications, such as valerian, which have the potential for producing acute withdrawal after long-term use.

Because the herbal medicine field is rapidly evolving, sources for reliable and updated information are important in helping physicians stay abreast of new discoveries about the effects of herbal medications and other dietary supplements. TABLE 2 lists several resources that are available on the World Wide Web as clinical aides.

In summary, the task of caring perioperatively for patients who use herbal medications is an evolving challenge. The limited evidence-based information about the safety and efficacy of

herbal medications, the absence of a standard regulatory mechanism for herbal medicine approval and surveillance, and improper patient assumptions about herbal medications represent important medical issues. Although there has been initiation of herbal medicine into medical school curricula at several institutions many practicing physicians remain unaware of potential perioperative complications of herbal medication use. Physicians should be familiar with all medications, whether conventional or herbal, their patients are taking. This information is necessary to prevent, recognize, and treat potentially serious problems associated with herbal medications, taken alone or in conjunction with conventional medications.

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The shrewd guess, the fertile hypothesis, the courageous leap to a tentative conclusion—these are the most valuable coin of the thinker at work.

—Jerome Seymour Bruner (1915-)

Research letters

Indinavir concentrations and St John's wort

Stephen C Piscitelli, Aaron H Burstein, Doreen Chaitt, Raul M Alfaro, Judith Falloon

St John's wort reduced the area under the curve of the HIV-1 protease inhibitor indinavir by a mean of 57% (SD 19) and decreased the extrapolated 8-h indinavir trough by 81% (16) in healthy volunteers. A reduction in indinavir exposure of this magnitude could lead to the development of drug resistance and treatment failure.

Herbal remedies and complementary medicines are widely used despite a lack of information about their pharmacology, pharmacokinetics, and potential drug interactions. St John's wort (*Hypericum perforatum*) is one of the most popular herbal dietary supplements. Preliminary data suggest that St John's wort induces the 3A4 isoform of the cytochrome P450 (CYP) enzyme system.¹ Because HIV-1 protease inhibitors are substrates of the CYP3A4 isozyme, induction by St John's wort might have serious clinical implications.² We evaluated the effect of St John's wort on plasma concentrations of the HIV-1 protease inhibitor indinavir.

We did an open-label study in healthy volunteers. The study was approved by the National Institute of Allergy and Infectious Diseases (NIAID) Institutional Review Board, and all participants gave written informed consent. Inclusion criteria included negative HIV-1 test, age over 18 years, laboratory values within established NIAID limits, and a normal physical examination. Volunteers were excluded if they had smoked in the past year, received St John's wort within 30 days, had a history of allergy or adverse reactions to indinavir, were pregnant or lactating, were receiving

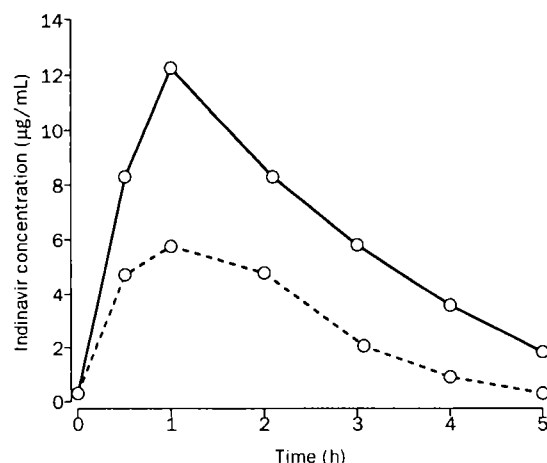
concomitant drugs metabolised via the CYP450 pathway, or had persistent diarrhoea or a history of malabsorption.

On the morning of day 1, fasting participants received indinavir 800 mg orally. They then received two more doses at 8 h intervals to achieve steady-state. On the morning of day 2, an 800 mg dose was given on an empty stomach in the clinic. Blood samples for indinavir pharmacokinetics were collected before and at 0.5, 1, 2, 3, 4, and 5 h after dosing, representing about 90% of the total area under the curve (AUC).

On day 3, participants began outpatient treatment with St John's wort (300 mg reagent grade tablets, lot 190217, Hypericum Buyers Club, Los Angeles, CA, USA). This preparation is standardised to 0.3% hypericin, which was confirmed in our laboratory by a USP/NF method.³ Each participant received 300 mg three times daily with meals, for 14 days. On day 16 (day 14 of St John's wort) participants again received indinavir 800 mg orally every 8 h on an empty stomach. On day 17, participants received 800 mg of indinavir in clinic with blood sampling before and serially for 5 h after dosing. Participants took their last dose of St John's wort with breakfast 90 min after indinavir dosing. Indinavir concentrations in plasma were measured by high performance liquid chromatography (HPLC) using modifications of a previously published method.⁴ The calibration range was from 25 to 10 000 ng/mL with a 25 ng/mL limit of quantitation. Inter-day and intra-day coefficients of variation ranged from 2% to 11%.

Indinavir pharmacokinetic indices were determined according to standard non-compartmental equations (WinNonlin V1.1, Scientific Consulting, Inc, Apex, NC, USA). Indices included maximum plasma concentration (C_{max}), time to maximum plasma concentration (T_{max}), concentration 5 h after the dose (C_5), area under the curve from time zero to 5 h after dose (AUC_{0-5}), and oral clearance (CL/F). The concentration 8 h after dosing (C_8) and the AUC over the 8-h dosage interval (AUC_{0-8}) were extrapolated with the elimination rate constant calculated by log-linear regression of the terminal phase of the concentration-time profile. Indinavir pharmacokinetic indices in the presence and absence of St John's wort were compared with a paired Student's *t*-test. The ratio of the mean AUC in the presence of St John's wort to indinavir alone was calculated, and 95% CI around the mean point estimate were determined.

Eight participants (six male) were enrolled and completed the study. Seven were Caucasian and one was Hispanic. Their ages ranged from 29 to 50 years. Mean concentration-time profiles of indinavir alone and with St John's wort are



Mean concentration-time of indinavir alone (solid line) and with concomitant St John's wort (dotted line)

shown (figure). The AUC_{0-8} of indinavir decreased by a mean (SD) of 57% (19)% (30.8 [8.4] to 12.3 [4.7]) after therapy with St John's wort ($p=0.0008$)*. All participants showed a reduction in C_{tr} , ranging from 49 to 99%, with a fall in the mean from 0.493 $\mu\text{g/mL}$ for indinavir alone to 0.048 $\mu\text{g/mL}$ after St John's wort ($p=0.027$). The mean C_{max} of indinavir decreased from 12.3 (4.1) $\mu\text{g/mL}$ to 8.9 (3.4) $\mu\text{g/mL}$. T_{max} was not significantly altered. For C_{tr} , the mean ratio of indinavir with St John's wort to indinavir alone was 0.194 (95% CI 0.059–0.329). The point estimate for the mean ratio of AUC_{0-8} was 0.458 (95% CI 0.335–0.581).

Study drugs were well tolerated by all participants, and none withdrew. The most commonly reported adverse effects included taste changes (50%), nausea (25%), and circumoral paresthesias (25%) and were associated with indinavir. One participant developed a rash during initial dosing that did not recur during subsequent dosing. The intensity and duration of reported adverse effects were less during the second phase of indinavir.

This study shows a large reduction in indinavir concentrations by concomitant St John's wort. These results have important clinical implications for HIV-infected patients receiving these two agents since low plasma concentrations of protease inhibitors are a cause of antiretroviral resistance and treatment failure.³

Several case reports and two studies examining urinary markers of CYP450 activity suggest that CYP3A4 induction is the mechanism for the decrease in indinavir exposure, although effects on p-glycoprotein cannot be ruled out.⁴ Because we expected CYP3A4 induction by St John's wort, we studied healthy, non-HIV-infected volunteers to avoid inadequate indinavir concentrations in HIV-infected participants. Many clinicians consider complementary medicines to be inert. These products are rarely thought a cause of adverse effects or treatment failure, and often are not included in a drug history. This study shows that drug interactions with these products do occur and might have profound clinical consequences, especially in HIV-infected patients in whom resistance can rapidly develop in the presence of suboptimum antiviral concentrations.

St John's wort should be avoided in patients receiving indinavir as their sole protease inhibitor. Since other protease inhibitors and non-nucleoside reverse transcriptase inhibitors are also metabolised by CYP3A4, it is reasonable to also avoid St John's wort with these agents in the absence of definitive data.

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*See *Lancet* website for full results (www.thelancet.com)

Acute heart transplant rejection due to Saint John's wort

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We report here acute rejection in two transplant patients due to a metabolic interaction of St John's wort and ciclosporin.

St John's wort (*Hypericum perforatum*) is a folk remedy frequently used for the treatment of skin injuries, burns, and neuralgia. Recently, it has gained a reputation as an effective treatment for depression.¹ However, the mechanism of action of the postulated antidepressant effects is unclear.

A 61-year-old heart transplant patient was admitted for elective endomyocardial biopsy. Orthotopic heart transplantation had been done 11 months earlier because of end-stage ischaemic cardiomyopathy (figure, A). Subsequently, the patient had an event free course (International Society of Heart and Lung Transplantation [ISHT], grading 0 or 1A) and was maintained on a standard immunosuppressive regimen of ciclosporin (125 mg twice daily), azathioprine (100 mg daily) and low dose corticosteroids (7.5 mg daily). Ciclosporin plasma levels remained stable throughout the year. Three weeks before admission the patient started self-medication with St John's wort because of mild depression. The standardised St John's wort extract LI160 (sold under the brand name Jarsin® containing 900 μg hypericin) was taken at a dose of 300 mg three times daily (further chemical analysis of the drug was not done). On admission, the patient had nonspecific fatigue, but was otherwise feeling well. Physical examination was normal, in particular there were no signs of infection or haemodynamic compromise. Laboratory investigation showed decreased ciclosporin plasma concentrations (95 $\mu\text{g/L}$), but no further abnormalities, in particular no signs of cytomegalovirus infection. Endomyocardial biopsy revealed acute cellular transplant rejection (ISHT-grading 3A, Quilty B). Interaction of St John's wort with ciclosporin was suspected and the patient's self-medication was stopped. Ciclosporin dosage was increased to 150 mg twice daily and bolus dose of corticosteroids (1 g intravenously per day) was given for 3 days, but proved to be ineffective, as endomyocardial biopsy done 7 days later showed prolonged acute rejection (ISHT-grading 3A, Quilty B). Hence, azathioprine was substituted by mycophenolate mofetil (1 g twice daily). Anti thymocyte globulin (ATG), 1250 mg daily, intravenously was given for 10 days. These drugs resolved the rejection episode (ISHT-grading 1 A). After stopping treatment with St John's wort, plasma ciclosporin remained within the therapeutic range with no further episodes of rejection.

1 week after the first patient presented, a 63-year-old patient was referred to our clinic for elective endomyocardial biopsy. Heart transplantation was performed 20 months earlier because of end-stage ischaemic cardiomyopathy (figure, B). The patient was maintained on a triple immunosuppressive regimen of ciclosporin (125 mg twice daily), azathioprine (125 mg daily) and corticosteroids (7.5 mg daily) and had an even-free course (ISHT grading 0 or 1A) and stable ciclosporin concentrations. 3 weeks before admission, a psychiatrist started treatment with St John's wort (Jarsin® 300 tid) because of anxiety and depression. On admission, ciclosporin plasma concentrations were below the therapeutic range (87 $\mu\text{g/L}$) and endomyocardial biopsy showed acute heart transplant rejection (ISHT 2). Physical examination and laboratory values did not show any other cause of rejection. After treatment with St John's wort was stopped plasma ciclosporin returned to therapeutic values. No further

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Review

Herb-drug interactions

Adriane Fugh-Berman

Concurrent use of herbs may mimic, magnify, or oppose the effect of drugs. Plausible cases of herb-drug interactions include: bleeding when warfarin is combined with ginkgo (*Ginkgo biloba*), garlic (*Allium sativum*), dong quai (*Angelica sinensis*), or danshen (*Salvia miltiorrhiza*); mild serotonin syndrome in patients who mix St John's wort (*Hypericum perforatum*) with serotonin-reuptake inhibitors; decreased bioavailability of digoxin, theophylline, cyclosporin, and phenprocoumon when these drugs are combined with St John's wort; induction of mania in depressed patients who mix antidepressants and *Panax ginseng*; exacerbation of extrapyramidal effects with neuroleptic drugs and betel nut (*Areca catechu*); increased risk of hypertension when tricyclic antidepressants are combined with yohimbine (*Pausinystalia yohimbe*); potentiation of oral and topical corticosteroids by liquorice (*Glycyrrhiza glabra*); decreased blood concentrations of prednisolone when taken with the Chinese herbal product xiao chai hu tang (sho-salko-to); and decreased concentrations of phenytoin when combined with the Ayurvedic syrup shankhapushpi. Anthranoid-containing plants (including senna [*Cassia senna*] and cascara [*Rhamnus purshiana*]) and soluble fibres (including guar gum and psyllium) can decrease the absorption of drugs. Many reports of herb-drug interactions are sketchy and lack laboratory analysis of suspect preparations. Health-care practitioners should caution patients against mixing herbs and pharmaceutical drugs.

"Poisons and medicines are oftentimes the same substances given with different intents."

Peter Mere Latham (1789-1875)

Many medicinal herbs and pharmaceutical drugs are therapeutic at one dose and toxic at another. Interactions between herbs and drugs may increase or decrease the pharmacological or toxicological effects of either component. Synergistic therapeutic effects may complicate the dosing of long-term medications—eg, herbs traditionally used to decrease glucose concentrations in diabetes¹ could theoretically precipitate hypoglycaemia if taken in combination with conventional drugs.

Herbal medicines are ubiquitous: the dearth of reports of adverse events and interactions probably reflects a combination of under-reporting and the benign nature of most herbs used. Experimental data in the field of herb-drug interactions are limited, case reports scarce, and case series rare. This lack of data is also true of drug-drug interactions: published clinical studies are mainly case reports (controlled trials are scarce, since the random assignment of patients to trials that examine unintended effects is not ethical). The true prevalence of drug interactions is substantial but unknown. One study

of 1000 elderly people admitted to a hospital from the emergency department found that 538 patients were exposed to 1087 drug-drug interactions; 30 patients experienced adverse effects as a consequence of these interactions.² In clinical practice, polypharmacy is common, and to the mixture physicians prescribe, patients add various over-the-counter medications, vitamins, herbs, and foods. All ingested substances have the potential to interact.

Source and extent of review

Sources for this review include MEDLINE 1966-98 (searched under MeSH terms "drug interactions" combined with "herbal medicine", "traditional medicine", "Chinese traditional medicine", "African traditional medicine", "Ayurvedic medicine", "Oriental traditional medicine", "Unani medicine", and "Arabic medicine"); EMBASE 1994-99 (searched under the same terms); reference dredging; and my own files on the subject.

Many reports of herb-induced interactions lack crucial documentation on temporal relations and concomitant drug use. Perhaps the most serious problem encountered in analysing such reports is the consistent absence of any effort (beyond that of reading the label) to establish a positive identification of the herb involved, and to exclude the effect of contaminants or adulterants. Unless noted otherwise, the reports mentioned herein did not include chemical analyses.

This review was limited to the most commonly used medicinal plants, and to clinical reports (animal studies

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Herb and drug(s)	Results & interaction	Comments
Betel nut (<i>Areca catechu</i>) Flupenthixol and procyclidine Fluphenazine Prednisone and salbutamol	Rigidity, brachyinesia, jaw tremor Tremor, stiffness, akathisia Inadequate control of asthma	Betel contains arecoline, a cholinergic alkaloid. Arecidine challenge caused dose-related bronchospasm in six asthma patients ⁸
Chili pepper (<i>Capsicum</i> spp) ACE inhibitor Theophylline	Cough ⁹ Increased absorption and bioavailability ¹⁰	Capsaicin depletes substance P
Danshen (<i>Saikoakikorihi</i>) Warfarin	Increased INR, prolonged PT/PTT ¹¹	In rats danshen decreases elimination of warfarin. ¹² Danshen is in at least one brand of cigarettes. ¹³
Devil's claw (<i>Harpagophytum procumbens</i>) Warfarin	Purpura ⁴	
Dong quai (<i>Angelica sinensis</i>) Warfarin	Increased INR ¹⁴ and widespread bruising ⁸	Dong quai contains coumarins.
Eleuthero or Siberian ginseng (<i>Eleutherococcus senticosus</i>) Digoxin	Raised digoxin concentrations ¹⁵	Herb probably interfered with digoxin assay (patient had unchanged ECG despite digoxin concentration of 5.2 nmol/L).
Garlic (<i>Allium sativum</i>) Warfarin	Increased INR ⁸	Postoperative bleeding ^{16,20} and spontaneous spinal epidural haematoma ²¹ have been reported with garlic alone. Whether garlic prolongs PT is unclear, but it does cause platelet dysfunction.
Ginkgo (<i>Ginkgo biloba</i>) Aspirin Paracetamol and ergotamine/cafeine Warfarin Thiazide diuretic	Spontaneous hyphema ²² Bilateral subdural haematoma ²³ Intracerebral haemorrhage ²⁴ Hypertension ²⁵	Ginkgo is a potent inhibitor of PAF. ^{22,24} May not be interaction but due to ginkgo alone. Subarachnoid haemorrhage ²⁶ and subdural haematoma ²⁷ have been reported with the use of ginkgo alone This effect may be an unusual adverse reaction to the drug or herb; ginkgo alone has not been associated with hypertension.
Ginseng (<i>Panax</i> spp) Warfarin Phenelzine Alcohol	Decreased INR ⁸ Headache and tremor, ²⁸ mania ²⁹ Increased alcohol clearance ³¹	In rats concomitantly administered ginseng had no significant effect on the pharmacokinetics or pharmacodynamics of warfarin. ³⁰ Patient with mania also ingested bupropion, and had previously had unipolar depression. In mice, ginseng increases the activity of alcohol dehydrogenase and aldehyde dehydrogenase.
Guar gum (<i>Cyamopsis tetraglobosa</i>) Metformin, phenoxymethylpenicillin, glibenclamide	Slows absorption of digoxin, paracetamol, and bumetanide decreases absorption of metformin, phenoxymethylpenicillin, and some formulations of glibenclamide ³²	Guar gum prolongs gastric retention

Table 1: Clinical reports of herb-drug interactions (B-G)



Eleutherococcus senticosus
(Siberian ginseng)

dopamine in vitro only at quite high concentrations (concentration to inhibit uptake by 50% [IC₅₀] 2.4 mg/L, 4.5 mg/L, and 0.9 mg/L, respectively).⁴ That anyone could consume enough of this herb to achieve these concentrations in blood is extremely unlikely. Nevertheless, there have been six cases of serotonin syndrome caused by mixing of St John's wort with

are cited where relevant). In-vitro experiments have been excluded, since extrapolation of in-vitro evidence to clinical effects is difficult. For example, St John's wort inhibits monoamine oxidase in vitro; however, in-vivo experiments have shown no such effects, and there have been no reported cases linking St John's wort with hypertensive crises associated with monoamine-oxidase inhibitors.¹ However, St John's wort inhibits the uptake of serotonin, norepinephrine, and

serotonin-reuptake inhibitors. The tables summarise the interactions identified by the search strategy.³⁻³⁵

Misidentification, adulteration, and contamination

Labelling of herbal products may not accurately reflect their contents, and adverse events or interactions attributed to specific herbs may actually be due to misidentified plants, pharmaceutical drugs, or heavy metals.³⁶ For example, a "Siberian ginseng" (*Eleutherococcus senticosus*) product implicated in a case of neonatal androgenisation³⁷ was found on analysis to be an unrelated species, Chinese silk vine (*Periploca sepium*).³⁸ In Hong Kong, encephalopathy and neuropathy associated with a Chinese herbal preparation purportedly made from the roots of long-dan-cai (*Gentiana rigescens*) turned out to be due to another plant *Podophyllum emodi*.³⁹ More than 48 cases of renal poisoning attributed to fang-ji (*Stephania tetrandra*) in a weight-loss preparation were actually caused by guang-fang-ji (*Aristolochia fangchi*); aristolochic acid is a known nephrotoxin.⁴⁰ The confusion in the latter case seems to have arisen from the similarity of the names in Chinese.

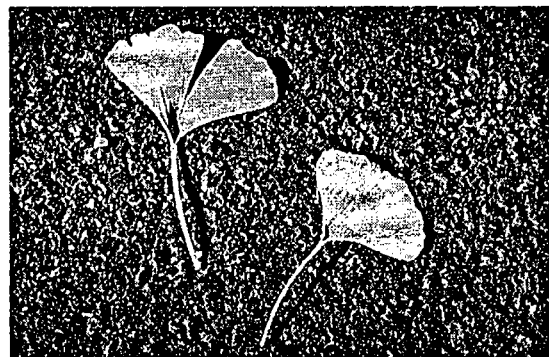
The addition of pharmaceutical drugs to "herbal" products is a particular problem with Chinese patent medicines. Of 2609 samples of traditional Chinese

Herb and drug(s)	Results of interaction	Comments
Karida or bitter melon (<i>Momodica charantia</i>) Chlorpropamide	Less glycosuria ⁴	Karida decreases glucose concentrations in blood. ¹⁵
Liquorice (<i>Glycyrrhiza glabra</i>) Prednisolone	Glycyrrhizin decreases plasma clearance, increases AUC, ¹⁶ increases plasma concentrations prednisolone. ¹⁷	11 β -dehydrogenase converts endogenous cortisol to cortisone orally administered glycyrrhizin is metabolised mainly to glycyrrhetic acid. ¹⁸
Hydrocortisone	Glycyrrhetic acid potentiates of cutaneous vasoconstrictor response ¹⁹	Glycyrrhetic acid is a moderate inhibitor of 5 α - β -reductase and 11 β -dehydrogenase than is glycyrrhizin. ¹⁸
Oral contraceptives	Hypertension, oedema hypokalaemia ⁴	Oral contraceptive use may increase sensitivity to glycyrrhizin acid. ¹⁸ Women are reportedly more sensitive than men to adverse effects of liquorice. ²⁰
Papaya (<i>Carica papaya</i>) Warfarin	Increased INR ⁴	
Psyllium (<i>Plantago ovata</i>) Lithium	Decreased lithium concentrations ⁴¹	Hydrophilic psyllium may prevent lithium from ionising.
St John's wort (<i>Hypericum perforatum</i>) Paroxetine Trazodone Sertraline Nefazodone Theophylline Digoxin Phenprocoumon Cyclosporin Combined oral contraceptive (ethinyl estradiol and desogestrel)	Lethargy/incoherence ² Mid serdonin syndrome ⁴ Mid serdonin syndrome ⁴ Mid serdonin syndrome ⁴ Decreased theophylline concentrations ⁴² Decreased AUC, decreased peak and trough concentrations ⁴³ Decreased AUC ⁴⁴ Decreased concentrations in serum ⁴ Breakthrough bleeding ⁴⁵	A similar case is described with the use of St John's wort alone Most, but not all, studies indicate that St John's wort is a potent inhibitor of cytochrome P450 isoenzymes ⁴
Saiboku-to (Asian herb mixture) Prednisolone	Increased prednisolone AUC ⁴⁶	Contains all the same herbs as Shosakoto, and <i>Poria cocos</i> , <i>Magnolia officinalis</i> , and <i>Perillae frutescens</i> .
Shankhapushpi (Ayurvedic mixed herb syrup) Phenytoin	Decreased phenytoin concentrations, loss of seizure control ¹	In rats, multiple coadministered doses (but not single doses) decreased plasma phenytoin concentrations; single doses decreased the antiepileptic effect of phenytoin ¹ . Shankhapushpi is used to treat seizures.
Sho-saiko-to or Xiao Chai Hu Tang (Asian herb mixture) Prednisolone	Decreased AUC for prednisolone ⁴⁰	Contains liquorice (<i>Glycyrrhiza glabra</i>), <i>Bupleurum falcatum</i> , <i>Pinellia ternata</i> , <i>Scutellaria baicalensis</i> , <i>Zizyphus vulgaris</i> , <i>Panax ginseng</i> , and <i>Zingiber officinale</i> .
Tamarind (<i>Tamarindus indica</i>) Aspirin	Increased bioavailability of aspirin ⁴⁷	Tamarind is used as a food and a medicine.
Valerian (<i>Valeriana officinalis</i>) Alcohol	A mixture of valpotriate reduces adverse effect of alcohol on concentration ¹	
Yohimbin (<i>Pausanystala yohimbin</i>) Tricyclic antidepressants	Hypertension ⁴⁸	Yohimbin alone can cause hypertension, but lower doses cause hypertension when combined with tricyclic antidepressants. Effect is stronger in hypertensive than normotensive individuals. ⁴⁹

ACE=angiotensin converting enzyme; INR=international normalised ratio; PT=prothrombin time; APTT=partial thromboplastin time; ECG=electrocardiogram; PAF=platelet-activating factor; AUC=area under the concentration/time curve.

Table 2: Clinical reports of herb-drug interactions (K-Y)

medicines collected from eight hospitals in Taiwan, 23.7% contained pharmaceutical adulterants, most commonly caffeine, paracetamol, indomethacin, hydrochlorothiazide, and prednisolone.⁵⁰ Non-steroidal anti-inflammatory drugs and benzodiazepines have been found in many Chinese patent medicines sold outside



Ginkgo biloba

Asia; these compounds include Miracle Herb, Tung Shueh, and Chuifong Toukuwan.⁴⁰ The latter preparation is notorious: at different times since 1974, the formulation has contained aminopyrine, phenylbutazone, indomethacin, hydrochlorothiazide, chlorthalidopoxide, diazepam, corticosteroids, diclofenac, mefenamic acid, and dexamethasone.⁶¹

Heavy-metal contamination is not uncommon in Asian herbal products. 24 of 251 Asian patent medicines collected from herbal stores in California, USA, contained lead (at least 1 ppm); 36 products contained arsenic, and 35 contained mercury.⁴²

Counselling of patients about herb-drug interactions

Use of herbal and dietary supplements is extremely common: in one US survey of adults who regularly take prescription medication, 18.4% reported the concurrent use of at least one herbal product or high-dose vitamin (and 61.5% of those who used unconventional therapies did not disclose such use to their physicians).⁶¹ A survey

**Panax ginseng**

of 515 users of herbal remedies in the UK found that 26% would consult their general practitioner for a serious adverse drug reaction associated with a conventional over-the-counter medicine, but not for a similar reaction to a herbal remedy.⁴⁴

Patients may not be forthcoming about the use of herbal medicine—even if it causes severe adverse effects—because they fear censure. Clinicians must ask patients about their use

of herbs in a non-judgmental, relaxed way: a disapproving manner will ensure only that a patient will conceal further use. The patient should be treated as a partner in watching out for adverse reactions or interactions, and should be told about the lack of information on interactions and the need for open communication about the use of herbal remedies. Formulation, brand, dose, and reason for use of herbs should be documented on the patient's charts and updated regularly.

Any laxative or bulk-forming agents will speed intestinal transit, and thus may interfere with the absorption of almost any intestinally absorbed drug.⁴⁵ The most popular stimulant laxative herbs are the anthranoid-containing senna (*Cassia senna* and *C. angustifolia*) and cascara sagrada (*Rhamnus purshiana*). Dried exudate from the aloe vera (*Aloe barbadensis*) leaf (not gel) also contains anthranoids and is used as a laxative. Aloe vera gel, found within the leaves, is used topically for burns and cuts, and is sometimes recommended by herbalists for internal ingestion to treat ulcers and other disorders. The gel (or juice made from the gel) does not contain anthranoids, but some oral preparations are contaminated by the laxative leaf. Less commonly used anthranoid-containing plants are frangula (*Rhamnus frangula*), yellow dock (*Rumex crispus*), and Chinese rhubarb (*Rheum officinale*).

Patients with clotting disorders, those awaiting surgery, or those on anticoagulant therapy should be warned against the concurrent use of ginkgo, danshen, dong quai, papaya, or garlic. Although the combined use of anticoagulants with these herbs should be discouraged, patients who insist on the combination should have their bleeding times monitored (most of these herbs interfere with platelet function, not the coagulation cascade, and thus will not affect prothrombin time, partial thromboplastin

**Valeriana officinalis**

time, or international normalised ratio [INR]). Many other herbs also contain anticoagulant substances; as a precaution, patients on warfarin should have an INR measurement within a week of starting any herbal treatment.

Patients on serotonin-reuptake inhibitors, cyclosporin, digoxin, phenprocoumon, or any critical chronic medication should avoid St John's wort; those on phenelzine should avoid ginseng; and those on tricyclic antidepressants should avoid yohimbine. Patients taking phenytoin should avoid Ayurvedic herbal mixtures for seizures. Liquorice (a very common ingredient in Chinese herb mixtures) may potentiate the action of corticosteroids, and betel nuts have pronounced cholinergic effects. There are doubtless many as yet undiscovered interactions.

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EDUCATION, INFORMATION, AND RESEARCH RESOURCES

Surveys of Complementary and Alternative Medicine: Part I. General Trends and Demographic Groups

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ABSTRACT

Data from the surveys of the Harvard team, led by David Eisenberg, M.D., are frequently used as a summary first paragraph introduction to the status of complementary and alternative medicine (CAM) in the United States. However, there is now a substantial body of literature on various facets of CAM use.

Six national surveys to date are briefly discussed and summarized in a table. Some surveys have been conducted at a regional level. Three are summarized but there are too few data yet to draw any conclusions. Eighteen more exploratory surveys of specific subpopulations are presented to help draw a clearer picture of income, ethnic, and age groups.

The search strategy is provided. The changing terminology in the field, the development of the CAM survey, and some common shortcomings are also addressed.

The 1993 Harvard survey conducted by Eisenberg and colleagues (Eisenberg et al., 1993) has become the most frequently referenced study in the literature on complementary and alternative medicine (CAM). The paper was historically significant and the much-quoted figures on prevalence, use, and out-of-pocket expenditure gave encouragement not only to researchers, practitioners, and patients, but also paved the way for commercial expansion into the area. This paper gave incentive to

insurance companies and health maintenance organizations to consider coverage of therapies and encouraged state legislatures to reconsider recognition and licensure of practitioners. A follow-up survey, published in the 1998 alternative medicine issue of the *Journal of the American Medical Association* (Eisenberg et al., 1998) updated the information from the earlier study and is now fast superseding the 1993 study as the most quoted reference.

Citing the Harvard studies has become al-

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This series provides summary overviews of surveys of complementary and alternative medicine (CAM) use in the United States, including:

- National and regional trends
- Use by specific patient populations—covering diagnosis, clinical setting, and special medical settings
- Health professionals and other professional groups
- Specific modalities and motivations for use.

Primarily, only surveys published in the peer-reviewed literature are included. Specific inclusion criteria and a justification for a topic are given in each article. Updated tables are provided as new surveys are published. If you have updated information on surveys that may be considered for inclusion, contact Jackie Wootton, M.Ed., at jacm@amfoundation.org

most an obligatory introductory section to all articles on CAM but these studies no longer stand alone. There is now a substantial literature that needs to be acknowledged and integrated into any serious study of the field. Some surveys discuss general trends, both national and regional; other surveys concentrate on different categories of patient groups or medical settings. Each category is discussed and reviewed and a summary table of the main characteristics of each of the surveys is provided in a series of articles of which this is the first. This article builds on and updates an earlier composite review published as a book chapter (Wootton and Sparber, 1999).

CHANGING TERMINOLOGY

One illuminating aspect of the survey literature on CAM medicine over the last 10–15 years in the United States is the changing terminology. Toward the end of the 1980s, when the surveys first started to appear, the tone was cautious if not alarmist. Authors referred to “unproven,” “nonproven,” or “questionable” therapies. In the early 1990s, the mood changed to one of defense, reflected in the literature by such terms as “unorthodox,” “nonorthodox,” “unconventional,” “nonconventional,” and even (misleadingly) “nontraditional” medicine. All terms are relative, but the now widely accepted convention is to reserve the term “traditional” for indigenous or ancient traditional systems of medicine, such as Ayurveda, Tibetan medicine, or Traditional Chinese Medicine. Such systems of medicine usually also encompass a whole cosmology or worldview. The relatively recently developed Western system is referred to as Western, conventional, or biomedicine, or any one of these three terms alone.

The founding of the Office of Alternative Medicine at the National Institutes of Health (NIH) in 1992 was a watershed event, conferring a measure of legitimacy to the area. The more challenging and assertive term “alternative medicine” became current, later softened by adding or substituting the terms “complementary” or “adjunct” therapies, favored in Europe and other English-speaking parts of the world. The recently established National Cen-

ter for Complementary and Alternative Medicine and the Office for Cancer Complementary and Alternative Medicine at the NIH reflect this trend. Both predate the current mainstreaming connoted by the concept of “integrated” or “integrative” medicine. The abbreviation, CAM, is used here unless some refinement of the concepts is needed.

METHODOLOGY AND INCLUSION CRITERIA

The databases searched for the original review of surveys (Wootton et al., 1999) were MEDLINE, BIOSIS, EMBASE, and IAC, Health & Wellness, accessed via a librarian search using Dialog (Thompson Co., North Carolina) software. A periodic independent search was made of the publicly available version of MEDLINE, known as PubMed, accessed via the World Wide Web (<http://www.ncbi.nlm.nih.gov/PubMed/>). For this series, weekly searches have been—and will continue to be—performed to identify newly published surveys using PORPOISE (Publish Or Perish with POISE!) software, developed for researchers at the NIH (<http://publishorperish.nih.gov>). See Figure 1. Bibliographies from retrieved articles have been—and will continue to be—checked for further references.

Only U.S. studies are included to restrict the large scope of this research project and in recognition of their distinct historical and cultural contexts. The overview of CAM surveys in each section covers primarily peer-reviewed literature from the period 1990 to the present, thus excluding numerous small-scale market-research surveys and many studies by practitioner and other groups for which the motivation seems to be promotional rather than academic. Occasional use of non-peer-reviewed literature is justified when it provides a unique insight or helps to corroborate findings from established surveys. Speculative or very-small-scale studies and those with a lower than 60% response rate were rejected, unless they were judged to be exploratory studies, indicating an important area for further study. Not all of the surveys that appear in the tables are discussed in the text. Citations can be found in the table if they are not given in the text.

PORPOISE (Publish Or Perish with POISE! at <http://publishorperish.nih.gov/>) enables researchers to define profiles of search terms that are automatically searched against the weekly update of the Web of Science. The Web of Science provides searching of the Science Citation Index Expanded and Social Science Citation Index databases. The particular search strategy developed for this series was designed to incorporate all aspects of the evolving field and terminology:

Search under email alias = as188s with identifier = zack

Using query: (<TO>((complementary medicine or alternative medicine or folk healing practices or chiropractic or osteopath* or acupuncture or electroacupuncture or aromatherapy or color therapy or homeopath* or massage or acupressure or traditional medicine or Ayurvedic medicine or herbal medicine or herbal or Oriental medicine or music therapy or naturopath* or organotherapy or radiesthesia or reflexotherapy or relaxation techniques or meditation or Therapeutic Touch or mental imagery or electroacupuncture or Ayurvedic or herbs or integrative medicine or holistic health or unconventional medicine) and (use or utilization or survey* or questionnaire* or prevalence or patterns of use or epidemiology))</TO>)

FIG. 1. Search Strategy using PORPOISE Automated Search*Science Citation Index. Expanded: Friday, January 5, 2001. Copyright ©1996, 1997 Institute for Scientific Information.

The surveys reviewed here have been summarized in 6 tables covering: (1) national surveys, (2) regional surveys, (3) surveys of low-income groups, (4) surveys of ethnic groups, (5) surveys concerning children, and (6) surveys of the elderly. In each section, common features of surveys have been systematically compared and put into tabular form, chronologically, but not attempt has been made to perform a meta-analysis because the studies are not sufficiently congruent. Lack of congruence is not necessarily a shortcoming because the survey tool can be used flexibly to capture the nuances of a particular patient population or other subgroup.

The issue of assessing effectiveness of therapies is not addressed here. Scientific investigation of all medical interventions is a separate topic of considerable current interest. The Cochrane Collaboration, in particular, has popularized the concept of evidence-based medicine, and set standards for meta-analyses and systematic reviews of clinical trials, whether they be conventional or alternative (Berman, 1997).

SURVEY DESIGN AND DEVELOPMENT

One objective of conducting health care surveys is to develop questions and document

trends for the purpose of making changes in health care planning and policy. This is the mandate of the U.S. National Center for Health Care Statistics. Little information is available yet from this agency about the surveys of CAM utilization or their impact. The most visible use of this literature is as background for study proposals, in introductions and discussions about published studies. To develop a body of knowledge, it is essential for researchers to review and build on existing studies. In response to the rapid increase of interest in CAM by health professionals and other investigators, most state-of-the-art CAM surveys are exploratory and cross-sectional in nature. Few survey tools have been validated or tested for reliability, although well-established scales are used when psychosocial factors are involved. Apart from the replication in 1997 of the early Harvard study there are no other longitudinal studies.

Most recent surveys use the definition of CAM from the first Harvard study (Eisenberg et al., 1993): "medical interventions not taught widely at U.S. medical schools or generally available at U.S. hospitals." This has provided some consistency through the surveys although it is difficult to assess how far this description has been used as an operational definition. It has certainly proved to be an

evolving definition as, in the interim, medical schools' curricula have been rapidly changing (Bhattacharya, 2000), with some therapies already being integrated into mainstream care. Many surveys have attempted to replicate the Harvard instrument with different population groups. While a consistent methodology or terminology may provide some continuity, it is important not to place undue emphasis on providing a formula for future surveys. Such a formulaic approach may distort the truth rather than illuminate it. As with all scientific methodology, researchers need to develop an appropriate framework for obtaining an objective picture of a situation. When used scientifically and systematically, the survey instrument is extremely adaptable.

The national surveys reported here used professional social scientists and statisticians for development of their instruments. Many of the surveys of regional trends in CAM use and the surveys of subpopulations rely on convenience or nonrandom cross-sectional samples. This is not necessarily a problem for an exploratory study, provided that it is clear that findings cannot be generalized formally to the population from which the data are drawn. Authors nonetheless frequently draw invalid conclusions from nonrandom samples. Other problems with the surveys include unspecific definitions, no operational definitions, inappropriate sampling frames, investigator biases, and discrepancies in secondhand reporting. All can be found or suspected in the surveys of subpopulations. This review does not assess the validity of the conclusions.

Methodological validity, however, does not ensure a true reflection of the study population. Randomization is likely to produce a representative sample, but there is no guarantee that it will. Carefully designed studies using nonprobability sampling may produce illuminating results and consistency with a number of other studies in the field that have used random sampling. This review charts the general trends, looks for consistencies and inconsistencies, and assumes some canceling out of random error. This enables a fascinating composite picture to emerge, particularly of the surveys of subpopulations.

GENERAL TRENDS FROM NATIONAL SURVEYS

A large random survey by Druss and Rosenheck (Druss and Rosenheck, 1999), suggests that use of CAM in the United States is substantially lower than previous reports would suggest. From responses to questions about behavior during the previous year, an estimated 6.5% of people in the general population were found to use both "unconventional therapies" (authors' choice of terminology) and conventional medical care. Only 1.8% used solely unconventional services. The data were collected from a set of questions attached to the Medical Expenditure Panel Survey, a national survey using scientific probability sampling. The figures contrast with those from the Harvard 1998 survey in which, by extrapolation, the percentage of the general population using CAM services was calculated as 19.3%, i.e., 46.3% of the 42.1% of CAM users.

The issue of congruence is pertinent here because the two surveys use different inclusion criteria for CAM services. The Druss and Rosenheck survey is concerned only with provider services while the Harvard survey includes self-care. The Druss survey is methodologically more rigorous and includes non-English-speaking participants. A common criticism of the Harvard telephone survey is that it is restricted to the English-speaking general public—and only to those in households with telephones; also individuals with cognitive or "physical impairment" were excluded. Despite these problems, the Harvard study captures one essential element of the use of CAM modalities, namely the intrinsic trend towards self-care and health freedom.

The 1998 Harvard study found that the percentage of the population estimated to be currently using at least one CAM therapy, either independently or through practitioners has risen from 34% in 1990 to 42% in 1997. A large market survey sponsored by Landmark Health Care Inc. (Landmark Health Care, 1998) was also conducted in 1997. Although this survey was not published in the peer-reviewed literature, the survey was notable for providing corroboration of the Harvard findings. A randomized telephone survey of 1500 adults

currently covered by some type of health insurance or health care plan independently found that 42% of respondents had used some form of alternative health care in the preceding year. Seventy-four percent had used CAM alongside their conventional care, while 15% used CAM instead of seeking conventional care.

A national survey by Astin (Astin, 1998) was based on a randomly drawn subsample of the National Family Opinion survey, carried out in 1994. He found that 40% of the general public reported using CAM therapies within the previous year. A Stanford review, by Astin and colleagues (Astin et al., 1998), of 25 international surveys conducted between 1982 and 1995 that examined the practices and beliefs of physicians about CAM, came to a similar conclusion. From the responses to referrals and discussions with patients, it was inferred that between 30% and 50% of the general adult population in industrialized nations are using some form of complementary and/or alternative medicine.

To assess these findings is like the process of triangulation in land surveys. By coming from different directions, a reasonably consistent picture emerges. The Harvard replication study independently reached the same conclusion as a national market-research study. Astin's independent national survey and his review of international surveys from a physician perspective point to the possible degrees of freedom around this figure of 42%. It is likely that the large percentage of people, 32.2%, in the Druss and Rosenheck (Druss and Rosenheck, 1999) survey who were found to be using neither conventional nor unconventional medical services is likely to include people who are self-medicating or using CAM preventive therapies.

Another large national survey by Paramore in conducted 1996 (Paramore, 1997) provides some confirmation of the Druss and Rosenheck findings on use of practitioners. A probability sample of 3450 subjects, taken from a subsample of the 1994 Robert Wood Johnson National Access to Care Survey, were asked only about their use of CAM practitioners. The finding of 10% who were consulting practitioners is higher than Druss and Rosenheck's 8.3% but is in the same "ballpark."

The early Harvard survey (Eisenberg et al., 1993) still has historic interest. The frequently quoted figure that 72% of CAM users do not inform their medical doctors has regularly been misinterpreted to imply 72% of patients, rather than 72% of the 34% of responders who used CAM. This was clarified in the replication study. Table 1 gives an overview of these surveys.

REGIONAL TRENDS

Some general-usage surveys have been conducted at the state or local level. A survey by Elder and colleagues (Elder et al., 1997), using a very small convenience sample of 113 general-practice patients in Portland, Oregon, found that 50% were using some form of alternative health care and that 53% did inform their family physicians. This greater proportion may partly reflect the higher incidence of CAM use in the western United States, which was also pointed out in the Harvard surveys, but may also be the result of an unrepresentative small sample.

A random telephone survey of Florida residents (Burg et al., 1998), conducted by the University of Florida College of Medicine, Gainesville, found 62% of the survey respondents had used one or more CAM therapies. The response rate was low and may reflect a bias toward more responders from the CAM-use group. A survey of CAM usage conducted in South Carolina (Oldendick et al., 2000), using an adaptation of the Harvard instrument, found that 44% of respondents had used a CAM therapy in the previous year.

There are still very few reputable statewide surveys. Until there are more replication studies available it is difficult to get a clear picture of regional variation. Table 2 summarizes the information on regional variation.

SOCIODEMOGRAPHIC PREDICTORS

The national surveys consistently found that women are more likely to use CAM therapies than men, although the difference is seldom or only marginally significant and is usually pro-

TABLE 1. NATIONAL SURVEYS CAM USAGE

<i>Author(s) and date of publication</i>	<i>Sample, description, and response</i>	<i>Focus</i>	<i>Types of CAM used</i>	<i>General findings</i>
Druss & Rosenheck, 1999	16,068; national General population Randomized 77% response rate (subsample of U.S. Medical Expenditure Panel Survey)	Utilization of CAM practitioners	Chiropractic Massage Herbals Meditation	8.3% visited CAM practitioners during 1996
Eisenberg et al., 1998	2055; national Repeat study of general trends in use covering 1990-1997 Randomized 67% response	Prevalence, costs, patterns of use, and disclosure of CAM to physicians	Herbal Massage Megavitamins Self-help groups Folk remedies Etc.	CAM use during previous year increased from 33.8% in 1990 to 42.1% in 1997
Astin, 1998	1035; national, General population Random (Subsample of National Family Opinion Survey) 69% response	Why people seek alternative medicine	Not applicable	Best predictor of CAM use: Education 40% general use in previous year
Landmark Health Care, 1998	1500; national, General population Market survey-random	Adults covered by a health insurance plan	Herbal Chiropractic Massage Megavitamins	42% CAM use in 1997
Paramore, 1997	3450; National, General population (based on National Access to Care Survey) 75% response Random	Use of 4 specific types of CAM practitioner	Chiropractic Acupuncture Massage Relaxation	10% saw CAM professionals during 1994
Eisenberg et al., 1993	1539; national General population Telephone survey 67% response Randomized	Prevalence, costs, patterns of use, and disclosure of CAM to physicians	Relaxation Chiropractic Massage Imagery Etc.	34% used unconventional therapy at least once in last 12 months \$13.7 billion spent 72% of CAM users did not inform M.D.

TABLE 2. REGIONAL SURVEYS OF CAM USAGE

<i>Author(s) and date of publication</i>	<i>Sample, description, and response</i>	<i>Focus</i>	<i>Types of CAM used</i>	<i>General findings</i>
Oldendick et al., 2000	1584; South Carolina residents Random 66% response	Utilization Patient satisfaction Physician involvement	Home remedies Relaxation Chiropractic Healing	44% use in past year 66% found CAM very effective 89% would recommend
Burg et al., 1998	1012; Florida residents Random telephone survey 54% response	Lifetime use	Home remedies Diets Relaxation Herbals Acupuncture	62% use at least one CAM 31% home remedies 24% diets 20% relaxation 8% herbals
Elder et al., 1997	113; convenience sample of patients	Family practice patients, Portland, Oregon	Chiropractic Massage Herbals Megavitamins	53% use 50% disclosed use to physician

portional to the gender balance of people seeking all forms of treatment. Women are the greater users of health care generally and tend to suffer more than men from chronic ailments.

CAM users were also found to be predominantly in higher-income brackets, better educated, and of middle age; there is a consistent, but not always significant, positive correlation running through the studies. This observation is based on many articles, including the national surveys. A study by Cassidy (Cassidy, 1998) found that the users of Chinese medicine in the United States are of middle age, well-educated, and in middle-income brackets, and express a high degree of satisfaction with their care. And Astin (Astin, 1998) concluded that, of the socioeconomic variables, educational level is the best predictor of CAM use.

The general-use surveys tend to be skewed toward sampling the more affluent end of the consumer market. Relatively little is known about patterns of use among the less affluent or minority ethnic groups in society. It is possible that the actual pattern of use of CAM therapies is bimodal, with peaks of usage at the more affluent and less affluent ends. One possible scenario is that, in the United States, people without health insurance and members of an ethnic community with their own healers and health workers, have long incorporated alternative systems of health care into their communities. Indigenous systems of medicine are part of the process of socialization into a given subculture.

LOW-INCOME GROUPS

This hypothesis is partially confirmed by a few small-scale surveys of low-income groups, presented in Table 3. A 1998 survey by Krastins and colleagues (Krastins et al., 1998) found only 29% of a sample of 199 lower-income middle-age patients on Medicaid, who attended a family health center clinic, used CAM therapies. By contrast, 70% of homeless young people in a Street Clinic Youth Program in Seattle, Washington, in 1998, reported using CAM (Breuner et al., 1998). In a more recent small-scale survey of a low-income rural community in Stockton, California (Planta et al., 2000), patients who attended a family practice clinic were

asked about their use of herbal and other dietary supplements. Fifty six per cent of the patient sample was found to be currently using herbs/supplements. It is not clear whether this figure included taking daily vitamin pills.

ETHNIC GROUPINGS

Table 4 summarizes the studies of ethnic groups. A 1996 study of 213 Mexican Americans (Keegan, 1996) found 44% had used an alternative medicine practitioner one or more times during the previous year. The percentage of subjects who used *curanderismo*, a complex healing tradition found in Mexican-American communities throughout the United States, was 13.6% for that one form of therapy alone. A study of Chinese immigrants (Ma, 1999) confirmed that use of Western medicine is circumscribed by cost, lack of insurance, and cultural experiences and attitudes. Self-treatment and use of Chinese physicians is high but so is the level of integration of therapeutic methods. Surprisingly, few studies of the Native American population have been conducted. One survey of Navajo use of native healers (Kim and Kwok, 1998) found that 62% of patients who attended the Indian Health Service had at some time used native healers and 39% did so on a regular basis.

Other recent surveys of cultural groups and their use of CAM include two studies of New York groups; one study used focus groups to explore attitudes of Hispanic and African-American women (Cushman, et al., 1999); the other used a convenience sample of patients who used a Dominican emergency department (Allen et al., 2000). Both studies provide an in-depth understanding of cultural attitudes rather than an estimate of CAM use. More anthropological research is needed on these and other ethnic groups.

CHILDREN

Most surveys of general CAM use report a preponderance among middle-age patients. A few surveys have focused on children and the elderly. These are featured in Tables 5 and 6 re-

TABLE 3. SURVEYS OF LOW-INCOME CAM USAGE

<i>Author(s) and date of publication</i>	<i>Sample, description, and response</i>	<i>Focus</i>	<i>Types of CAM used</i>	<i>General findings</i>
Planta et al., 2000	187; convenience sample Rural family practice	Utilization	Herbs Supplements	56% use 41% information from family/friends 69% no education about products
Krastins et al., 1998	199; convenience sample of patients Low-income population	Utilization and prevalence	Prayer Chiropractic Meditation	29% use
Breuner et al., 1998	157; convenience sample Homeless youths 96.3% response	Utilization	Vitamins Herbs Special diet Massage Acupuncture	70.1% use

TABLE 4. SURVEYS OF ETHNIC GROUPS CAM USAGE

<i>Author(s) and date of publication</i>	<i>Sample, description, and response</i>	<i>Focus</i>	<i>Types of CAM used</i>	<i>General findings</i>
Allen et al., 2000	50; convenience sample of Dominican emergency room patients	Utilization	Medicinal plants Teas Spirituality	50% use
Ma, 1999	75; convenience sample of Chinese immigrants	Use of traditional and use of Western health services	Not applicable	94.6% self-treatment and home remedies 45% both kinds of health care 32% travel to Orient for health care
Cushman, et al., 1999	39; African-American and Hispanic women Pilot study using focus groups	Utilization	Teas Herbs Vitamins Supplements Prayer Spiritual healing	Use of CAM therapies and practitioners more common in both groups among older women
Kim & Kwok, 1998	300; Navajos attending Indian Health Service hospital 99% response	Use of native healers	Not applicable	62% use of native healers 39% regular basis
Keegan, 1996	213; Convenience sample of Mexican-Americans	Utilization	Herbals Prayer/spiritual Massage Relaxation Chiropractic Curandero	44.2% herbals 29.9% spiritual 13.6% to curanderos
Higgenbotham, et al., 1990	3623; Mexican-Americans NCHS survey	Use of curanderos Predictors for use during past year	Herbalists Folk medicine practitioners	4.2% use these practitioners

NCHS, National Center for Health Statistics.

TABLE 5. SURVEYS OF CHILDREN CAM USAGE

<i>Author(s) and date of publication</i>	<i>Sample, description, and response</i>	<i>Focus</i>	<i>Types of CAM used</i>	<i>General findings</i>
Kelly et al., 2000	78; convenience sample of parents of children with cancer 96% response	Utilization	Diet Supplements Herbals Mind-body	84% use 50% not reported to M.D. 85% concurrently enrolled in clinical trials
Friedman et al., 1997	161; convenience sample of parents of children with cancer	Compare use of CAM by patients with cancer and general patients	Prayer Exercise Spiritual healing Massage	65% use by patients with cancer 51% use by controls
Risser and Mazur, 1995	51; convenience sample of Hispanic children—responses by caregivers General health	Use of folk remedies	Herbs	70% Mal ojo 53% Molera caida ^a 37% Susto ^b 10% saw curanderos
Pachter et al., 1995	118; convenience sample of Puerto Rican children with asthma—responses by caregivers	Use of ethnomedicine	Herbs Magicoreligious practices	70–90% use

^aFallen fontanel.^bSoul loss; literally “fright of the soul.”

TABLE 6. SURVEYS OF ELDERLY CAM USAGE

<i>Author(s) and date of publication</i>	<i>Sample, description, and response</i>	<i>Focus</i>	<i>Types of CAM usage</i>	<i>General findings</i>
Astin et al., 2000	728; elderly on Blue Cross/Medicare Random sample 51% response	Utilization	Herbs Chiropractic Massage Acupuncture	41% use 80% reported benefit
Johnson, 1999	175; convenience sample of elderly rural women	Utilization	Spiritual Vitamins Herbs Music Humor Diet	84% use with Western medicine 16% only CAM 23% told M.D.
Pourat et al., 1999	223; elderly Koreans Random 74% response	Predictors of use of Traditional healers	Traditional healers	Predictors: arthritis, lung disease, pain, availability of insurance, and strong social ties
Wyatt et al., 1999	699; convenience sample of elderly patients with cancer 73% response	Utilization	Exercise Herbals Spiritual healing	33% use CAM users were more optimistic—self- report
Coleman et al., 1995	101; convenience sample of caretakers of patients with Alzheimer's disease	Utilization	Vitamins Health foods Herbals "Smart pills" Home remedies	55% of caretakers tried at least one CAM to improve memory 25% used CAM for behavioral problems

spectively. Two of the four studies of children also focused on Hispanic children. A study of 51 Hispanic mothers or caregivers (Risser and Mazur, 1995) revealed that most used a combination of Western and indigenous practices and that belief in folk practices was common. For example, 20% had taken their children to *curanderos*. Puerto Rican children experience high rates of asthma and a study of their treatment (Pachter et al., 1995) revealed that most families used both conventional and folk treatments. The folk treatments were found to be logical in their cultural contexts and were rarely harmful. Two recent studies of children with cancer found high rates of use. In the most recent, 84% were using alternative treatments, mostly as adjunct therapy and 50% did not tell their attending physicians (Kelly et al., 2000). The studies of children and CAM usage mainly examined patient groups. This means that the figures are not necessarily typical of all children. A 1997 study by Friedman and colleagues (Friedman et al., 1997) addressed this issue by comparing patients with cancer (65% use of CAM) to a control group of children in good health (51% CAM use).

THE ELDERLY

As in the children's studies, the elderly turn out to be average or higher-than-average users of CAM, if the average is taken to be approximately 42%, as found in the national general population surveys. Findings from the surveys of senior populations confound the picture of CAM use as a predominantly middle-age, middle-class activity. A large survey of Californians who were enrolled in a Medicare program found that 41% of the respondents were using CAM (Astin et al., 2000). A "snowball" sample of rural women, 71–97 years-old (Johnson, 1999) revealed that all of the women were using some form of CAM, 16% of them were using it exclusively, and only 23% informed their doctors or nurse-practitioners. This finding is suspect but indicative. A snowball approach is a progressive recruitment sampling method, using acquaintances of an original small sample, inevitably frequently resulting in a skewed sample. Fifty-five percent of caregivers of patients with Alzheimer's disease (Coleman et al., 1995) re-

ported trying at least one alternative therapy to improve memory. A survey of 699 older patients with cancer (Wyatt et al., 1999) found that 33% were using CAM. In a representative sample of Korean seniors in Los Angeles, California (Pourat et al., 1999), 42% were found to be using traditional healers for chronic conditions.

DISCUSSION

Several anomalies and areas of ignorance remain and further high quality research is needed. However, there is no doubt that people have been turning increasingly toward complementary and alternative therapies during the past decade both for self-care and use of alternative practitioners. The new users may reflect a middle-age, middle-class movement but it is clear that use by ethnic groups predates recent trends. Ethnic and low-income groups together constitute a significant population of users who are underrepresented in the main national surveys. The net picture is of a bimodal distribution. Higher-income groups are willing to use disposable income for CAM products and services in addition to using conventional health care. Lower-income groups and those with their own traditions of healing, self-medicate with CAM or use folk methods and healers often as a substitute for conventional care.

It is equally clear that the age distribution is more complex than it appeared to be in the national surveys. The young and the elderly are also significant users of CAM modalities. Reliable and valid survey instruments are needed, but these need to be sensitive to the nuances of the population. Replication studies are desirable but so are targeted surveys using disproportional sampling, to build a clearer picture of subpopulation CAM use. Overreliance on the Harvard findings and instrument provides only a partial picture.

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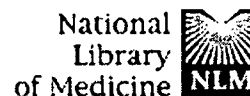
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1: J Altern Complement Med 2001
Feb;7(1):19-32

Related Articles, Books,
LinkOut

Comment in:

- J Altern Complement Med. 2001 Feb;7(1):1-3

Assessment of outcomes at alternative medicine cancer clinics: a feasibility study.

Related Names

Richardson MA, Russell NC, Sanders T, Barrett R, Salveson C.

University of Texas--Center for Alternative Medicine Research, The University of Texas--Houston Health Science Center School of Public Health, USA. marich@mail.nih.gov

OBJECTIVE: This pilot study tested the feasibility of performing outcomes and more advanced research regarding cancer patients at two complementary and alternative (CAM) clinics. The primary objectives were to determine the feasibility of (1) obtaining and collecting data from medical records, (2) determining 5-year survival, and (3) comparing 5-year survival to that of conventional treatment. In addition, in this paper we present the barriers and recommend strategies to facilitate high-quality research.

SETTINGS/LOCATION: The Bio-Medical Center in Tijuana, Mexico, and the Livingston Foundation Medical Center in San Diego, California.

SUBJECTS: New patients who were treated for cancer during 1992 at the Livingston Foundation Medical Center and during the first quarter of 1992 at the Bio-Medical Center. **RESULTS:** Charts were available for 89.6% of the 307 new patients treated at the Bio-Medical Center; 149 (54%) patients were treated for cancer and 65 (43.6%) cases were confirmed by pathology reports. In contrast, all records were available for 193 new patients treated for cancer at the Livingston Clinic; 152 (78.8%) cases had pathology confirmation. At both clinics, patients were equally divided by gender and were predominantly Caucasian, were married, and were U.S. residents. On average, patients were 51-54 years old and within 1 year of diagnosis for breast, colorectal, lung, or male genital cancer. Most patients (61.1%-63.7%) arrived with distant or regional disease after conventional surgery and/or chemotherapy/radiotherapy. Survival at 5 years was determined for 57.0% at

the Bio-Medical Center (11.4% were alive and 45.6% were deceased) and 94.8% at Livingston (14.5% were alive and 80.3% were deceased). The limited number of cases by cancer site prevented comparison to conventional treatment. CONCLUSIONS: Historical, widespread use of clinics such as these with anecdotal reports of extraordinary survival merit prospective, systematic monitoring of patient outcomes. For data to be meaningful, however, disease status must be pathologically confirmed and patient follow-up improved.

PMID: 11246933 [PubMed - indexed for MEDLINE]

2: Acad Med 2001 Mar;76(3):230-7

Related Articles, Books, LinkOut

Full text article at
www.academicmedicine.org

Alternative medicine and common errors of reasoning.

Beyerstein BL.

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Why do so many otherwise intelligent patients and therapists pay considerable sums for products and therapies of alternative medicine, even though most of these either are known to be useless or dangerous or have not been subjected to rigorous scientific testing? The author proposes a number of reasons this occurs: (1) Social and cultural reasons (e.g., many citizens' inability to make an informed choice about a health care product; anti-scientific attitudes meshed with New Age mysticism; vigorous marketing and extravagant claims; dislike of the delivery of scientific biomedicine; belief in the superiority of "natural" products); (2) psychological reasons (e.g., the will to believe; logical errors of judgment; wishful thinking, and "demand characteristics"); (3) the illusion that an ineffective therapy works, when actually other factors were at work (e.g., the natural course or cyclic nature of the disease; the placebo effect; spontaneous remission; misdiagnosis). The author concludes by acknowledging that when people become sick, any promise of a cure is beguiling. But he cautions potential clients of alternative treatments to be suspicious if those treatments are not supported by reliable scientific research (criteria are listed), if the "evidence" for a treatment's worth consists of anecdotes, testimonials, or self-published literature, and if the practitioner has a pseudoscientific or conspiracy-laden approach, or promotes cures that sound "too good to be true."

Publication Types:

- Review
- Review, tutorial

PMID: 11242572 [PubMed - indexed for MEDLINE]

3: West J Med 2001 Mar;174(3):203-6

Related Articles, Books, LinkOut



Complementary medicine use by Mexican migrants in the San Francisco Bay Area.

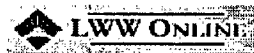
Napolitano V.

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PMID: 11238360 [PubMed - indexed for MEDLINE]

4: Med Care 2001 Feb;39(2):190-6

Related Articles, Books, LinkOut



Demographic and health-related correlates to visits to complementary and alternative medical providers.

Bausell RB, Lee WL, Berman BM.

University of Maryland, School of Medicine, Complementary Medicine
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bbausell@compmed.ummh.umaryland.edu

OBJECTIVES: The objective of this study was to ascertain the extent to which demographic and health-related variables are related to visits to a complementary or alternative medicine (CAM) practitioner. **METHODS:** This study reports a secondary analysis of visits to CAM practitioners during the year before the 1996 Medical Expenditure Panel Survey (n = 16,038). **RESULTS:** Overall visits to CAM providers (9%) were lower than reported in widely cited surveys but quite consistent with a previous Robert Wood Johnson study that used a similar sampling procedure. Gender, education, age, geographic location, and race (Hispanics and African Americans proved to be less likely to visit CAM providers than whites) were statistically significant predictors of visits to CAM providers. Individuals in poorer health and those suffering from mental, musculoskeletal, and metabolic disorders also tended to be more likely to have visited a CAM provider. **CONCLUSIONS:** Although the choice of alternative versus orthodox treatment appears to be a complex phenomenon, these data suggest that the heaviest users of CAM therapies tend to be individuals with comorbid, non-life-threatening health problems. This finding may help to ameliorate concerns that this type of care is being used in lieu of therapies with more definitive efficacy evidence.

PMID: 11176556 [PubMed - indexed for MEDLINE]

15: Am J Psychiatry 2001 Feb;158(2):289-94

Related Articles, Books, LinkOut

0

**Full text article at
ajp.psychiatryonline.org****The use of complementary and alternative therapies to treat anxiety and depression in the United States.****Kessler RC, Soukup J, Davis RB, Foster DF, Wilkey SA, Van Rompay MI MI, Eisenberg DM.**

Department of Health Care Policy and the Center for Alternative Medicine Research and Education, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA 02115, USA.

OBJECTIVE: This study presents data on the use of complementary and alternative therapies to treat anxiety and depression in the United States. **METHOD:** The data came from a nationally representative survey of 2,055 respondents (1997-1998) that obtained information on the use of 24 complementary and alternative therapies for the treatment of specific chronic conditions. **RESULTS:** A total of 9.4% of the respondents reported suffering from "anxiety attacks" in the past 12 months; 7.2% reported "severe depression." A total of 56.7% of those with anxiety attacks and 53.6% of those with severe depression reported using complementary and alternative therapies to treat these conditions during the past 12 months. Only 20.0% of those with anxiety attacks and 19.3% of those with severe depression visited a complementary or alternative therapist. A total of 65.9% of the respondents seen by a conventional provider for anxiety attacks and 66.7% of those seen by a conventional provider for severe depression also used complementary and alternative therapies to treat these conditions. The perceived helpfulness of these therapies in treating anxiety and depression was similar to that of conventional therapies. **CONCLUSIONS:** Complementary and alternative therapies are used more than conventional therapies by people with self-defined anxiety attacks and severe depression. Most patients visiting conventional mental health providers for these problems also use complementary and alternative therapies. Use of these therapies will likely increase as insurance coverage expands. Asking patients about their use could prevent adverse effects and maximize the usefulness of therapies subsequently proven to be effective.

PMID: 11156813 [PubMed - indexed for MEDLINE]

6: J Altern Complement Med 2000
Dec;6(6):531-8Related Articles, Books,
LinkOut

Ethnic differences in complementary and alternative medicine use among cancer patients.

Maskarinec G, Shumay DM, Kakai H, Gotay CC.

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OBJECTIVES: This study estimated the prevalence of complementary and alternative medicine (CAM) use and its relation to quality of life (QOL) among cancer patients from diverse ethnic backgrounds. Given the ethnically diverse population in Hawaii, we hypothesized that CAM use may be related to the ancestry and the cultural heritage of cancer patients.

DESIGN AND SETTING: Participants for this mail survey were identified through the Hawaii Tumor Registry, a state-wide population-based cancer registry. **SUBJECTS:** Patients with invasive cancer diagnosed 1995-1996.

Of the 2,452 questionnaires received, 1,168 (47.6%) were returned.

OUTCOME MEASURES: Prevalence of CAM use and QOL measures.

RESULTS: One in four respondents reported at least one CAM therapy ^{25%} since cancer diagnosis. CAM use was highest among Filipino and Caucasian patients, intermediate for Native Hawaiians and Chinese, and significantly lower among Japanese. Some ethnic preferences for CAM followed ethnic folk medicine traditions, e.g., herbal medicines by Chinese, Hawaiian healing by Native Hawaiians, and religious healing or prayer by Filipinos. CAM users reported lower emotional functioning scores, higher symptom scores, and more financial difficulties than nonusers. **CONCLUSIONS:** This study detected ethnic differences in CAM use, in particular a low use among Japanese patients, and supports the importance of cultural factors in determining the frequency and type of CAM therapies chosen. Consideration of patients' cultural heritage may facilitate communication between physicians and patients about CAM with the goal to achieve optimal cancer care.

PMID: 11152058 [PubMed - indexed for MEDLINE]

7: Diabetes Educ 2000 Sep-Oct;26(5):821-32 Related Articles, Books, LinkOut

Long-term disease management needs of southern African Americans with diabetes.

Anderson-Loftin W, Moneyham L.

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PURPOSE: This qualitative study explored the issues, concerns, and needs of low-income, southern African Americans in managing type 2 diabetes

over time. **METHODS:** Two focus groups (N = 22) were conducted with the target population to collect data. Group sessions were audiotaped and transcribed verbatim. Content analysis was used to analyze the data. **RESULTS:** The data revealed an overall theme of learning to live with diabetes, which consisted of 3 processes: (1) symptom management, (2) making healthy choice, and (3) emotional adjustment. This article focuses on the processes of symptom management and making healthy choices. Findings suggest that the sequential processes of symptom management and making healthy choices occurred over time primarily through experiential learning in this population and were influenced by social support, caring and collaborative provider-client relationships, and access to resources and culturally sensitive supportive services. **CONCLUSIONS:** Experiential educational methods that incorporate social support and access to resources may be more appropriate than the traditional didactic method of teaching diabetes self-care.

PMID: 11140010 [PubMed - indexed for MEDLINE]

[8](#): J Am Geriatr Soc 2000 Dec;48(12):1560-5 Related Articles, Books, LinkOut

Alternative medicine use in older Americans.

Foster DF, Phillips RS, Hamel MB, Eisenberg DM.

Center for Alternative Medicine Research and Education, and Department of Medicine, Harvard Medical School, Boston, Massachusetts 02215, USA.

OBJECTIVES: Because there are few data describing alternative medicine use in older populations, we analyzed a nationally representative survey to quantify and characterize the use of alternative medicine in people aged 65 and older. **DESIGN:** We utilized data collected in a nationally representative, random, telephone survey of adults, measuring use of conventional medical services and use of 20 alternative medicine therapies in the last 12 months. **PARTICIPANTS:** A total of 2,055 adults, 311 of whom were aged 65 and older and who constituted our sample of older Americans. **RESULTS:** Overall, 30% of people aged 65 and older used at least one alternative medicine modality in the last year compared with 46% of those less than age 65 ($P < .001$), and 19% of older people saw a provider of alternative medicine within the past year compared with 26% of those less than age 65. The alternative medicine modalities used most commonly by those aged 65 and older were chiropractic (11%), herbal remedies (8%), relaxation techniques (5%), high dose or mega-vitamins (5%), and religious or spiritual healing by others (4%). Older persons with a primary care provider used alternative medicine more frequently (34% vs 7% $P < .05$) than those with no primary care provider. Patients who saw their physician more frequently were more likely to use alternative medicine (0 visits 7%, 1-2 visits 22%, 3-6 visits 35%, 7 or more visits 44% $P < .05$). Six percent of older patients were taking both herbs and prescription drugs. Of older

patients who used alternative medicine, 57% made no mention of their use of any alternative modality to their doctor. **CONCLUSIONS:** Thirty percent of Americans aged 65 and older reported using alternative medicine (amounting to 10 million Americans based on extrapolations to census data) and 19% visited an alternative medicine provider (making 63 million visits based on extrapolations to census data) within the past year. The two modalities used most commonly were chiropractic and herbs, both of which may be problematic in older patients. Physicians should ask all patients, including those aged 65 and older, about their use of alternative medicine, and in those aged 65 and older, physicians should ask specific questions about the user of chiropractic and herbal medicine.

PMID: 11129743 [PubMed - indexed for MEDLINE]

9: Pharmacotherapy 2000 Nov;20(11):1289-94 Related Articles, Books, LinkOut

The psychosocial aspects of complementary and alternative medicine.

Caufield JS.

GeM Integrative Pharmacotherapy, Inc., North Jupiter, FL 33478, USA.

Approximately one in four persons in the United States uses complementary and alternative medicine (CAM). Out-of-pocket costs of CAM rival medical treatment at \$21.2-32.7 billion versus \$29.3 billion, respectively. Users of CAM tend to have high incomes and high levels of education. They also have medical conditions not easily treated by modern medicine such as chronic pain, poor mental health, human immunodeficiency virus infection, and cancer. The most common therapies are noninvasive (acupuncture, chiropractic, massage), however, consumption of dietary supplements has grown dramatically. Patients often use CAM in addition to modern medicine and are reluctant to discuss CAM with their physicians. Pharmacists' professional approach to science may bias them against CAM therapies. Complementary and alternative medicine use should be included in visit histories and discussed in an objective, nonjudgmental manner to encourage patient disclosure.

Publication Types:

- Review
- Review, tutorial

PMID: 11079276 [PubMed - indexed for MEDLINE]

10: J Altern Complement Med 2000
Oct;6(5):445-8

Related Articles, Books,
[LinkOut](#)

Patient risk-taking attitude and the use of complementary and alternative medical services.

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OBJECTIVES: Study users and nonusers of complementary and alternative medicine (CAM) with respect to their attitude toward risk. **SETTINGS AND SUBJECTS:** National household telephone survey fielded in the United States in 1998 (n = 9,585). **DEPENDENT VARIABLE:** CAM use in previous year. **RESULTS:** Patients of CAM practitioners consider themselves more likely to take risks than the average person (odds ratio [OR] 2.47, 95 confidence interval [CI] [1.91, 3.19] compared to the general population). Risk attitude is as strong (or even stronger) a predictor of visits to CAM providers than the main sociodemographic predictors of female gender, higher education, or middle age. Individuals using only self-administered CAM treatment rate themselves as being relatively more cautious (OR, 1.08; not statistically significant from the general population). **CONCLUSIONS:** Patients of CAM practitioners perceive themselves as risk taking, whereas patients that only rely on self-administered CAM treatment rate themselves not differently from the general population. This major difference within the group of CAM users and compared to the general population has not been studied before.

PMID: 11059507 [PubMed - indexed for MEDLINE]

11: J Altern Complement Med 2000
Oct;6(5):429-35

Related Articles, Books,
[LinkOut](#)

Use of herbal therapies by adults seen in an ambulatory care research setting: an exploratory survey.

Johnson EM, Wootton JC, Kimzey R, McCullagh L, Wesley R, Byrd DC, Singh KK, Rubino D, Pucino F.

Warren G. Magnuson Clinical Center, National Institutes of Health, Bethesda, Maryland 20892-1863, USA. johnsone@intraneih.nih.gov

OBJECTIVE: To identify and characterize patterns of use of herbal products among patients participating in selected research clinics. **DESIGN:** Survey of three National Institutes of Health (NIH) ambulatory care research clinics.

SUBJECTS: Convenience sample of 490 adult patients (168 male, 322 female) attending rheumatology, liver, and endocrinology/metabolic research clinics. **RESULTS:** Of the patients surveyed, 16.7%: (n = 82) reported using herbs. There were no significant sociodemographic differences between herb and nonherb users. Indications for herb use differed among the disease groups; patients in the endocrine and rheumatology clinics were taking herbs predominantly for "energy" or "wellness"; those attending the liver clinic tended to use herbal therapies as treatment for their disease. Mean and median monthly expenditure for herbal products was \$30 and \$10, respectively. There was a significant positive correlation between number of herbs used and use of other dietary supplements ($p < 0.0001$). **CONCLUSIONS:** One in six patients in ambulatory clinical research settings may be taking herbal products in addition to prescribed treatment. This figure is lower than in the general population, possibly because the patients may stop using herbs when participating in a research project. Although empirical evidence on the beneficial or adverse effects of herb therapy alone or in combination with drug therapies is limited, clinical researchers should be aware of the potential for confounding clinical trial results.

PMID: 11059505 [PubMed - indexed for MEDLINE]

 **12: J Altern Complement Med 2000**
Oct;6(5):415-22

[Related Articles, Books,
LinkOut](#)

Use of complementary medicine by adult patients participating in HIV/AIDS clinical trials.

Sparber A, Wootton JC, Bauer L, Curt G, Eisenberg D, Levin T, Steinberg SM.

National Institutes of Health, Clinical Center, Nursing, Bethesda, Maryland 20892, USA. asparber@ccnih.gov

OBJECTIVE: To identify and characterize patterns of use of complementary and alternative (CAM) therapies by human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) patients participating in clinical trials in a research setting. **DESIGN:** A descriptive survey using a nonrandom sample of 100 patients was conducted over 17 months, using a 99-item interview schedule adapted from a previous study. **SETTING:** National Institutes of Health (NIH) Warren G. Magnuson Clinical Center. **SUBJECTS:** Patients diagnosed with HIV/AIDS, participating in clinical research protocols at the National Institute of Allergy and Infectious Diseases and the National Cancer institute (NCI) at the NIH. **RESULTS:** Ninety-one percent (91%) had used at least one CAM therapy, as defined by a 1993 study by Eisenberg et al., sometime in their lives. Postdiagnosis, 84% used at least one CAM therapy with an average of

just fewer than 5. The increase in frequency of use from 64% prediagnosis was significant ($P = 0.019$). Therapies that became significantly more popular postdiagnosis were, imagery ($P = 0.00012$), high-dose vitamins, ($P = 0.000019$), weight gain ($p = 0.000244$), massage ($p = 0.00091$), relaxation ($p = 0.0033$), herbals ($p = 0.013$), spiritual ($p = 0.024$), and acupuncture ($p = 0.035$). They were primarily used for HIV/AIDS-related problems: dermatological, nausea, depression, insomnia, and weakness. There was a high level of agreement that benefits of CAM use were: feeling better, 51 (98.1%), increased coping, 52 (100%), feeling in control, 44 (88.5%), and enhanced treatment outcome, 49 (94.2%) with 32 (61%) stating CAM was as, or more effective than conventional treatment. Fifty-three percent (53%) were specifically asked by physicians whether they were using adjunct therapies. **CONCLUSIONS:** Subjects used a variety of CAM therapies to cope with their diseases and rigors of treatment and clinical trials. Further research is needed to identify CAM therapies that may be used as adjunct treatments during clinical trials.

PMID: 11059503 [PubMed - indexed for MEDLINE]

13: Am J Psychiatry 2000 Nov;157(11):1851-7 Related Articles, Books, LinkOut

Full text article at
ajp.psychiatryonline.org

Mental disorders and the use of alternative medicine: results from a national survey.

Unutzer J, Klap R, Sturm R, Young AS, Marmon T, Shatkin J, Wells KB.

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unutzer@ucla.edu

OBJECTIVE: The study examined the relationship between mental disorders and the use of complementary and alternative medicine. **METHOD:** Data from a national household telephone survey conducted in 1997-1998 ($N=9,585$) were used to examine the relationships between use of complementary and alternative medicine during the past 12 months and several demographic variables and indicators of mental disorders. Structured diagnostic screening interviews were used to establish diagnoses of probable mental disorders. **RESULTS:** Use of complementary and alternative medicine during the past 12 months was reported by 16.5% of the respondents. Of those respondents, 21.3% met diagnostic criteria for one or more mental disorders, compared to 12.8% of respondents who did not report use of alternative medicine. Individuals with panic disorder and major depression were significantly more likely to use alternative medicine than those without those disorders. Respondents with mental disorders who reported use of alternative medicine were as likely to use conventional mental health services as respondents with mental disorders who did not use alternative medicine. **CONCLUSIONS:** We found relatively high rates of

use of complementary and alternative medicine among respondents who met criteria for common mental disorders. Practitioners of alternative medicine should look for these disorders in their patients, and conventional medical providers should ask their depressed and anxious patients about the use of alternative medicine. More research is needed to determine if individuals with mental disorders use alternative medicine because conventional medical care does not meet their health care needs.

PMID: 11058485 [PubMed - indexed for MEDLINE]

 **14: J Altern Complement Med 2000**
Aug;6(4):321-6

Related Articles, Books,
LinkOut

Alternative/complementary medicine: wider usage than generally appreciated.

Wolsko P, Ware L, Kutner J, Lin CT, Albertson G, Cyran L, Schilling L, Anderson RJ.

Department of Medicine, University of Colorado School of Medicine, Denver 80262, USA.

OBJECTIVE: To test the hypothesis that there is substantial use of a practitioner of alternative/complementary medicine by patients traditionally considered to be underserved. **DESIGN:** Cross-sectional, self-administered survey study. **SETTINGS:** Three university hospital-affiliated general ambulatory clinics serving patients of different socioeconomic status and racial origin. **SUBJECTS:** Five hundred and thirty-six (93% of those attending) consecutive clinic attendees. **OUTCOME MEASURES:** Past use and desired future use of one or more practitioners of five modalities of alternative/complementary medicine and willingness to pay for these modalities out-of-pocket. **RESULTS:** Past usage and desired future usage of one or more practitioners of alternative/complementary medicine was comparable at the three clinic sites despite wide differences in socioeconomic status and willingness/ability to pay out-of-pocket for these services. Multivariable analyses revealed lower self-rated health status and female gender (both $p < 0.006$) but not income, race, age or education as independent, significant predictors of use of a practitioner of alternative/complementary medicine. **CONCLUSION:** Usage of alternative/complementary medicine is not confined to any well-circumscribed socioeconomic group and is common in patients often considered to be underserved. Self-assessed lower health status is significantly and independently associated with use of a practitioner of alternative/complementary care.

PMID: 10976978 [PubMed - indexed for MEDLINE]

- 15: Arch Gen Psychiatry 2000 Jul;57(7):708-14 Related Articles, Books, LinkOut

ARCH GEN PSYCH

Use of practitioner-based complementary therapies by persons reporting mental conditions in the United States.

Druss BG, Rosenheck RA.

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BACKGROUND: To our knowledge, this study provides the first national estimates for use of practitioner-based complementary treatments by US residents reporting mental conditions. **METHODS:** A total of 16038 respondents to the 1996 Medical Expenditure Panel Survey were asked about visits for 12 complementary medical services (eg, chiropractic services and herbal remedies). Bivariate and multiple regression models examined use of these therapies in individuals reporting a mental condition (n= 1803), fair or poor mental health status (n=992), and 1 of 4 chronic medical conditions (n = 3262) and in the remainder of the sample (n= 10 793). **RESULTS:** A total of 9.8% of those reporting a mental condition made a complementary visit, and about half of these (4.5%) made a visit to treat the mental condition. Persons reporting transient stress or adjustment disorders were most likely (odds ratio, 9.1%; 95% confidence interval, 5.5%-12.7%), and those with psychotic (odds ratio, 1.5%; 95% confidence interval, 0.0%-4.2%) and affective (odds ratio, 2.6%; 95% confidence interval, 1.5%-3.8%) conditions least likely, to use complementary therapies to treat their mental condition. In multivariate models controlling for medical comorbidity, fair or poor mental health status, and demographic factors, report of a mental condition predicted a 1.27-fold increase in the odds of a complementary visit (95% confidence interval, 1.04-1.54). **CONCLUSIONS:** Self-reported mental conditions were associated with increased use of complementary treatments, although use of these treatments was concentrated in respondents with transient distress rather than chronic and serious conditions. More research using structured diagnostic interviews is needed to examine the prevalence, patterns, and clinical implications of use of these treatments by individuals with mental conditions in "real world" community settings.

PMID: 10891042 [PubMed - indexed for MEDLINE]

- 16: Complement Ther Med 2000 Jun;8(2):88-96 Related Articles, Books, LinkOut



The prevalence of complementary and alternative medicine use among the general population: a systematic review of the

literature.

Harris P, Rees R.

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OBJECTIVE: To conduct a systematic review of published research investigating the prevalence of complementary and alternative medicine (CAM) use in the general population. **DESIGN:** A protocol was developed for a systematic review of survey literature identified using two bibliographic databases and citation tracking. The protocol specified criteria for: 1) database searches; 2) selection of studies for review; and 3) description of methodological and substantive aspects of the studies. **RESULTS:** Twelve studies were reviewed. These estimated the prevalence of CAM use in Australia, Canada, Finland, Israel, the UK, and the USA. The most rigorous studies, conducted in Australia and the USA, showed that a high proportion of the population was using CAM. There was evidence from the USA that CAM use increased significantly among the general population during the 1990s. **CONCLUSION:** CAM is used by substantial proportions of the general population of a number of countries, but differences in study design and methodological limitations make it difficult to compare prevalence estimates both within and between countries.

Publication Types:

- Review
- Review, academic

PMID: 10859601 [PubMed - indexed for MEDLINE]

 17: Oncol Nurs Forum 2000 May;27(4):623-30 Related Articles, Books, LinkOut

Use of complementary medicine by adult patients participating in cancer clinical trials.

Sparber A, Bauer L, Curt G, Eisenberg D, Levin T, Parks S, Steinberg SM, Wootton J.

National Institutes of Health (NIH), Bethesda, MD, USA.
asparber@cc.nih.gov

PURPOSE/OBJECTIVES: To document the prevalence, demographic correlates, patterns of use, and beliefs about complementary and alternative medicine (CAM) therapies of adult patients enrolled in National Cancer Institute (NCI) clinical trials. **DESIGN:** Prospective, cross-sectional, descriptive survey. **SETTING:** W.G. Magnuson Clinical Center of the National Institutes of Health in Bethesda, MD. **SAMPLE:** Convenience

sample of 100 English-speaking, adult patients with cancer admitted to intramural clinical trials. **METHODS:** A standardized, 99-item questionnaire assessing use of CAM therapies pre- and postcancer diagnosis was administered by face-to-face interview. **MAIN RESEARCH VARIABLES:** Use of CAM therapies, beliefs, communication with physician. **FINDINGS:** 63% used at least one CAM therapy, with an average use of two therapies per patient. Men were significantly less likely to use a therapy than women; women were more likely to use numerous therapies. Cancer diagnosis seems to have had no influence overall on the frequency of use of CAM therapies. The major reasons stated for CAM use were for treatment-related medical conditions as well as depression, anxiety, and insomnia. The most frequently reported therapies were spiritual, relaxation, imagery, exercise, lifestyle diet (e.g., macrobiotic, vegetarian), and nutritional supplementation. Patients unanimously believed that these complementary therapies helped to improve their quality of life through more effective coping with stress, decreasing the discomforts of treatment and illness, and giving them a sense of control. **CONCLUSIONS:** Patients with cancer use various complementary therapies to cope with their disease and the rigors of clinical trials. Women and those with higher educational backgrounds were more frequent users. **IMPLICATIONS FOR NURSING PRACTICE:** Nurses who provide care to subjects of biomedical research have an opportunity and responsibility regarding their patients' use of CAM therapies. Nurses may use in-house resources to help evaluate subjects' use of a CAM modality or to provide quality-of-life therapies such as relaxation, imagery, or healing touch. Discussing these health practices in a nonjudgmental manner adds to the assessment of patients' coping skills and ability to make decisions about their health care.

PMID: 10833691 [PubMed - indexed for MEDLINE]

 18: Am J Emerg Med 2000 Jan;18(1):51-4

[Related Articles](#), [Books](#), [LinkOut](#)

Use of complementary and alternative medicine among Dominican emergency department patients.

Allen R, Cushman LF, Morris S, Feldman J, Wade C, McMahon D, Moses M, Kronenberg F.

Center for Population and Family Health, Columbia University School of Public Health, New York, NY, USA.

This small, pilot study examined presenting complaint, brief health history, use of complementary and alternative medicine (CAM), and sociodemographic characteristics, among patients attending the emergency department (ED) of a large urban hospital. The sample (n = 50) was primarily Dominican and of low socioeconomic status. Almost half had used CAM for their presenting complaint or another health problem during the past year, most commonly in the form of medicinal plants made into herbal

teas. CAM users were more likely to be female, longer-term residents of the United States, and to have also used religious practices for health problems. Subjects who had used CAM for any problem other than the presenting complaint during the past year rated its effectiveness higher than subjects who had used CAM for their presenting complaint. In conclusion, it is likely that a significant proportion of Dominican ED patients use CAM, suggesting that they should be asked about their CAM use during triage.

PMID: 10674532 [PubMed - indexed for MEDLINE]

19: Gerontologist 1999 Dec;39(6):711-9

Related Articles, Books

Predictors of use of traditional Korean healers among elderly Koreans in Los Angeles.

Pourat N, Lubben J, Wallace SP, Moon A.

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Many ethnic groups are known to use traditional healers often in conjunction with Western biomedical medicine, thus combining treatment regimens and medical advice as they see fit. Awareness of the use of traditional healers is an increasingly salient issue due to the growing diversity and aging of the U.S. population. To explore the determinants of use of traditional healers, we studied demographics, health status, and social support networks of a representative sample of elderly Koreans in Los Angeles County, California. The results revealed that chronic conditions such as arthritis, lung disease, and stomach pain, fewer depressive symptoms, availability of health insurance, and stronger social networks were significant predictors of use of traditional healers. Better understanding reasons for and patterns of health care use may enhance the delivery of care to the heterogeneous elderly population by preventing potential treatment complications and increasing health providers' cultural sensitivity.

PMID: 10650681 [PubMed - indexed for MEDLINE]

20: J Natl Cancer Inst 2000 Jan 5;92(1):42-7

Related Articles, Books, LinkOut

Full text article at
jnci.oupjournals.org

Alternative therapies used by women with breast cancer in four ethnic populations.

Lee MM, Lin SS, Wrensch MR, Adler SR, Eisenberg D.

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BACKGROUND: Interest in alternative therapies is growing rapidly in the United States. We studied the types and prevalence of conventional and alternative therapies used by women in four ethnic groups (Latino, white, black, and Chinese) diagnosed with breast cancer from 1990 through 1992 in San Francisco, CA, and explored factors influencing the choices of their therapies. **METHODS:** Subjects (n = 379) completed a 30-minute telephone interview in their preferred language. Logistic regression models assessed factors associated with the use of alternative therapies after a diagnosis of breast cancer. **RESULTS:** About one half of the women used at least one type of alternative therapy, and about one third used two types; most therapies were used for a duration of less than 6 months. Both the alternative therapies used and factors influencing the choice of therapy varied by ethnicity. Blacks most often used spiritual healing (36%), Chinese most often used herbal remedies (22%), and Latino women most often used dietary therapies (30%) and spiritual healing (26%). Among whites, 35% used dietary methods and 21% used physical methods, such as massage and acupuncture. In general, women who had a higher educational level or income, were of younger age, had private insurance, and exercised or attended support groups were more likely to use alternative therapies. About half of the women using alternative therapies reported discussing this use with their physicians. More than 90% of the subjects found the therapies helpful and would recommend them to their friends. **CONCLUSIONS:** Given the high prevalence of alternative therapies used in San Francisco by the four ethnic groups and the relatively poor communication between patients and doctors, physicians who treat patients with breast cancer should initiate dialogues on this topic to better understand patients' choices with regard to treatment options.

PMID: 10620632 [PubMed - indexed for MEDLINE]

21: Cancer 1999 Dec 15;86(12):2642-8

[Related Articles](#), [Books](#), [LinkOut](#)



Alternative medicine use in patients with localized prostate carcinoma treated with curative intent.

Lippert MC, McClain R, Boyd JC, Theodorescu D.

Department of Urology, University of Virginia Health Sciences Center, Charlottesville, Virginia 22908, USA.

BACKGROUND: Alternative medicine therapies are estimated to be used by 7-64% of cancer patients but up to 72% do not inform their physician. To the authors' knowledge little useful information is available regarding the prevalence of alternative medicine use by patients with prostate carcinoma.

Thus, the authors attempted to evaluate the prevalence of alternative medicine use by prostate carcinoma patients treated with curative intent by either radical prostatectomy, brachytherapy alone, or a combination of brachytherapy and external radiation therapy. **METHODS:** Between January 1997 and May 1998, 234 men with clinically localized prostate carcinoma underwent radical prostatectomy (54 patients) or brachytherapy (180 patients) with (74 patients) or without (106 patients) external beam radiation therapy. In July 1998 a questionnaire was mailed to all patients comprised of multiple questions regarding alternative medicine use to which 190 patients (81%) responded. The overall prevalence and types of alternative medicine therapies used were assessed and the relation between age at procedure, pretreatment prostate specific antigen level, clinical stage, pretreatment Gleason score, and type of treatment with the use of alternative medicine therapies was evaluated using univariate and multivariate analysis. **RESULTS:** The prevalence of alternative medicine use by prostate carcinoma patients responding to the survey was 43% (81 of 190 patients). No significant differences in alternative medicine use were observed between the patients who received brachytherapy alone (38%), those who underwent radical prostatectomy (40%), and those treated with combined brachytherapy and external beam radiation therapy (51%). Vitamins, prayer or other religious practices, and herbal medicines were the most commonly used therapies in these patients. Higher pretreatment Gleason scores were associated with a greater use of alternative medicine therapies on both multivariate and univariate analyses. Finally, using multivariate analysis, younger prostate carcinoma patients were more likely to use alternative medicine therapies than older patients. **CONCLUSIONS:** Alternative medicine use is very prevalent among patients treated for localized prostate carcinoma. Because some of these treatments may have a potential biologic impact on tumor behavior and, consequently, on definitive or surrogate therapeutic endpoints, patients should be questioned carefully regarding alternative medicine use during routine tumor follow-up. Copyright 1999 American Cancer Society.

PMID: 10594859 [PubMed - indexed for MEDLINE]

22: J Am Med Womens Assoc 1999
Fall;54(4):193-5

Related Articles, Books,
[LinkOut](#)

Use of complementary and alternative medicine among African-American and Hispanic women in New York City: a pilot study.

Cushman LF, Wade C, Factor-Litvak P, Kronenberg F, Firester L.

Center for Population and Family Health, Joseph Mailman School of Public Health, Columbia University, USA.

OBJECTIVE: To explore the use of complementary and alternative medicine (CAM) among African-American and Hispanic women residing in New York City, including use of specific treatments and practitioners, perceived effectiveness of CAM, and culturally specific words or expressions for CAM. **METHODS:** Focus groups were conducted with two groups of African-American and two groups of Hispanic women (age 18-40 and 41-80) as preparation for the development of a quantitative instrument to assess the prevalence and determinants of CAM use among women of various ethnic backgrounds. Participants were recruited using a standard random digit dial procedure. **RESULTS:** The most commonly used CAM remedies were teas and herbs, vitamins and nutritional supplements, prayer and spiritual healing, meditation and relaxation techniques. Practitioners most frequently seen were chiropractors, herbalists, and acupuncturists. Use of alternative remedies and practitioners, particularly the latter, was most common among older women in both groups. Younger Hispanic women reported the most skepticism toward CAM, especially when it was used by relatives as a substitute for conventional medical care. Overall, these African-American and Hispanic women used CAM for a wide range of health conditions and for prevention. Few racial and ethnic differences emerged in patterns of CAM use for either self-care or treatment by practitioners, but there was a distinct age variation, especially in attitudes toward CAM.

PMID: 10531761 [PubMed - indexed for MEDLINE]

 **23:** JAMA 1999 Aug 18;282(7):651-6

[Related Articles](#), [Books](#), [LinkOut](#)

Comment in:

- JAMA. 2000 Jan 5;283(1):56; discussion 57

Association between use of unconventional therapies and conventional medical services.

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CONTEXT: The terms alternative and complementary medicine suggest 2 contradictory possibilities. Whether individuals use unconventional therapies as a substitute for or as an "add on" to conventional medical treatments is uncertain. **OBJECTIVE:** To determine the association between use of unconventional therapies and conventional medical care in a national sample. **DESIGN, SETTING, AND PARTICIPANTS:** The 1996 Medical Expenditure Panel Survey was distributed to a probability sample of the noninstitutionalized civilian US population. Of 24676 individuals responding (77.7% response rate), 16068 adults 18 years or older were included in the analysis. **MAIN OUTCOME MEASURES:** Visits to

practitioners for unconventional therapies and conventional medical services, including number of inpatient, outpatient, and emergency department visits and use of 8 types of preventive medical services (blood pressure, cholesterol level, physical examination, influenza vaccination, prostate examination, breast examination, mammography, and Papanicolaou test). RESULTS: During 1996, an estimated 6.5% of the US population had visits for both unconventional therapies and conventional medical care; 1.8% used only unconventional services; 59.5% used only conventional care; and 32.2% used neither. Compared with those with only conventional visits, those who used both types of care had significantly more outpatient physician visits (7.9 vs 5.4; $P<.001$), and used more of all types of preventive services except mammography. These groups did not differ significantly in inpatient care, prescription drug use, or number of emergency department visits. Individuals in the top quartile of number of physician visits were more than twice as likely as those in the bottom quartile to have used unconventional therapies in the past year (14.5% vs 6.4%; $P<.001$). The association between unconventional treatments and physician visits remained after adjusting for potential confounders and across different types of unconventional treatment. CONCLUSIONS: In this sample, use of unconventional therapies was substantially lower than has been reported in previous national surveys, but was associated with increased use of physician services. From a health services perspective, practitioner-based unconventional therapies appear to serve more as a complement than an alternative to conventional medicine.

PMID: 10517718 [PubMed - indexed for MEDLINE]

24: J Rural Health 1999 Spring;15(2):233-9

[Related Articles, Books, LinkOut](#)

Comment in:

- J Rural Health. 1999 Spring;15(2):210-1

Factors affecting use of chiropractic services in seven midwestern states of the United State.

Hawk C, Long CR.

Palmer Center for Chiropractic Research, Davenport, IA 52803, USA.

Although chiropractic is used by approximately 10 percent of the U.S. population, predictors of its use have not been definitively described. Previous studies have suggested that chiropractic users differ from nonusers in a number of sociodemographic characteristics, but their findings are inconsistent, perhaps because of differences in populations sampled and dates of data collection, most of which are prior to 1990. Regional studies have been conducted in rural areas based on the premise that rural residents are more likely than non-rural residents to use chiropractic; however, this premise has not been definitively documented. The purpose of this study

was to provide clarification of these sociodemographic predictors of chiropractic use in Illinois, Iowa, Minnesota, Missouri, Nebraska, South Dakota and Wisconsin by characterizing chiropractic users and nonusers in terms of sociodemographics, including rural or non-rural residence, and presence of low back pain. Data from 1,511 respondents to a 1994 population-based survey, conducted by the University of Iowa Social Science Institute, were analyzed. Unconditional logistic regression was used to derive odds ratios and 95 percent confidence intervals for univariate and multiple regression models. Overall, 15.1 percent of respondents had used chiropractic within the last year, most often for low back pain (57 percent). Chiropractic use was less likely in African Americans, Hispanics and Asians than whites, less likely by non-rural than rural residents, and less likely in Catholics than Protestants in states other than Iowa and South Dakota. Overall, 42.7 percent of workers with low back pain reported using chiropractic, and use increased with age but remained significantly related to race, rural or non-rural residence, state of residence and religious preference. Race, rural or non-rural residence, state of residence and religious preference, independently of low back pain, affect use of chiropractic in seven Midwestern states.

PMID: 10511760 [PubMed - indexed for MEDLINE]

 **25: J Nerv Ment Dis 1999 Sep;187(9):539-48** Related Articles, Books, LinkOut

Self-reported health, and illness and the use of conventional and unconventional medicine and mind/body healing by Christian Scientists and others.

Benson H, Dusek JA.

Mind/Body Medical Institute, Beth Israel Deaconess Medical Center, Department of Medicine, Harvard Medical School, Boston, Massachusetts 02215, USA.

A cross-sectional national telephone survey was used to determine whether Christian Scientists (N = 230), a religious group that uses mind/body (including spiritual) healing, self-report more or less illness than non-Christian Scientists (N = 589). The primary outcome measure was the proportion of Christian Scientists and non-Christian Scientists that, during the previous 12 months: a) experienced any of 13 common medical conditions or symptoms; and b) used conventional medicine, unconventional medicine, and mind/body (including spiritual) healing. Fewer Christian Scientists experienced an illness or symptom than non-Christian Scientists (73% vs. 80%, respectively, $p = .05$). A multivariate analysis showed that Christian Scientists were less likely to have experienced illness than non-Christian Scientists (odds ratio [OR] .66, 95% confidence interval [CI] .44 to .99, $p = .04$). Similar proportions of Christian Scientists and

non-Christian Scientists used some type of conventional medicine (74% vs. 78%, respectively), although Christian Scientists were less likely to take prescription medications than non-Christian Scientists ($p = .034$). Although use of unconventional medicine was similar in both groups (52% vs. 45%), more Christian Scientists than non-Christian Scientists used at least one type of mind/body medicine (67% vs. 42% $p < .00001$), notably special religious services and spiritual healing. Additional studies are needed to determine whether there are health benefits associated with the use of conventional and unconventional medicine in combination with mind/body (including spiritual) healing.

PMID: 10496509 [PubMed - indexed for MEDLINE]

 26: J Transcult Nurs 1999 Apr;10(2):136-42 Related Articles, Books, LinkOut

The use of folk healing and healers by six Latinos living in New England: a preliminary study.

Zapata J, Shippee-Rice R.

University of Rhode Island, USA.

The purpose of this qualitative study is to describe Latinos' use of folk medicine and the values associated with it in the context of mainstream health care. The research questions focused on the meaning of folk medicine in the Latino culture and how participants made decisions regarding the use of folk medicine or modern biomedicine. Interviews were conducted with six Latinos living in a New England city who had used folk medicine. Three themes were identified: being sick, healers and healing, and faith and believing. The participants in this study valued their cultural folk medicine and folk healers. However, none relied exclusively on folk medicine. All used mainstream health care providers for specific purposes. A major reason for not using mainstream health care providers more frequently was the perceived lack of holistic care and the use of medicines that are not natural.

PMID: 10476165 [PubMed - indexed for MEDLINE]

 27: South Med J 1999 Aug;92(8):795-8 Related Articles, Books

Folk remedy use in the inner city.

Plotkin SR, Post R.

Department of Medicine, Tulane University School of Medicine, New Orleans, LA, USA.

BACKGROUND: Folk remedies (FRs) are common in some minority communities within the United States. However, little information is available about the use of FRs in the inner city. The objectives of this study were to identify the prevalence and types of FRs used in the inner city, to characterize the population using FRs, and to study patient attitudes toward discussing FRs with physicians. **METHODS:** We interviewed 71 patients over the age of 18 who visited an inner city ambulatory clinic. **RESULTS:** The rate of FR use ranged from 10% to 50% among common medical conditions, with most patients (59%) using at least one remedy. Folk remedy use did not correlate with patient age. Most patients used FRs because they believed them to be efficacious, and most felt comfortable discussing FRs with their physicians. **CONCLUSIONS:** Inner city residents of all ages use FRs to treat illness. These FRs are benign and consist of common household items. Health care workers should feel comfortable discussing FRs with their patients since their patients are comfortable with the topic.

PMID: 10456718 [PubMed - indexed for MEDLINE]

 **28:** Med Anthropol Q 1999 Jun;13(2):214-22 [Related Articles, Books, LinkOut](#)

Complementary and alternative medicine use among women with breast cancer.

Adler SR.

Department of Anthropology, History, and Social Medicine, University of California at San Francisco, USA.

The legacy of 19th-century social theories applied to the study of non-mainstream treatment use continues to affect contemporary research into complementary and alternative medicine (CAM). Quantitatively based studies of CAM use have been hindered by the lack of an adequate lexicon, inaccurate characterizations of the people who use CAM, and underestimates of the prevalence of usage. Results from a qualitative prospective cohort study challenge previous stereotypes by indicating that CAM usage does not increase dramatically with the initial diagnosis of cancer and that younger women are more likely to use CAM than older women. Qualitative research methods are uniquely appropriate for obtaining accurate information about health practices that, despite growing acceptance in some areas of society, are still viewed as outside of the mainstream.

Publication Types:

- Review
- Review, tutorial

PMID: 10440030 [PubMed - indexed for MEDLINE]

29: South Med J 1998 Dec;91(12):1126-31

[Related Articles](#), [Books](#), [LinkOut](#)

Lifetime use of alternative therapy: a study of Florida residents.

Burg MA, Hatch RL, Neims AH.

Department of Community Health and Family Medicine, University of Florida College of Medicine, Gainesville 32610-3588, USA.

BACKGROUND: Clinically relevant questions remain about who uses alternative medicine, which treatments they use and why. **METHODS:** The random digit dialing survey method was used to ask Florida residents about their lifetime use of 11 different alternative therapies. The response rate was 54% (n=1,012). **RESULTS:** Sixty-two percent of respondents had used one or more of these alternative therapies. Women, unmarried persons, those with regular physicians, and those with poor self-rated health were the highest users. Home remedies were used by 31% of the respondents, followed by special diets (24%), relaxation techniques (20%), and herbal medicines (18%). Acupuncture, biofeedback, energy healing, and hypnosis were used by less than 5% of the sample. **CONCLUSIONS:** Most respondents used an alternative therapy at some time. Ethnic diversity may be a useful marker for more diversity in alternative therapy. These results affirm the need for accelerated physician education in alternative medicine to help physicians respond appropriately to patients' inquiries about alternative therapy.

PMID: 9853724 [PubMed - indexed for MEDLINE]

30: JAMA 1998 Nov 11;280(18):1569-75

[Related Articles](#), [Books](#), [LinkOut](#)

Comment in:

- JAMA. 2000 Feb 16;283(7):884-6

Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey.

Eisenberg DM, Davis RB, Ettner SL, Appel S, Wilkey S, Van Rompay M, Kessler RC.

Center for Alternative Medicine Research and Education, Department of Medicine, Beth Israel Deaconess Medical Center, Boston, Mass 02215, USA.

CONTEXT: A prior national survey documented the high prevalence and

costs of alternative medicine use in the United States in 1990. **OBJECTIVE:** To document trends in alternative medicine use in the United States between 1990 and 1997. **DESIGN:** Nationally representative random household telephone surveys using comparable key questions were conducted in 1991 and 1997 measuring utilization in 1990 and 1997, respectively. **PARTICIPANTS:** A total of 1539 adults in 1991 and 2055 in 1997. **MAIN OUTCOMES MEASURES:** Prevalence, estimated costs, and disclosure of alternative therapies to physicians. **RESULTS:** Use of at least 1 of 16 alternative therapies during the previous year increased from 33.8% in 1990 to 42.1% in 1997 ($P \leq .001$). The therapies increasing the most included herbal medicine, massage, megavitamins, self-help groups, folk remedies, energy healing, and homeopathy. The probability of users visiting an alternative medicine practitioner increased from 36.3% to 46.3% ($P = .002$). In both surveys alternative therapies were used most frequently for chronic conditions, including back problems, anxiety, depression, and headaches. There was no significant change in disclosure rates between the 2 survey years; 39.8% of alternative therapies were disclosed to physicians in 1990 vs 38.5% in 1997. The percentage of users paying entirely out-of-pocket for services provided by alternative medicine practitioners did not change significantly between 1990 (64.0%) and 1997 (58.3%) ($P = .36$). Extrapolations to the US population suggest a 47.3% increase in total visits to alternative medicine practitioners, from 427 million in 1990 to 629 million in 1997, thereby exceeding total visits to all US primary care physicians. An estimated 15 million adults in 1997 took prescription medications concurrently with herbal remedies and/or high-dose vitamins (18.4% of all prescription users). Estimated expenditures for alternative medicine professional services increased 45.2% between 1990 and 1997 and were conservatively estimated at \$21.2 billion in 1997, with at least \$12.2 billion paid out-of-pocket. This exceeds the 1997 out-of-pocket expenditures for all US hospitalizations. Total 1997 out-of-pocket expenditures relating to alternative therapies were conservatively estimated at \$27.0 billion, which is comparable with the projected 1997 out-of-pocket expenditures for all US physician services. **CONCLUSIONS:** Alternative medicine use and expenditures increased substantially between 1990 and 1997, attributable primarily to an increase in the proportion of the population seeking alternative therapies, rather than increased visits per patient.

PMID: 9820257 [PubMed - indexed for MEDLINE]

 31: Arch Intern Med 1998 Nov 9;158(20):2257-64

Related Articles, Books,
LinkOut

Comment in:

◦ Arch Intern Med. 1999 May 24;159(10):1143-4

Patterns of use, expenditures, and perceived efficacy of complementary and alternative therapies in HIV-infected patients.

Fairfield KM, Eisenberg DM, Davis RB, Libman H, Phillips RS.

Department of Medicine, Beth Israel Deaconess Medical Center, and Harvard Medical School, Boston, Mass 02215, USA.

BACKGROUND: Complementary and alternative medicine (CAM) use is common in the general population, accounting for substantial expenditures. Among patients with human immunodeficiency virus (HIV) infection, few data are available on the prevalence, costs, and patterns of alternative therapy use. **METHODS:** We carried out detailed telephone surveys and medical chart reviews for 289 active patients with HIV in a general medicine practice at a university-based teaching hospital in Boston, Mass. Data were collected on prevalence and patterns of CAM use, out-of-pocket expenditures, associated outcomes, and correlates of CAM use. **RESULTS:** Of 180 patients who agreed to be interviewed, 122 (67.8%) used herbs, vitamins, or dietary supplements, 81 (45.0%) visited a CAM provider, and 43 (23.9%) reported using marijuana for medicinal purposes in the previous year. Patients who saw CAM providers made a median of 12 visits per year to these providers compared with 7 visits per year to their primary care physician and nurse practitioner. Mean yearly out-of-pocket expenditures for CAM users totaled \$938 for all therapies. For the main reason CAM was used, respondents found therapies "extremely" or "quite a bit" helpful in 81 (81.0%) of 100 reports of supplement use, in 76 (65.5%) of 116 reports of CAM provider use, and in 27 (87%) of 31 reports of marijuana use. In multivariable models, college education (odds ratio [OR]=3.7, 95% confidence interval [CI]=1.9-7.1) and fatigue (OR=2.7, 95% CI=1.4-5.2) were associated with CAM provider use; memory loss (OR=2.3, 95% CI=1.1-4.8) and fatigue (OR=0.4, 95% CI=0.2-0.9) were associated with supplement use; and weight loss (OR=2.6, 95% CI=1.2-5.6) was associated with marijuana use. **CONCLUSIONS:** Patients with HIV infection use CAM, including marijuana, at a high rate; make frequent visits to CAM providers; incur substantial expenditures; and report considerable improvement with these treatments. Clinical trials of frequently used CAMs are needed to inform physicians and patients about therapies that may have measurable benefit or measurable risk.

PMID: 9818806 [PubMed - indexed for MEDLINE]

 **32:** Acupunct Electrother Res 1998;23(2):135-42 Related Articles, Books, LinkOut

Use of alternative therapies by a low income population.

Krastins M, Ristinen E, Cimino JA, Mamtani R.

Preventive Medicine Residency Program, New York Medical College, USA.

Patients in a family health center clinic were surveyed about their use of

alternative/complementary medicine. These were mostly low-income individuals on Medicaid. The aim was to estimate prevalence and patterns of use of medically unconventional therapies such as chiropractic, homeopathy, and acupuncture in this population. Nearly two hundred patients (N = 199) filled out questionnaires inquiring about medical conditions and illnesses, personal health habits (physical activity, tobacco smoking, alcohol intake, etc.), and use of preventive measures or therapies that are neither taught widely in US medical schools nor generally available in US hospitals, and which we refer to as 'alternative' therapies (ATs). The term 'alternative' is not intended to imply that ATs are necessarily chosen to replace, rather than to be used in combination with standard treatments, although that may indeed be so in specific cases. Twenty-nine percent of respondents (58/199) reported using at least one type of AT, as defined for the purposes of the survey. Frequency of use varied somewhat, with greatest AT use reported by those over 29 years of age with more education and higher incomes ($p < 0.10$, defined as chi 2 tests at $p < 0.10$). While no significant differences were found between AT users and nonusers with respect to exercise participation, alcohol intake or smoking, there was a difference with respect to the reporting of at least one medical condition ($p < 0.01$). Among those who have used ATs, 90% reported more than one medical condition. Of those reporting no AT use, 70% indicated only a single medical condition for which they had sought treatment. In conclusion, use of alternative therapy (AT) appears to be common in all socio-economic groups, although AT use is apparently slightly less among low-income persons than in the general population. It is therefore important for physicians and other medical providers to be aware that their patients may be using ATs. Obviously, such practices should be taken into account in case management.

PMID: 9789588 [PubMed - indexed for MEDLINE]

33: JAMA 1998 Sep 2;280(9):784-7

[Related Articles, Books, LinkOut](#)

Comment in:

- JAMA. 1999 Feb 17;281(7):609-10; discussion 610-1
- JAMA. 1999 Feb 17;281(7):609; discussion 610-1
- JAMA. 1999 Feb 17;281(7):610-1

Courses involving complementary and alternative medicine at US medical schools.

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CONTEXT: With the public's increasing use of complementary and alternative medicine, medical schools must consider the challenge of educating physicians about these therapies. OBJECTIVES: To document the

prevalence, scope, and diversity of medical school education in complementary and alternative therapy topics and to obtain information about the organizational and academic features of these courses. DESIGN: Mail survey and follow-up letter and telephone survey conducted in 1997-1998. PARTICIPANTS: Academic or curriculum deans and faculty at each of the 125 US medical schools. MAIN OUTCOME MEASURES: Courses taught at US medical schools and administrative and educational characteristics of these courses. RESULTS: Replies were received from 117 (94%) of the 125 US medical schools. Of schools that replied, 75 (64%) reported offering elective courses in complementary or alternative medicine or including these topics in required courses. Of the 123 courses reported, 84 (68%) were stand-alone electives, 38 (31%) were part of required courses, and one (1%) was part of an elective. Thirty-eight courses (31%) were offered by departments of family practice and 14 (11%) by departments of medicine or internal medicine. Educational formats included lectures, practitioner lecture and/or demonstration, and patient presentations. Common topics included chiropractic, acupuncture, homeopathy, herbal therapies, and mind-body techniques. CONCLUSIONS: There is tremendous heterogeneity and diversity in content, format, and requirements among courses in complementary and alternative medicine at US medical schools.

PMID: 9729989 [PubMed - indexed for MEDLINE]

 **34: J Invest Allergol Clin Immunol** 1998
Mar-Apr;8(2):73-7

Related Articles, Books,
LinkOut

The use of complementary/alternative medicine for the treatment of asthma in the United States.

Davis PA, Gold EB, Hackman RM, Stern JS, Gershwin ME.

Department of Internal Medicine, University of California at Davis, USA.

Despite our advances in the diagnosis and treatment of asthma, the incidence of mortality is increasing in developed countries. As patients and health care providers seek new options for the treatment and prevention of asthma, various complementary and alternative medical therapies are being used. With funding from the Office of Alternative Medicine, National Institutes of Health, our goal was to identify the type and prevalence of complementary and alternative treatments for asthma in use in the United States in order to establish a research agenda for the study of the most promising therapies. A survey was developed by an expert panel. After undergoing a preliminary round of testing and improvement, the survey was then sent along with a postage-paid return envelope as inserts in the May 1996 issue of *Alternative Therapies in Health and Medicine*, a peer-reviewed periodical of complementary and alternative medical research and scholarly activity; 10,000 surveys were distributed. We asked that only those who treated

asthma respond. The surveys were designed to identify characteristics of the respondent, their particular practice type, use of complementary and alternative medicine, or conventional medicine in general, patient characteristics and numbers, and their use of 20 specific potential therapies to treat asthma. A total of 564 surveys were returned. The 5.64% response rate was low but was reflective of the demographics of the readership of this journal of complementary and alternative medicine. The survey population was 46% male and 43% female; 11% did not specify gender. They ranged in age from under 31 years old to over 70. The largest group (37%) of respondents held degrees as medical doctors, 27% held doctorates in complementary and alternative medicine related disciplines, 11% had registered nursing degrees, 4% were acupuncturists and 18% did not specify their training. Practice characteristics between MD and non-MD asthma care providers did not differ. The majority had general practices (75%) seeing all ages of patients. MDs were less likely to employ complementary and alternative medicine techniques for asthma compared to non-MDs. Both groups identified dietary and nutritional approaches as their most prevalent and useful asthma treatment option. Use of botanicals, meditation and homeopathy were frequently cited; statistically significant differences appeared in the rankings of treatment usefulness and prevalence between MD and non-MDs. Non-MD asthma care providers were more likely to ask patients about their use of complementary and alternative treatments for asthma than MDs (92% vs. 70%), while both groups showed statistically significant increases in their levels of patient inquiries compared to 2 years previously (up 9% and 8% for MDs and non-MDs respectively). The predominance of diet and nutrition supplementation used by MDs and non-MDs suggests that further attention and research efforts should be directed toward this area of complementary and alternative practice. Other complementary and alternative medicine practices such as botanicals, meditation and homeopathy appear to warrant research efforts. Differences between MDs and non-MDs in their use of such therapies may reflect different philosophies as well as training.

PMID: 9615298 [PubMed - indexed for MEDLINE]

 35: JAMA 1998 May 20;279(19):1548-53

[Related Articles](#), [Books](#), [LinkOut](#)

Comment in:

- JAMA. 1998 Nov 18;280(19):1659-60; discussion 1661
- JAMA. 1998 Nov 18;280(19):1660-1
- JAMA. 1998 Nov 18;280(19):1660; discussion 1661

Why patients use alternative medicine: results of a national study.

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CONTEXT: Research both in the United States and abroad suggests that significant numbers of people are involved with various forms of alternative medicine. However, the reasons for such use are, at present, poorly understood. **OBJECTIVE:** To investigate possible predictors of alternative health care use. **METHODS:** Three primary hypotheses were tested. People seek out these alternatives because (1) they are dissatisfied in some way with conventional treatment; (2) they see alternative treatments as offering more personal autonomy and control over health care decisions; and (3) the alternatives are seen as more compatible with the patients' values, worldview, or beliefs regarding the nature and meaning of health and illness. Additional predictor variables explored included demographics and health status. **DESIGN:** A written survey examining use of alternative health care, health status, values, and attitudes toward conventional medicine. Multiple logistic regression analyses were used in an effort to identify predictors of alternative health care use. **SETTING AND PARTICIPANTS:** A total of 1035 individuals randomly selected from a panel who had agreed to participate in mail surveys and who live throughout the United States. **MAIN OUTCOME MEASURE:** Use of alternative medicine within the previous year. **RESULTS:** The response rate was 69%. The following variables emerged as predictors of alternative health care use: more education (odds ratio [OR], 1.2; 95% confidence interval [CI], 1.1-1.3); poorer health status (OR, 1.3; 95% CI, 1.1-1.5); a holistic orientation to health (OR, 1.4; 95% CI, 1.1-1.9); having had a transformational experience that changed the person's worldview (OR, 1.8; 95% CI, 1.3-2.5); any of the following health problems: anxiety (OR, 3.1; 95% CI, 1.6-6.0); back problems (OR, 2.3; 95% CI, 1.7-3.2); chronic pain (OR, 2.0; 95% CI, 1.1-3.5); urinarytract problems (OR, 2.2; 95% CI, 1.3-3.5); and classification in a cultural group identifiable by their commitment to environmentalism, commitment to feminism, and interest in spirituality and personal growth psychology (OR, 2.0; 95% CI, 1.4-2.7). Dissatisfaction with conventional medicine did not predict use of alternative medicine. Only 4.4% of those surveyed reported relying primarily on alternative therapies. **CONCLUSION:** Along with being more educated and reporting poorer health status, the majority of alternative medicine users appear to be doing so not so much as a result of being dissatisfied with conventional medicine but largely because they find these health care alternatives to be more congruent with their own values, beliefs, and philosophical orientations toward health and life.

PMID: 9605899 [PubMed - indexed for MEDLINE]

36: J Altern Complement Med 1997
Winter;3(4):337-42

Related Articles, Books,
LinkOut

Alternative medicine in Vermont--a census of practitioners:

prevalence, patterns of use, and national projections.

McPartland JM, Soons KR.

Vermont Alternative Medicine, Middlebury, USA.

The number of alternative/holistic practitioners in Vermont was estimated by two methods: scanning advertisements (yellow pages, newspaper and magazine ads, brochures), and by word-of-mouth canvassing. We located 897 Vermonters who derive most of their annual income practicing at least 1 of 97 different types of alternative medicine and therapy. Most practitioners were female and most practiced more than one type of healing. Bodyworkers were the most prevalent practitioners, followed by chiropractors, acupuncturists, herbalists, and holistic psychotherapists. On a per-capita basis, there is 1 alternative practitioner per 652 Vermonters (or 153 practitioners per 100,000 population). This census nearly equals that of Vermont's M.D. population. Extrapolating this Vermont census to a nationwide estimate of alternative practitioners suggests there are over 403,000 full-time alternative/holistic healers practicing in the United States.

PMID: 9449055 [PubMed - indexed for MEDLINE]

37: J Health Soc Policy 1998;10(3):71-95

[Related Articles, Books, LinkOut](#)

Alternative treatments of cancer: trends over time and implications for the future.

Apostolides AD.

ADA Associates, Cincinnati, OH 45242, USA. aposto19@worldnet.att.net

There has been increasing utilization of alternative treatments for cancer, affected primarily by the dissatisfaction of the public with the outcomes of conventional treatments. Mortality rates from cancer have been increasing over time while spending by government on conventional cancer research rose. The lack of clinical trials on alternative therapies has left them open to criticism by mainstream medicine. Pharmaceutical companies have not funded trials because of an anticipated negative result to their profits. The government also has not shown much interest in research on alternative treatments although large expenditures on conventional treatments have not produced successful results. There is substantial evidence to support effectiveness of alternative therapies, based primarily on retrospective studies and case studies. Recently, clinical trials have been initiated with government approval, for a few alternative therapies; and such government involvement would improve the information available on treatments, to the benefit of the public.

PMID: 10185057 [PubMed - indexed for MEDLINE]

 38: Health Soc Work 1997 May;22(2):95-100 Related Articles, Books, LinkOut

Alternative health practices in ethnically diverse rural areas: a collaborative research project.

Vest GW, Ronnau J, Lopez BR, Gonzales G.

Department of Social Work, New Mexico State University, Las Cruces
88003-8001, USA.

Many alternative health practices are gaining popularity in traditional medical centers throughout the country. However, social workers and allied health professionals are rarely educated in these practices. The collaborative pilot research project discussed in this article involved community health providers and a state university department of social work. The project, conducted in rural health clinics, introduced an approach to skillful, safe, and appropriate use of touch synthesized with an awareness of the breath for giver and receiver to a group of Mexican Americans diagnosed with diabetes and their families. This alternative health practice holds promise for reducing stress, promoting health and well-being, and building relationships and warrants further study.

Publication Types:

- Clinical trial
- Controlled clinical trial

PMID: 9131355 [PubMed - indexed for MEDLINE]

 39: S D J Med 1997 Feb;50(2):65-6 Related Articles, Books, LinkOut

Alternative/complementary therapies.

Freeman JW, Landis J.

Department of Neurosciences, USD School of Medicine, Sioux Falls, USA.

The national trends and our regional experience of the utilization of complementary therapies suggest that a significant number of our patients will continue to employ remedies that are outside the mainstream of what has been defined as conventional Western medicine. The data obtained from our survey is very consistent with the national survey published in 1993. Indeed the national interest in alternative/complementary therapies seems to be growing. A recent newspaper article from Minneapolis noted that Allina,

one of Minnesota's largest hospital and HMO systems, found, in a 1995 survey, that two-thirds of surveyed households had a least one member who had used some type of alternative or holistic care over the prior two year period. Certainly continued study of the safety and efficacy of alternative/complementary therapies is warranted. This work is being done on many fronts, including the Office of Alternative Medicine at the National Institutes of Health. A most important aspect of such investigations is to improve the understanding of why patients choose these unconventional remedies. For many patients, the answer is simple. They believe these alternative treatments work. For such patients, alternative therapies may constitute a practical way to move from the sterile "high tech" realm of traditional medicine to a more intimate, "high touch" intervention offered by non-physicians. In the end, physicians' most pressing mandate is "to be of use" to patients in their struggles with illness, disability, and impending death. None of us have all the answers, and the studies alluded to in this essay suggest that a significant segment of the population yearns for interventions that have been traditionally outside the practice of most physicians and nurses. The data from our survey corroborates the high utilization rate of alternative/complementary therapies, regionally and is consistent with national data. Our challenge, as caregivers, is to appropriately respond to the notable prevalence of alternative health practices and to the complex societal factors which nurture this usage.

PMID: 9062449 [PubMed - indexed for MEDLINE]

 **40: Arch Pediatr Adolesc Med 1995**
Sep;149(9):978-81

Related Articles, Books,
LinkOut

Comment in:

- Arch Pediatr Adolesc Med. 1995 Sep;149(9):949-50
- Arch Pediatr Adolesc Med. 1996 May;150(5):560

Use of folk remedies in a Hispanic population.

Risser AL, Mazur LJ.

Department of Pediatrics, University of Texas Health Science Center, Houston, USA.

OBJECTIVES: To identify the types of home remedies used for common pediatric problems in a Hispanic population and to study traditional folk illnesses and their cures. **DESIGN:** Survey of 51 Hispanic caregivers, mostly mothers. **SETTING:** A pediatric primary care facility in an urban Hispanic neighborhood in Houston, Tex. **MAIN OUTCOME MEASURES:** Remedies used for common pediatric illnesses and for the traditional folk illnesses: mal ojo (evil eye), empacho (blocked intestine), mollera caida (fallen fontanelle), and susto (fright). **RESULTS:** A combination of herbs and pharmaceuticals was used for many illnesses. Teas were most commonly

used for colic, upper respiratory tract symptoms, and abdominal pain. Pharmaceuticals were most commonly used for upper respiratory tract symptoms, fever, and diarrhea. Belief in folk illnesses was common: 36 (70%) had experience with mal ojo, 33 (64%) with empacho, 27 (52%) with mollera caida, and 19 (37%) with susto; 10 (20%) had taken their children to curanderos (traditional healers) for treatment of folk illnesses.

CONCLUSIONS: Cultural health beliefs were widely maintained in this Hispanic population. Many patients integrated cultural health practices with reliance on medical practitioners. Knowledge and acknowledgement of these practices are important for physician-patient communication and may affect compliance with other medical procedures and treatments.

PMID: 7655602 [PubMed - indexed for MEDLINE]

41: N Engl J Med 1993 Jan 28;328(4):246-52 Related Articles, Books, LinkOut

Comment in:

- N Engl J Med. 1993 Jan 28;328(4):282-3
- N Engl J Med. 1993 Oct 14;329(16):1200-1; discussion 1203-4
- N Engl J Med. 1993 Oct 14;329(16):1201; discussion 1203-4
- N Engl J Med. 1993 Oct 14;329(16):1203; discussion 1203-4

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Unconventional medicine in the United States. Prevalence, costs, and patterns of use.

Eisenberg DM, Kessler RC, Foster C, Norlock FE, Calkins DR, Delbanco TL.

Department of Medicine, Beth Israel Hospital, Boston, MA 02215.

BACKGROUND. Many people use unconventional therapies for health problems, but the extent of this use and the costs are not known. We conducted a national survey to determine the prevalence, costs, and patterns of use of unconventional therapies, such as acupuncture and chiropractic. **METHODS.** We limited the therapies studied to 16 commonly used interventions neither taught widely in U.S. medical schools nor generally available in U.S. hospitals. We completed telephone interviews with 1539 adults (response rate, 67 percent) in a national sample of adults 18 years of age or older in 1990. We asked respondents to report any serious or bothersome medical conditions and details of their use of conventional medical services; we then inquired about their use of unconventional therapy. **RESULTS.** One in three respondents (34 percent) reported using at least one unconventional therapy in the past year, and a third of these saw providers for unconventional therapy. The latter group had made an average of 19 visits to such providers during the preceding year, with an average charge per visit of \$27.60. The frequency of use of unconventional therapy varied somewhat among socio-demographic groups, with the highest use

reported by nonblack persons from 25 to 49 years of age who had relatively more education and higher incomes. The majority used unconventional therapy for chronic, as opposed to life-threatening, medical conditions. Among those who used unconventional therapy for serious medical conditions, the vast majority (83 percent) also sought treatment for the same condition from a medical doctor; however, 72 percent of the respondents who used unconventional therapy did not inform their medical doctor that they had done so. Extrapolation to the U.S. population suggests that in 1990 Americans made an estimated 425 million visits to providers of unconventional therapy. This number exceeds the number of visits to all U.S. primary care physicians (388 million). Expenditures associated with use of unconventional therapy in 1990 amounted to approximately \$13.7 billion, three quarters of which (\$10.3 billion) was paid out of pocket. This figure is comparable to the \$12.8 billion spent out of pocket annually for all hospitalizations in the United States. **CONCLUSIONS.** The frequency of use of unconventional therapy in the United States is far higher than previously reported. Medical doctors should ask about their patients' use of unconventional therapy whenever they obtain a medical history.

PMID: 8418405 [PubMed - indexed for MEDLINE]

42: West J Med 1992 Sep;157(3):310-5

Related Articles, Books

Use of traditional and modern health services by Laotian refugees.

Gilman SC, Justice J, Saepharn K, Charles G.

Regional Medical Education Center, Veterans Affairs (VA) Medical Center, Long Beach, San Francisco, CA.

Although refugee health care emerged as a special interest in the United States following the influx of almost a million Southeast Asians since 1975, few studies have been done of the influence of refugee traditions on the use of Western medical services. The illness patterns, medical beliefs, and health care behavior of a Southeast Asian refugee group, the Mien from Laos are described in this study. A cohort of 119 Mien refugees living in Richmond, California, was observed for a 6-month period. In-home interviews were undertaken about all episodes of ill health, including treatment and health care decisions. This study shows that the Mien integrate traditional healing beliefs and practices with the use of American health services. Such findings are important because the increasing cultural diversity in the United States, particularly in Western states, necessitates that health care professionals understand the importance of cultural factors for access to and the use of health care by all patients including refugees and other immigrant groups.

PMID: 1413776 [PubMed - indexed for MEDLINE]

43: West J Med 1992 May;156(5):507-11

[Related Articles](#), [Books](#), [LinkOut](#)

Use of traditional health practices by Southeast Asian refugees in a primary care clinic.

Buchwald D, Panwala S, Hooton TM.

Department of Medicine, Harborview Medical Center, University of Washington, Seattle 98104.

To determine the prevalence of use of traditional health practices among different ethnic groups of Southeast Asian refugees after their arrival in the United States, we conducted a convenience sample of 80 Cambodian, Lao, Mien, and ethnic Chinese patients (20 each) attending the University of Washington Refugee Clinic for a new or follow-up visit. Interpreters administered a questionnaire that dealt with demographics, medical complaints, traditional health practices, health beliefs, and attitudes toward Western practitioners. In all, 46 (58%) patients had used one or more traditional health practices, but the prevalence varied by ethnic group. Coining and massage were used by all groups except the Mien, whereas moxibustion and healing ceremonies were performed almost exclusively by the Mien. Traditional health practices were used for a variety of symptoms and, in 78% of reported uses, patients reported alleviation of symptoms. The use of traditional health practices is common among Southeast Asian refugees. Clinicians who care for this population should be aware of these practices because they may supersede treatments prescribed by physicians or leave cutaneous stigmata that may be confused with disease or physical abuse. Good patient care may necessitate the use or tolerance of both Western and traditional modalities in many Southeast Asian refugees.

PMID: 1595275 [PubMed - indexed for MEDLINE]

44: CA Cancer J Clin 1992 May-Jun;42(3):181-91

[Related Articles](#), [Books](#),
[LinkOut](#)

The prevalence of questionable methods of cancer treatment in the United States.

Lerner IJ, Kennedy BJ.

University of Minnesota, Minneapolis.

OBJECTIVE: To assess nationally the use of questionable cancer therapies.
DESIGN: Survey of cancer patients or their families regarding use of questionable methods of cancer treatment; sample survey of physicians'

perception of use. PARTICIPANTS: 36,000 households; 5,047 individuals; 91 physicians. RESULTS: The prevalence of use of questionable cancer methods was nine percent overall. An increase in use was directly proportional to increased income and education. Prolonged illness and certain types of cancer were more commonly associated with use. Harmful side effects of questionable cancer treatments were regarded as modest (six percent). There was a wide range in cost. Third-party reimbursement was reported by 25 percent of patients. Important discrepancies were found between patients' and physicians' perceptions of questionable therapies. CONCLUSIONS: While some questionable therapies are harmless or inexpensive, others have toxic effects and may be costly, and none have scientifically proven efficacy. Although the percentage of usage reported is relatively low, overall large numbers of patients are involved, especially in certain groups. The physician plays a key role in encouraging or preventing the use of questionable methods, and substantial improvements in public and professional education are needed.

PMID: 1568137 [PubMed - indexed for MEDLINE]

45: N Engl J Med 1991 Apr 25;324(17):1180-5 Related Articles, Books, LinkOut

Comment in:

- N Engl J Med. 1991 Oct 10;325(15):1103-5

Survival and quality of life among patients receiving unproven as compared with conventional cancer therapy.

Cassileth BR, Lusk EJ, Guerry D, Blake AD, Walsh WP, Kascius L, Schultz DJ.

Psychosocial Research Programs, University of Pennsylvania, Philadelphia.

BACKGROUND. Cancer treatments without proved efficacy have achieved new levels of popularity, particularly among well-educated patients. The value of these therapies is vigorously debated. **METHODS.** We compared the length of survival and quality of life in patients who received treatment at a prominent unorthodox cancer clinic in addition to conventional treatment and in matched control patients from an academic cancer center who received only conventional treatment. All the patients had documented extensive malignant disease associated with a predicted median survival time of less than one year. The study sample consisted of 78 pairs of patients matched according to sex, race, age, diagnosis, and time from the diagnosis of metastatic or recurrent disease, who were enrolled over a period of 3 1/2 years. Periodic follow-up (approximately every two months) continued until death. **RESULTS.** There was no difference between the two patient groups in length of survival. Median survival for both groups was 15 months ($P = 0.22$; relative risk, 1.23; 95 percent confidence interval, 0.88 to 1.72). Quality-of-life scores were consistently better among conventionally treated

patients from enrollment on. **CONCLUSIONS.** For this sample of patients with extensive disease and for this particular unorthodox treatment regimen, conventional and unorthodox treatments produced similar results.

PMID: 2011162 [PubMed - indexed for MEDLINE]

 **46:** Child Welfare 1991 Mar-Apr;70(2):157-67 Related Articles, Books, LinkOut

Folk-healing among Mexican-American families as a consideration in the delivery of child welfare and child health care services.

Krajewski-Jaime ER.

Eastern Michigan University, Ypsilanti.

If practitioners in cross-cultural services do not understand traditional health beliefs and practices and find ways to incorporate a compatible approach to them in their work, their clients and patients will go their own ways, sometimes with dire results. Practices among Mexican-American families are described.

PMID: 2036870 [PubMed - indexed for MEDLINE]

 **47:** Am J Public Health 1990 Dec;80 Suppl:32-5 Related Articles, Books

Utilization of curanderos by Mexican Americans: prevalence and predictors. Findings from HHANES 1982-84.

Higginbotham JC, Trevino FM, Ray LA.

Department of Preventive Medicine and Community Health, University of Texas Medical Branch, Galveston, USA.

Data from the Southwest sample of the Hispanic Health and Nutrition Examination Survey (HHANES) were analyzed to examine whether the use of a curandero or other folk medicine practitioner hindered, enhanced, or did not affect the utilization of western health care services by Mexican Americans. Findings revealed that only 4.2 percent of the HHANES sample persons between the ages of 18-74 years reported consulting a curandero, herbalista, or other folk medicine practitioner within the 12 months prior to the survey. Income, self-perceived health status, the language of the interview, and dissatisfaction with modern medical care recently received independently predicted curandero utilization (adjusted OR 2.01 and 1.66, respectively). Low income and self-perceived health status were less

strongly related to curandero utilization.

PMID: 9187579 [PubMed - indexed for MEDLINE]

 **48: J Manipulative Physiol Ther 1990**
Oct;13(8):427-36

Related Articles, Books,
LinkOut

Nonmedical illness behavior: a model of patients who seek alternatives to allopathic medicine.

Semmes CE.

Afro-American Studies Program, Eastern Michigan University, Ypsilanti 48197.

This project investigated the process by which African-Americans in Chicago decided to access drugless, natural health care systems in conjunction with, or as alternatives to, orthodox medical care. The study focused on African-American users of the drugless, natural health care systems of chiropractic and naprapathy. The data for the study were qualitative and ethnographic, and included over 100 in-depth interviews, extensive field notes based on participant observation and related documents. The findings involved constructing a five-stage sequential model that describes the process of conversion to regular use of natural health care. The purpose of this article is to present a model of nonmedical illness behavior that can sensitize health care practitioners to the situational and contingent factors affecting patients' choices.

PMID: 2230605 [PubMed - indexed for MEDLINE]

 **49: Nurs Res 1983 Mar-Apr;32(2):97-101**

Related Articles, Books

Retention of a folk-healing practice (matiasma) among four generations of urban Greek immigrants.

Tripp-Reimer T.

This article reports a field investigation (N = 328) of a folk-healing practice (matiasma) among a population of urban Greek immigrants in Ohio. While orthodox Western health care is used by this community, the Greek population has also retained ethnomedical beliefs and practices that differ dramatically from those of scientific health care. This study delineates specific facets of matiasma, the configuration surrounding the evil eye. By tracing the retention of knowledge and use of this configuration over a four-generation period, this paper demonstrates the importance of generation

depth as a variable in transcultural nursing research.

PMID: 6551772 [PubMed - indexed for MEDLINE]

50: J Ethnopharmacol 1981 Sep;4(2):207-21 Related Articles, Books, LinkOut

Folk remedies as indicators of common illnesses: examples from the United States-Mexico border.

Trotter RT 2nd.

A sample of 1235 case examples of remedios caseros (home remedies) were analyzed to determine the characteristics of the ethnopharmacological resources currently in use in Mexican American communities along the eastern end of the United States-Mexico border. The data analysis confirms that there is a core group of most frequently used remedies that constitute the bulk of the home treatment of common ailments in that area. The data further indicate that there is a relatively well-defined group of ailments that are considered to be more amenable to ethnopharmacological intervention than to treatment by the conventional medical system. Some of the remedios (both botanical and non-botanical) are presented, and a preliminary model of ailments that receive treatment from home remedies, as opposed to medical treatment, is proposed.

PMID: 7311597 [PubMed - indexed for MEDLINE]

51: Am J Chin Med 1976 Spring;4(1):31-45 Related Articles, Books

The role of Chinese medicine in New York City's Chinatown. 1.

Chan CW, Chang JK.

This study reports on use patterns of traditional Chinese and Western medical resources in New York City's Chinese community. Extensive data from field-work and interview are presented which provide significant new information concerning the health-care attitudes and problems of this unique community.

PMID: 1266799 [PubMed - indexed for MEDLINE]

52: Community Ment Health J 1976 Winter;12(4):392-8 Related Articles, Books

The role of folk healers in community mental health services.

Ruiz P, Langrod J.

This paper deals with the relationship between sociocultural factors and psychopathology in Hispanic groups in a disadvantaged urban area. The data were drawn from a 6-year collaborative undertaking between the Lincoln Community Mental Health Center and two local spiritualistic centers in the Southeast Bronx, New York. Comparisons are offered between classical mental health personnel and indigenous folk healers with emphasis on terminology, means of communication, and diagnosis techniques, as well as the utilization of social behavior and moral values. Relevant inferences are drawn regarding the broader relationship between religion and psychiatry. The importance of understanding of utilization of local folk resources in the planning and implementation of mental health services in urban ghettos is documented.

PMID: 1000932 [PubMed - indexed for MEDLINE]

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Department of Health and Human Services

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INSPECTOR GENERAL**

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**Complementary and Alternative
Medicine Laboratory Tests**



JUNE GIBBS BROWN
Inspector General

DECEMBER 2000
OEI-05-00-00250

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Bambi Straw, *Program Specialist*

EXECUTIVE SUMMARY

PURPOSE

To examine how the Health Care Financing Administration (HCFA) regulates laboratories conducting Live Blood Cell Analysis and other complementary and alternative laboratory tests.

BACKGROUND

Complementary and alternative medicine (CAM) encompasses a broad range of philosophies and treatments not widely accepted by western medicine. In the 1990's, HCFA began to identify laboratory sites doing complementary and alternative medicine laboratory tests. One such test, Live Blood Cell Analysis (LBA), uses a drop of blood from a patient's finger. The blood is placed on a slide and viewed under a specialized microscope connected to a video monitor. Testing of this type is regulated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and HCFA is responsible for its implementation. This report discusses the problems encountered in trying to regulate complementary and alternative medicine laboratory testing, particularly LBA.

FINDINGS

Complementary and Alternative Medical Laboratory Testing Cannot Meet CLIA Requirements

An unknown, but perhaps significant, number of complementary and alternative medicine laboratories may be operating without CLIA certification. Of the 200 CAM laboratories, we identified during this study, 80 percent do not have a CLIA certificate. The HCFA has difficulty identifying laboratories that perform complementary and alternative medicine tests. Getting these laboratories to comply with CLIA requirements is difficult. The program relies on laboratories to identify themselves for enrollment voluntarily but CAM laboratories have few, if any, incentives to do so. The HCFA has no administrative remedies that would permit them to take action against laboratories that refuse to enroll or comply with the Federal law.

To date, laboratories conducting Live Blood Cell Analysis have not been able to meet all CLIA requirements. Many LBA providers are nutritionists, herbologists, naturopaths, chiropractors and others who are unlikely to meet CLIA personnel requirements. Laboratories performing LBA are also unable to meet requirements pertaining to the

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establishment and verification of test method. Consequently, the remaining laboratories identified as offering LBA may be improperly operating outside their CLIA certificate.

Some Laboratories Performing Live Blood Cell Analysis May Have Been Improperly Issued CLIA Certificates

The HCFA may be unaware that laboratories with waived or provider-performed microscopy CLIA certificates are conducting complementary and alternative laboratory testing. Obtaining these types of certificates is relatively easy. Applications from laboratories do not require disclosure of CAM testing, and laboratories seeking waived and provider-performed microscopy certificates are not routinely visited. Consequently, HCFA may never discover that these laboratories are performing LBA and that they may have been improperly issued a CLIA certificate.

Laboratories that perform LBA and other CAM testing and apply for a certificate of compliance to conduct complex testing are more likely to be detected and have their certificate revoked because CLIA surveyors routinely visit them. However, this process is resource intensive and may take up to 3 years to complete. All CLIA laboratories that conduct complementary and alternative medicine tests do so outside the scope of their certificate. These certified laboratories should not be performing LBA and may be violating the law.

State Agency and Complementary and Alternative Medicine Respondents Believe Testing Should Be Regulated, but They Differ on How this Should Be Accomplished

Most State agencies believe that CLIA regulation of LBA laboratories would help to ensure the quality of testing and help protect patients from unscrupulous providers. Two-thirds of State agencies believe that HCFA should change CLIA policies to better address CAM testing. Most complementary and alternative medicine providers agree that LBA should be regulated to protect patients, but feel that the CLIA program is the wrong entity to do this.

Few States Restrict Complementary and Alternative Medicine Laboratory Testing and Oversight by Other Federal Agencies Is Limited

The CLIA program plays the primary role in oversight of laboratories. State laws and other Federal regulations may affect laboratories, but only HCFA is responsible for overseeing the quality of testing performed at every laboratory. Many States place restrictions on who can order and receive laboratory test results, but only a few have laws that prohibit non standardized laboratory testing. Other Federal agencies enforce regulations that affect the marketing of laboratory equipment, advertising claims, and disposal of biohazardous materials but these agencies have no direct impact on tests provided to patients.

OPPORTUNITIES FOR IMPROVEMENT

The growth and acceptance of complementary and alternative medicine poses challenges not only to HCFA but also to other Department of Health and Human Service (HHS) regulatory bodies. Conflict exists between established rules and regulations inherent in HHS systems and the public's desire for access to complementary and alternative medicine.

The Department, including the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health and the Health Care Financing Administration, will need to decide how best to protect consumers in a changing health care arena.

If the Department determines that CLIA is the appropriate structure for regulating complementary and alternative medicine laboratory tests it should:

Take action to improve and enforce current CLIA policies and procedures for addressing laboratories performing complementary and alternative medicine tests.

If the Department does not wish to enforce CLIA compliance and wishes to allow access to complementary and alternative medicine laboratory testing while still protecting the public, it must consider approaches such as the following:

Change the current law or regulations to create a special regulatory category within CLIA for complementary and alternative medicine laboratory tests, or

Establish a new regulatory agency and program to oversee complementary and alternative medicine laboratory testing.

TABLE OF CONTENTS

	PAGE
EXECUTIVE SUMMARY	i
INTRODUCTION	1
FINDINGS	
CAM Testing Cannot Meet CLIA Requirements	7
CLIA Laboratories Perform CAM Illegally	9
Respondents Believe CLIA Needs to Change	10
State Laws and Federal Oversight Is Limited	12
OPPORTUNITIES FOR IMPROVEMENT	16

INTRODUCTION

PURPOSE

To examine how the Health Care Financing Administration (HCFA) regulates laboratories conducting Live Blood Cell Analysis and other complementary and alternative laboratory tests.

BACKGROUND

In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA). The CLIA law establishes "quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed." The HCFA is responsible for implementing CLIA, including laboratory registration, fee collection, onsite surveys and enforcement. The HCFA contracts with State Agencies and professional organizations to carry out the provisions of the law.

Under current law, all laboratories except those specifically exempted by law, must be CLIA certified to perform testing on human specimens. The CLIA regulations define a laboratory as:

"[A] facility for the . . . examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body."

The CLIA regulations exempt some laboratories from regulation. Forensic laboratories, drug testing laboratories certified by the Substance Abuse and Mental Health Services Administration and some Federal laboratories are exempt from CLIA regulation. Research laboratories that do not report patient test results to physicians and patients are also exempt from CLIA regulation.

As of July 2000, nearly 170,000 laboratories were registered under CLIA. About 86,500 laboratories have been issued a certificate of waiver. These laboratories only perform simple laboratory procedures cleared by the Food and Drug Administration. Laboratory surveyors do not make routine visits to them to ensure compliance with CLIA requirements.

Approximately 36,000 laboratories hold provider performed microscopy certificates. These certificates are issued to physicians and other approved providers who meet CLIA requirements to perform certain moderate level microscopic procedures. In addition to specified microscopic procedures, providers issued this type of certificate can also perform waived tests. As with laboratories issued a Certificate of Waiver, laboratories issued a Certificate for Provider-Performed Microscopy Procedures are not routinely visited under the CLIA program.

The remaining 41,500 laboratories conduct moderate or high complexity testing. They have been issued a Certificate of Compliance or a Certificate of Accreditation. All laboratories conducting moderate and high complexity testing are required to meet specific CLIA requirements. When these laboratories apply for certification they are issued a Certificate of Registration that enables them to participate in the Medicare and Medicaid program until an onsite visit can be conducted to verify compliance with CLIA standards. They are then issued a Certificate of Compliance. State and accrediting agency surveyors revisit these laboratories at least every 2 years to ensure continued compliance with CLIA requirements.

Types of CLIA Certificates

Certificate of Waiver

This certificate is issued to laboratories that only perform tests approved for home use or that employ methodologies that are so simple and accurate the likelihood of erroneous results is negligible or they pose no reasonable risk of harm to the patient if the test is performed incorrectly. These laboratories are not routinely visited.

Certificate for Provider-Performed Microscopy (PPM) Procedures

This certificate is issued to laboratories where a physician or other qualified provider performs specific microscopic procedures permitted by CLIA. Laboratories with PPM certificates are also permitted to perform waived tests. These laboratories are not routinely visited.

Certificate of Registration

This certificate is issued to laboratories that conduct moderate or high complexity testing or both. This certificate is issued when a laboratory's application is accepted by CLIA and is valid until the laboratory is surveyed.

Certificate of Compliance

This certificate is issued after a laboratory is surveyed and found to be in compliance with all applicable CLIA requirements. Onsite visits to these laboratories are routinely made to ensure compliance.

Complementary and Alternative Medicine

The National Institutes of Health (NIH) defines complementary and alternative medicine (CAM) as "those treatments and healthcare practices not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies." According to NIH, complementary and alternative medicine covers a "broad range of healing philosophies, . . . approaches, and therapies that mainstream Western

(conventional) medicine does not commonly use, accept, study, understand, or make available.”

Studies estimate that between ten and 40 percent of the population uses some form of CAM treatment. One study asserts that more than 42 percent of Americans used an alternative therapy in 1997, up from about 33 percent in 1990. This study also claims that, in 1997, Americans spent more than \$27 billion on these therapies. A more recent study argues that only 10 percent of Americans use CAM treatments and that expenditures are lower than previous studies suggest.

The number of providers that promote complementary and alternative medicine may be increasing. Most CAM providers are largely unregulated by States or the Federal Government. Little data exists about the types of complementary and alternative medicine treatments and services being provided to the public. Even less is known about the use of complementary and alternative medicine laboratory services. Information suggests that complementary and alternative medicine laboratory tests are a very small segment of the overall CAM marketplace.

Federal Efforts to Address Complementary and Alternative Medicine

There has been a growing Federal interest in complementary and alternative medicine. Except for HCFA's efforts, the Federal focus had not been on CAM laboratory services but on broader issues such as public access to complementary and alternative medicine treatments, patient protection and evaluation of CAM treatments.

In 1992, NIH established the Office of Alternative Medicine to facilitate and coordinate “the evaluation of alternative medical treatment modalities through research projects and other initiatives.” In 1998, that office became the National Center for Complementary and Alternative Medicine through Congressional mandate.

The Congress has also expressed an interest in consumer access to complementary and alternative medicine treatments and in ensuring patient safety. In 1999, the House proposed the Access to Medical Treatment Act (H.R.2635), and a similar bill (S.1955) was introduced in the Senate. The Access to Medical Treatment Act would establish provisions to allow consumers freedom to choose alternative therapies while protecting patients from dangerous and ineffective treatments. Both of these bills have been referred to committee.

On March 7, 2000, the President established The White House Commission on Complementary and Alternative Medicine Policy. The Commission was established “to develop a set of legislative and administrative policy recommendations that will maximize the benefits of complementary and alternative medicine practices and products for the general public.”

Live Blood Cell Analysis

The HCFA has identified several complementary and alternative medicine laboratory tests that use blood, urine and saliva. One such laboratory test, Live Blood Cell Analysis, uses a drop of blood from a patient's finger. The blood is placed on a slide and viewed while the cells are alive using a specialized microscope connected to a video monitor.¹ The video monitor allows patients to view their blood cells while the provider describes substances found in the blood sample. Some providers use results to assess nutritional deficiencies, to outline a course of treatment or to assess the effects of treatment. Other providers may use LBA for other purposes.

Under current regulations, meeting all CLIA requirements for certification is virtually impossible for a laboratory performing LBA. Many LBA providers are nutritionists, herbologists, naturopaths, chiropractors and others who are unlikely to meet CLIA personnel requirements. Facilities performing Live Blood Cell Analysis must also meet CLIA requirements for high complexity testing including patient test management, proficiency testing, quality control, and quality assurance.

Every high complexity laboratory must establish and verify every test method used in the laboratory. Establishing and verifying a test method is usually demonstrated, in part, by 1) comparing the new test results with the results obtained from established methods, 2) testing samples of known value, and 3) testing the same sample multiple times to see if the results are comparable.

Laboratories are required to run quality control samples to ensure that a test is working correctly from day to day. The laboratory must also verify test accuracy by participating in a proficiency testing program. Because LBA is performed on freshly drawn blood samples, it is much more difficult to comply with these CLIA quality assurance requirements.

HCFA's Efforts to Address Live Blood Cell Analysis

In 1995, HCFA created a work group to address regulation of Live Blood Cell Analysis and other CAM laboratory tests. The work group asked their Office of General Counsel and the Centers for Disease Control and Prevention (CDC) for assistance in understanding what role, if any, the program should play in regulating laboratories conducting Live Blood Cell Analysis. The Office of General Counsel advised HCFA that laboratories conducting LBA are subject to all CLIA requirements. The CDC determined that laboratories performing this test must meet all of the requirements for laboratories conducting high complexity testing. The HCFA posted the CDC and Office of General Counsel findings in a Special Alert on their website.

¹ The laboratory method used for LBA is also used in CAM tests with the following names: Peripheral Blood Assessment, High Resolution Blood Morphology, High Resolution Microscopy, Live Cell Analysis, Live Blood Demonstration, Unchanged Blood Analysis, Vital Hematology, darkfield microscopy and nutritional microscopy.

The work group developed guidelines for State surveyors to help them apply CLIA regulations to laboratories conducting LBA. The work group has also asked States and their regional offices to provide them with information on laboratories identified as providing LBA and other complementary and alternative medicine tests.

METHODOLOGY

For the purposes of this study, we will use the phrase “complementary and alternative laboratory tests” (or “CAM tests”) to mean laboratory testing procedures that are not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies. Although we collected some information on other complementary and alternative medicine laboratory tests, we focused this report on LBA because it is the CAM test most often encountered by CLIA personnel, and because HCFA has made an effort to address how this test should be regulated by the program.

This inspection examines how HCFA addresses laboratories performing LBA and other complementary and alternative medicine tests. This study does not address the validity or accuracy of LBA or any other CAM laboratory test. Nothing in this report should be construed as an endorsement or condemnation of any CAM laboratory test.

We reviewed CLIA regulations, policies and procedures to determine how they relate to laboratories conducting Live Blood Cell Analysis and other CAM tests. We interviewed HCFA central office staff and regional office staff in five regions. We discussed CLIA enrollment and certification processes, and staff experiences relating to LBA testing and CAM laboratory sites. Similar discussions were held with representatives from the College on Office Laboratory Accreditation, the Joint Commission on Accreditation of Healthcare Organizations and the College of American Pathologists. These accrediting organizations were contacted because they have contracts with HCFA to provide survey and certification services for some laboratories.

We contacted the State agencies responsible for carrying out the CLIA provisions in all 50 States, the District of Columbia and Puerto Rico. We conducted in-person interviews with State CLIA staff in the District of Columbia and 11 States: Arizona, California, Delaware, Illinois, Kansas, Maryland, Missouri, New Jersey, New York, Pennsylvania and Wisconsin. We discussed CLIA enrollment and certification processes and obtained information and opinions about CLIA regulation of CAM laboratories. The remaining 39 States and Puerto Rico completed written surveys. Overall, we have 52 State agency respondents.²

² Collectively, the respondents from the 50 States, the District of Columbia, and Puerto Rico will be referred to as “State Agencies” or “States” in this inspection report.

To identify facilities offering LBA, we solicited information from HCFA central and regional offices, State agencies and the three accrediting organizations. We also used Internet searches to identify manufacturers, instructors, promoters and practitioners of LBA. We were unable to obtain reliable data to determine the total number of laboratory sites performing LBA or other CAM laboratory tests. From the information we obtained, we compiled a list of laboratory sites conducting LBA in the United States.

To obtain the perspective of those involved in complementary and alternative medicine, we interviewed people involved in LBA laboratory testing. We contacted industry representatives identified as manufacturing, promoting or offering Live Blood Cell Analysis. Of the 38 potential respondents that we attempted to contact, 18 agreed to participate in this study. Others could not be contacted or were unable to meet with us.

We also interviewed staff at CDC, NIH, the Food and Drug Administration, the Federal Trade Commission, and the Occupational Safety and Health Administration. These agencies were identified by State agencies and HCFA staff as playing a role in regulating CAM laboratory tests. We conducted these interviews to determine what, if any, oversight responsibility each agency has in relation to laboratory testing.

FINDINGS

Complementary and alternative medical laboratory testing cannot meet CLIA requirements

An unknown, but perhaps significant, number of LBA sites operate without CLIA certificates

We identified 200 laboratories in 38 States that purport to offer Live Blood Cell Analysis or other complementary and alternative laboratory tests. One hundred fifteen sites were identified using information we received from HCFA and State CLIA surveyors. We believe that the remaining 85 sites have not been identified by HCFA and State survey staff.

We asked industry representatives to estimate the number of laboratories offering LBA. One respondent claims to have trained 300 to 400 American physicians to conduct LBA. Another respondent stated that he had trained about 3,000 practitioners. Based on his knowledge of the industry, this respondent estimates that between 10,000 and 15,000 sites may be conducting LBA in the United States.

We checked the names and addresses of the 200 CAM laboratory sites we identified during this inspection against CLIA enrollment records. We found that nearly 80 percent did not have a CLIA certificate. The remaining sites were certified by the CLIA program. They had been issued Certificates of Waiver, Certificates for Provider-Performed Microscopy Procedures and Certificates of Compliance. Some of these certificates were revoked when HCFA discovered that they were doing LBA. Other certificates remain in effect because the laboratory has assured HCFA that it has ceased performing LBA.

When a non-certified CAM laboratory is identified, the laboratory is sent a letter advising them to cease testing and to apply for CLIA certification if they wish to resume testing. State agency respondents suspect that some CAM laboratories continue testing despite agreeing to cease and desist. Other laboratories claim they are exempt from CLIA because they are conducting LBA as research. To qualify for this exemption laboratories must agree not to provide test results to patients. Some State agency respondents have expressed concern that these facilities may be providing test results to patients.

Complementary and alternative medicine laboratories cannot meet all CLIA requirements

All laboratories that perform LBA must meet regulatory requirements for laboratories performing high complexity testing. To date, no laboratory performing LBA has successfully met these requirements. Many complementary and alternative medicine providers often do not meet CLIA personnel requirements. Those laboratories that can

meet the personnel requirements cannot meet other CLIA requirements. Meeting the regulatory requirement concerning the establishment and verification of test methods has been particularly problematic for the LBA test method. To meet this requirement each laboratory must prove that LBA is accurate, precise and an analytically sensitive test. The laboratory must also establish reference ranges to distinguish normal or acceptable results from abnormal or unacceptable results.

Getting complementary and alternative medicine laboratories to enroll in the CLIA program is difficult

Laboratories conducting LBA have little or no incentives to enroll in the CLIA program. The main incentive for traditional laboratories to enroll under CLIA is reimbursement by Medicare or Medicaid. Nearly all CAM providers bill patients for CAM laboratory tests. Medicare, Medicaid and most other insurance programs do not cover complementary and alternative medicine laboratory tests.

Most State agencies believe that at least 95 percent of all laboratories in their State voluntarily identify themselves for CLIA enrollment. States report that laboratories operating without CLIA certificates often decide to enroll when Medicare and other insurance payers deny their claims.

The CLIA program's reliance on laboratories to identify themselves for enrollment is problematic when it comes to laboratories conducting LBA and other CAM tests. Some complementary and alternative medicine providers have heard that HCFA forces laboratories conducting Live Blood Cell Analysis to close; consequently, laboratories that perform LBA and other CAM tests may seek to avoid HCFA detection.

Chiropractors, herbologists, naturopaths, nutritionist, therapists, health food store owners and other CAM providers may be unaware of the CLIA program. These practitioners may not be associated with such schools or organizations that offer a laboratory curriculum. Physicians (medical and osteopathic) who perform or offer their patients LBA and other CAM laboratory tests appear more likely to be aware of CLIA. Traditional medical schools and professional organizations help to keep physicians informed about CLIA and other Federal and State regulations that affect laboratories. Training programs, schools and organizations for complementary and alternative medicine practitioners may not inform their clients about CLIA and CLIA requirements.

HCFA cannot take administrative actions against laboratories that refuse to enroll in CLIA and must rely on other agencies to take action

According to HCFA staff, CLIA's enforcement provisions work well for CLIA certified laboratories, but are problematic for laboratories not enrolled in the program. When a State agency or HCFA discovers that a laboratory is operating without a CLIA certificate, they send the laboratory a letter advising them that they must cease and desist from testing until the laboratory is CLIA certified.

There are no administrative remedies available to HCFA when a laboratory refuses to enroll in CLIA and refuses to cease testing. The HCFA cannot impose monetary or other administrative penalties on laboratories that defy the law. The only course of action available to HCFA is to refer cases to other Federal or State agencies for civil suit or criminal prosecution. There are no intermediate remedies with more proportionate administrative penalties. The only recourse available to HCFA is to convince an outside agency that a laboratory has intentionally violated the law and that the agency should take criminal or civil action that may result in fines or imprisonment. Under Federal law, a criminal conviction can result in a fine of up to \$10,000 and up to 1 year in prison or both.

The HCFA can refer a case for an injunction if they can prove there is a "significant hazard to the public health." It may be difficult for HCFA to establish that LBA and other CAM tests pose a significant hazard to patients or the public. During our in person interviews, we asked State and Federal respondents whether LBA had harmed any patients. We found no evidence that would suggest that LBA or any other CAM test has harmed patients. As with some traditional laboratory test methods, the LBA test method itself appears to pose little harm to patients. Harm to patients is more likely when providers fail to recognize and take appropriate action based on test results and other non-test related factors.

Some laboratories performing Live Blood Cell Analysis may have been improperly issued CLIA certificates

The number of laboratories that perform LBA and other CAM tests is unknown. We do know that some laboratories doing these tests have been issued CLIA certificates. In some cases, a laboratory applied for a CLIA certificate because they were performing traditional laboratory procedures. They subsequently added LBA or other CAM tests and did not notify CLIA. Others stopped doing the traditional laboratory tests that they were approved to perform under CLIA and only offer LBA and other CAM tests.

Laboratories doing complementary and alternative medicine tests can easily obtain a CLIA certificate

Any laboratory, including complementary and alternative medicine laboratories, can easily obtain a Certificate of Waiver or a provider-performed microscopy (PPM) certificate. Applications from laboratories for these types of certificates may be approved and CLIA numbers issued because the CLIA application does not ask laboratories if they are doing LBA or any other CAM testing. Since laboratories with waived and PPM certificates are not routinely visited, HCFA may never know that they are performing Live Blood Cell Analysis and that they have been improperly issued a CLIA certificate.

Laboratories that do CAM testing and apply for a certificate of compliance are more likely to be detected and have their certificate revoked. However, the process may take

up to 3 years to complete. Despite their inability to meet CLIA requirements, HCFA requires that surveyors complete a full site visit of LBA laboratories that submit correctly completed applications. Surveyors examine and determine which CLIA requirements the laboratory meets. Deficiencies noted during onsite surveys are documented on Statements of Deficiency. Statements of Deficiency for some laboratories conducting LBA have approached 30 pages in length - significantly more than most laboratories. One LBA laboratory response to CLIA survey findings exceeded 200 pages, and we have seen other complex responses to Statements of Deficiency. The HCFA must respond to each laboratory response and the laboratory has the opportunity to reply again. Laboratories may not be visited for 2 years and are given up to 1 year to correct deficiencies before their CLIA certificate is revoked.

All CLIA laboratories that conduct complementary and alternative medicine tests do so outside the scope of their certificate. These CLIA certified laboratories *should not be performing LBA* and may be violating the law.

State agency and complementary and alternative medicine respondents believe testing should be regulated, but they differ on how this should be accomplished

More than two-thirds of the State agencies believe that laboratories conducting LBA create difficulties for CLIA enrollment and certification. State agencies reported several difficulties including: identifying laboratories conducting LBA, enforcing CLIA requirements for certification for all laboratories, and fitting LBA to CLIA standards. Several States reported that extensive amounts of time are spent on LBA laboratories that attempt to comply with CLIA.

Laboratory surveyors and CAM providers disagree on the validity of Live Blood Cell Analysis. They also disagree as to whether CLIA is the appropriate program to regulate LBA and other complementary and alternative medicine laboratory procedures. Most State agency respondents and complementary and alternative medicine providers do, however, agree that LBA should be regulated.

Most of our State agency respondents believe LBA should be regulated under CLIA to protect the public

Most State agency respondents believe that CLIA regulation of laboratories performing LBA and other CAM tests is needed to protect the public. State surveyors protect the public by verifying that laboratories meet CLIA requirements designed to ensure accurate laboratory testing. The CLIA surveyors cannot ensure that LBA laboratories conduct quality testing if the laboratory fails to enroll in CLIA.

State surveyors are not convinced that LBA provides quality diagnostic information. Many State surveyors generally believe that LBA tests yield results that are inconsistent

with basic principles of biology, chemistry and physics. One State respondent said that the scientific application of LBA is limited to what performance characteristics the laboratory can actually validate. This respondent and others believe that complementary and alternative medicine practitioners often make claims about LBA testing that cannot be supported.

Some State respondents also believe that laboratories should be regulated because the public assumes that some governmental agency is ensuring that their laboratory tests are reliable and accurate. One State said, "If the public is led to believe that any test, whether standard or alternative, is one on which they could or should base some lifestyle adjustment, then there should be accountability of the testing person and the site. . . ." Another State respondent said that "the general public operates under the assumption that anyone in a laboratory coat is a professional and will operate in a professional manner."

A majority of States believe HCFA should change CLIA processes rather than the law to address complementary and alternative medicine laboratories

Two out of three States believe CLIA regulations, policies and processes should be adapted or changed to better address LBA and other CAM procedures. Some respondents believe that clarification of processes and better guidelines would help them determine whether CAM laboratories can comply with current CLIA requirements. Others believe that changes to regulations, policies and processes are needed to better address CAM laboratories and complementary and alternative medicine testing.

State agency respondents are divided as to whether the CLIA law needs to be changed to address CAM laboratories and CAM testing. Some State respondents believe that the current law is adequate. Other State respondents believe that any changes would dilute the existing law and encourage exceptions for other procedures. Of the States that would like to see a change in the law, many mentioned stronger enforcement authority. A few would like to see language that would specifically exclude complementary and alternative medicine laboratory tests from CLIA regulation.

Some CLIA surveyors are uncomfortable evaluating LBA test methods

Several State surveyors expressed concern about their ability to evaluate non-traditional tests. Others indicated that CLIA regulations and policies are unclear as to what levels of proof are necessary to meet regulatory requirement concerning validation of test methods. They mentioned that their training is based on traditional laboratory practices and that they often have no experience with complementary and alternative medicine tests. Some State surveyors and HCFA personnel would like another entity, such as CDC or FDA, to determine whether LBA is a reliable and accurate test method. If this question were resolved, CLIA surveyors felt they would be more comfortable evaluating LBA test validity.

Complementary and alternative medicine providers that we spoke with believe LBA should be regulated, but not by the CLIA program

Most complementary and alternative medicine providers with whom we spoke would like to be regulated by their peers and not by the CLIA program. One respondent summarized the sentiments of many LBA providers when he said, "CLIA is not in a position to make definitive statements about LBA technology." They believe that many CLIA surveyors have little or no understanding of LBA. Nonetheless, many CAM providers believe that there needs to be some checks and balances to protect the public from unscrupulous providers.

One CAM provider with whom we spoke believes that there should be no regulation of LBA testing when providers do not bill Medicare or other insurance. Some pathologists and other physicians who perform Live Blood Cell Analysis also shared this viewpoint. They believe that LBA falls within the scope of their license to practice medicine and that it should not be regulated under CLIA.

Half of our CAM respondents believe that an alternative laboratory division should be established. This new division would be responsible for registration and oversight of CAM laboratory tests. It would regulate complementary and alternative medicine testing, set standards and enforce requirements. This new division would protect the public from providers who fail to act in the best interest of their patients while not impeding access to complementary and alternative medicine laboratory tests.

A few complementary and alternative medicine laboratory providers want to comply with CLIA requirements but with some modifications

Three physician respondents who perform LBA said that they are not opposed to CLIA regulation. They are willing to comply with CLIA if standards more applicable to CAM are developed. They believe that the CLIA program needs to provide more guidance on how they can come into compliance. They also believe that HCFA needs to be more reasonable in assessing new technologies. One respondent said, "CLIA is going to drive the legitimate people out of LBA, and the illegitimate ones will prevail underground."

These three physicians operate laboratories certified to perform moderate and high complexity testing. They meet most CLIA requirements for LBA testing, but they cannot establish the validity of the LBA test method to meet HCFA requirements.

Few States restrict complementary and alternative medicine laboratory testing, and oversight by other Federal agencies is limited

The HCFA plays the primary role in oversight of laboratories. Little oversight exists outside CLIA. Half the States require that laboratories obtain a State laboratory license but the requirements for these licenses do not differ substantially from CLIA except in a few States. A few States have laws that may affect laboratories offering LBA or other CAM tests. Other Federal agencies have limited roles in laboratory oversight.

Laboratories, the tests they perform, and the equipment they use may also come under the scrutiny of FDA, CDC, FTC and OSHA.

Few State laws and regulations restrict complementary and alternative medicine laboratories

The CLIA regulations require that laboratories comply with all State laws to receive CLIA certification. Half the States require that laboratories obtain a State laboratory license but the requirements for these licenses do not differ substantially from CLIA. A few States have laws that go beyond CLIA provisions, which may affect laboratories conducting complementary and alternative medicine tests.

Only three States reported that they had State statutes that they believe prohibit laboratories from performing CAM testing. These three laws, while somewhat different, prohibit laboratories from conducting tests that do not have "substantial proof of efficacy," and are not "substantiated by an independently conducted and documented scientifically based clinical trial." The Alabama Administrative Code states that procedures employed in a laboratory "... shall be the standard procedures which are generally accepted by leading authorities or are equivalents approved by the Alabama Department of Public Health." Maryland and Pennsylvania have statutes with similar language. These States believe that they have the authority to deny or revoke the State laboratory license of any laboratory doing CAM testing.

Several States reported that they had State laws restricting who can order or receive laboratory test results. Connecticut, Georgia, Hawaii, Oregon, Pennsylvania and Tennessee require that laboratories examine specimens only when requested by a physician or other person authorized by State law to use the findings of laboratory examinations. These States also require that laboratory test results be provided only to physicians or other persons authorized to receive such tests by State law. Some of these State laws also prohibit the reporting of laboratory test results directly to patients.

Three States believe that complementary and alternative medicine providers may not meet State standards governing laboratory personnel. California, Hawaii and Tennessee respondents mentioned that they had State personnel standards that would affect some laboratories doing CAM testing. For example, California law prohibits chiropractors from drawing blood and thus affects chiropractors who conduct LBA.

Federal agencies play a limited role in regulating complementary and alternative medicine laboratory practices

The CLIA provisions are intended to ensure the quality of laboratory testing. These provisions directly affect patient care. Poor test quality can lead to misdiagnosis, inappropriate treatment, and patient harm. No other Federal agency looks at how well laboratories perform tests. However, other Federal agencies play a role in regulating discrete elements of laboratory practice, including manufacturer and provider claims, equipment and employee safety.

The Food and Drug Administration. The FDA's Office of Device Evaluation ensures that medical devices are safe and effective. They ensure that these devices perform as claimed and that valid scientific evidence supports the claims made about a product. New medical devices for use in laboratories must receive FDA approval before manufacturers can market them. The FDA is also responsible for classifying new laboratory tests and kits into the various CLIA regulatory categories.

Manufacturers of laboratory equipment and chemical reagents are not required to seek FDA approval to market products that do not substantially differ from products already approved by FDA. The FDA advised us that the microscopes used to perform LBA testing do not differ substantially from microscopes already approved by the FDA for other diagnostic purposes. They indicated that additional FDA approval would only be required if a manufacturer of the microscopes made new claims about the capabilities and uses for their microscope.

Some LBA practitioners make claims as to how this test can be used to assess nutritional deficiencies, diseases and patient health status. These claims are made by the user and not the manufacturer of LBA equipment; therefore, the FDA has no jurisdiction.

The Centers for Disease Control and Prevention. The mission of the CDC is to promote health and quality of life by preventing and controlling disease, injury and disability. The CDC conducts research and provides services to meet public needs and to achieve public health goals. The CDC is responsible for CLIA program and policy evaluation. The CDC has provided support and technical advice to HCFA, and has helped HCFA in the development of CLIA regulations and guidelines. Until this year (when the FDA assumed this task) CDC was also responsible for classifying new laboratory tests and kits into the various CLIA regulatory categories. It was CDC that first advised HCFA that laboratories performing LBA would need to meet CLIA requirements for laboratories doing high complexity testing.

We asked CDC if Live Blood Cell Analysis posed any health risks to the population. They advised us that the risk of infection and disease transmission to patients from a finger stick (such as that used in LBA) is low. Our CDC respondents stressed that while the risk of disease transmission was low, it did not mean that no risk existed. They pointed out that anything contaminated with blood poses a potential biohazard. Such products should be properly handled and disposed of to prevent transmission of disease, particularly hepatitis that can remain virulent longer than most other contagious diseases. As with all patient provider encounters, CDC respondents expressed concern about potential harm that might occur when providers fail to recognize seriously ill patients.

The Federal Trade Commission. The Federal Trade Commission is responsible for enforcing Federal antitrust and consumer protection laws. It has enforcement and administrative responsibilities for statutes relating to business competition and consumer protection. The FTC seeks to protect consumers against unfair, deceptive or fraudulent practices by combating actions that threaten consumers' opportunities to exercise

informed choice. The FTC can stop advertisers who are making false claims about products.

The FTC's Bureau of Consumer Protection reviews the advertising claims made by sellers of health care products to consumers. They focus their investigation and prosecution efforts on large providers where they can have a greater impact and where national publicity is likely to have the greatest deterrent effect. Infractions by smaller businesses are usually addressed through more cost-effective, non-enforcement activities, such as consumer education. The FTC remains a potential source for HCFA to use when they find that a CAM provider makes false or misleading claims in their advertising about CAM laboratory testing. False or misleading claims that providers make to their patients are not addressed by the FTC.

As part of its oversight responsibility, the FTC monitors the Internet for sites containing "bogus claims for products and treatments touted as cures for various diseases." This campaign, known as "Operation Cure.all" uses the Internet both as a law enforcement tool to identify bogus claims and as a communication tool to give consumers reliable health care information. Operation Cure.all has identified five areas of interest: dietary supplements, products that make therapeutic claims, medical devices, diagnostic tests (including LBA) and fraudulent foreign clinics. It is too early to evaluate the effect Operation Cure.all will have on laboratories performing complementary and alternative medicine tests.

The Occupational Safety and Health Administration. Some State and HCFA respondents suggested that OSHA could help protect patients from exposure to potentially harmful laboratory tests including CAM tests. We discussed this with OSHA and found that they (OSHA) do not play a role in protecting consumers or patients. The mission of OSHA is to save lives, prevent injuries and protect the health of America's workers. The Agency and its State partners ensure that employers provide safety guidelines and adequate protections for their employees. They ensure that employees are safe and that they are not exposed to hazardous materials or events in the workplace.

The Health Standards Programs Division within OSHA ensures that workers follow universal precautions for drawing blood. They also ensure that laboratories properly equip their staff with the tools to perform their jobs in a safe and sterile environment, and that laboratories properly dispose of blood products and biohazardous wastes. To date, OSHA headquarters is not aware of any laboratories offering LBA that would warrant their intervention. The OSHA would become involved in CAM laboratories if they felt that any of these laboratories exposed their employees to biohazardous wastes or any other potential harm.

OPPORTUNITIES FOR IMPROVEMENT

The CLIA was enacted to improve the quality of laboratory testing and to protect the public from harm that might result from poor quality laboratory testing. It recognizes that the risk of harm to patients differs from test to test. The greater the risk of harm the greater the regulatory requirements.

The Department, including the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health and the Health Care Financing Administration, will need to decide how best to protect consumers in a changing health care arena.

If the Department determines that CLIA is the appropriate structure for regulating CAM laboratory tests it should:

Take action to improve and enforce current CLIA policies and procedures for addressing laboratories performing complementary and alternative medicine tests.

Laboratories performing LBA and other CAM procedures that do not meet CLIA requirements would be prohibited from doing these tests until they can satisfy all CLIA requirements. In theory, this would force laboratories to stop CAM testing or force them to operate underground.

The Department would need to seek legislation that would give HCFA additional administrative authorities to ensure that laboratories performing LBA and other CAM tests cease this type of testing until they can meet all CLIA certification requirements for these tests. The HCFA should consider: 1) improving its methods for identifying CAM laboratory sites, 2) requiring that all laboratories currently in the CLIA program or seeking CLIA enrollment sign an attestation that they do not perform LBA or any other CAM laboratory test, 3) promoting the use of the surveyor guideline package developed by the LBA workgroup, and 4) requiring that LBA providers who claim they will continue testing as a research facility sign an agreement that they will not give results to patients.

The practical consequence of the above option would be that LBA would never be approved under CLIA without a major scientific breakthrough. However, LBA would probably still exist.

If the Department does not wish to enforce CLIA compliance and wishes to allow access to CAM laboratory testing while still protecting the public, it must consider approaches such as the following:

- ▶ **Change the current law or regulations to create a special regulatory category within CLIA for complementary and alternative medicine laboratory tests, or**
- ▶ **Establish a new regulatory agency and program to oversee complementary and alternative medicine laboratory testing.**

Both approaches would permit patients who want CAM laboratory tests to have access to such testing and provide a regulatory remedy if patients are harmed. Under both options the Department would need to decide how complementary and alternative medicine laboratories would be distinguished from certified CLIA laboratory sites. It would also need to decide which tests and which providers fit into each category.