

# Medical Decision Making in Integrative Medicine

Safety, Efficacy, and Patient Preference

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The essence of providing patient care revolves around the process of medical decision making (MDM). For most health care providers, this process flows smoothly from diagnosis to treatment planning. Practitioners typically become aware of this complex process only when questions arise. Occasionally, a health care provider will seek some secondary source of information, a book, a colleague, or a website to reach clarity. Only very occasionally, will the patient come into this inner sanctum of health care practitioners: treatment planning. It is hoped that all will routinely engage the patient in a discussion to arrive at informed consent, so that treatment may begin.

This process of MDM is at the core of what makes up health care. In the last 20 years, evidence-based medicine (EBM) has made huge inroads into medical training in an effort to instill sound reasoning about efficacy and effectiveness in all medical graduates. In this article, the terms *efficacy* (demonstration of benefit under ideal conditions, typically in randomized controlled trials [RCTs]) and *effectiveness* (demonstration of benefit in real-life conditions) are used very carefully, and not interchangeably.

The value of efficacy lies mainly in its ability to indicate potential for effectiveness accurately. Sadly, in the drive to emphasize the importance of delineating clearly sound measures of clinical effectiveness, modern medicine has come to equate RCTs as the final arbitrators of clinical decision making. As discussed below, RCTs are but one tool to sort out these complex questions. In integrative medicine (IM), particularly, with its emphasis on patient variables and practitioner participation, evaluation of efficacy is not sufficient.

For some time, IM has functioned like a stepchild to conventional care in MDM as the research base and number of large RCTs remains imbalanced. Almost all decision making based on the primacy of large RCTs creates a strong preference for the conventional care options, given the primacy of pharmaceutical funding, which drives the vast majority of large RCTs. In fact, overdependence on RCTs has been fostered by the need for conventional pharmaceuticals to meet Food and Drug Administration (FDA) requirements for marketing. Gradually, the influence of EBM has been misinterpreted to

embrace RCTs as the only form of evidence considered to be valid. It is also important to note that some of the assumptions upon which RCTs gained favored status over observational data have now been shown to be without merit.<sup>1</sup>

This article describes the process of MDM from the perspective of IM. First, the article reviews why RCTs are but one approach to sorting out the issue of efficacy and effectiveness. This article proposes an amended scale of effectiveness that includes alternative criteria. Second, the article examines why treatment benefit is but one of the two crucial questions that we need to ask about every treatment that we consider. Maizes et al.<sup>2</sup> and others in IM have argued that risk issues must be an increasing part of the discussion about treatments plans. This article proposes a scale for risk concerns aimed to create a needed dialectic process to balance every discussion of effectiveness. Finally, the importance of patient variables is discussed in the context of IM.

## Medical History and the Emergence of the Safety–Efficacy Split

The tension between safety and efficacy has historical roots going back thousands of years. Soon after the time of Hippocrates, medical thought progressively split into two generally opposing camps: the rationalists and the empiricists.<sup>3</sup> Rationalists tend to be driven by theory and broad principles. Empiricists tend to be driven by sensory impressions and observed detail.

This dichotomy played out in the American medicine of the early nineteenth century. The rationalist camp was mainly composed of the Solidist tradition that followed the principles of the Scottish doctors William Cullen, FRS, FRSE, FRCPE (1712–1790), and John Brown, DM (1735–1788), as well as the prominent American, Benjamin Rush, MD (1746–1813). The vast majority of American physicians practiced the principles of conventional medical doctrine expounded by these three physicians who used reason and logical analysis based upon emerging principles in mechanics, hydraulics, and chemistry.

The conventional treatments of preference at that time were bloodletting and purging (typically accomplished via the use of calomel, a mercury-containing compound). The basic approach was built on the foundation of fighting disease. The empiricist camp at that time was composed of a mix of herbalists, Eclectics, Thompsonians, and homeopaths, all with a strong preference for safe and gentle approaches that caused less direct morbidity. The most critical philosophical distinction was that practitioners in the empiricist camp applied a philosophy that centered on using the body's own innate powers of healing.

Since that time, American medicine has followed similar divergent lines of philosophy: the allopaths (a name given to MDs by Samuel Hahnemann, MD, that means "against disease") prefer potent, external interventions that fight disease; and the complementary and alternative medicine (CAM) community prefers safe, natural approaches that leverage the body's ability to heal. That dialectic of efficacy versus safety continues to this day. Allopathic, conventional medicine continues to apply a premise of fighting illness without a model of the body's healing power. Safety appears to fall secondary to efficacy in the treatment selection hierarchy for allopathy. As

## Rethinking Medical Decision Making

### *A Example of How It Could Work*

A 50-year-old woman comes to see her primary care provider (PCP) with a chief complaint of fatigue and sleep issues. She has had issues with chronic back pain for years, has gained significant weight, and her marriage of 24 years is struggling. Currently, her 19-year-old son is failing classes at his community college and she suspects marijuana abuse. She ruminates about this and has lost interest in her usual activities. After reviewing her laboratory results (thyroid-stimulating hormone, complete blood count, and comprehensive metabolic panel) her PCP tells her that she thinks that this woman is depressed.

The physician tells her that exercise and weight loss would help her feel better, but the patient responds with rejoinders about her back pain and how it has limited her ability to engage in any vigorous activity. Her PCP then offers a prescription for a selective serotonin reuptake inhibitor (SSRI) antidepressant, saying that it is well-tolerated with minimal side-effects, and it should help her recover. After learning that it might cause a headache or rarely fatigue, the woman provides her informed consent.

This scenario plays out in very similar ways thousands of times each day in offices all over the United States. The concern here is not with the diagnosis, but rather with the limited treatment plan and lack of real informed consent. This woman has not been apprised of some of the real risks involved with SSRI treatment and has not been informed of alternative treatment options. Never mentioned were the increased risks of gastrointestinal bleeding, sexual side-effects, and suicidal thinking, among other concerns. Also, the physician never mentioned St. John's wort or S-adenosylmethionine (SAMe) as reasonable treatment options with safer side-effect profiles. The article by Linde and Bernier in the Cochrane Review notes that St. John's wort was found to be as effective as conventional antidepressants for treating major depression.\* The Agency for Healthcare Research and Quality (AHRQ) in the Department of Health and Human Services sponsored a major meta-analysis on SAMe in the treatment of major depression in 2003.† This review of 47 studies found no differences between SAMe and conventional antidepressants in the treatment of major depression. Both SAMe and St. John's wort share a more favorable side-effect profile than SSRI antidepressants.

Using the concepts presented in this article, the treatment encounter with this middle-age woman would proceed differently. After a discussion of the value of exercise and weight loss, the physician would let this woman know that her choices should include three agents that reach level one in grading of efficacy: St. John's wort; SAMe; and a conventional antidepressant (a number in this class have multiple positive RCTs).

Then the provider would share that St. John's wort has a safety rating of *Excellent Safety* (Level 2) with only minor issues reported: headache; sun-related rash, nausea, and no known fatalities for St. John's wort alone. (However, given the risk of drug-drug interactions resulting from cytochrome p450 effects, the rating would have to be lowered to *Moderate Safety* (Level 3) if the woman is using other medications.) SSRIs could obtain a safety rating of *Unsafe* (Level 5), as there have been multiple reported fatalities with SSRIs alone from serotonin syndrome (10 in 2008 of 98,898 exposures).‡ However, as these issues have only occurred with overdoses, the rating would be more appropriately set at *Poor Safety* (Level 4) given the increased risk of GI bleeding. SAMe would obtain a safety rating of *Moderate Safety* (Level 3) based on its ability to trigger manic cycling.

At this point, the PCP would share these safety ratings with the patient and explore questions or concerns. The patient might have a preference among these three choices and this preference (and belief system) would improve the probability of a positive response to the treatment chosen, thus creating some separation in terms of efficacy from the other treatment choices. This new approach would create a level and accurate playing field that would make true informed consent possible as all efficacious treatments are considered in the light of new safety ratings.

As becomes evident, a revised approach to safety ratings would change the character of our patient interactions, as we are forced to share a much more severe look at safety issues. Clearly, a review of safety ratings that embrace this rather harsh level of scrutiny would steer patients away from some commonly accepted treatments, but, as practitioners we could regain the patient respect that has been lost over the last 20 years as more and more safety violations from previously respected medications arise in the lay press. The public would dearly appreciate this enhanced level of caution on safety issues as well as a broader review of treatment options.

\*Ref. 22.

†Hardy M, Coulter I, Morton SC, et al. S-Adenosyl-L-Methionine for Treatment of Depression: Evidence/Report Technology Assessment Number 64. AHRQ Publication Number 02-E04. Rockville, MD: Agency for Healthcare Research and Quality, 2002.

‡Bronstein AC, Spyker DA, Cantilena LR, et al. 2008 annual report of the American Association of Poison Control Centers' National Data System (NPDS): 26th annual report. Clinical Toxicol 2009;47:911–1084.

evidence, deaths secondary to correctly prescribed medication reactions now constitute the fifth leading cause of death in the United States, while all iatrogenic deaths amount to 225,000 per year and rank as the third leading cause of death in the United States.<sup>4</sup>

In contrast, most of IM is built around treatment approaches (mind–body medicine, lifestyle changes, dietary adjustments, etc.) that have minimal risk of harm. The use of herbs and supplements constitutes the most risky area of IM. Since 2008, the federal government has mandated that all supplement manufacturers list toll-free numbers on their product

***In 2008, only 1013 events were reported for natural products versus more than 500,000 for pharmaceuticals.***

labels and requires these manufacturers to relay to the FDA all serious side-effect reports. This new adverse events reporting system (AERS) forms a mirror complement to the mechanism that exists for pharmaceutical medications and uses the same definitions for “serious events.” In 2008, only 1013 events were reported for natural products versus more than 500,000 for pharmaceuticals. Eight patient deaths were reported from these unregulated products<sup>5</sup> versus more than 100,000 documented in the Starfield report above.

Public concern over this preference for safety has contributed to a growing interest in CAM and IM, as documented by a rapid increase in rates of utilization over the last 20 years.<sup>6</sup> CAM and IM tend to prefer natural or lifestyle approaches to treating illness. They recognize a healing power within the body, and this carries with it a high priority on avoiding unneeded risks in the provision of care.

Ultimately, the authors of this article hope to create a starting point for discussion on how the foundation of MDM must reflect the priorities of IM. It is our belief that (1) amended measures of efficacy, (2) a much stronger emphasis on risk concerns, and (3) a considered exploration of specific patient issues will create a more fully elaborated foundation for MDM in IM.

## Efficacy and Effectiveness

RCTs have dominated decision making about efficacy in health care for almost 50 years. Many researchers have explored the difficulty of subjecting IM treatment approaches to RCTs. There are some characteristics of IM interventions that make RCTs particularly difficult to carry out, and perhaps even less relevant, than for conventional allopathic medicine. As Fønnebø pointed out,<sup>7</sup> the gap between published studies of integrative approaches on the one hand, and the clinical reports by practitioners on the other hand, may partially result

from the fact that placebo-controlled RCTs are designed to evaluate pharmaceutical interventions.

Certainly, there is strong evidence that RCTs lack external (or ecologic) validity.<sup>8</sup> This issue has been addressed quite often over the last decade, but nowhere has it been more strongly demonstrated than in the recent STAR\*D evaluation that showed that only 22% of the STAR\*D participants would have passed screening criteria to be entered into a conventional RCT.

There are other criticisms of RCTs worth noting. For instance, the emphasis on RCTs is based on the premise, now known to be false,<sup>1</sup> that all other forms of evidence provide biased information on treatment effects. In addition, RCTs are too expensive, which can result in pressure to bury negative results that will block market approval and decrease corporate income. The high cost of RCTs has resulted in pressure to make them shorter and shorter, so that, currently, physicians are in the untenable position of making treatment recommendations for medication use that may continue for decades on the basis of data derived from 6 weeks of exposure to an agent. In other words, clinicians are making guesses about long-term effectiveness based on efficacy data collected over a period of 6 weeks.

## Alternative Sources of Valid Information

There are reasonable alternatives to the overdependence on the RCT as *the* measure of the potential impact of a treatment. First, recall that history has taught us that fact in science is never determined by a single study, but rather, by the weight of the evidence. It is right that medicine rests upon a foundation that begins with good clinical observations, case reports, and careful interpretations. Replication across scientists, which is the true hallmark of valid science, establishes whether those clinical observations are important and perhaps generalizable.

For interventional treatments, multiple experimental designs can then be used to test hypotheses of efficacy: case-control studies; within-subject crossover designs; blinded comparisons to other treatments; and (when appropriate) placebo controls. Walach and colleagues have written a critique of the hierarchical approach to medical research (which places RCTs at the top) as it has been applied to CAM interventions.<sup>9</sup> Their alternative to the hierarchical approach, which they refer to as a *circular model*, is consistent with the ideas just presented regarding multiple methodologies with replications resulting in a proper evaluation of the weight of the evidence, especially for complex interventions.

Recently, clinical scientists have been rediscovering a particularly useful set of criteria for defining causality. Sir Austin Bradford-Hill, FRS (1897–1991), was a British statistician and epidemiologist who promoted the use of randomization for clinical trials used to test health care interventions, a position he took prior to World War II.<sup>10</sup> In 1965, Bradford-Hill, in his presidential address to the Section of Occupational Medicine of the Royal Society of Medicine, proposed a set

of criteria to be used for drawing conclusions about causality in terms of disease etiology.<sup>11</sup> However, his criteria have also proven valuable for evaluating treatments. As he pointed out, not all criteria are appropriate for all issues being analyzed, but he listed nine in total from which appropriate ones should be selected for any given situation:

- (1) *Strength*—referring to the robustness of the association between the causative agent and the outcome
- (2) *Consistency*—meaning being able to obtain similar results across different research sites and methodologies (i.e., replication)
- (3) *Specificity*—by which Bradford-Hill meant one disease having one specific outcome, which may not be relevant to complex disorders (e.g., psychiatric problems)
- (4) *Temporality*—referring to the commonsense notion that the cause always precedes the outcome
- (5) *Biologic gradient*—which is best described as a dose-response curve: increased treatment would presumably result in a proportionate increase in the effect (again, not relevant in all disorders)
- (6) *Plausibility*—referring to whether the results are biologically sound
- (7) *Coherence*—which refers to the agreement of a study's findings with what is already known (hence, not relevant in situations of truly novel interventions)
- (8) *Experiment*—the situation in which randomly introducing the causative agent results in the outcome
- (9) *Analogy*—which is the idea that a similar cause results in a similar outcome.

It is particularly interesting to note that the Bradford-Hill criteria, specified by the individual who influenced the methodology we now accept for RCTs massively, lists *experiment* with randomization methods as only one of nine criteria for establishing causality.

## Unique Features of IM Research

In addition to issues such as ecologic validity (mentioned above), there are several other methodological issues that clearly distinguish IM research from the environment of classic pharmaceutical RCTs. Two of these relate to patient variables (discussed further below). For instance, the healing relationship of a doctor and patient is generally excluded or “controlled for” in conventional RCTs, whereas some researchers would argue that unconditional positive regard forms the underpinnings of the healing relationship between two people.<sup>12</sup>

The enhanced focus on the healing relationship is thus another factor delineating IM from conventional health care models. A second example is the concept of individualized care, which is rarely included in RCTs (perhaps the MTA study in childhood ADHD is a notable exception<sup>13</sup>). The notion that each patient is unique and quite different permeates IM.

However, classic RCT research design requires patients to be broken out into groups with a similar diagnosis, which impairs the ability to evaluate an individualized treatment system, such as classical homeopathy, Traditional Chinese Medicine, or Ayurveda. In each of these systems, the patient must be individualized into a quite unique pattern that does not lend itself to a more broad disease generalization such as that found in conventional allopathic medicine. Curiously, the cutting edge of modern medicine anticipates that customized and individualized care looms as a result of advances in single nucleotide polymorphisms (SNPs) and the ability to create a specific genetic fingerprint for each individual.

A third methodological issue that distinguishes IM from the environment of pharmaceutical RCTs involves systems thinking. With its roots in holistic, natural, and aboriginal medicine, IM has always embraced a more systems-based orientation to patient care than conventional care. It should come as no surprise that a narrow modality for evaluating treatment effectiveness would become increasingly limiting to IM research. The movement toward increasingly narrow scientific evaluations may create an artificial and arbitrary view of human health, medicine, and treatment effectiveness. Fritjof Capra, PhD, the well-known physicist, indicated that the great surprise of twentieth century science was that complex systems cannot be understood by analysis.<sup>14,15</sup> Ecology and epigenetics are examples of the strong movement toward systems thinking in modern biology.

In spite of these issues, the IM community has acknowledged the importance of RCTs in the EBM pantheon. In 1982, only 11% of the CAM studies published were RCTs. By the 2000s, this number had increased to > 80%.<sup>16</sup> In spite of the rising number of RCTs, many of the studies published in IM struggle with small size and/or poor methodology. This information, added to the weaknesses of efficacy-based RCTs suggests the importance of reevaluating our methods of evaluating research results.

## Commercial Funding and the Distortion of Data

The previous discussion ignores the fact that the dependence on efficacy-based RCTs for MDM rests on the premise that the available database exists without compromise. Sadly, a spate of recent publications have documented that this is not the case. In psychiatry, the recent article by Turner<sup>17</sup> highlights the commercial distortion of the existing evidence. That article documents the massive publication bias found across antidepressant trials (50% of negative studies published versus 91% of positive studies) and the consistently upward “adjustment” of effect size (ranging from 11% to 69%; averaging 33%) by the commercially funded authors.

Psychiatry ranks as the number-one specialty for payments by the pharmaceutical industry to clinical practitioners not engaged in research.<sup>18</sup> Psychiatry also generates a disproportionate amount of pharmaceutical revenues with two of the top four drug categories (antipsychotics, #1 and antidepressants,

#4) in total sales. With its more ambiguous diagnostic criteria, psychiatry also stands as a prime target for this commercial distortion of evidence and applied external influence. However, similar data continue to accrue from a variety of different specialties supporting a skeptical view of commercial neutrality in modern pharmaceutical research.<sup>19</sup>

In psychiatry, three massive noncommercially funded studies published in the last 7 years (CATIE, STEP-BD and STAR\*D) share a few common traits besides the lack of commercial funding: more naturalistic designs; longer length of study; and a humbling negative reappraisal of the value of psychiatric medications. Their results reinforce the need for more independence in the funding of medical research. In a step toward protecting the sanctity of the body of evidence in medicine, perhaps all financial support should be routed through an independent funding body that will assign payments based on value to the field. Such a system would in effect create a third tier of blinding: patient; practitioner; and payment.

## The Issue of Blinding in IM

Bradford-Hill was a strong proponent of the value of blinding in studies of external medical interventions, but many IM treatments (such as acupuncture, manipulation, and Reiki) make it nearly impossible to blind a study, as the person delivering the treatment knows whether it is being done correctly. Interpretation of results in IM settings with the challenge of having a placebo control is another area of concern. Recently, a number of large studies in acupuncture have been published that demonstrate both sham acupuncture and true acupuncture produce significantly better outcomes than conventional care.<sup>20,21</sup> Some scientists interpret these results as a demonstration that acupuncture is no better than the control. Others argue that the results show that all forms of acupuncture (true or sham) appear to be more effective than conventional care. Linde's recent study documents a significant nonspecific effect for sham acupuncture (2010).<sup>22</sup> This controversy highlights the inherent difficulties in IM research design.

## Proposed Scale for Grading Treatment Value in IM

Clearly, all levels of evidence have strengths and weaknesses; no level is without value or completely useful. Our job as clinicians is to sort out the evidence base in MDM, not wait for large RCTs as they typically have limited value for most complex cases. In IM, our job is more complex and heightens the need to be comfortable in this process of sorting evidence. A new scale for grading treatment efficacy and effectiveness might look like this:

- *Level one—Very strong indicators of efficacy:* large RCTs that were not commercially funded; multiple (three or more) commercially funded RCTs without evidence of publica-

tion bias or negative studies; the weight of evidence across multiple designs, replicated by multiple sites

- *Level Two—Strong indicators of efficacy:* one or two commercially funded RCTs without any negative studies within treatment class or type; open randomized clinical trials; multiple large observational studies with strong support from the Hill criteria; replication from multiple sites
- *Level Three—Moderate indicators of effectiveness:* multiple RCTs with conflicting RCTs for same treatment type or class; at least one large observational study (cohort study); multiple small studies with strong support from the Hill criteria and replication across sites
- *Level Four—Weak indicators of uncertain value:* poorly designed studies without strong support from the Hill criteria; small observational studies
- *Level Five—Very weak indicators of efficacy or effectiveness:* expert opinion of effectiveness; case series; multiple anecdotal reports.

## Proposed Scale for Grading Treatment Safety in IM

Health care professionals typically agree on the relative ordering of treatments based on the level of evidence when there are no concerns about safety. However, there is less agreement when safety issues are present, which is almost the norm. Following the historical divide, IM typically prefers treatments that have a high level of safety and enhance patient autonomy, while, in conventional allopathic medicine, the relative emphasis is on efficacy. For example, conventional care may prefer a statin medication for preventing heart disease while IM practitioners will prefer diet, exercise, and supplements. IM practitioners will say their treatments are safer, make more sense, and help the patient become healthier. Conventional allopathic practitioners will say their approach is more practical, facilitates compliance, and is more scientific.

Thought leaders in EBM have proposed a few different grids for integrating safety and efficacy information for

## How do we define harm? What does risk mean?

MDM. These grids (effective, not effective, safe, not safe) form a useful foundation for this process. Other statistical tools such as number needed to harm and number needed to treat also add to this discussion. However, the paradigm of safety does not yet have the clarity and sophistication that can be found in considerations of efficacy. How do we define harm? What does risk mean?

Our position is that, much as EBM has led the way for guiding MDM based on rigorous efficacy evaluations, so must IM establish criteria that lead the way to MDM based on eval-

ations of effectiveness that address the risks to patient safety more rigorously. IM has already begun to set the standards for surveillance of the safety issues within health care, and for evaluation of effectiveness that accommodates safety concerns. As with EBM, the criteria must be rigorous and beyond reproach as we seek to reinstate one of the most time-honored tenets of medicine: *primum non nocere* (first, do no harm). A new safety scale would look like this:

- *Level One—Absolute safety:* no indications of significant risk; no fatalities or severe chronic debility; evidence that treatment supports health; if invasive: multiple noncommercial long-term studies (over 2 years in length) documenting this safety; no risks evident for developing youth and, if suspect, they are ruled out by negative studies; must be in active use as a treatment for > 5 years
- *Level Two—Excellent safety:* minor concerns about safety are present; time-limited issues (e.g., nausea, headaches) may be present; must be in active use for > 5 years
- *Level Three—Moderate Safety:* some concerns noted with severe health risks, but uncommon (under 1/1000); no fatalities noted; must be in active use > 3 years
- *Level Four—Poor safety:* suspected issues with more common (1/1000–1/100) major health risks; one report of suspected fatal outcome
- *Level Five—Unsafe:* tied to multiple fatalities or frequently related to the onset of severe chronic illness (1/100 or more).

## Patient Factors

From the perspective of IM, the belief systems of both patient and practitioner play a central role in all MDM. Jerome D. Frank, MD (1909–2005), the famous psychotherapy researcher and psychiatrist, co-wrote the book *Persuasion and Healing: A Comparative Study of Psychotherapy*,<sup>23</sup> almost 50 years ago, in which he and his coauthor outlined many factors that alter and drive the healing relationship. These considerations of set, setting, meaning, and context can be thought of as the foundation of the psychologic and emotional factors that drive the placebo response. More broadly, it can be seen as an outline of the non-biologic elements of healing itself.

Weil has argued that many modern medical treatments function as active placebos having both physiologic and psychologic facets,<sup>24</sup> suggesting that practitioners should try to maximize the placebo response as it elicits the healing power of the body without risk. Perhaps the commercialization of MDM is merely a process to engender belief in new commercial products. If antidepressants carry weak inherent biologic effectiveness, the confidence of the prescribing physician may enhance their impact. As many physicians have been quoted as saying: “One should use a new treatment as much as possible while it still has the power to heal.” Based on recent data,<sup>25</sup> that window for our current antidepressants may be closing as we are now witnessing a steady decline in

the perception of antidepressant potency as more scientific questions arise about their efficacy.

Given the history and philosophical preferences of allopathic medicine, it should come as no surprise that the factors defining the healing response become minimized or ignored in current practice. This failing must be remedied, as these factors account for a huge component of how humans heal and recover. The healing relationship has taken a much larger role in IM as practitioners in nearly all CAM modalities place a much higher emphasis on it. The importance of these issues can be demonstrated most clearly in psychiatry research, where the placebo response plays a huge role accounting for as much as 40%–90+ of the total response.<sup>26</sup>

Significant placebo and expectancy responses inhabit other areas of medical practice, such as dealing with pain and even life expectancy in patients with terminal cancer. Clearly, patient factors must compose a significant part of all treatment selection processes. Ideally, every treatment should be matched to the individual’s belief system to reach the highest level of response possible.

## An Ecologic Model of Evaluation

A larger, broad framework of patient factors must drive the treatment selection process in health care. Otherwise many relevant concerns drop from view. This is the case currently in much of modern health care. The bio-psychosocial model has potential as a template. Patient-centered care (PCC) approached this issue from another angle. PCC focuses more on the specifics of the doctor–patient relationship,<sup>27</sup> while the bio-psychosocial model uses a broad net for evaluation.<sup>28</sup> However, both are only an approximation of the more-inclusive ecologic model that, by definition, incorporates all elements of the patient’s life in consideration. The ecologic model also carries an appreciation of sustainability as a core element for all biologic interventions. Within the ecologic framework, various structures for consideration are feasible. One helpful structure would set up six tiers or niches. These would be environmental, physical, emotional, mental, social, and spiritual.

Using this model, the practitioner assesses the effect of a considered treatment upon each niche. The details of this evaluation are beyond the scope of this article but have been outlined elsewhere.<sup>29</sup> However, the environmental niche deserves emphasis as it has yet to fully enter our consideration. This is a two-way evaluation. First, does a treatment damage or alter the environment for other people? Of what benefit is a helpful treatment for 1 patient if it damages the health of 10 others?

Technically, this aspect is not about a particular practitioner’s patient but about the effect of a treatment (and its associated cascade of events) on all other living creatures. However, if this concern about sustainability is ignored, it will ultimately decay the health of every patient. It most likely already has. For example, medicine has recently acknowledged the complexities of indiscriminate antibiotic use in creating resistant strains of bacteria. Second, does the environment alter the pa-

tient's health? Increasingly, our failure to protect our environment has translated into widespread health risks. Soon, we will all understand that to protect our health we must protect the environment. Any line separating the two is illusionary. In addition, the overharvesting of wild botanicals threatens species viability and access for other patients in need.

## Patient Preference, Cost, and Access Issues

At times, other issues will drive the MDM process. Most public-sector patients in the United States have no access to the use of evidence-based nutritional supplements, as there is little likelihood of overcoming the FDA hurdle for an indication without commercial funding. Given this reality, it is extremely improbable that any nutritional product will be available for low-income populations who are not able to pay out-of-pocket for a safe, effective treatment that matches their belief systems. Given the current financial stresses and the extreme limitations of our insurance model, these issues are relevant for many middle-class Americans as well. Thus, access and cost constitute a huge issue in MDM.

Also, patients will, at times, make choices that are based more on practicalities than on belief systems. For example, a holistically oriented patient who develops severe back pain in the face of intense life stress may acknowledge all of the needed inner work and lifestyle changes needed to come back to balance and address the pain. That patient may also have some real-life urgencies (job, child care, etc.) that push him or her toward the perceived speed of pain medications and surgery even though that patient has some deep hesitations about that approach.

## Informed Consent

The current model of informed consent must be called into question as we acknowledge the bifurcated nature of modern health care (CAM versus conventional). As an example, conventional practitioners typically do not have familiarity with integrative techniques, given the training system that often artificially divides treatment modalities by issues other than science. Even as far back as the early 1990s, Eisenberg's two large studies,<sup>30,31</sup> documented that conventional practitioners and patients practiced a health care version of "don't ask, don't tell" about CAM approaches. The converse situation is quite likely true as well, but has not been documented in the same manner.

What practitioner can accurately obtain informed consent? Most practitioners know well and prefer only one side of this philosophical fence. Thus, what patient ever receives a full and balanced overview of all possible treatment choices? IM providers may have to play a role in the recognition and resolution of this deficiency. As one of the few providers in the health care arena educated specifically on both sides of the conventional/CAM dichotomy, the IM community may

be the only group able to appreciate the limits of our current system of informed consent. As such, we must begin a dialogue to highlight, address and resolve this rather massive medicolegal shortcoming.

The ideal process in MDM would remodel the process of informed consent. The actively engaged patient would be offered a quick overview of appropriate treatments (both CAM and conventional) with an unbiased reflection of both safety and effectiveness. The patient would then declare a preference for one over the other(s). Once a practitioner ascertains the basic worldview of a patient (natural versus conventional; safety versus effectiveness) many simple elements of MDM would flow quickly in the future.

## Conclusion

Three elements form the irreducible basis for appropriate MDM: safety; efficacy; and patient factors. Practitioners must eliminate the significant, artificial, and philosophically driven divide between CAM and conventional care as reflected in the full appreciation of the safety and effectiveness of possible treatments. Any treatment choice should reflect the needs and desires of the individual patient.

The evidence base in medicine reflects enormous complexity. The search for causality in possible treatments filters many divergent concerns. RCTs represent one of many tools in treatment selection and the ranking of efficacy. Other tools such as the Bradford-Hill criteria can deliver a more balanced consideration of evidence. Commercial bias in funding of research distorts the evidence base needed for MDM and must be acknowledged. Our vigilance for the safety of treatments should be heightened. Rankings of effectiveness for medical treatments form one corner of the triangle of MDM.

The protection of health forms a crucial foundation for all MDM. Is a treatment valuable if it cures the illness at hand but damages the health of a patient in some other manner? IM can support the creation of a needed dialectic between effectiveness and safety in the examination of any possible treatment. The rankings of safety should be severe and honest, and take a public health orientation that guards the sanctity of each individual's well-being. Risk must be acknowledged in all forms.

Patient belief and other patient-centered factors should drive much more that occurs in MDM. The individual patient forms the apex of the triangle in MDM. Every treatment may have rankings of safety and effectiveness but there is no right or wrong in MDM without considering the specific needs of the individual patient. The individual's belief system will affect the value of a treatment significantly and cannot be ignored. A comprehensive consideration of the patient's ecosystem as it relates to MDM will offer the best filter for treatment selection. Other patient factors such as cost and access may drive MDM. Finally, a deep reevaluation of the informed consent process will bring MDM closer to an ideal that is rarely met today.

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