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WHOLE SYSTEMS RESEARCH: A DISCIPLINE FOR STUDYING COMPLEMENTARY AND ALTERNATIVE MEDICINE

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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. This article describes the pre-defined goals, issues that were developed, and opportunities that were revealed in a workshop held in Vancouver BC, in which scientists, practitioners, and policy makers met to lay the foundations of WSR. Important issues were identified, such as treatment individualization, problems of diagnosis, patient-practitioner interaction, varying therapeutic contexts, and patient-determined outcome values. Research design issues that were addressed included a variety of challenges to the study of intact systems, in relation to both synergy and emergent behaviors, and the opportunities to innovate the conventional RCT. As the network of CAM scientists and practitioners engaged in WSR expands, a common nomenclature and body of techniques will help us to a better understanding of the ways in which whole systems affect healing.

Complementary and alternative medicine (CAM) systems include a wide range of modalities—from acupuncture to diet and supplements to physical manipulation and energy medicine—combined into an array of systems—from Ayurveda to natural medicine to Traditional Chinese Medicine. Most of the research to date has focused on the specific actions of individual modalities, often isolated from the medical systems in which they are embedded. An international workshop to begin to define the area of inquiry that we are calling “Whole Systems Research

(WSR)” was held in Vancouver, British Columbia, in October 2002, and funded from US and Canadian sponsors (see acknowledgment). The participants included scientists, practitioners, and policy makers (see list of attendees in acknowledgments). This paper presents an overview of the key issues emanating from the workshop, particularly in light of recent publications, and the implications of these issues for future CAM research. More detailed reports of the conference findings will appear separately.

WHOLE SYSTEMS RESEARCH DEFINITION AND CONCEPTS

While various researchers and scholars refer to the need for developing research approaches to study systems of care in CAM there has not been a working agreement about what is meant by a whole system of healthcare or whole systems research.^{1,2} In an online Delphi process conducted before the WSR conference, participants discussed and debated the issues around definitions of Whole Systems of Healthcare and Whole Systems Research. Resulting draft definitions were circulated for review and consideration. While the participants made modifications during the workshop, they did not reach full consensus on these definitions. The working definitions provided below are based on those efforts and are provisional. They will continue to evolve as more individuals begin to work in this field.

Whole systems of healthcare are approaches to health care in which practitioners apply bodies of knowledge and associated practices in order to maximize the patients’ capacity to achieve mental and physical balance and restore their own health, using individualized, non-reductionist approaches to diagnosis and treatment. In whole systems the practitioner-patient relationship plays an important role and continues to evolve over time.

Examples of whole systems of healthcare include Traditional Oriental (or East Asian) Medicine, Naturopathic Medicine, Homeopathy, Integrative Medicine, Ayurveda, various Indigenous Healing systems, and many others. Biomedicine may also be considered as a whole system of care.

Treatments, products, specific modalities, and techniques used within these healthcare systems may be studied/examined as part of the whole system.

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Whole systems research encompasses investigation of both the processes and the outcomes of complex health care interventions. Whole systems research entails the intention to include conceptually as part of the investigative context all aspects of any internally consistent approach to treatment, including its philosophical basis, patients, practitioners, setting of practice, and methods/materials used. Whole systems research acknowledges unique patient, family, community, and environmental characteristics and perspectives. The aim is to use appropriate research designs so that the system can be assessed within its explanatory model.

Given our working definitions, it is apparent that a wide variety of research approaches—from observational and qualitative studies to experimental trials of various sorts—fall within the context of WSR. Throughout the workshop, there was a healthy tension between research questions best addressed through studies focused on components of whole systems, and other research questions that targeted understanding the whole system itself. This tension can be seen in the examples below. The workshop participants clearly intend the field to encompass research both on the components and on the whole.

Whole Systems Research Background and Rationale

During the past several years, a number of excellent papers have focused on the general issues facing CAM clinical research and provide schema to frame its various components.³⁻⁶ There have also been advances in specific fields of CAM research. For example, there have been advances in the study of acupuncture regarding standards for placebo and sham acupuncture,^{7,8} and the Samueli Institute for Information Biology recently developed a series of papers on the state of methods in the study of energy medicine (supplement to May/June *Alternative Therapies*) including papers on evolving standards for clinical trials in energy medicine⁹ and intercessory prayer.¹⁰

At the same time that this work has been progressing, however, it has become clear that in the lived experience of CAM patients and practitioners there is a complex set of transactions that also contribute to the value that patients receive from CAM therapies. These transactions need to be studied as well. Patients and practitioners themselves have conceptualizations of what is important to them about the CAM approaches, but for the most part their views have not been fully translated into the research paradigm. Features that we need to study if we are to fully understand what is occurring in CAM include patient expectations, patient and practitioner perspectives on outcomes, individualization of treatment, the patient-practitioner interaction, practitioner characteristics, and the novel explanatory models of the CAM systems being studied. Population-based surveys in the US,^{11,12} that show increasing levels of CAM use and satisfaction among the public, underscore the need for research that can begin to account for the reported patient satisfaction with CAM therapies.

Two papers on patient-practitioner interaction in the AT supplement referenced above^{13,14} provide excellent overviews and point to the need for additional focus and research in this

area. Features such as patient-practitioner interaction and patient expectations have occasionally been considered in studies of biomedicine, but these and many other features of the healthcare interaction and setting are all too often lumped under the catch-all term, “non-specific effects.” Currently, there is growing scientific interest in the placebo effect (one component of the non-specific effects), as exemplified by the National Institutes of Health’s request for applications to research placebo mechanisms and recent books on the subject.¹⁵

As these topics become legitimate areas of inquiry, the need to examine the overall impact of a whole system of health care on a wide variety of patient and system outcomes has become apparent.⁶ However, only a small portion of the research currently funded by the National Center for Complementary and Alternative Medicine (NCCAM) falls into this category.¹⁶

This multivariate conceptualization contrasts starkly with the assumptions underlying the two cornerstones of modern medicine: epidemiology and classical randomized controlled trials (RCTs). Epidemiologic studies tend to look at factors 1 at a time; the emphasis is on finding the strongest predictors of particular outcomes (generally diseases). Epidemiologists readily admit that interactions of multiple factors are indeed extremely important, but very large studies are needed to detect such interactions, and few studies have the power to explore them.

In RCTs, the outcome examined is often a shift in the group mean of a particular parameter such as blood pressure or cholesterol; less frequently it is percent of individuals who develop (or recover from) a particular condition. The model is to deliver the same treatment to many people, and look for the average effect. The desired outcome is new practice guidelines for biomedical practitioners. The intent to treat analysis is required for good science, and analyses by level of adherence to the intervention are considered at best less important, and at worst, misleading. Sub-group analyses that seek to understand who benefits most or least are often discouraged by grant reviewers or journal editors as being contrary to the spirit of RCTs. There are several good reasons why these rules have evolved over time, particularly in relation to developing treatment guidelines. But the underlying trial philosophy is to determine a single best treatment for all patients, rather than individualization of treatments to particular patients. The new emphasis on genomics may begin to move conventional medicine toward individualization as treatments are increasingly understood to vary in their efficacy by each patient’s genomic constitution.

CAM practitioners, however, often have a more complex conceptualization of individualization than is suggested by genomics. By individualization we are referring to the way in which CAM medical systems conceptualize patients as having unique combinations of features that derive from the patients’ genetic inheritance, lived experience, and current state. Some examples of frequent types of individualization include individualization of diagnosis and complex treatment for each patient, often including the patient state at that moment in time; patient-practi-

tioner interaction specific to the dyad (different practitioners might legitimately treat the same patient differently depending on what they bring to the consultation); and patient-practitioner-treatment interaction with the broader context (different treatment approaches may be chosen depending on contextual factors for the patient). These situations are highly multivariate and complex for the most common methods of research; however, these are characteristics of the situations in which patients “heal.” In US clinical practice, biomedical practitioners also individualize their approaches under the rubric of the “art of medicine.” However, even that term suggests that the process is less prestigious (and therefore presumably less important) than the “science of medicine.” In contrast, Canadian family medicine has adopted patient-centered care as a model of practice, expressed in 6 guiding principles: 1) exploring both the disease and the illness experience, 2) understanding the whole person, 3) finding common ground regarding treatment/management, 4) incorporating prevention and health promotion, 5) enhancing the doctor-patient relationship, and 6) being realistic in terms of what a single practitioner can reasonably expect to achieve in providing patient-centered care.¹⁷

CAM provides a particularly fruitful venue for beginning to articulate how whole systems of healthcare work. There are several reasons for this; we provide 2 as examples. First, CAM whole systems often appear strange in 1 or more ways to Western-trained scientists and patients alike. Anthropologists have long counseled their students to study foreign cultures in order to see the features of their own societies that they take for granted. Indeed, many students of foreign languages have found themselves better able to understand the structure of their native language by contrasting it with the new one they are studying. We would argue that by studying CAM whole systems, we might better come to understand how healing and curing occur more generally. The features of many CAM systems, ranging from treatment modalities to diagnostic tests to the interaction of patient and practitioner, look sufficiently different from conventional medicine to Western researchers that they appear in high relief. In other words, they appear so out of the ordinary as to be amenable to examination, while their biomedical counterparts have become so much a part of everyday life as to be invisible. Furthermore, CAM features often look strange to the patients themselves. This phenomenon provides an opportunity to better understand the role certain characteristics such as patient expectations or the adoption of a new or different explanatory model play in healing. A second advantage is that the presence of multiple CAM systems for study allows the comparison of multiple whole systems with quite different features. This permits the development of an understanding of the similarities and differences for patients, practitioners, costs, and outcomes of wide practice variations at multiple levels, whether for the comparison of intact or whole systems, or for the evaluation of components. Now seems to be an optimal time to begin to fully understand how whole systems of health care function. Patients are seeking CAM practitioners to meet needs apparently not met within the mainstream healthcare system. What are in fact those needs? What outcomes are patients seeking? Are they finding them? What can we learn from CAM sys-

tems that can help to explain the numbers of clinicians and nurses leaving biomedical practice and taking up CAM disciplines?

Key Research Issues within Whole Systems Research

Through 3 rounds of questions and answers in the Delphi process before the workshop convened, the participants began to identify several important components of whole systems research requiring further attention. They included development of appropriate research designs and data analysis to address questions at the level of the intact whole system, as well as research on key components of patient-practitioner-treatment interaction, context, diagnosis and treatment, and patient and practitioner perspectives (particularly in relation to outcomes). These issues are described separately in more detail below.

The need for appropriate designs and analysis strategies: Workshop participants pointed to the need for methodologies to study intact whole systems. They called for the further development of designs that would permit the assessment of “whole systems” in such a way as to move toward understanding them as complex adaptive systems. In this way, WSR would begin to address issues such as emergent system behaviors, and whether there is synergy (or antagonism) among the features of systems.⁵

WSR also calls for attention to the features mentioned above—patient-practitioner-treatment interaction; context; diagnosis and treatment issues; patient and practitioner perspective—in relation to any whole systems design utilized. These features may be evaluated using qualitative research within a more standard trial design, or may be explicitly controlled in some way, or may be the focus of observational or experimental studies.^{18,19} Further, the concept of “model validity” should always be a central feature of CAM study design. According to Lewith et al,³ model validity “assesses the likelihood that the research has adequately addressed the unique theory and therapeutic context of the CAM system.” Because each of these dynamics will directly affect the design as well as outcome measurements, they should be explicitly addressed.

The WSR workshop identified data analytic strategies as an area of interest and work for future meetings. Participants recognized the need to utilize the concepts of systems science in WSR to facilitate the understanding of both discrete components of CAM whole systems and of the systems themselves. Experts in the quantitative sciences (biostatistics, biomathematics, systems scientists) have historically modified and developed quantitative methods to address new design challenges as they emerge at the forefront of scientific inquiry.²⁰ Their participation in WSR will be central to moving forward in this new focus of inquiry.

Studying interactions of patients and practitioners: Two papers from the recent Samuelli Conference expand on this topic specifically in terms of patient-physician¹⁴ and patient-nurse interactions.¹³ The Miller et al. paper provides a rich detailing of the variables that can influence this interaction and its outcomes, while the Quinn et al paper examines the dynamics of the interaction itself within the context of nursing. The broader literature in the area of patient-practitioner interaction

to date has largely focused on psychotherapy, where the “therapeutic alliance” between therapist and client is consistently found to be the most powerful predictor of outcome across many different psychotherapeutic approaches.^{13,14} The same depth of research has not been undertaken with regard to other types of healing encounters.

WSR suggests that the patient-practitioner dyad must become a major focus for the understanding of healing, including what both practitioner and patient bring to the encounter. Examples of variables for practitioners include their personal experiences, their individual syntheses of modalities, their training paradigms, and also their personalities and styles. Examples of variables that may be explored for patients would include personal health history (including mind, body, spirit, and experiences with other practitioners), expectations, and knowledge of their own bodies. WSR also highlights the need to understand the healing encounter itself, a topic discussed in some detail by Quinn et al¹³. This includes patient-practitioner interactions at several levels, such as the energetic level, personality, and the patient’s story. Once an encounter has concluded, both practitioner and patient have changed, and their future interactions will be different in some way. Both exit the healing encounter having learned something new, having changed in some way, whether that change is small or large. To understand healing and to comprehend why people change their behaviors and/or self care, it will be necessary to investigate how changes and learning occur in the healing encounter, and their ramifications in the lives of both patients and practitioners.

The Healthcare Environment: The context for the interaction of patient and practitioner is often ignored in biomedicine, but some aspects of it become more visible in the study of CAM. In the current environment of American healthcare, the stress practitioners face in their work environments is increasingly well documented. Recent papers^{13,14,21} clearly highlight the issues for practitioners. As examples of context, CAM practitioners have traditionally worked in solo practices, small group practices, or within their teaching institutions, in physical environments often managed in a conscious way to promote a feeling of peace and healing. As health care plans increasingly employ CAM practitioners to deliver service in mainstream health care facilities, it becomes possible to study the effect of this aspect of context on CAM practice outcomes. These shifts in practice patterns offer natural experiments to learn more about the role of context in healing. Miller et al¹⁴ provide rich detail on the features of context that may affect healing outcomes. These features can readily become the targets of research, once there is an orientation to their potential importance.

Understanding and measuring CAM diagnoses and treatment decisions: Research on CAM practices has been hampered by the lack of systems for coding CAM assessments and treatments, although recent development of such a system should open the door to more efficient observational research (Alternative Link, Inc. 2003). CAM diagnosis/assessment frameworks frequently differ from biomedical systems, although sometimes the same terms may be used. The requirement in CAM WSR is to look carefully at those frameworks as they articulate with the other features of the

system. It is important to evaluate the consistency of diagnosis between practitioners evaluating the same individuals at the same point in time, and to understand the sources of differences where they exist. As scientists studying CAM move toward fastidious trials, they are utilizing dual diagnosis (biomedical and CAM diagnosis) and randomization within CAM diagnostic strata. This design presumes, however, that diagnoses are unique to patients rather than also a function of the practitioner or the patient-practitioner dyad. We hope the new emphasis on fastidious trials will promote a series of research projects that examine the nature of diagnosis and treatment within CAM settings. This would allow us to more deeply understand the sources of variability and the negotiations that occur in the real world.

Choice of study outcomes: Much of the available biomedical research literature focuses on technologically defined (“hard”) endpoints. Exceptions include quality of life measures, and outcome measures for pain studies. In both of these categories, the data source is patient self report. Scientists trying to improve measurement characteristics and decrease patient “bias” often include functional measures that relate patients suffering to alterations in their ability to carry out daily functions. The WSR workshop endorsed the call for outcome measures based more closely on patient-held values. What are patients seeking when they come to CAM practitioners? What outcomes do they experience that cause them to continue receiving treatment? One type of outcome discussed at the workshop was “unstuckness,” the quality of life change that occurs when patients begin to do the things in their lives that need to be done but have previously seemed overwhelming or impossible. Workshop attendees reported observing this outcome across a range of CAM modalities, and some²³ are moving to develop a measurement instrument for “unstuckness.” Quinn et al¹³ in their paper provide a table of some measurement instruments relevant to these outcomes of value to patients.

Next Steps

The issues raised in the preceding paragraphs point to research challenges for the future and obvious next steps to be taken. Two key challenges are widening the network of individuals doing work within this emerging field and/or interested in beginning to work in this area, and developing a common language to facilitate progress. This paper is a step in widening that network. Interested scientists should contact any of the authors, or others who attended the workshop (see list in acknowledgments). Through sharing research experience in research papers, at professional meetings and anticipated future workshops on WSR, scientists will continue to move the field forward, especially through development of definitions and common language, borrowed as appropriate from systems science and other disciplines. We hope that past and current projects developed from more standard perspectives will yield additional analyses from WSR viewpoints. Literature reviews and reanalysis of qualitative data will provide new insights regarding many of the issues presented above, especially in regard to outcomes. As the design challenges presented listed begin to be met, new ones will appear. These experiences

will help to refine our notions of what is needed and what is possible in whole systems research. The key will be to focus on the development of methods that allow us to investigate both the whole system as well as the components of the system in context.

Acknowledgment

We would like to acknowledge the financial support of the National Center for Complementary and Alternative Medicine (NCCAM), NIH grant #1 R13 AT00956-01, the Institute of Health Services and Policy Research in the Canadian Institutes of Health Research; Kaiser Permanente's Center for Health Research (Portland, Oregon), the National Health Products Directorate, Health Canada; the Cancer and CAM Team of the Socio-behavioural Cancer Research Network (Canada), the Lotte and John Hecht Memorial Foundation (Canada); and the Hospital for Sick Children Foundation (Toronto, Canada).

We thank Theodore de Bruyn for serving as facilitator and rapporteur, and Deirdre Steinberg and Mikel Aickin for their editorial review and support. The Whole Systems Research Workshop Planning Committee includes: Cheryl K. Ritenbaugh, PhD, MPH, Kaiser Permanente Center for Health Research (Portland, OR); Marja Verhoef, PhD, University of Calgary (Calgary, Alberta); Susan Fleishman, BA, Kaiser Permanente Center for Health Research (Portland, OR); Heather Boon, PhD, University of Toronto (Toronto, ON); Ann Leis, PhD, University of Saskatchewan (Saskatoon, SA). The WSR working group includes: Mikel Aickin, PhD, Kaiser Permanente Center for Health Research (Portland OR); Iris Bell, MD, PhD, The University of Arizona Health Sciences Center (Tucson AZ); Lea Bill, RN, First Nations & Inuit Health Branch, Health Canada (Millerville, Alberta); Carlo Calabrese, ND, MPH, National College of Naturopathic Medicine (Portland OR); Ron Chez, MD, Samuelli Institute (Corona del Mar, CA); Barb Findlay, RN, BSc, Tzu Chi Institute of CAM (Vancouver, BC); Peter Fisher, MD, London Homeopathic Hospital (London, UK); Richard Hammerschlag, PhD, Oregon College of Oriental Medicine (Portland OR); Christine Harrison, PhD, Hospital for Sick Children Foundation (Toronto ON); John Hoffer, MD, PhD, Lady Davis Institute for Medical Research, Montreal, PQ; George Lewith, MD, Royal South Hants Hospital (Southampton, UK); Robin Marles, PhD, Brandon University (Brandon, MB); Dieter Melchart, PhD, Technical University of Munich (Munich, Germany); Richard L. Nahin, PhD, NCCAM/NIH (Bethesda, MD); Bonnie O'Conner, PhD, Brown University (Providence RI); Janet Quinn, PhD, RN, FAAN (Boulder CO); Jeffrey Quon, DC, (Vancouver, BC); Ron Rosenes (Toronto, ON); Rosa N. Schnyer, LAc, Osher Institute, Harvard Medical School (Cambridge MA); Karen Sherman, PhD, Center for Health Studies (Seattle, WA); Michael Smith, MRPharmS, ND, Natural Health Products Directorate, Health Canada (Ottawa, ON); Joseph Tai, MD, Children's and Women's Health Centre of British Columbia (Vancouver, BC); Carmen Tamayo, MD, Foresight Links Corporation (London, ON); Kate Thomas, PhD, University of Sheffield (Sheffield, UK); Heather Throop, Natural Health Products Directorate (Ottawa ON); Sara Warber, MD, University of Michigan (Ann Arbor, MI).

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