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Title Page

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Abstract:

This paper looks at the way that healthcare is changing as evidence-based medicine is incorporated into education and practice. It considers the hierarchy of evidence, the validation of evidence for decision-making and the extent to which this includes aspects of cultural and social constructs of health. The paper looks at the influence and the methodology of EBM as it is applied to CAM, and suggests that there is an uneasy relationship as the two approaches to health have divergent understandings of health and evidence. There are fundamental philosophical and epistemological differences between orthodox and complementary medicine and it is suggested that EBM is limited in how it can be applied to CAM. The paper questions how the two approaches to healthcare can work together to create optimal outcomes in practice.

The movement towards evidence-based practice underscores the division between biomedicine and CAM. Historically there has been little scientific research done in CAM, largely because of its place as a 'fringe' profession. Most research is funded by private sector interests who might see the economic benefit of a certain procedure or product. The research culture that has developed has been one that emphasises an evidence-based approach to establishing the efficacy of single herbs and nutrients, which overlooks the way that complementary therapists use these substances. The paper concludes with a concern that the relationship between evidence-based medicine and complementary medicine may become unbalanced, and the proponents of one system ignore or dismiss the values of the other. This lack of cross-paradigmatic respect is the wellspring for division and suspicion that is currently permeating the arranged marriage between CAM and EBM.

A change has been happening in healthcare practice in the Western world over the last 10 years. It is the concept of evidence-based medicine (EBM) and it is profoundly influencing the way healthcare is practiced, taught, funded, researched and reported. The enthusiasm with which it has been embraced is reflected in the literature. In 1992 there was one Medline citation for EBM, in 2004 there were over 13,000 [1]. This paper examines the implications for complementary and alternative medicine (CAM) and the uneasy marriage between divergent philosophical approaches. The skill set of the CAM practitioner is built on an empirical basis and lengthy tradition. The EBM approach is positivist, relying heavily on evidence recognised as scientific. Imposition of one model over another inevitably causes friction and raises necessary debate, including the question: is this advance part of the endless quest for excellence in practice or a covert power struggle?

Evidence–based practice (EBP) is a methodology for decision making in clinical practice, a way of coming to terms with the vast quantity of research information produced. Evidence-based medicine (EBM) refers to the use of evidence, particularly quantitative research data, as a basis for decision-making about the efficacy of interventions in clinical practice. It is described as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" [2]. Evidence-based medicine describes finding the 'best quality' information about treatment, with reference to a hierarchy of evidence it regards as applicable in practice. The golden mean for establishing authority of treatment is the randomised-controlled trial (RCT) and at the

bottom of the list is the clinical anecdote … "knowledge gained from the clinical experience of the practitioner" [3].

The designated hierarchy of evidence is a grading of research findings that identifies those most likely to encompass the "truth" (i.e. it rates the statistical reliability) of a particular intervention and in particular recognises study design as a way of reducing bias. The randomised controlled trial (and increasingly the systematic review and the meta-analysis) are regarded as the most methodologically sound ways of establishing evidence for practice.

This development in healthcare practice has emerged as a way of coming to terms with the volume and complexity of research information available to clinicians. It is seen as a way of encouraging the critical appraisal of clinical evidence for its 'validity' and 'relevance' to clinical problems. Clinical epidemiology, as it is known, has established itself not just as a way of maintaining life-long learning, but has also become a way for health services evaluation teams to monitor and manage the distribution of health funds.[4] More than that, evidence-based practice has become a by-word for establishing knowledge in all arenas of life.

The National Health and Medical Research Council (NHMRC) grades evidence (or research findings) according to level, quality, relevance and strength. The NHMRC defines these as follows:

Level of evidence:	Study design used as an indicator of the degree to which bias has been eliminated by design
I	evidence obtained from a systematic review of all relevant randomised controlled trials.
II	evidence obtained from at least one properly designed
	randomised controlled trial.
III-1	evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III-2	evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies, or interrupted time series with a control group.
III-3	evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
IV	evidence obtained from case series, either post-test or pre-test and post-test.

(Taken from A Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines, NHMRC Publications, Canberra, 1998.p8)

Evidence-based medicine has become profoundly influential in healthcare worldwide in the last decade. It has been enthusiastically supported and advocated by members of the medical profession, healthcare policy makers and researchers. There is, however, debate about blanket acceptance of this system of evidence review and its implications for practice. The ethical, philosophical and sociological positioning of EBM has been questioned [5]. Some raise questions about the shift from the authority and experience of the practitioner to the authority of the RCT, others argue that the "methods for obtaining knowledge in a healing art must be coherent with that art's understanding of and theory of illness" [6] .

As Willis and White comment: "EBM, as a methodology, privileges certain kinds of evidence over others"[7]. They argue that the EBM approach to medicine sidelines disciplines such as public health and the social aspects of disease that are explored by social epidemiology. It is suggested that the view of scientific knowledge on which EBM is based is an "impoverished account of scientific knowledge" [8]. EBM excludes almost all qualitative research and includes evidence based largely on robust, reproducible, statistically supported studies. Whole disciplines and fields of knowledge are thus excluded from EBM as being 'untestable' or 'unreproduceable'; or not part of clinical treatment – in the case of the social, cultural and psychological aspects of disease. There are specialties within biomedicine which find the EBM approach 'impoverished' in much

the same way as CAM does. Family medicine and pediatrics in particular value the psychosocial and cultural aspects of medicine, as do many individual medical practitioners in all specialties. It would appear that the application of EBM to practice amounts to a furthering of the reductionist view of illness. What can be measured exists and therefore is suitable to be dealt with by treatments that fit easily into prescribed scientific protocols.

In the absence of randomised controlled trials, EBM advocates the use of "the best available scientific evidence". This is the theoretical perspective however the reality is different as Richardson reports:

"the pressure to adopt the "gold standard" (high level evidence) of randomised controlled trials and systematic reviews is overwhelming" [9].

Biomedicine and CAM: the nature of CAM knowledge

The movement towards evidence-based practice underscores the division between biomedicine and CAM. Historically there has been little scientific research done in CAM, largely as a result of its place as a 'fringe' profession. Most research is funded by private sector interests who might see the economic benefit of a certain procedure or product. Until the huge uptake in CAM services and products in the latter half of the twentieth century [10.11] , monies did not flow into research in CAM. The research culture that has developed has been one that emphasises an evidence-based approach to establishing the efficacy of single herbs and nutrients, which overlooks the way that complementary therapists use these substances [12].

However, the underpinning of complementary therapies practice is a holistic approach to the patient which understands the complexity of illness and focuses on the social, emotional and spiritual aspects of disease as well as the physical basis of illness [13].

The developing research culture is thus reinforcing an evidence-based approach to the profession that is narrow in its focus and ignores both the kinds of knowledge that have predominated within most complementary therapies disciplines in the past, and the way in which complementary therapists practice. Researchers of CAM from biomedicine ignore the challenges of exploring CAM on its own terms, in favour of what is described as a 'scientific' approach to its knowledge base.

The argument that CAM is unscientific stems from more than a historical difference. Debate concerning the use of EBM by CAM is not just about methodology. There has been much discussion about the adoption of EBM into CAM teaching institutions and what the ramifications are for teaching CAM [14,15]. The rise of EBM has re-ignited the discussion between biomedicine and CAM about the nature of CAM knowledge and about how this kind of knowledge should be regarded. It also brings to issue the balance between an approach to healthcare that is based on a reductionist view of illness causation and treatment and one that is based on a more inclusive view of the many factors that influence heath.

What is not made explicit in the suggestion that EBM should be used as the prime method of validating CAM practices is the conflict that exists between these two professions with such dramatically different ways of knowing. The Western biomedical tradition has an authority that is built on a construct of scientific knowledge that is not just the dominant force in medical thinking, but also is the dominant way of knowing in Western societies.

It has been argued that the protocols used by EBM (e.g. population based studies) are not suited to a profession whose epistemology is based on the context of the individual. [6.8] We argue that the location of EBM within the positivist paradigm means that the "social, cultural and biographical features of the individual are swept away" and further posit that the push for EBM is a paradigm shift and attempt by the dominant paradigm to co-opt the practices of CAM by neatly avoiding any philosophical bedrock of practice.

This difference in theoretical approaches has been used to call CAM into disrepute as 'unscientific' and has contributed to the low regard in which the profession has been held by proponents of biomedicine [16]. However, Pelletier [17] asserts that conventional medicine is not grounded in EBM and notes that 'as much as 20% to 50% of all conventional care and virtually all surgery has not been evaluated by RCTs'. The successes of complementary medicine may be legion; they are also to a large degree anecdotal. Richardson [9] points out that that the evidence base is limited, as there simply haven't been enough studies done. The oral tradition and 'folksy' culture of reporting may have kept the authenticity of purpose that pervades complementary health

professions but has also worked to hinder acceptance of the profession by orthodox medicine.

Mills et al. [18] argue strongly for the importance of developing an EBM culture in CAM in order to integrate the profession into the healthcare system, and to be able to have subsequent influence upon health policy. There are barriers to this ambition situated in the divergent philosophies of CAM and Western medicine.

When there is no evidence

When using EBM as a way of appraising the research on complementary medicine, it is often the case that RCTs about specific treatment approaches or medicines have not been performed. This has a number of consequences. Many commentators conclude that there is no evidence to support the use of a particular complementary therapy or medicine. It is more accurate to say that no research has been conducted and that it is unknown whether a medicine or therapy is effective in a particular situation.

Other conclusions that are drawn from the lack of RCTs in a particular area may be the suggestion that a particular therapy is ineffective or dangerous. Again, not a conclusion warranted by lack of research. A further extrapolation by EBM of the lack of research in the field of CAM is the suggestion that it is only ethical to use a treatment approach for which there is evidence [19]. There is a history of medical practitioners who have used CAM being charged with medical incompetence, despite the lack of evidence of harm or even in the absence of medical complaints. [20]

These are the kinds of problems that arise frequently in an area as vast as complementary medicine and one that is so recently researched. While there has been a burgeoning interest in complementary medicine in the last 15 years, the amount of research done since then barely touches the surface in terms of answering the questions that remain unanswered about usage, tradition, and practice of complementary therapies. Developing an adequate 'evidence-base' about efficacy is important, however the philosophical context of practice is a salient feature and paring it away in the interests of scientific efficiency gives a very limited view about why a practice/protocol might work. As one supporter of the teaching of EBM to complementary medicine students admits, there is a significant gulf in philosophical contexts:

> "A more difficult barrier centers on the divergent philosophies between CAM and mainstream medicine regarding the pathophysiology and diagnosis of disease. This is an area that must be more thoroughly understood. In order to do so, methods for testing the philosophical bases of CAM diagnoses and etiologies must be developed. The philosophic elements of CAM therapy and diagnosis cannot be underestimated as a barrier. Many students and practitioners of CAM have invested a great deal of personal, intellectual and physical capital in learning these approaches to disease. It is unclear, in these cases, as to how much or how pervasive the evidence would need to be to convince them to forego particular therapies."

(Mills E et al. Teaching EBM CAM : 1 A learning structure for clinical decision changes. Journal of Alternative and Complementary Medicine 2002;8(2): 207-214.)

For complementary therapists the concerns that arise here are about the difference between what biomedicine wants to know about complementary medicine and what complementary therapists want to know about their own therapies and practice. There is a distinct difference between what kinds of knowledge are valuable to these two different professional groups and what kinds of questions they want answered.

EBM and evidence

The use of 'lower' quality evidence (as designated by the hierarchy of evidence) when RCTs are not available is generally advocated but there is little agreement on the value of the kinds of information that predominate in the area of complementary medicine. For complementary medicine this is particularly problematic. Much complementary medicine practice has derived from folk and oral traditions [21]. While this traditional knowledge has contributed greatly to the expertise of large numbers of practitioners over extended periods (sometimes thousands of years), the worth of this is barely recognised by EBM (it is sometimes included as Level IV evidence, sometimes as level V).

This devaluing of traditional knowledge is also a considerable problem for generations of practitioners still in practice whose education has consisted principally of empirical teachings of this kind and for the complementary therapies disciplines such as Traditional

Chinese Medicine (TCM) and Western herbal medicine who base their practice on this kind of information [12]. The core content of disciplines such as naturopathy, herbal medicine and TCM is based in empirical clinical experience. If these kinds of evidence are ignored many complementary therapists would be ignoring the current basis of their practice knowledge [9,12,14,18,21] .

One of the problems encountered in the practice of EBM by both orthodox and complementary practitioner is the reliance on epidemiological knowledge for treatment of the individual. The tension here is between the nature and the quality of scientific evidence and the complexity of the information required to make clinical judgements [22] . As Feinstein and Horowitz argue, the difficulty with evidence-based medicine for the clinician, is that the randomized controlled trial and the meta-analysis create data which is relevant to the 'average patient'. There is often a lack of information to guide the clinician when it comes to the individual the clinician actually sees in practice. A whole range of clinical variations such as the severity of illness, concurrent presenting conditions, and the specific clinical presentation of the patient, the so-called 'soft data' which contributes to clinical judgements, is rarely the subject of randomized controlled trials [22] .

An area that patients have acknowledged complementary medicine as being particularly useful, is pre-clinical disease that is, disease not clearly diagnosed by pathology tests.

This kind of disease is described by White and Willis as "the patient who presents without indicative symptoms or with atypical pathology of an underlying disease (page 10)" [8]. Complementary therapists recognise the wide area of 'unwellness' that precedes disease and indeed treat these kinds of conditions particularly well. However this is exactly where the lack of confirmed pathology and the failure to diagnose a specific disease 'disables' the use of EBM by the complementary therapist. Disease is described and categorized in different terms by epidemiology, by the orthodox physician in clinical practice and again by the complementary therapist (whose diagnostic methods and disease classifications are not those of orthodox medicine).

In addition to this many complementary therapists recognise that what is valuable about their style of practice is the fact that they allow patients the time and place in which to voice "the narrative of their illness". Kleinman [23] explains that the therapeutic relationship becomes an opportunity to explore the meaning of their illness and to develop an interaction that is empowering, offering them the opportunity for new perspective and insight. This is an aspect of practice also recognized as valuable by many biomedical practitioners but something which is absent from the EBM approach.

As stated, what is considered good practice in EBM is combining current best evidence with the individual practitioners' clinical experience and the patients' preferences, to provide advice that uses best evidence along with these vital clinical elements. However, the significance of the diverse elements that contribute to clinical decision-making for both biomedical practitioners and for complementary practitioners (traditional

knowledge, clinical experience and patients preferences) is often downplayed or ignored by EBM. [22.23]. Clinical judgements are often derived from exploring the social and cultural context in which the patient experiences their illness and this information may produce different questions and different answers to the questions that may be asked by a RCT performed in an isolated clinical setting [22] . How is this dilemma resolved by EBM? Can EBM draw together these two sources of knowledge give them both credence and unite them in an approach to medicine that is inclusive rather than exclusive?

We have identified three fundamental characteristics of CAM that make the marriage of CAM and EBM an uncomfortable one. The epistemological basis of CAM as a holistic approach to both illness and health encompasses a much broader view of health illness and causation than can be tested by EBM. CAM is based on the fundamental premise that there may be a range of factors contributing to disease and these may be social emotional spiritual or physical. Such a multi-factorial approach to illness lies beyond the scope of a purely evidenced based approach. Secondly the kind of knowledge used by CAM relies on traditional and empirical sources and this kind of knowledge based in experience is accorded little recognition in the EBM hierarchy. Thirdly, in CAM healing is seen a process rather than an endpoint and this more subjective view of illness mitigates against the use of a narrow evidence based approach.

So why is CAM so eager to attach itself to evidence-based practice when CAM and EBM seem such uncomfortable partners? And why is orthodox medicine so keen to evaluate CAM with the narrow range of tools offered by evidence-based medicine? Perhaps there

is a hint in what Lundberg and Fontarosa say: “There is no alternative medicine. There is only scientifically proven, evidence-based medicine supported by solid data or unproven medicine, for which scientific evidence is lacking” [24] . The answer lies somewhere with the authority that has adhered to evidence-based medicine as a concept. The adoption of EBM has been rapid and as many have commented, overwhelming. It has gained this authority with ease because its precepts suit the current power structure in medicine and more widely in modern western society [7] .

For a marginalised profession like CAM, one that is often described as being invisible, EBM brings the mantle of respectability; and the potential of money for research [7]. By describing complementary medicine as evidence-based, the complementary health professions are aligning themselves with the power and authority of the current ideology in medicine and society. By allying itself to EBM, CAM may hope to win the recognition and authority associated with conventional medicine.

Conversely for orthodox medicine one of the better ways of co-opting a profession whose practice is so radically different from its own, is to judge it by the standard of science and find it wanting. EBM is the perfect tool. Evidence-based medicine is symptomatic of a way of thinking which has developed in order to shore up a certain philosophy of medicine. If we consider that healing is a social exchange [25] it is interesting to look at the implications of the strong political and economic support given to the positivist construct of knowledge. When 'science' becomes the God of health then it is not surprising that there should develop a methodology that excludes, to a large degree,

experience and tradition, in favour of the laboratory based models of measure and management.

The increasing interactions between the two paradigms of healthcare (largely consumer driven) require a critical review of the overt and covert forces constructing the nature of the alliance. EBM offers to some proponents a simple, clear and logical guide to making treatment decisions and making practice more effective. To others it represents a co-option of complementary medicine, subtly and irrevocably changing the nature of the profession, rendering its philosophy superfluous, irrelevant.

The goal of greater efficacy in healthcare is agreed by all, but a partnership of healthcare practice needs to be inclusive, not exclusive. As Lewith, Jonas and Walach [26] point out, groups differ on what information is important to them and the difference "involves values, not science" (p4). To exclude a group because its values are different, is a kind of 'methodological tyranny' (p4). Both EBM and CAM can undoubtedly benefit from a more co-operative relationship, the culture of each informing the other. What is of concern is when the relationship becomes unbalanced and the proponents of one system ignore or dismiss the values of the other. This lack of cross-paradigmatic respect is the wellspring for division and suspicion that is currently permeating the arranged marriage between CAM and EBM.

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