

Unproven (Questionable) Cancer Therapies

MALCOLM L. BRIGDEN, MD, FRCPC, *Victoria, British Columbia*

More than half of all cancer patients use some form of alternative treatment during the course of their illness. Alternative therapies are often started early in patients' illness, and their use is frequently not acknowledged to health care professionals. Some alternative therapies are harmful, and their promoters may be fraudulent. Persons who try alternative cancer therapies may not be poorly educated but may ultimately abandon conventional treatment. Recent attention has focused on aspects of questionable therapies that make these treatments attractive to patients and that may be perceived as being deficient in the practice of conventional health care professionals. Physicians with patients with cancer should always make sure that unproven therapies are discussed early in the therapeutic relationship. They should also attempt to be aware of alternative therapies that are in vogue in their particular geographic area.

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During the next year, several hundred thousand Americans will be diagnosed with cancer. Of these new patients, more than 50% will participate in some form of "unproven" or "unorthodox" therapy.^{1,3} About 40% of these patients with cancer will begin such therapy when they are free of symptoms or in the first stages of their disease.³ In more than 70% of such cases, patients will not tell their physicians that they are using unconventional therapy.⁴ Studies indicate that most patients tend to use questionable cancer therapies as adjunctive rather than primary therapies.² Other investigations have shown, however, that as much as 40% of patients who commence unorthodox therapy ultimately completely abandon conventional treatments.^{1,3} "Unproven," "unorthodox," or "alternative" cancer treatments have been broadly defined as those therapies that have not been objectively, reliably, responsibly, and reproducibly demonstrated in peer-reviewed studies to be more effective than suggestion or doing nothing.⁵ The demonstration of efficacy must be carried out in a way that separates cause and effect from coincidence, suggestibility, the natural history of the disorder, and pure fabrication. Simply because a treatment is unproven or alternative does not mean it is always of questionable value. But, according to the rules of science and law, proponents of new therapies bear the burden of scientifically validating their efficacy and safety. Simply claiming effectiveness on the basis of testimonials is not sufficient. On the few occasions that alternative treatments have actually been subjected to properly controlled scientific trials, they have been found wanting. For most questionable cancer treatments, no such trials have been carried out.⁶⁻⁸

Quackery is a lay term that is frequently applied to unproven treatments if they are given for profit.^{9,10} This

term originates from the German *quacksalver*, which means to quack like a duck about oneself or the virtues of one's therapies. A 1993 telephone survey found that 34% of Americans had used at least one or more questionable health care treatments in the past year, whereas more than a third of these had seen providers for unconventional therapy.² In both the United States and Canada, quackery has become a multibillion-dollar industry. As a result, an army of multilevel marketing entrepreneurs, health food store operators, and nonscientific health care providers are available to mobilize whenever attempts are made to regulate the use of vitamins, herbs, dietary supplements, or other unproven products.⁹

Although conventional health care seeks to explain illness on the basis of a biomedical model, much nonscientific cancer therapy has its origins in "vitalism," or a common-sense model of disease that the general public finds appealing (Table 1).^{11,12} Vitalism is the belief that various "life forces" are the ultimate determinants of health or disease. Patients with cancer are thus informed that their disease has resulted from a failure to eat and exercise in accordance with nature's laws, but that the body's defenses can be rejuvenated and harmonized by exercise, diet, and stress reduction.¹¹ A holistic approach that includes meditation or imagery therapy, diet, and exercise is offered as an alternative to what may be perceived as an impersonal and disease-oriented medical system. Many alternative cancer treatments involve the use of specific diets that are said to detoxify or cleanse the body.¹³

Other treatments advocate a comprehensive philosophy or behavior system such as is incorporated in Ayurvedic medicine or traditional Chinese medicine. Patients today are well aware of possible unpleasant side

effects associated with chemotherapy or radiation treatment. Natural approaches such as herbal therapies or the use of vitamins are touted as side-effect-free methods for strengthening a person's intrinsic defenses by boosting the immune system.^{6,7} Such nontoxic-appearing, natural therapies are intuitively satisfying to patients who naively imagine that nature is always kind and gentle. Further empowering the nature of such therapies is that they stress the role of patients as their own therapist and appear to provide patients with a degree of control over their disease processes. Such concepts fit in well with the current general mistrust of authority and institutions and the prevalent "take charge, do it yourself" attitude.¹ The most common reasons cited by individual cancer patients who seek out unproven therapies have been well documented (Table 2).¹⁰

Studies of the social and demographic background of persons embracing unproven therapies have shown that they tend to be better educated with higher-than-average incomes.⁶ As an example, the British royal family has expressed an ongoing interest in alternative medicine. Prince Charles made a special trip to assist at the opening of the Bristol Cancer Health Centre, a facility in the United Kingdom that specializes in unorthodox therapy. The major consumers of vitamins and health food supplements also tend to be financially well-off, educated, middle-class persons.¹¹

Possible Toxicity of Unproven Therapy

The range of unorthodox therapies available today is staggering.^{8,9,14} These are partially categorized in Table 3. Unfortunately, many of these unproven therapies are not necessarily benign. Laetrile (*l*-mandelonitrile- β -glucuronic acid; amygdalin) contains cyanide that has caused deaths.¹⁵ Intravenous hydrogen peroxide therapy has resulted in severe hemolysis and cardiopulmonary arrest.¹⁶ Vitamins and minerals, which are physiologically active chemicals, are recognized to have toxic effects at high doses, especially in the case of the fat-soluble vitamins A, D, and K.¹⁷ But even the water-soluble vitamins are not without danger when consumed in large doses. The use of vitamin B₁ (thiamine) has been associated with cardiovascular toxicity, including cardiac arrhythmias, edema, and vasodilation.¹⁸ Because the product is available in 100- to 500-mg pills, the consumption of a toxic dose of several grams a day is not difficult. Large doses of vitamin B₆ (pyridoxine)

TABLE 2.—Most Common Reasons Given for Using Alternative Therapy

The appeal of "natural," holistic-appearing remedies as opposed to radiation or surgical therapy or chemotherapy
The possibility of improving quality or quantity of life, especially if told "nothing further can be done"
The need to have a sense of control over life
Possible pressure from family and friends
Mistrust of the conventional medical establishment and authority figures in general

have been associated with peripheral neuropathies.¹⁸ Megadoses of vitamin B₃ (niacin) have liver toxicity and have produced acid peptic disease, myocardial infarct, gouty arthritis, glucose intolerance, hyperkeratosis, and skin rashes.¹⁸ Adverse effects that have rarely been reported with megadoses of vitamin C include hyperoxaluria, nephrolithiasis, and renal sodium loss.¹⁹ It is also important for clinicians to remember that regular vitamin C consumption can interfere with dipstick testing for glycosuria and hematuria and cause false-negative results with the test cards used for detecting occult blood in stool. The consumption of the amino acid tryptophan was recently linked to a newly described, possibly fatal muscular disease, the eosinophilia-myalgia syndrome.²⁰ Fortunately, the number of cases in Canada was small compared with that in the United States because the sale of amino acid supplements had been banned in Canada.

Herbal products available in the form of teas, powders, tablets, and capsules are heavily promoted by pharmacies, supermarkets, and health food stores. Nutritional and body-building magazines also advertise these products. Herbal preparations are typically assumed by the public to be bland because of their natural image. Another myth perpetrated by the promoters of herbal therapy is that organic chemicals produced in nature by the metabolic processes of plants and animals possess an innate superiority over the same products synthesized in chemical laboratories.²¹ A second dogma is that whole plants, leaves, or roots have physiologic properties different from the various constituents isolated from the same plant parts.

Herbal preparations may have substantial toxicity. Because they are not regulated by federal or state agencies, usually neither safety nor efficacy have been verified.²² Given the wide variety of herbal remedies and their inconsistent and multiple ingredients, it may be impossible to identify the toxicity of specific herbal agents. Comfrey tea may cause hepatic veno-occlusive disease, and certain other herbal teas are also rich in hepatotoxic pyrrolizidine alkaloids.²³ The spectrum of liver injury associated with the long-term ingestion of hepatotoxic herbal remedies is broad ranging, from mild hepatocyte necrosis to extensive inflammation, cholestasis, veno-occlusive disease, chronic hepatitis, and cirrhosis.²⁴ It is entirely possible that chaparral or other herbal preparations may be responsible for some cases of cryptogenic

TABLE 1.—An Alternative Model of Cancer

Cancer is a single, simple process that represents symptoms, rather than a disease
Cancer symptoms arise from problems with diet, stress, mental outlook, or the environment
Fitness, nutrition, and mental attitude can fend off cancer; properly motivated cancer patients should be able to mobilize these defenses
Conventional treatments such as irradiation or chemotherapy are toxic and will weaken the body and fail to remedy the underlying disease

TABLE 3.—Some of the More Common Questionable Cancer Therapies

<i>Unproven Therapy</i>	<i>Major 'Common-Sense' Premise</i>	<i>Examples</i>
Metabolic therapy.....	Toxins and wastes are cellular poisons, which treatment can detoxify	Laetrile (amygdalin) Isador or mistletoe Hydrazine sulfate Hydrogen peroxide Dimethyl sulfoxide
Herbal remedies.....	Herbal preparations have secret, curative properties	Essiac Comfrey Taheebo tea Chaparral tea Pau D'Arco tea Aloe vera Barley green Blue-green algae Beet root juice Hoxsey's Herbal Tonic
Megavitamins.....	High doses of vitamins can kill cancer cells and rejuvenate tissues	High-dose vitamins C, B, A, D, and E and niacin
Diet therapy.....	"You are what you eat": a therapeutic diet can balance "out-of-whack" body function	Gerson method Grape diet Macrobiotic diet Coffee enemas Shark cartilage
Electronic devices.....	Can harmonize the body's "life forces" and cure or prevent cancer	Galvanic therapy Magnetic field therapy Negative ion therapy Color and light therapy
Imagery therapy.....	Guided mental imagery can destroy cancer cells or arrest cancer growth	Simonton technique
Immune therapy.....	Cancer thrives due to defective immune mechanisms, which treatments can restore	Autologous and fetal vaccines Burton treatment

chronic hepatitis or cirrhosis.²⁵ Cases have been reported wherein herbal preparations have been adulterated with other medications such as steroids, phenylbutazone, or warfarin sodium.²⁶ Whereas limiting the consumption of herbs could be beneficial, this is not likely to occur in the immediate future. Accordingly, practical advice has been developed for those who are determined to use these medications (Table 4).

Diets that have been purported to be curative or beneficial for cancer have been described in a variety of ways, including nutritional, metabolic enzyme, macrobiotic, nontoxic, and oxidative. Coffee and colonic enema therapy has resulted in electrolyte imbalance, bowel necrosis with perforation, toxic colitis, amebiasis, campylobacter sepsis, and dehydration.²⁷ Bland vegetarian macrobiotic diets may result in hypocalcemia, scurvy, or serious protein fat malnutrition, especially in an already cachectic cancer patient.^{13,14} Cases of vitamin B₁₂ and iron-deficiency anemias have also been reported as a result of such diets. A macrobiotic program that includes special supplementary tapes, literature, and follow-up can end up costing thousands of dollars. High-fiber macrobiotic diets may be dangerous for patients who have had bowel resections. There is some question that the

shorter survival experienced by a cohort of women with breast cancer at the Bristol Cancer Help Centre was in fact related to their macrobiotic diet.²⁸ Certain cancer vaccines given intravenously as immunoenhancement therapy have been found to include specimens positive for both the hepatitis B antigen and antibody to the human immunodeficiency virus.²⁹

Various electronic devices appear to be making a comeback as bogus cancer treatments. Such therapeutic modalities have included magnetic field therapy, galvanic devices, low-voltage treatment devices, negative ion and ozone generators, and color and light treatments.³⁰ Electronic devices have a strong appeal to those who adhere to a vitalistic philosophy and who also claim that the well-known patterns found in electrocardiograms or electroencephalograms are expressions of life forces that conventional scientists have failed to fully understand and exploit.

Even mental imagery therapy can occasionally cause problems when used as an adjunct to cancer treatment if patients are left feeling guilty or inadequate when there is progressive tumor growth.³¹ Properly used, visualization and imagery techniques should be beneficial because they aid in coping and provide patients a degree of

TABLE 4.—*Practical Advice Regarding Herbal Preparations*

<p>Only buy herbs from reputable stores or dealers</p> <p>Only buy herbal preparations with the plants listed on the packet</p> <p>Do not take a large quantity of any one herbal preparation</p> <p>Do not take any herb on a daily basis</p> <p>Do not take herbs if pregnant or attempting to become pregnant</p> <p>Do not take herbs if nursing</p> <p>Do not give herbs to your children</p> <p>Do not take anything containing comfrey</p>

control that may decrease feelings of helplessness.³² Unfortunately, some practitioners of imagery therapy do not blame their therapy when disease progresses, but imply that the users lack discipline or have not followed instructions properly. Personality traits that have been labeled as being responsible for the development and progression of cancer include a limited capacity for trust, a tendency toward self-pity, and the inability to develop long-term relationships.¹² Such blame-the-victim explanations appear to be without scientific merit, as several controlled studies have failed to document the existence of any “cancer-prone personality” or that psychosocial factors in general are correlated with cancer survival.^{33,34} Patients with cancer should be made aware that no scientific evidence to date has confirmed that imagery therapy or other alternative treatments have any effect on tumor growth, tumor regression, or overall patient survival.^{31,35} Similarly, patients with cancer should not be led to think that their cancer is a punishment for wrong thinking, a weak will to live, or a loser mentality.

Finally, besides the direct physical harm caused by some unproven treatments, as previously discussed, these therapies in some cases may also result in a delay in proper diagnosis, a fatal abandonment of possibly curative treatment, unjustifiable financial or emotional hardship, or even simply the wasting of a patient’s valuable remaining time.^{6,15} In this sense, some alternative treatments are more restrictive than orthodox treatments could ever be and can seriously interfere with family relationships. It is not surprising that studies comparing orthodox with alternative treatments have shown that the quality of life for those using alternatives may be considerably worse.

Investigators compared the length of survival and quality of life of patients who received unorthodox treatment at the Livingston-Wheeler Medical Clinic, San Diego, California, with those of control patients who received only conventional therapy at the University of Pennsylvania Cancer Center, Philadelphia.³⁵ Patients at the Livingston-Wheeler clinic were treated with an autologous bacilli Calmette-Guérin vaccine, vegetarian diets, and coffee enemas. In this study, patients were matched according to sex, race, age, diagnosis, and time from diagnosis of metastatic or recurrent disease. The length of survival did not differ between the two groups, but the quality of life was substantially better in the patients receiving conventional care.

Fraudulent Methods of Cancer Diagnosis or Investigation

Bogus and unscientific laboratory investigations constitute an area that has been growing increasingly lucrative in the alternative therapy field.^{8,9,30} Their proponents are often slick promoters who use plausible scientific jargon, operate high-tech modern facilities, and boast walls of diplomas.¹⁰ Computerized health questionnaires are widely available that claim to diagnose various nutritional deficiencies, metabolic problems, or the presence of precancerous states based on patient response.⁹ Typical questions include “Do you feel chronically tired, crave sugar, or suffer mood swings?” or “Are you subject to frequent viral illnesses?” If a certain number of affirmative replies are generated, the computer program then diagnoses a high probability of yeast infection, hypoglycemia, or premalignancy. This is often followed by a solicitation to purchase various vitamin and dietary aids from the therapist to remedy the situation.

Although hair testing has for years constituted a scientifically valid method for assessing certain heavy metal toxicities, unscrupulous nutritionists claim to be able to use hair analysis results to prescribe replacement dietary supplements that may help to ward off cancer. Cytotoxic testing involves the mixing of food extracts with individual blood specimens, with any changes in agglutination purportedly predictive of food sensitivities or toxicity, allergies, immune deficiency, or a precancerous state. Live blood cell analysis consists of a detailed analysis of an unfixed blood specimen conducted by a sophisticated videocamera microscope. Patients are encouraged to participate in the interpretation with the therapist and also to decide which is the best route to correct any perceived dysfunction of their blood cells and immune system. This analysis is touted as being able to demonstrate the activity or inactivity of the immune system, the presence of live fungi or bacterial forms in the blood, parasites, crystalline structures such as arterial plaque, and other bodily imbalances. Live blood cell analysis costs about \$150 for a 45-minute to an hour session and is usually concluded with an invitation to purchase various remedies.

Herbal crystallization analysis involves the drying of a drop of saliva with a drop of reagent on a glass slide. Crystals that form are analyzed for predictive or curative patterns. For instance, the appearance of two parallel lines might be interpreted as representing a blood vessel and the person subsequently advised to take vitamin supplements. With another popular diagnostic system, test tubes containing various extracts and dietary substances in liquid suspension are passed over a cancer patient’s sternum. If a tube changes color or appears to be attracted to the sternum, the patient will be diagnosed as allergic to or deficient in the substance in question.³⁰ Such pseudoscience in the diagnostic field is not limited to patients with cancer. These quasi-diagnostic and other therapeutic methods have been widely used to promote such diagnoses as the chronic yeast syndrome, dental amalgam toxicity, or the total allergy syndrome.⁹

Characteristics of the Promoters of Unproven Therapies

Unlike the proverbial purveyors of snake oil of yesteryear, today's proponents of unproven therapy are well educated and presentable. One study showed that more than 65% of alternative medicine practitioners actually hold an MD or DO degree.³ In their promotion of unproven therapy, they emphasize testimonials over the results of scientific clinical trials in such a way that the audience hears only of successes.¹⁰ To justify the lack of proper statistical records, the statement is often made that "we are simply too busy treating patients to collect and analyze data." Patients who are repeatedly exposed to testimonial results are usually unaware that the vast majority of those whose condition deteriorated while they were taking the unorthodox therapy in question are no longer available to testify. Scientific follow-up of individual cases involving testimonials has frequently shown that the diagnosis of malignancy was never firmly histologically established or, most commonly, that the person in question also partook of concomitant conventional cancer therapy.¹⁵ At testimonials, however, any successful result is always attributed to the unconventional rather than conventional treatment. Nothing is dearer to the heart of an unorthodox therapist than a Hollywood star or other celebrity with cancer, such as Steve McQueen or Michael Landon. By operating on the principle that any publicity is good publicity, even when the outcome is unfavorable, unorthodox practitioners later claim that the patient in question arrived too late to benefit from their treatments.⁷

In their book *Magic or Medicine?* Buckman and Sabbagh have extensively discussed possible perceived differences between conventional and unorthodox health care practitioners.³⁶ Table 5 summarizes many of these observations. As Buckman writes,^{36(p244)}

In my medical training, I didn't learn very much about the human qualities that might help me in medical practice. In those days, there was no teaching of "Interpersonal Skills" in the medical school curriculum—and that was a serious omission. I needed to learn more about how to respond to the symptoms of humans at the same time as I treated their diseases. Nowadays, things are changing. Contemporary medical students are taught far more about the human aspects of medicine and about communication and empathic skills than in my day. However, as a group, we conventional doctors have not yet taken this lesson fully on board.

What Conventional Health Care Professionals Can Do

Conventional health care professionals can learn from unorthodox practitioners by embracing those aspects of their treatments that may be beneficial to the therapeutic relationship, such as empathy, continuity of care, and the provision of hope. Health care workers need not specifically share a patient's belief system, but they must understand and respect it for any treatment to be effective. Unconventional practitioners are often seen as positive, empathic, and available, whereas conven-

tional health care professionals may be perceived as neutral, cautious, evasive, or impersonal.²⁹ Honesty and openness must be used in all discussions with cancer patients. The current lay literature strongly endorses patients' right to the freedom of informed choice. Health care professionals must respect this right with ongoing open and frank discussions.

Initial patient interactions are crucial. Holland and others have recommended that physicians raise the issue of unorthodox treatments routinely with cancer patients at the time of the first visit.³⁷ This is important because studies have clearly shown that most consumers of unconventional therapy do not mention these treatments to their physicians, suggesting a deficiency in current patient-physician relationships. For instance, one investigation revealed that 75% of 300 informants did not tell their physicians that they were using an alternative therapy.⁴ It may well be that this lack of communication derives from physicians' mistaken assumption that most patients do not routinely use unconventional therapies for serious medical problems. In addition, many physicians are reluctant to discuss the use of unconventional therapies because they lack adequate knowledge of these techniques and also think they do not have the time. In either case, such a failure to communicate is not in the best interest of patients.³⁸ Nurses, social workers, and dietitians may play a key role in this regard, as they are frequently the first to see new cancer patients who may confide to them things they would not tell their physician.

The American Cancer Society is helpful in providing up-to-date information on various alternative therapies. Since 1954, it has maintained a Committee on Questionable (formerly "Unproven") Methods of Cancer Management. Reviews of questionable treatments are published regularly in the American Cancer Society's journal, *CA: A Cancer Journal for Clinicians*.

Rather than being rejected out of hand and thus making a patient feel foolish, unproven therapies should always be discussed objectively. To accomplish this, health care professionals need to be aware of which unproven therapies are in vogue in their particular geographic area. This will necessitate paying attention to news media and having a member of the health care team attend various meetings, symposia, and public lectures. Health care professionals might also consider visiting health food stores to review what products are available. Useful information can be gathered by browsing through the many brochures and leaflets that are for sale or distributed free of charge. Individual patients should be warned that at some point in their illness, they are likely to be approached by well-meaning relatives, friends, or others regarding some type of unproven therapy. At the same time, they should be urged not to turn their back on conventional treatments if they elect to try the unconventional.¹⁰ Because many alternative therapies seem to be lifestyle-oriented, the individual topics of diet, vitamins, and stress reduction should be specifically reviewed early on with each cancer patient.⁷ A realistic discussion of foods may prevent patients from sub-

TABLE 5.—Differences That Patients May Perceive Between Conventional and Unorthodox Therapists*

Perceived Quality	Conventional Practitioner	Unorthodox Therapist
Time	May be rushed; average 6-10 min/patient	Unrushed; average 90 min for first consultation, 20 per follow-up
Setting	May be depersonalized and institutionalized	Considerable effort made for patient's comfort and personalization
Continuity	Patient may see different person on follow-up visits	Patient usually sees same person
Symptom handling	Trained to interpret patient's symptoms in light of knowledge of underlying disease; may "disbelieve" or contradict patient's perceptions	Accepts patient's symptoms at face value
Emotional handling	Empathic abilities may be lacking	Empathic abilities central to therapist's skill
Dealing with patient's uniqueness	May try to compensate for or minimize personal idiosyncrasies of patient	Therapist regards patient's personal features as central to the illness and its treatment
Dealing with social context	Variable; importance of social context may be ignored or underestimated	Social context regarded as central to understanding of illness
Appearance of certainty	May appear uncertain; obliged to express both sides of any controversy regarding therapy	Absolutely certain and confident; testimonials quoted assure 100% success rate
Ability to give a clear prognosis	Obliged to be statistically accurate; answers may not seem clear or intelligible	Free to deceive—usually provides clear and optimistic prognosis
Ability to provide hope	Variable; may not be a major component of the therapeutic relationship	Usually a major part of the therapeutic relationship

*Modified with permission from Buckman and Sabbagh.³⁶

sequently embracing a bizarre diet as well as provide an awareness of a holistic concern for health. A practical approach to vitamin therapy is to point out that whereas the North American diet is usually adequate, moderate extra doses of the water-soluble vitamins such as B and C do not ordinarily constitute a health hazard. The possible dangers of the excessive consumption of vitamins such as A, D, and K should be mentioned, however. Because many patients wonder if a stressful lifestyle was responsible for their tumor, they should be reassured that to the best of our current knowledge, cancer is not related to thoughts, feelings, personality characteristics, or any mental or emotional state.^{12,33} At the same time, the benefits of support groups or other patient counseling services should be stressed. Providing advice on relaxation therapy and mental imagery techniques may also enhance a sense of control and emotional well-being.³²

Finally, patients with cancer should always be left with hope. New patients can be reminded that research is continually providing different therapeutic agents and methods of treatment. Terminally ill patients especially should not be left with a feeling of being hopelessly abandoned, as this may put them at high risk for embracing unorthodox treatments.³⁹ Appropriate pain and palliative care management, coupled with an empathic approach, may help to facilitate a sense of control and negate possible feelings of rejection.

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