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Conventional and integrative medicine – evidence based? Sorting fact from fiction

Kenneth R Pelletier

On May 14, 1796, Edward Jenner transferred material from a cowpox lesion on the hand of Sarah Nelms to the arm of James Phipps. What possessed him? He was motivated by the writings of poets who extolled the pock-free complexions of milkmaids by a decade of observing what happened to milkmaids during smallpox outbreaks. Fortunately, the boy showed immunity to smallpox and this bold experiment ushered in the vaccine era, which is today's foundation for public health vaccinations and inoculations world-wide. Virtually all of conventional and integrative medicine has evolved out of such clinical practice over time and is accepted as a standard of practice or discarded based on perceived efficacy.[1] Such a clinical focus is rather like the cumulative case studies forming the tort precedents in the practice of law. All clinical care involves adapting general guidelines, research findings and procedures or pharmaceuticals given to one particular individual, with a specific condition at one point in time. This constitutes the 'art' of medicine. Such a clinical approach does not easily lend itself to a randomised clinical trial (RCT), which represents the gold standard of biomedical research. Skilled clinicians virtually always report better patient outcomes than is documented in the research literature. Is this self-deception or testimony to the elegant accuracy of clinical judgement, especially in the clinical applications of alternative or integrative medicine?

At the root of this debate is a ubiquitous assertion that conventional medicine is grounded in evidence-based research while integrative medicine is not. That assertion is grossly inaccurate and this brief article is intended to defrock this assertion while challenging both conventional and integrative medicine to a higher standard. To provide a baseline against which to measure complementary and alternative medicine (CAM), it is important to point out that as much as 20–50% of conventional care, and virtually all surgery, has not been evaluated by RCTs. According to Richard Smith, editor of the *British Medical Journal*, 'Only about 15% of medical interventions are supported by solid scientific evidence... This is partly because only 1% of the articles in medical journals are scientifically sound and partly because many treatments have never been assessed at all'.[2] In 1998, James Dalen, Dean of the University of Arizona and editor of *Archives of Internal Medicine* focused on the evidence basis for cardiology which is often cited as one of the more empirical medical specialities. According to Dalen, in 1986 the American College of Chest Physicians rated the evidence base of cardiology from 'A' (large RCTs with positive results) to 'C' (non-randomised, no controls and/or case series). Only 24% of the therapies rated 'A' while 45% rated 'C'.[3] When this was repeated in 1998, 44% were rated as 'A'. Most recently, Brian Berman, coordinator of the Cochrane CAM reviews at the University of Maryland School of Medicine, took a random subset of 159 out of 326 completed Cochrane reviews of conventional medicine only.[4] These were sorted into six categories ranging from 'Evidence of Positive Effect' at 20.8% to 'Evidence of Negative Effect' or the treatment was more harmful than beneficial at 6.9%. Overall, the 'positive' to 'possibly positive' totalled 38.4% compared with 'no evidence of effect' to 'negative effect' totalling an

alarming 61.6%. Perhaps the most alarming statistic is that in the category of 'Evidence of Negative Effect': that figure stands at 6.9%, which represents common medical procedures that are known to have a negative effect and yet remain in common usage. To place that 6.9% in perspective, an article in JAMA in 1994 posited a minimum 'error rate' in medicine of 1%.[5] In that article, the author quotes the prominent business scholar W E Deming, who stated: 'If we had to live with about 99.9% (error rate), we would have two unsafe plane landings at O'Hare every day; 16 000 pieces of mail lost every hour, and 32 000 bank checks deducted from the wrong account every hour.' Surely, even 0.5–1% error rate is alarming and a documented 6.9% is intolerable. In addition, a frequently cited report from 1978 by the Office of Technology Assessment found that only an estimated 10–20% of allopathic medical interventions are empirically proven. That figure remains accurate nearly 25 years later.

Groucho Marx quipped, 'Be open minded, but not so open minded that your brains fall out.' There is probably no other area of research that generates such an acrimonious debate than between advocates versus critics of integrative medicine over 'evidence-based' medical practices. For brevity, consider the following findings (based on a January 2002 Medline Search) with regard to conventional medical practice and the percentage of common, everyday procedures based on rigorous RCTs (1st percentage) versus 'non experimental evidence' (2nd percentage):

1 General medicine in a UK District General Hospital at 53% vs. 29%[6]
2 General medical 'suburban' practice in the UK at 30% vs. 51%[7]
3 Acute adult psychiatry at 65% vs. no data on non-experimental evidence[8]
4 General psychiatry in the UK at 53% vs. 10%[9]
5 General medicine in Japan at 21% vs. 60%[10]
6 Regional paediatric surgery in the UK at 11% vs. 66%[11]
7 Surgical/vascular unit in a UK teaching hospital at 24% vs. 71%[12]
8 Haematology at 70% with no estimate on non-experimental evidence[13]
9 Tertiary referral paediatric surgical unit at 26% vs. 71%[14]
10 Dermatology in a Danish university hospital at 38% vs. 33%[15]
11 Internal medicine in Canada at 20.9% vs. no non-experimental estimate[16]
12 Eleven general hospitals in France at 50% vs. 28%[17]
13 Cancer centre in the USA at 24% vs. 21%[18]
14 Anaesthesia in Australia at 32% vs. 64.7%[19]
15 Twelve community paediatricians in the UK at 39.9% vs. 7%[20]
16 Tertiary cancer surgical centre in the USA at 14% vs. 64%[21]
17 General medical care at 34 primary care clinics in Spain at 38% vs. 4%[22]
18 Internal medicine in a Swedish teaching hospital at 50% versus 34%.[23]

Again, the focus here is upon conventional medicine only since advocates of an evidence-based approach consistently cite conventional practice as the gold standard. Therefore, it is entirely appropriate to gauge the standard that is clearly found to be grossly deficient in a rigorous evidence base.

Bear in mind that these studies and resulting statistics are compounded in their assertion by the fact that the 'non supported' percentages, or those practices that continue despite no evidence or actual evidence of harm, ranges from a low of 3% in a tertiary, paediatric surgical unit[14] to an alarming 58% not supported in the study of 34 primary medical care clinics in Spain.[22] One review cited many of these same studies but drew the opposite conclusion that, 'claims that conventional medicine is not widely based on evidence should be rejected, as should logically fallacious arguments based on such claims.'[24] Unfortunately, this act-of-faith conclusion is based on two fallacies. One is their faith in 'self evident interventions' or the non-experimental percentages that they assert are acceptable in conventional medicine and secondly that such self-evident interventions are 'probably not in alternative medicine'. Both assumptions are presumptuous at best and erroneously reinforce a double standard that fails the fundamental definition of evidence-based medicine. In contrast, insisting upon equally rigorous evidence-based standards, many alternative medicine interventions actually have a stronger evidence base than many conventional medicine practices:[1] in nautical terms, let all boats rise with the tide. This is not to diminish the necessity of rigorous standards in integrative medicine but to urge that both conventional and integrative medicine raise their 'evidence-based' standards!

One of the most widely accepted definitions of evidence-based medicine is offered by David L Sackett, as the 'Integration of individual clinical expertise with the best available external clinical evidence from systematic research' and 'without clinical expertise, (clinical) practice risks being tyrannised by evidence'.[25] This is a delicate and complex balance but is increasingly necessary. As but one instance in conventional medicine, clinicians have argued over the value of *Digitalis*, a commonly used heart medication for over 200 years! Advocates support its use to treat congestive heart failure (CHF), critics argue that *Digitalis* is toxic and should be curtailed. After a 200-year scientific and clinical debate, the *New England Journal of Medicine* published a study of over 7000 patients using *Digitalis*.[26] Although

Digitalis did reduce CHF hospitalisations by 8%, it did not reduce CHF death and more patients taking *Digitalis* died of lethal heart arrhythmias. This study by Milton Packer of the Columbia Medical School may finally relegate *Digitalis* to a second-tier drug only if newer medications, such as angiotensin-converting enzyme (ACE) inhibitors and/or beta-blockers, prove to be ineffective.

In contrast to these ubiquitously cited articles is the rigor of Cochrane reviews which empirical evidence suggests have, on average, greater methodological rigour than individual studies, systematic reviews, or meta-analyses published in peer-review journals according to Alejandro R Jadad and colleagues in a *Journal of the American Medical Association* article of 1998.[27] One frequent misconception of Cochrane reviews is that they exclude qualitative, non-experimental findings; however, that is not accurate. Although the Cochrane Collaboration is primarily a repository of RCTs, the approved protocols have and can include qualitative data and non-experimental case studies. There is growing interest in the contribution of such qualitative research findings to the health and medical care evidence base. Qualitative research is concerned with the subjective world. It offers insight into psychosocial, psychoneuroimmunological, emotional and experiential phenomena in health care to determine what, how and why such factors influence both health and disease. Therefore, findings from qualitative research may contribute to systematic reviews and reviewers need to consider how to incorporate them. There is potential for findings from qualitative research to enhance both the quality and relevance of systematic reviews and their applications to clinical practice and research. When framing questions, such findings can help to define the intervention more precisely and contribute to the choice of outcome measures. Qualitative research may also generate data on the subjective experience of an intervention to be included in a systematic review on an equal basis with quantitatively measured outcomes.

Finally, both conventional, CAM, and integrative RCTs need to fully acknowledge and incorporate the fact that patients, practitioners and procedures are complex, interactive, dynamic systems with other even larger and more complex ethical, philosophical, economic, and spiritual dimensions. It is well beyond the scope of this article to describe the specifics of advanced biostatistical techniques in quantitative research. However, the applications of advanced methods of biostatistical data analysis does enable investigators to evaluate a CAM system as an integrated whole within its own context. According to Iris R Bell and her colleagues at the University of Arizona School of Medicine, 'Path analysis (an extension of multiple regression), structural equation modelling (analysis that includes latent variables), and confirmatory factor analysis (a systematic analysis of the pattern of relationships among variables that attempts to explain that pattern in terms of a smaller number of underlying hypothetical factors) represent only a few of the examples applicable to this type of healthcare outcomes research. These techniques allow us to look at the complex relationships among many dependent and independent variables at the same time, consistent with the higher level of organisation in a complex systems theory model.'[28] By specifying paths by which specific variables affect others, then it becomes possible to demonstrate more explicit causal inferences. Through acknowledging the lack of 'evidence based' procedures in both conventional and integrative medicine and implementing RCTs with more innovative designs and biostatistical methodologies, the standards whereby all medicine should be judged will be raised for the benefit of both patients and practitioners.

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Kenneth R Pelletier, PhD, MD(hc) is Chairman of the American Health Association and is based at 1990 North California Boulevard, Suite 830, Walnut Creek, California 94596, USA. He is also Clinical Professor of Medicine at the University of Maryland School of Medicine, and the University of Arizona School of Medicine.