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Ethical Dimensions in the Borderland Between Conventional and Complementary/Alternative Medicine

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ABSTRACT

Consumer enthusiasm for complementary and alternative medicine presents complex challenges for conventional Western biomedically dominated health care systems and for those who practice within them. In particular, this trend forces new ethical dilemmas related to how we create consensus about the nature of ethical clinical practice and what constitutes evidence sufficient for public health policy. In this paper, we examine the historical context into which complementary and alternative medicine has been introduced, and consider the ethical and scientific challenges with which it confronts mainstream health systems.

INTRODUCTION

Advances in the development and application of complementary and alternative medicine (CAM) have created a social, political, and health care climate in most Western biomedical health care systems in which new and challenging ethical issues confront medical practitioners on a daily basis (LaValley and Verhoef, 1995; Verhoef and Sutherland, 1995). CAM includes a wide spectrum of health and healing strategies that derive from systems of evidence quite distinct from those practices that have emerged from Western biomedical science (Achilles, 2000; Chez and Jonas, 1997; Eisenberg et al., 1993; Eskinazi, 1998; NIH Panel on Definition and Description, 1997). Despite an ongoing contentious debate over CAM within many conventional health care arenas, there is overwhelming evidence of its escalating integration into major research institutions, medical schools, and mainstream medical practice (Baer, 2001; Cassileth, 2000; Ernst, 2000b; Rees and Weil, 2001). This combination of public pressure and a conflicted medical community creates inherent ethical challenges for those in clinical practice (Owen et al., 2001) and complicates the processes with which a public policy and health care delivery systems decisions are made. In this discussion, we explore some of the intricately interconnected ethical challenges illuminated by the CAM movement, illustrate the degree to which they must be considered in an interrelated context, and examine

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approaches to the ethical dilemmas raised by the integration of conventional medicine and CAM into a coherent health care system.

SOCIAL AND SCIENTIFIC CONTEXT OF THE CURRENT CHALLENGE

Population survey polls consistently document the rising popularity of CAM within mainstream society in most Western nations, to the degree that a majority of citizens now either use CAM or are open to its use (Consumer Reports, 2000; de Bruyn, 2000; Eisenberg et al., 1998; Ernst, 2000a; Kelner and Wellman, 1997; Ramsay et al., 1999; Saks, 2000; Siahpush, 1999). This trend toward an increasing prevalence of CAM use represents the combination of a number of social forces. It involves the formal introduction into Western societies of a range of health practices that have always been present at a relatively invisible or private level. These include the folk or traditional practices that many Westerners inherit by virtue of their ancestral, social, or cultural origins (examples might include Ayurvedic medicine, herbal remedies, or shamanic practices). It also involves the more systematized introduction of health practices, the foundational basis of which is rooted in forms of evidence other than biomedical science, but that may have extensive formal and substantive theoretical structures and practice traditions (such as chiropractic, massage therapy, naturopathy, or homeopathy). Because the logic of biomedicine has been the dominant force within public discourse about health and healing throughout most Western nations, the ideas on which it was founded are typically accepted as more accurate, true, and correct than are other ideas originating from other traditions. Thus, the practitioners and scholars of the Western biomedical tradition have gained social authority as the arbiters of truth as far as many matters of social and health policy are concerned (Saks, 2000; Sharma, 2000).

Until the latter part of the twentieth century, with the rapid increase in CAM popularity among mainstream population groups, consumer critique of health care decision-making, and significant challenges in the economic climate in which health care is delivered, the practitioners and scholars of Western biomedicine assumed an undisputed authority over matters of health and illness within society (Jonas, 2000; Sugarman, 1998). Recent challenges to this authority have been linked to a number of factors: an escalating recognition of the implications of multinational medical-pharmaceutical interests on shaping the health industry; an increasingly sophisticated consumer challenge to the reductionistic, mechanistic model of biomedicine; and the growing enthusiasm across all population sectors for health services, practices, remedies, and comfort measures that have not traditionally been recognized as an inherent component of the publicly supported health care system (Best and Herbert, 1998; Boon et al., 2000; Cassileth, 1999; Pawluch et al., 2000).

This social context creates an important backdrop to any analysis of the ethical issues arising from CAM practices. Ethics, or the study of how we might determine morally correct action under various circumstances, requires some consensus or agreement as to how we will be able to know the greater individual or social good. In the context of health and medical care, the field of biomedical ethics has been driven by a foundational underpinning rooted in many of the same assumptions that ground Western biomedicine. Thus, while ethical reasoning is considered the domain of philosophy, its application in the domain of health care has been largely shaped by competing arguments about what is right and proper action on behalf of particular patients, or what is right and proper action on behalf of society (Bankowski, 1996). Because of this, it is difficult to untangle our ideas about how we work out ethical problems in relation to complex social challenges such as CAM. When we understand that each application of an ethical problem is inherently linked to the larger issues associated with how our society collectively concludes what might be right and wrong in any situation, we must locate the discussion of all such problems within the larger context of the ideologic orientation within which they reside (Cassell, 2000). By understanding that conventional and alternative health care practitioners represent the foundational philosophical positions of

dramatically different ways of thinking about what counts as truth and how knowledge can be judged, we can begin to make sense of such ethical dilemmas as the conflict that arises between professional groups charged with advocating for quite different interests (Eskinazi, 1998; Jonas, 1998; Sugarman, 1998).

Recognizing that the current body of scientifically based "evidence" is itself a social construction in that those questions that have been asked and advances that have been pursued have been dramatically skewed by various interests rather than reflecting an objectively neutral progression of knowledge, we begin to appreciate how our different positions on the question of CAM can produce radically different interpretations of what might constitute an ethical response to a situation or even an ethical principle to be followed. Moving beyond the limitations of more conventional bioethical principles and into the domain of applied ethics, we will attempt to illuminate the manner in which competing ideas of ethics have complicated the discourse surrounding CAM practice, policy, education, and research. Through this process, we propose some guidelines from which some of the most contested ethical issues associated with CAM can be identified, articulated, and interpreted.

ETHICAL ISSUES IN CAM PRACTICE

It has long been established within the conventional health care professions that clinical practice must be governed by an explicit code of ethics (World Medical Association, 2000). While conventional practitioners practicing CAM are obliged to comply with their professional codes of ethics, some aspects of CAM practice may contravene accepted understandings of the codified principles. For example, guidelines such as the Canadian Medical Association Code of Ethics (Section 12) (Canadian Medical Association, 1996), the American Medical Association Principles of Medical Ethics (Section 5) (American Medical Association, 2001), and the British Medical Association Code of Practice (Section 3) (British Medical Association, 1995) require physicians to provide sufficient information for informed consent. Because there is little formal research on the scientific basis of many CAM practices, the recommendations of the practitioner will rarely meet an expected standard for evidence-based information (Stone, 1999; Sugarman, 1998). Similarly, such codes often charge the physician with providing the "generally held opinions of the profession" (Canadian Medical Association, 1996) that, at this point in history would typically be incompatible with many forms of CAM practice. Certainly, there is a history in many Western countries of medical practitioners whose practice includes CAM being charged with medical incompetence by their practice review authorities, even in the absence of patient complaints or evidence of harm (Sharma, 2000). Thus, the social and scientific context within which conventional medical practice has evolved have created a set of assumptions and understandings that fit those established expectations, but are often at odds with the conditions and understandings inherent in CAM practice (Lynoe, 1992).

In keeping with the conventional practice of recognizing one's own limitations and recommending additional expert opinions, many conventional clinicians regularly make referrals so that their patients can obtain the clinical benefits of CAM services (LaValley and Verhoef, 1995; Verhoef and Sutherland, 1995). While such referrals may reflect an integrated model of medical practice in which the practitioners consult with each other on an ongoing basis, these referrals may also arise from acknowledgement of the limited expertise of physicians who genuinely desire to provide their patients with a more global approach to health promotion or to offer supportive care or comfort measures. However, because most CAM practitioners to whom physicians might refer their patients are unregulated and therefore operate outside of any binding ethical regulations, such collaboration poses a further complication to the physician concerned with adherence to ethical practice guidelines (Lynoe, 1992).

As one step forward in resolving these ethical challenges, working toward the development of a code of ethics that would apply to all CAM and conventional health practitioners would seem advisable. Such a code would pre-

sumably contain many of the values already built into established health professional codes, and would have to address a number of particularly complex issues explicitly. For example, the notion of informed consent for treatment would have to be interpreted in relation to the lack of conventional evidence on effectiveness and safety of many CAM practices (Habiba, 2000; Sugarman, 1998). Such a code would also have to address the issue of standards for CAM practice, such that practitioners could be held responsible for complying with a set of ethical standards appropriate to their profession. Because most CAM practice currently takes place outside the conventional health care system, the issue of advertising or marketing unproven practices would require thoughtful consideration. Similarly, because many CAM products (such as certain raw herbs or dietary supplements) are not widely available, the ethical principles governing CAM practitioners' participation in the sale of such products would also have to be made explicit.

Because of the lack of general CAM acceptance among the conventional medical community (Barrett, 1998; Beyerstein, 1997; Fontanarosa and Lundberg, 1998), as well as the limited amount of research evidence on CAM, compliance with the established codes of ethics can be challenging for those physicians who aspire to an integrated model of care (Ernst, 1996). However, because the public has the right to expect that conventional and CAM practitioners will operate in an ethical manner, these issues deserve thoughtful consideration and resolution. Beyond the formal codes of ethics that may be adopted by various CAM professions as they are increasingly sanctioned and regulated, there will be an ongoing need for the development of interpretations and community standards to protect both clinicians and their patients (Browne, 1999; Owen et al., 2001).

ETHICAL ISSUES IN CAM RESEARCH

The application of ethical principles in the conduct of medical and health service research has become codified and standardized (Evans, 2000). Certain expected processes relating to informed consent, management of therapeutics and placebos in clinical trials, randomization and confidentiality have come to be considered as fundamental ethical principles in their own right rather than as accepted procedures for creating scientifically acceptable conditions for controlling human variables and maximizing generalizability of results (Avins, 1998; Trotter, 2000). In much of conventional medical practice, the double-blinded randomized controlled trial (RCT) has become the gold standard for research methodology (Glik, 2000). Because of this, despite the fact that many accepted conventional medical procedures actually derive from epistemologic traditions that do not include such science, the results of RCTs are generally considered the highest quality evidence for application of ideas to clinical practice. A corollary to this is that the RCT is uncritically accepted for its truth value, and evidence from sources other than RCTs tend to be regarded with considerable skepticism.

However, as has been hotly debated by some (Vickers, 1996) but clearly recognized by others (Hilsden and Verhoef, 1999), the RCT has variable utility for evaluating the effectiveness of CAM practices. While it is well recognized that the effects of various somatic and supportive practices are inherently difficult to evaluate (Long et al., 2000), even herbs and other natural products are not always amenable to traditional forms of trials for various reasons. First, randomization can be problematic in that it extends beyond offering or withholding a product and must assume an equivalent willingness to engage or not engage in other symptom relief measures and/or lifestyle management. Second, blinding the patient and the practitioner to the therapeutic option are often difficult, if not impossible, given the contextual nature of diagnostic processes, negotiations around options, and the degree of active involvement that each party must typically play in the delivery of CAM. Third, the notion of placebo raises considerable suspicion in the CAM context (Hilsden and Verhoef, 1999). Recognizing that a placebo effect exists, common sense would tell us that the simple helpful interaction in which some assistance has been offered is in and of itself beneficial. When conventional medical therapeutics are evaluated

outside the context of caring, interactive, and helpful relationships, this kind of reductionism violates the tenets of many CAM practices (Neims, 1999). Evolving as they have out of ancient traditions of healing, comfort measures and shamanic arts, factors such as trust, relationship, and transmission of healing energy are an inherent component of the therapeutic, not something from which it can be isolated to remove the contaminating effect (Glik, 2000; Rose, 1998). Thus the philosophical origins of CAM practices often make them inappropriate for simple RCT testing and, if such trials are conducted, can render the results meaningless (Linde and Jonas, 1999; Mike, 1999). More elaborate RCT designs or alternative ways of estimating effect may be more appropriate, and inquiry methods that can reconcile public safety with public demand must be developed and agreed on.

One complicating factor associated with CAM research is the accepted ethical principle derived from curative medicine that innovations in therapy be measured against standard practice. Thus, mathematical probabilities calculated from large populations are used to determine whether, across the entire group, the innovation is more or less effective than the standard. This model of evaluation becomes problematic in CAM research because it assumes a relative equivalence of all cases with a particular condition, and therefore averages out the uncertainty factor (Mike, 1999). In so doing, it provides no mechanism by which interactions between the intervention itself and the key person–practitioner–setting–context variables can be studied. While creative RCTs can address these interactions if they are included in the design logic, the model of interpretation more familiar to the CAM practitioner might assume that some people might do better with one treatment than others, and that the goal of the practitioner would be to assess ongoing responses so as to match an individual case with the optimal therapeutic approach. Factors that might be involved in this decision might include the patient's beliefs and values, the body's immunologic or physiologic response patterns, or the sociocultural conditions within which the therapeutic will be delivered. Thus, the bottom line for both conventional and complementary medicine is that designs that fail to take individual differences and contexts into account may distort or skew the effects that actual practice patterns would have upon health outcomes (O'Connor, 2000). Interestingly, with advances in genomics and increased attention to the multicausality and variable treatment response of chronic disease, the importance of these more complex research methodologies is becoming increasingly appreciated by biomedical researchers as well (Ernst, 2000b; Neims, 1999; Vickers, 1996).

Concurrent with these challenges is the further complication of definitional shifts related to relevant health outcome measures. In spite of a health care system customarily oriented toward "disease" care, health care consumers are demanding attention to their "illness experience" and health promotion (Ritvo et al., 1999; Truant and McKenzie, 1999). In conventional terms, the effectiveness of a particular therapeutic strategy was determinable simply in terms of symptom progression, organ function, biologic markers, or other disease-related variables. However, patients are also demanding that effectiveness be considered in terms of their overall health and well-being, and consequently, there has been tremendous pressure on those evaluating therapeutic measures of all kinds to account for such outcome measures as "quality of life" (Long et al., 2000; Truant and McKenzie, 1999). As theorists from various perspectives have become involved in evaluating such issues as effectiveness, the complexities inherent in understanding value of various modalities of health care are becoming apparent within conventional medical science as well as among the general public (Anderson, 1999; Berridge and Stanton, 1999; Glik, 2000).

Thus, beyond the obvious matters of ensuring that CAM recipients are treated ethically and respectfully, that their rights and safety are not violated, and they have access to the information that they require with which to make decisions pertaining to their own health care, thoughtful commentators suggest that CAM raises ethical issues that challenge the very standards on which we currently develop evidence for clinical practice (Glik, 2000; Jonas, 1998; Mike, 1999). These issues are as germane to many conventional as well as complemen-

tary practices, but the emergence of the CAM debate brings them into sharp focus. For example, although we have consensus that coercion is not accepted within clinical trials, it is well recognized that many patients feel that they will not be as fully supported by their practitioners or hospitals if they refuse to participate in such studies. Although patients are expected to report all concurrent therapeutic measures they are taking to their clinicians, they often withhold information about CAM therapies and practices for fear of being discredited or challenged by their conventional practitioners (Smith and Boon, 1999). Furthermore, although it is well recognized that substantial numbers of patients enrolled in clinical trials for conventional therapeutics also engage in CAM practices, many of them fail to report such practices because of those same attitudes (Sparber et al., 2000). Thus, in a world in which many consumers are seeking and utilizing both CAM and conventional health care simultaneously, it has become extremely important to sort out some of the ethical issues associated with interactions, covert practices, and the unnecessary stress of withholding information to preserve positive relations within the health care system.

Making genuine advances in CAM research will therefore necessitate rethinking our approach to the larger question of how we know the effects of what we offer patients (Best and Herbert, 1998; Herbert et al., 1999). Not only must we investigate the safety and effectiveness of CAM practices themselves, but we must also reexamine the limits associated with currently accepted evidence about conventional therapies (Ernst, 2000a).

ETHICAL ISSUES IN HEALTH POLICY

The health policy devised by a society is always a product of specific historic and political circumstances. In modern Western nations, medical science and doctors are no longer the sole arbiters of what constitutes health and illness or what ought to be done to enhance health and treat illness. The preferred direction and shape of health policy is currently under active debate and generating strong emotions (Sharma, 2000). In general, most nations agree that ethical health policies should reflect a just distribution of the resources available to the society, without barriers erected by socioeconomic differences or prejudices against particular types of health care.

In Canada, as in other nations with a socialized health care system, government-supported health insurance is mandated to provide universal, essential, portable, comprehensive, and accessible health care to all citizens (de Bruyn, 2000). Given that there is always a scarcity of resources to accomplish these goals, thoughtful decisions are required to determine how these resources can be ethically distributed (Ernst, 1996). In such contexts, ethical decision-making about health care policies should clearly include such criteria as perceived effectiveness, relative lack of harmful side-effects, congruence with the goals of the population for their own standards of health, and some objective measures of cost effectiveness. Such policies will necessitate an equitable system for evaluating efficacy, safety and cost effectiveness, but as we have established, similar standards and criteria may be inapplicable or inappropriate across the range of healing paradigms.

One logical solution is to establish policies of regulation and accountability in relation to CAM modalities. Practice licensing for the discrete approaches to delivering care and policies governing the educational preparation of practitioners becomes possible if we assume that the healing goals of each type of care can be evaluated in an appropriate format and standard. Nonetheless, although some of the more established CAM practices, such as chiropractic, massage therapy, and naturopathy are relatively amenable to regulation (Sharma, 2000), not all CAM practices and practitioners are likely to accept organizing themselves in a manner that formalizes practice and structures formal education, and this variation will pose a significant ethical challenge to integrated care within public policy. In general, we might agree that the right of CAM practitioners to practice their specialty should be protected as long as there are patients who want to use their services and there is no credible evidence that they do harm. However, it might also be rea-

sonably argued that financial support from society should be limited to those services for which accountability mechanisms exist. The ethical challenge before us, then, is to consider how our societies can create feasible mechanisms for deciding which practices ought to be regulated and formalized, and which are best left to the private and folk sectors.

Over recent decades, a dramatic shift toward consumers reclaiming their own power in health care decision-making has been evident (de Bruyn, 2000; Kelner and Wellman, 1997), and with this trend comes a requirement to rethink the larger notions of social responsibility and accountability as they influence our policy decisions. Just as the focus of evaluating therapeutic measures has shifted from the amelioration of disease-related symptoms to creating the conditions for wellness, both conventional and CAM practices are being challenged with their impact on the larger social context in which the determinants of health arise. Thus, the care modalities are subject to critique not only for their effect on comfort and quality of life, but also for their effect on social values, equitable distribution of health resources, and consumer satisfaction. For example, as herbal products and nutritional supplements are becoming increasingly popular, it has become important to consider such issues as regulating their quality, the indications for their use, and the degree to which multinational corporations rather than practitioners control which products are available and in which forms (Eskinazi, 1998).

As the enthusiasm for a broader definition of health care and a wider scope of therapeutic and supportive resources is increasingly demanded by the public at large, it becomes an imperative for some socially sanctioned body to accept responsibility for supporting and monitoring the evolution of the existing health care system. Such a body would require an intimate understanding of the practical and ethical issues at hand, and be designed to extend conventional thinking about health care delivery and medical services. For example, it will be important to be able to influence decisions about research priorities, product development, and marketing. Matters related to licensing, reimbursement, and quality control will also become increasingly challenging in this evolving social climate. In this context, a thoughtful and reasonable public discourse is required so that ethical issues can be exposed, inflated promises can be challenged, rhetoric can be deconstructed, and consumers have a reasonable opportunity to access the most meaningful and useable information possible.

CONCLUSION

In conclusion, we believe that CAM raises some vitally important ethical issues that require consideration and resolution on a public policy level. Consideration of the ethical issues that CAM practice raises inevitably challenges us to rethink the way we understand the ethical context of all health care practices, and to work toward developing a more comprehensive code of ethics that can guide practitioners of all disciplines and orientations toward the provision of safe and effective health services to Canadians. Scratching below the surface of CAM research and policy issues, we are forced to recognize the extensiveness of limits to what we think we know, and to acknowledge the complications that this entails for such matters as informed consent and public safety. Practice and research ethics codes will only be effective if articulated within the context of a broad and comprehensive understanding of ethical reasoning as it is applied to an analysis of both individual and social responsibility in the changing world. Clearly, that world will necessarily include diverse and sometimes contradictory perspectives on what constitutes a legitimate medical or health care practice.

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