Complementary or Alternative? Strong Versus Weak Cancer Integration Policies

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Abstract

Scientific research is particularly important as a guide to health care policy regarding the integration of complementary and alternative medicine (CAM) into conventional medical practices. A spectrum of possibilities has emerged around the question of balancing integration toward complementary versus alternative usages.

Although scientific research can guide policies and practices, it has become subject to greater scrutiny and linked to differences on policy issues. Using CAM cancer therapies as a case study, this commentary explores relationships between methodology and policy regarding the integration of CAM therapies.

Under an evidence-based medicine model, policies for the integration of complementary and alternative medicine (CAM) into mainstream public health and medical practice are, ideally, guided by scientific research. Scientific research holds out the promise of depoliticizing and rationalizing a policymaking process in which interest group politics could overwhelm concerns with safety and efficacy. However, the emphasis on research-guided policy also increasingly politicizes scientific methods and research funding decisions. This essay will explore some of the linkages between research design and CAM policy.

The terms "alternative" and "complementary" are understood here to refer to how a therapy is used, that is, either as a replacement for conventional therapies or as an adjuvant to them. In other words, the same therapy may be alternative or complementary depending on its use and position in a therapeutic protocol (e.g., a nutritional protocol that is either complementary to cancer chemotherapy or an alternative to it). Increasingly, complementary/alternative therapies are being "integrated" into mainstream practices, and the integration process involves a spectrum of options. At one end, what I call "strong integration," patients are given greater choices to replace conventional therapies, under the care of a physician or another qualified health-care professional (e.g., the option to pursue complex nutritional programs instead of one or more conventional, drug-based regimens for a chronic disease). At the "weak" end of the integration spectrum, choices are mostly adjuvant to conventional therapeutic packages, as occurs in cancer hospitals that offer adjuvant nutritional counseling. The difference corresponds roughly to the trade-off in medical ethics between autonomy and paternalism.

The design decisions of research protocols can become linked to the spectrum of stronger to weaker integration. To understand the linkages, this commentary will focus on

research on CAM cancer therapies in the U.S. In this field, about which there is a substantial literature, the politics of research methods have been heavily scrutinized in controversies over substances such as laetrile, vitamin C, and antineoplastons.[1-4] In addition, the politics of research bias have also been well explored in this field for conventional therapy research.[5]

The Dilemmas of Research Design Choices

One example of the linkage of research design with integration politics is the difference between a single-agent used in complementary modality versus a complex regimen used as an alternative to a conventional therapy. (These designs correspond to the currently funded U.S. National Institutes of Health [NIH] CAM cancer trials of a cartilage product and a complex nutritional-enzyme regimen, but other examples are possible.) The single-agent, complementary-modality design has the advantage of drug-like precision and portability, but it is likely only to lead to incremental advances on existing therapies. In contrast, the complex regimen may lead to very new and different clinical options, but because portability is likely to be limited, greater choice may be accompanied by increased uncertainty.

Another methodological issue is the choice between randomized clinical trials and retrospective studies. For many researchers and clinicians, clinical trials remain the most credible methodological choice. However, they are both expensive and time-consuming, and in the CAM field clinical trials have a history of design controversies. Furthermore, it is difficult to accommodate the individualized orientation of some CAM therapies to the standardization of clinical trials.[1-6]

An alternative is to evaluate existing clinical data sets, particularly outside the U.S., where regulatory oversight is less likely to be triggered by investigations and a wider range of alternative protocols is available for study. One example is the best-case series of the Office of Cancer Complementary and Alternative Medicine of the National Cancer Institute.[7] Retrospective methods have also been adopted by privately supported organizations, as in the research of Gar Hildenbrand and colleagues or of Berkley Bedell and colleagues.[8-10] The alternatives to clinical trials can suffer from selection bias and other drawbacks, but in some cases (e.g., pancreatic cancer) the prognosis is so dismal that even a best case series can be clinically significant. Furthermore, recent analyses indicate that well-designed observational studies do not overestimate the magnitude of treatment effects in comparison with randomized clinical trials.[11, 12] Observational methods are often relatively inexpensive and able to produce data fairly rapidly. In addition, analyses of existing clinical protocols can help provide patients with valuable consumer information about the relative safety and efficacy of various clinics. Because observational studies can also be applied to alternative regimens outside the U.S., they can help balance a portfolio of research back toward an alternative dimension.

Given limited funds, policy dilemmas characterize the new politics of CAM research: at one extreme, funders can invest limited resources in a small number of randomized clinical trials of single agents in a complementary modality, or, at the other extreme, they can invest in a larger number of retrospective studies of complex regimes in an alternative modality. Between these 2 poles are mixed options, such as clinical trials of comprehensive alternative regimens or retrospective studies of single, complementary agents. The weighting of research investments across this spectrum is a critical policy issue, because research results will guide and legitimate

the range of therapeutic choices that patients are likely to have, and, in turn, the extent to which patients will live in a world of weaker or stronger integration.

The Trend Toward Weaker Integration

One indication of future direction is the establishment of 2 university CAM cancer research centers by the National Center for Complementary and Alternative Medicine of the NIH.[13] Although all the projects are of high quality and clearly worthy of public support, the rather substantial investment of limited funds does not include any studies of the complex dietary and nutritional programs that are the hallmark of the alternative end of the CAM cancer therapy spectrum. The focus on this type of center raises the following question: Do research portfolios of public and private agencies exhibit a selection preference for what some in the CAM community have called "COM" therapies (complementary only therapies)?

One example of an explicit policy favoring COM is the Operational Statement of the American Cancer Society in 1999.[14] In this statement, "alternative" is defined as unproven, and "complementary" is defined as supportive or adjunctive. Here 2 categories overlap: the evidentiary status of a therapy (proven/unproven) and its role as adjuvant to or replacement for conventional therapies (complementary/alternative). Under the American Cancer Society definitions, the role of CAM therapies for cancer is repositioned as palliative care, which is targeted to receive funding for evaluation in contrast to forms of intervention that more directly compete with conventional therapies. Although the change represents a tremendous shift from the older quackbusting policy and the unproven methods list, the new policy directs research away from alternative toward complementary modalities.

At the level of practice, there is a similar selection toward the complementary end of the spectrum. In the late 1990s, several of the major cancer centers in the U.S. set up complementary medicine facilities, albeit with precarious funding.[15, 16] The therapeutic portfolios of the centers are mostly limited to complementary care. One of the major U.S. cancer centers even changed the acronym of CAM to CIM, that is, "complementary and integrative medicine."[15] This orientation contrasts with that of the many alternative cancer clinics and hospitals in Tijuana. Yet in 2001 the Mexican government closed between 6 and 20 clinics, temporarily or permanently.[17] Although some of the Tijuana clinics offered therapies that many even in the CAM cancer therapy community have long regarded as questionable, there are also some well-established and well-run clinics and hospitals that have provided a choice at the alternative end of the spectrum for thousands of patients per year.

In clinical settings outside the major hospitals similar patterns are emerging. Some integrative oncology practices provide adjunctive therapy by yoga instructors, massage therapists, nutritional counselors, acupuncturists, and so on as auxiliary health-care providers under the guidance of the physician. A more theoretical discussion of the problems of integrative clinical care is developed by David Eisenberg, M.D., whose model situates the physician as the gatekeeper who oversees the patient's utilization of CAM providers who would be covered under insurance plans.[18] Having coordination over various therapeutic and preventative interventions for each patient can avoid some fatal outcomes (such as drug-herb interactions). However, because the policy focuses on physicians as gatekeepers and controllers of the system, it is likely to involve a selection of the CAM spectrum toward complementary and away

from alternative modalities; that is, it will lead to clinical practices at the weak integration end of the spectrum.

Conclusion and Policy Implications

The general policy question that follows from this brief commentary is, Do patients in the aggregate benefit from the "weak integration" end of the spectrum in contrast with a more alternative, "stronger" form that is practiced in a few private clinics and some out-of-country hospitals? In favor of "weak" integration is the argument that patients who are given the choice to replace conventional therapies (such as radiation therapy or chemotherapy following surgery) will risk the opportunity cost of foregoing known benefits from conventional therapies. In favor of "stronger" integration is the argument that for some types of cancer, conventional therapy only affords limited survival benefit at considerable loss of quality of life, so the decision to risk unknown or poorly understood benefits from alternative treatments should rest in the hands of the patient. Given the small number of therapeutic studies that are currently in the pipeline and the apparent future orientation of most of those studies toward COM cancer therapies, the current research base is unlikely to change dramatically in the near future, and therefore scientific research is unlikely to resolve this ethical and policy dilemma. In the absence of research, the default policy will probably remain at the weak integration end of the spectrum of possibilities.

Still, it is helpful to think through what an alternative, strong integration policy would look like. At the research level, the funding portfolio would be weighted more heavily toward the kinds of design choices discussed above: alternative protocols, complex regimens, and observational methods. At the insurance and clinical practice levels, strong integration would grant patients greater ability to link and unlink therapeutic modalities without suffering loss of access to insurance and conventional health-care providers. Such a choice-oriented form of integration would require protections for both clinicians and patients. As is suggested by the various state and federal bills and laws regarding access to medical treatment, physicians and other health-care professionals who offer CAM programs would need protections against malpractice suits from patients and against prosecution from their professional peers. Likewise, patients would need better informed consent that describes the relative uncertainties involved, should they choose CAM therapies, as well as a realistic assessment of the side effects and benefits of conventional therapies such as chemotherapy for their particular cancer type. From the viewpoint of some patient advocacy leaders, the ability to link and unlink the elements of a therapeutic package—both conventional and CAM—emerged as a key desideratum to the no-choice packages that are currently available.[19]

Although stronger forms of integration may not become a political reality for a long time, it is helpful at this historical juncture to examine the range of possibilities, if only to avoid "COM-placency." Yet, one should also recognize the sociological and political dimensions of stronger integration as a policy: CAM programs for cancer are often based on nutritional agents and knowledge competencies that would tend to undermine the professional status of oncologists and other cancer treatment professionals, at least until nutritional and mind-body science can be thoroughly integrated into the oncology education. A policy of "strong integration" is therefore likely to meet heavy obstacles at the present. Still, a clearer discussion

of the public interest in this arena may arrive at the conclusion that patients are best served by maintaining the "A" in CAM cancer therapies.

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