Evidence-Based Alternative Medicine?

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ABSTRACT The validity of evidence-based medicine (EBM) is the subject of ongoing controversy. The EBM movement has proposed a "hierarchy of evidence," according to which randomized controlled trials (RCTs) and meta-analyses of RCTs provide the most reliable evidence concerning the efficacy of medical interventions. The evaluation of alternative medicine therapies highlights problems with the EBM hierarchy. Alternative medical researchers—like those in mainstream medicine—wish to evaluate their therapies using methods that are rigorous and that are consistent with their philosophies of medicine and healing. These investigators have three ways to relate their work to EBM. They can accept the EBM hierarchy and carry out RCTs when possible; they can accept the EBM standards but argue that the special characteristics of alternative medicine warrant the acceptance of "lower" forms of evidence; or they can challenge the EBM approach and work to develop new research designs and new standards of evidence that reflect their approach to medical care. For several reasons, this last option is preferable. First, it will best meet the needs of alternative medicine practitioners. Moreover, because similar problems beset the evaluation of mainstream medical therapies, reevaluation of standards of evidence will benefit everyone in the medical community—including, most importantly, patients.

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THE NATIONAL INSTITUTES OF HEALTH (NIH) Panel on Definition and Description defines complementary and alternative medicine (CAM) as "a broad domain of healing resources that encompasses all health systems, modalities and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period" (Panel 1997). This broad definition, as applied in the United States and Canada, encompasses biologically based treatments (herbs, special diets, and vitamins), manipulative and body-based treatments (chiropractic, massage, osteopathy), energy therapies (reiki, magnet therapy, qi gong), mind-body treatments (yoga, spirituality, relaxation/meditation), and entire alternative medical systems (traditional Chinese medicine [TCM], naturopathy, ayurveda). Alternative medicine is often contrasted with "mainstream," "conventional," or "Western" medicine.

Alternative medicine has a tremendous amount of public support in North America. Americans spent between $37 and $47 billion on alternative medicine in 1997, and these numbers are growing. According to the most recent survey released by the U.S. National Center for Health Statistics (NCHS), approximately 36% of American adults are currently using some form of alternative medicine (NIH 2004). Similar polls in Canada indicated that between 42 and 50% of the population have used some form of alternative medicine in the past year. This was a more than 80% increase when compared with a poll conducted five years earlier (Angus Reid 1997). Despite what critics continue to regard as a serious lack of scientific evidence, alternative medicine appears to be gaining acceptance within Canada and the United States.

Two recent articles typify the mainstream reaction to alternative medicine:

> There is no alternative medicine. There is only scientifically proven, evidence-based medicine supported by solid data or unproven medicine, for which scientific evidence is lacking. Whether a therapeutic practice is "Eastern" or "Western," is unconventional or mainstream or involves mind-body techniques or molecular genetics is largely irrelevant except for historical purposes and cultural interest. (Fontanarosa and Lundberg 1998, p. 1619)

> It is time for the scientific community to stop giving alternative medicine a free ride. There cannot be two kinds of medicine—conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted. But assertions, speculation, and testimonials do not substitute for evidence. Alternative treatments should be subjected to scientific testing no less rigorous than that required for conventional treatments. (Angell and Kassirer 1998, p. 839)

According to these powerful demands, alternative medical researchers should

strive to conduct the same sorts of clinical trials currently regarded as the gold standard of medical research.

The current standards in medicine are set by a "hierarchy of evidence" developed in the last 13 years by the EBM movement. EBM was created in response to a lack of standardization in medical care, and out of concerns that physicians were not utilizing new research in their clinical decisions. Under the EBM approach to medical decision making, physicians are advised to critically assess the best available evidence (for a presented illness) with the assistance of an evidence hierarchy and to apply those results judiciously to individual patients. This is meant to replace the "authority-based medicine" of the past, whereby physicians tended to base clinical decisions on basic science (pathophysiology), personal experience, and the authority of colleagues, rather than on research evidence. The hierarchy, which provides the "evidence base" for clinical decisions, ranks research methodologies according to the generalizability of their results, as well as their perceived ability to eliminate bias and establish clear causal connections between treatments and effects. At the top of the hierarchy of best evidence is the meta-analysis of randomized controlled trials (RCTs). Outcomes research (non-randomized trials, such as cohort studies and case-control studies), qualitative research, case-series, case studies, and other small-scale studies are considered to be of lower quality in the evidence hierarchy, and are therefore less likely to earn respect within the mainstream medical community.

Alternative medical researchers working toward legitimacy within the medical community are faced with three options in light of the standards just outlined. They can follow accepted EBM standards and design studies according to the demands of the evidence hierarchy. Alternately, they can eschew these constraints in favor of studies that are ranked much lower on the evidence hierarchy such as qualitative studies, cohort studies, and case studies. Finally, they can critically engage with the EBM standards and devise new research designs that more closely reflect the needs and goals of alternative medical practitioners.

OPTION 1: PLAYING BY THE RULES OF EBM

There are a number of advantages to playing by the rules of EBM. EBM has been widely accepted in medical schools and hospitals around the world as the best approach to medical decision making and as an excellent guide for the assessment of research methodologies. As such, it influences the evaluation of studies by medical journals and the allocation of research dollars by funding agencies. The most obvious decision that alternative medical researchers might make is to concede the legitimacy of this epistemic stance and to try to work within in. If researchers in alternative medicine are motivated by a desire to earn legitimacy for what they believe to be excellent and often overlooked treatments, they may be motivated to choose this first option. Alternative medical researchers may also choose this option out of a desire to be included under med-

ical insurance plans or, in the case of large herbal companies, by a desire to influence the prescribing power of physicians.

Some alternative medical researchers have taken the demands for "gold standard" research seriously, and, especially in the last decade or so, there have been numerous studies evaluating a variety of alternative medical treatments. Some results have been negative; for example, in two studies published in the 1998 special issue of *JAMA* dedicated to alternative medicine, acupuncture was found to be no more effective than placebo in relieving pain caused by HIV-related peripheral neuropathy, and *Garcinia cambogia* failed to produce significant weight loss (Heymsfield et al. 1998; Shlay et al. 1998). On the other hand, the use of moxibustion (burning herbs at an acupuncture point) to correct breech presentation in late pregnancy, TCM herbs for irritable bowel syndrome, glucosamine for the treatment of osteoarthritis, and acupuncture for nausea and vomiting, among others, have been shown to be effective in RCTs (Bensoussan et al. 1998; Cardini and Weixin 1998; McAlindon et al. 2000; Panel 1997). These are examples of alternative medical research that have "passed the test" and lived up to the standards outlined by EBM. Many of these successful treatments, despite achieving the status of best evidence, have not been accepted into mainstream medical practice, although there is some indication that medical students and new physicians are taking more of an interest in certain alternative treatments. The vast majority of alternative medical treatments, however, are not even at this preliminary stage of acceptance.

Much research into alternative medicine has failed to meet the methodological requirements of the EBM evidence hierarchy; research designs commonly consist of individual case studies or other small-scale or qualitative studies. There are several commonly cited reasons for this failure to produce RCT evidence within the alternative medical literature. According to Anthony (1993), alternative medical treatments are often highly individualized (as compared to the generalized treatments offered in an RCT), complex (have a number of therapeutic components), require physical treatment to which it is difficult to "blind" patients and practitioners (for example, needling in acupuncture), actively involve the therapist as an integral part of treatment (making randomization difficult), set different (and multiple) end points based on different philosophies of medicine, and rely on principles of self-healing and mind-body control (which incorporate, rather than rule out, the placebo effect). These and other problems, including social and economic difficulties in funding and organizing large-scale studies on often unpatentable treatments, are often raised as explanations for the lack of high-quality evidence in alternative medicine. I will consider the most significant of these possible "differences" of alternative medicine in detail later.

Alternative medicine must prove itself equal to conventional medical treatments by, at the very least, meeting current standards; in some cases, alternative medical research is even required to exceed current standards, based on certain Bayesian ideas that advise extra scrutiny for those practices and treatments that

have low prior probabilities.[1] In such a situation, a few isolated alternative medical treatments will jump through the appropriate hoops, prove themselves, and gain the respect and equal treatment they deserve. Treatments such as herbs (which resemble and are testable like drugs) are the best candidates for selective incorporation into mainstream medical care. This approach has also been referred to as the "greening" of mainstream medicine, as isolated alternative treatments are adopted by mainstream medicine while the underlying metaphysical view of health that originally produced the treatments is discarded. For example, while certain acupuncture points and procedures might be proven effective in RCTs and adopted into mainstream medicine, the underlying philosophy of traditional Chinese medicine, including the existence of the chi or vital force and the commitment to health as the balance of chi will be lost. In another case, mainstream medicine might adopt particular herbs (St. John's wort, ginseng, or garlic, for example), but the naturopathic approach to health (including a commitment to holism, highly individualized care, and a principle of self-healing) will likely be left behind. For the millions of people choosing to spend out-of-pocket for alternative health care today, these elements of healing philosophy are of critical importance, and their loss would be substantial. In a national study on the reasons why patients use alternative medicine, researchers found that a majority of users described alternative medical treatments as more congruent with their "values, beliefs, and philosophical orientations toward health and life" (Astin 1998, p. 1548). Certainly, from the perspective of alternative health care providers, the philosophy of health is foundational. This first option for alternative medical researchers might be characterized as an assimilation of alternative medicine into the mainstream. This provides some reason (especially for patients and alternative medical practitioners) to doubt whether an uncritical acceptance of current standards of evidence in medicine is the best route for alternative medical research.

OPTION 2: DECLARE DIFFERENCE AND REQUEST SPECIAL TREATMENT

In light of concerns with the option of assimilation to EBM, alternative medical practitioners and researchers could choose, instead, to insist that because they practice in a different paradigm, from a different world view, and hold a differ-

[1] Of course, alternative medical research is not alone in failing to live up to current standards of evidence. As Morreim (2003) points out: "Much of actual clinical practice does not and never can measure up to the scientific standards to which critics of CAM would like to hold alternative modalities" (p. 222). A large percentage (roughly estimated around 80%) of medical treatments currently offered in hospitals and clinics across North America have never been tested by an RCT (University of Sheffield 2004). Research into alternative medicine is required to meet the highest standards, even though many currently accepted medical practices have not met (and may never meet) those same standards.

ent philosophy, they should not be held to the same standards as mainstream medical research. In essence, they could accept the EBM hierarchy as legitimate but argue that special exceptions should be made for alternative medical research because it cannot meet the standards of EBM.

The motivation for this option is clear. Even when best evidence exists, successful high-quality RCTs of alternative medical treatments are not affecting the treatment decisions of many physicians. In addition, much historical evidence demonstrates that what is considered to be "mainstream" medicine in North America today is in part the result of social, political, and economic forces in the past century. By no means do the boundaries of mainstream medicine correspond perfectly with any formal distinction between science and pseudo-science. Many alternative medical practitioners are aware of historical data about the development and use of standards as a method of keeping outsiders from infiltrating the Western medical profession: sociologists Timmermans and Berg (2003) point out that, "Professions have relied on credentialing, registration and licensing mechanisms to safeguard their jurisdiction against competitors" (p. 85). There is no reason to think that mainstream medicine (as, in part, a product of these social forces) has any exclusive grasp of the true nature of health or disease or any special claim to epistemological superiority in the assumptions of the evidence hierarchy. Finally, as we will see more clearly in the next section, given that meeting these standards forces alternative medical researchers to frame only a narrow range of research questions that are not always relevant to their practice or true to their philosophy of health, the move to accentuate "special differences" has clear motivation.

In response to these appeals to difference, critics decry the "quackery" of alternative medicine and caution patients to avoid alternative medical practitioners. Even people who are generally sympathetic to alternative medicine respond negatively to this sort of approach. A representative response is offered by Jonas (1998): "Claiming that their practices are too 'individual' or 'holistic' to study scientifically, many alternative medical practices hide behind anecdote, case series, or 'outcomes' research" (pp. 1616–17). Notice that anything short of full commitment to the EBM hierarchy is provoking this response—even outcomes research is not enough. (This demonstrates the elevation of the RCT within the medical community and the clear demands for RCT evidence placed on alternative medical researchers.) Alternative medical researchers have found that there is no guarantee that labeling yourself different will earn you any respect from the mainstream medical community. In fact, it is just as—if not more—likely to lead to worse treatment. In the eyes of the mainstream medical community, there is an epistemological standard that alternative medicine simply fails to meet. When it is assumed that everyone should meet the same standard, an appeal to difference comes across as a sign of weakness—an indication of failure and an appeal for special treatment (MacKinnon 1991).

The second option also appears to undermine many of the motivations that

alternative health researchers begin with, including the desire to gain legitimacy for alternative treatments and the desire to become part of the scientific community in order to discover which alternative treatments "really work." There are good reasons for anyone to accept at least the most basic principles of scientific research, including empirical testing and attempts at falsification of hypotheses. Even though they may not translate directly into the evidence hierarchy, there are some basic elements of good evidence (trial-and-error empiricism, for example) that can be agreed upon and should be upheld. Applying for special exemptions from the demands of EBM could be tempting, but it requires that researchers write off the value of the scientific endeavor—a decision that, for reasons far beyond those just outlined, is far from ideal.

OPTION 3: CHALLENGE AND REVISE THE STANDARD

According to this third option for alternative medicine, the vital step in attaining legitimacy is to critically engage with the ostensibly neutral standard of research proposed by EBM. What researchers of alternative medicine might do is question the current standard of evidence: the evidence hierarchy designed by the EBM movement. Relevant questions would include, though by no means be limited to: Where did this standard of evidence come from? Is this standard best designed to answer all questions of medical significance? What are the assumptions underlying this approach to medical evidence? Does this epistemological view presuppose a particular metaphysical commitment regarding the nature of health and disease?

In order to determine whether alternative medical researchers have good reason to call into question the assumptions of EBM, I will outline the challenges faced by alternative medical researchers as they attempt to design studies that are both scientifically rigorous and relevant to their medical practice. To narrow the focus, I will consider researchers in naturopathic medicine. Although homeopaths and TCM practitioners may face distinct problems that are not fully incorporated into this discussion, many of the challenges faced by naturopaths (the "GPs" of alternative medicine) are likely to be representative of alternative medicine as a whole.

The guiding principles of naturopathic medicine (some of which are shared with conventional medicine) are to (1) identify and treat the causes; (2) do no harm; (3) view the doctor as teacher; (4) treat the whole person; (5) emphasize prevention; and (6) support the healing power of the body (CCNM 2004). Naturopathic doctors are directed to treat each patient by taking into account individual physical, mental, emotional, environmental, and social factors. The patient is a vital part of the healing process and is encouraged to take personal responsibility for his or her own health. Treatments are offered that enhance and support the healing power of the body. Naturopaths employ a selection of treatment modalities, usually including Asian medicine/acupuncture, botanical (her-

bal) medicine, clinical nutrition, homeopathy, lifestyle counseling, and physical medicine (massage, ultrasound, hydrotherapy, etc.).

Researchers in naturopathic medicine encounter a number of challenges when attempting to follow the EBM hierarchy. Some of these difficulties will sound all too familiar to conventional physicians, as they have been raised repeatedly in the medical literature in recent years. These concerns might, however, take on extra significance given an explicit philosophical commitment to the naturopathic principles outlined above. As such, while both naturopaths and mainstream medical practitioners share concerns with EBM, these concerns are often more starkly evident in the alternative case. Attention to these difficulties, then, will allow us to spotlight and emphasize concerns shared by all medical practitioners.

The first such difficulty arises from the extraordinary importance of the individual in medical practice. As Tonelli (1998) points out: "Clinical research, as currently envisioned, must inevitably ignore what may be important, yet non-quantifiable, differences between individuals. Defining medical knowledge solely on the basis of such studies, then, would necessarily eliminate the importance of individual variation from the practice of medicine" (p. 1237). The classic concern raised by physicians is that RCTs are not very good at assisting decision making at the level of the individual. This occurs for several reasons. The evidence hierarchy, as it currently exists, clearly values internal over external validity; that is, it elevates methodologies that evaluate the causal efficacy of treatments under ideal conditions rather than the effectiveness of treatments under usual conditions. Naturopaths, like conventional practitioners, must apply their clinical expertise to determine whether a particular patient will benefit from the results of a recent study. The difficulty arises in judging how simple research results about the "average patient" can apply to extraordinarily complex patient situations. This is exacerbated by the fact that RCTs are often designed with strict inclusion and exclusion criteria. The highest-ranked clinical research focuses on large-scale studies designed to determine simple causal relationships between treatments and their effects. In many cases, a particular patient would never have qualified for the study because he or she has other underlying illnesses or comorbidities or does not meet certain age or gender requirements.

The problem, which is especially evident in naturopathic medicine because of the number of patients with chronic or multiple conditions, is that "excellent evidence does not necessarily translate into excellent or successful therapy" (Upshur 2000, p. 24). The applicability of scientific evidence, especially large-scale, single-factor studies, "depends on the individual being conformable to the group in all relevant aspects," which is rarely—naturopaths might argue never—the case (Black 1998, p. 1). Again, these are old concerns, raised repeatedly by conventional practitioners, that are shared by naturopaths because of their explicit philosophical commitment to highly individualized care.

There is a further concern arising from the holistic approach in naturopathic

practice, about the limited number of research questions (and, as a result, treatment questions) that can be legitimately asked within the EBM model. Naturopaths, along with many concerned conventional physicians, believe that a trend toward pill-based treatments for all illnesses is currently underway in conventional medical research and practice. This is supported by extensive anecdotal evidence, as well as studies such as that by Everitt, Avorn, and Baker (1990), in which general practitioners were presented with the hypothetical case of an elderly patient suffering from insomnia (one of the most common symptoms in outpatient medicine), and "despite many possible non-pharmacologic therapies for the patients presented, 46% of physicians identified a prescription medication as the single most effective therapy." The population of North America is one of the most heavily medicated in the world (some would suggest "overmedicated" [Angell 2004]). Making judgments about the care of individual patients on the basis of RCT research alone may contribute to this problem. RCT evidence is not always (or even usually) helpful at answering social, economic, or environmental questions related to health. The average RCT is six weeks long and investigates simple relationships within a closed system, while studies on, for example, the social factors in health tend to be long-term and necessarily involve open, complex systems. Other methodological approaches are better designed to answer these broader sorts of questions, and insofar as the EBM hierarchy downplays the value of these other sources of evidence, it seriously limits the scope of good research and the corresponding scope of recommended treatments. This is especially unhelpful within a holistic model of health. The social, economic, and environmental context of research is diminished within the EBM model. While conventional medicine focuses on physical problems and biological causes of illness, naturopaths look closely at social, economic, and environmental factors when evaluating the health of patients.

Naturopaths, like many conventional medical practitioners, face challenges in conforming to the EBM demands because they take shared decision making and patient-centered care seriously. The EBM movement has been plagued by this aspect of the decision-making process. The initial formulation of EBM seemed to require an almost algorithmic approach to decision making (physicians assess the evidence then apply it to the particular case). Later formulations attempted to incorporate patient values by suggesting that best evidence be "conscientiously" and "judiciously" applied in practice. These concessions were meant to leave some room in the medical decision-making process for patient values, but patient-centered care requires more than this; it requires input from evidence produced by other levels of the hierarchy. For example, qualitative evidence indicating that patients often visit physicians for reassurance rather than for prescriptions would be vital for a proper assessment of patient needs. It also seems reasonable to suggest that, if we take patient-centered care seriously, "best evidence" will vary depending on the values of the patient and the nature and context of illness. This appears to call into question the basic nature of "best evi-

dence." Naturopaths and mainstream physicians who emphasize the patient's role in the decision-making process are likely to see serious problems with the current evidence hierarchy, as they are likely to regard "lower" ranked evidence as relevant to treatment decisions.

In addition, basic scientific research is currently ranked as lowest on the evidence hierarchy. Yet this is the type of evidence most likely to get at the fundamental causes of disease. The first principle of naturopathy is to identify and treat the causes, and this is supplemented by the principle emphasizing prevention. According to alternative medical practitioners such as naturopaths and many critical voices within the conventional medical community, one of the chief problems with the current direction of mainstream medicine (as it is increasingly influenced by the pharmaceutical industry) is the emphasis on symptom alleviation rather than on addressing the root causes of disease. RCT research is by nature unconcerned with "first causes." RCTs are about evaluating simple treatments, often at the most superficial level. Will treatment X alleviate symptom Y? Will drug X improve condition Y? The questions "Why does symptom Y exist?" "Why does treatment X work?" and "Is condition Y caused by biological, environmental, emotional, or social factors?"—the more basic questions of pathophysiology—are not the focus. Naturopaths and mainstream practitioners have good reason to be suspicious of the overemphasis on symptom relief inherent in the derogation of basic scientific research in the EBM model. How are we to treat the root causes of disease if our research is directed elsewhere?

Finally, underlying the six naturopathic principles is a metaphysical account of health, emphasizing self-healing, vital force, and balance, that differs in significant ways from the account of health currently dominating mainstream medicine, and this philosophical gap will only continue to grow as mainstream medicine adopts EBM. Standards of evidence, wherever they are designed and employed, serve to shape the direction of the field or discipline in which they are adopted. Standards of evidence that insufficiently account for individual variation or that limit the type of question that can be asked in research to those that isolate simple, short-term relationships shape the definitions of knowledge and health in the systems to which they are applied. This, in turn, limits the scope of "legitimate" treatments. Health becomes merely the state in which specific quantifiable symptoms or diseases are not present. Acceptance of EBM will ultimately require naturopaths to commit to a metaphysical view of health that does not fit with their own. We are currently (however slowly and covertly) in the process of adopting increasingly narrow definitions of knowledge and health in medicine, and naturopaths have as much reason as any one else to remain committed to their current metaphysical account of health and to worry about the distorting impact of the adoption of EBM.

Naturopaths, as representative of alternative medical practitioners more generally, have raised a number of serious concerns with the standards of EBM. These concerns provide support for the suggestion that the third option—criti-

cally evaluating and reconceptualizing EBM—is not only the most reasonable and well-supported of the paths available to alternative researchers, but it is also critical to the integrity of future medical research.

BUILDING ON COMMON GROUND: DIRECTIONS FOR MAINSTREAM AND ALTERNATIVE MEDICINE

The good news for alternative medical researchers is, as we have seen, that many of these concerns with EBM are already fiercely debated within the conventional medical community. The extraordinarily influential EBM movement has not only rewritten the standards of evidence required of physicians and researchers, it has also galvanized debate within the medical community on, among other topics, the role of clinical expertise and case studies in medicine and the challenges of finding appropriate evidence to inform clinical decisions at the level of the individual patient.

The roots of medical practice are captured in the famous saying attributed to Hippocrates, "It is more important to know what kind of person has the disease than what kind of disease the person has." There is ample support for this principle in conventional medicine. The gulf between the results of general RCT evidence and complex individual patient care has been raised time and again in medical literature. Feinstein and Horowitz (1997) remind us that "When transferred to clinical medicine from an origin in agricultural research, randomized trials were not intended to answer questions about the treatment of individual patients" (p. 531). Here we see an issue that is identified as problematic from inside and outside the conventional medical community. Other concerns raised by alternative medicine that will likely resonate with mainstream physicians include the shift to physical/biological care at the expense of holistic care, the exclusion of social and environmental evidence from medicine through strict application of the evidence hierarchy, the devaluation of the patient in the decision-making process, the deemphasis of qualitative evidence designed to help physicians understand the needs and values of patients, the lack of attention to pathophysiology and basic scientific research, and the narrow definition of health shaped by the evidence hierarchy. These latter concerns have not so far been the focus of significant critical discussion amongst medical practitioners and researchers. Awareness of these concerns may provide conventional medical researchers with more reasons to join forces with alternative medical researchers and delve critically into the assumptions and theoretical goals of EBM.

One of the possible implications for alternative medical researchers of choosing the third, more critical, option is that they will be involved in the development of new and better research designs. The beginnings of this sort of advance are evident in discussions of "Whole Systems Research" as proposed by one group of international researchers in alternative medicine: "The new discipline of whole systems research (WSR) targets the study of complex CAM therapies

as system-level phenomena, as opposed to single-agent or uni-dimensional effects. . . . Research design issues that were addressed included . . . opportunities to innovate the conventional RCT" (Ritenbaugh et al. 2003, p. 32). Whole systems researchers propose new, more complex versions of RCTs (with multiple streams and greater sub-group analysis), and also stress the value of already existing methodologies that tend to be overlooked, such as observational studies (with long-term follow-up), "n of 1" studies, and qualitative research. Some of the tools of data analysis, borrowed from the social sciences, have also been suggested as ways of getting at some of the individual patient data hidden within the results of RCTs. These methods would include structural equation modeling, path analysis, and event stream analysis, and would help in identifying some of the individual reactions to treatments that often get lost in the "average patient" data of RCTs. These sorts of innovations of the RCT, combined with an emphasis on the value of certain underused research methodologies, could be an important contribution to a shift in the conventional understanding of "best evidence" that accepts the need for, and value of, rigorous testing in medicine without unduly and unnecessarily restricting the scope of evidence. The work being done in alternative medicine right now is not merely something to be dismissed as "fringe" science, but is an attempt to rework the EBM hierarchy for the benefit of patients in a way that is consistent with values underlying all of medical practice, broadly construed. This is a movement that all practitioners have good reason to welcome and encourage.

Recognition of the need for more individualized health care, a concern stressed by both mainstream and alternative medical practitioners, can also be found in one of the most unlikely places: statements made by some members of the pharmaceutical industry. According to a landmark study published in *JAMA*, "the incidence of serious and fatal ADR's [adverse drug reactions] in US hospitals was found to be extremely high" (Lazarou, Pomeranz, and Corey 1998, p. 1200). In fact, serious adverse drug reactions are estimated to be between the fourth and sixth leading cause of death in the United States. While the precise numbers have been subject to much discussion and debate, the general concern with adverse drug reactions persists. In fact, pharmaceutical companies are beginning to draw some attention to these problems as they move to publicly announce the new era of personalized drugs or 'pharmacogenomics' (Phillips et al. 2001). Perhaps the move to individualize and reshape health care is not so unreasonable or impractical as some might expect.

Attempts to be make medicine "more scientific" by designing studies which can give us law-like generalizations across all humans ("Treatment X is effective") have certainly been helpful in improving medical care, but we are becoming more aware of the consequences and limitations of this approach. In the end, generalized results about the "average patient" fail to give physicians the kind of information that will be most helpful at the bedside and may even contribute to the serious problem of adverse drug reactions. Medicine will continually be faced with the irreducible

complexity and individuality of particular human beings, and although research that fails to take this into consideration may be scientifically rigorous in a narrow sense, it ultimately may prove problematic as a guide to practice.

CONCLUSION

Alternative medical researchers will achieve recognition and legitimacy within the medical community only if they involve themselves in constructive critique and reevaluation of the standards to which they are being held. This is reinforced by models of scientific communities (such as those proposed by social epistemologists), whereby objectivity of a discipline is established and upheld only by active critical participation of all diverse community members (Longino 2002).

It would be astonishing to find that the standards currently adopted by conventional medicine are perfect, and that we can incorporate entirely different systems of healing into the mainstream system without having to make any changes or modifications, especially given the immature state of our current standards. (EBM is just 13 years old.) If alternative medical researchers concede the perfection of the EBM hierarchy and conventional medicine slowly integrates elements of alternative medicine into common practice, there may not be any change to the current hierarchy. That would be a shame, because there is significant common ground between the concerns with EBM raised by alternative medical researchers and those identified by conventional medicine. When the diverse communities of medical practitioners and researchers all engage in critical discussion, we are in the best possible position to identify and create truly excellent standards of evidence. Conventional medical practitioners and researchers, and certainly patients, have much to gain from attention to diverse perspectives on health—and much to lose if alternative medical researchers submit uncritically to the hegemony of EBM.

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