**Response from the European Herbal and Traditional Medicine Practitioners Association to Charity Commission’s Consultation “The use and promotion of complementary and alternative medicine”**

**Question 1: What level and nature of evidence should the Commission require to establish the beneficial impact of CAM therapies?**

There appears a general assumption that the majority of mainstream medical practice is firmly rooted in an established evidence base of clinical effectiveness. However, as an ongoing study published by the BMJ Journal *Evidence Based Medicine* demonstrates, this is not the case.

*Evidence Based Medicine* selects around 3000 treatments that have subject to research analysis and divides their effectiveness for specific indications into categories. The Journal regularly updates this data noting that it devotes considerable time on this assessment, calling on the knowledge of information specialists, editors, peer reviewers and expert authors, and revisiting its categorisations at each update. Its current on-line review[[1]](#footnote-1) is displayed below.



This pie chart shows that of the 3000 treatments only 11% are rated as beneficial, 24% likely to be beneficial, 7% as trade off between benefits and harms, 5% unlikely to be beneficial, 3% likely to be ineffective or harmful, and 50%, the largest proportion, as having unknown effectiveness. **These figures suggest that most decisions about treatments within conventional medical practice still rest on the individual judgements of clinicians and patients.**

An editorial in a previous edition of *Evidence Based Medicine* draws attention to a clear double standard which sees CAM therapies under fire for lack of evidence and contrasts this to the way conventional medicine is incorrectly portrayed as being largely supported by a secure evidence base.

“Is the concept of evidence-based medicine flexible enough? In particular, can it embrace interventions for which there is a long history of use, but a lack of hard research data? It should do, according to a famous definition published 12 years ago in which evidence-based medicine (EBM) was portrayed as ‘the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients’. This definition made allowances for missing or inappropriate evidence, and, crucially, required the application of clinical judgment and recognition of patient values. Today, however, there is a common, rigid mindset that equates EBM solely with the conclusions of randomised controlled trials and systematic reviews of these studies, to the exclusion of other 'best evidence' and the needs of individual patients. This simplistic thinking is being increasingly challenged by new moves to enhance the status of older, under-researched treatments: for example, the registration of herbal medicinal products by the UK Medicines and Healthcare products Regulatory Agency (MHRA).

When it comes to older treatments, there is often a gap between empirical evidence, clinical practice, and patient experience. Moreover, there are conspicuous double standards in attitudes to older treatments. For example, about half of all so-called conventional healthcare interventions continue to be used even though research on their efficacy is non-existent or equivocal. By contrast, traditional complementary and alternative therapies that have been widely used for many years and continue to be popular with patients are regularly dismissed out of hand on the grounds that there is little 'scientific' evidence to confirm whether they work.

There are also obvious problems associated with focusing entirely on published trial literature as the supposed basis for evidence-based practice. The efficacy studies that form the backbone of EBM represent only a small part of the total research literature, and may be of limited value in assessing safety. And, of course, most efficacy research is sponsored by the pharmaceutical industry and is drug orientated. Potentially valuable traditional medicines, non-drug interventions, or other aspects of health care receive much less attention. It is dangerous to assume that concentrating exclusively on published trials and systematic reviews at least identifies those interventions that have proven their worth to clinical practice. In reality, a good look through the Cochrane Library or other research databases reveals that the interventions and questions assessed by RCTs are often far removed from the real needs of patients and their healthcare professionals. This distortion reflects not just the selectivity of the research conducted, but also positive and negative publication biases. Examples include publication biases in trials of treatment for acute stroke, and also in trials of antidepressant drugs.

Less obviously, and more controversially, there are questions about whether the pharmacological randomised controlled trial model for research is sufficient to assess long-established interventions. One concern is that, because many of these interventions comprise several components, the individual effects of which may be hard to isolate and measure separately (e.g. palliative care, public health, or many complementary and alternative therapies), artificially standardising them to fit a drug-trial model may involve over-simplification. This will then raise questions about the real-world applicability of the study results. Accordingly, there is an argument for a different type of research strategy for long-established interventions, with a different order of priority...” [[2]](#footnote-2)

There is growing unease, referred to in this editorial, about the appropriateness of much conventional research to provide EBM. This concern was explored by Professor Sir Michael Rawlins, Chairman of the Medicines and Healthcare products Regulatory Agency (MHRA), in his Harveian Oration to the Royal College of Physicians in October 2008.[[3]](#footnote-3)

“The dispute about the evidential basis of modern therapeutics has become particularly apparent with the emergence, over the past 30 years, of what are known variously as ‘rules’, ‘levels’ or ‘hierarchies’ of evidence... Such hierarchies place randomised controlled trials (RCTs) at their summit with various forms of observational studies nestling in the foothills. They are used – as a form of shorthand – to provide some intimation of the ‘strength’ of the underlying evidence; and, particularly by guideline developers, to then ‘grade’ therapeutic recommendations on the basis of this perceived strength...

The notion that evidence can be reliably placed in hierarchies is illusory. Hierarchies place RCTs on an undeserved pedestal for, as I discuss later, although the technique has advantages it also has significant disadvantages. Observational studies too have defects but they also have merit. Decision makers need to assess and appraise all the available evidence irrespective as to whether it has been derived from RCTs or observational studies, and the strengths and weaknesses of each need to be understood if reasonable and reliable conclusions are to be drawn. Nor, in reaching these conclusions, is there any shame in accepting that judgements are required about the ‘fitness for purpose’ of the components of the evidence base. On the contrary, judgements are an essential ingredient of most aspects of the decision-making process....

Hierarchies attempt to replace judgement with an oversimplistic, pseudoquantitative, assessment of the quality of the available evidence. Decision makers have to incorporate judgements, as part of their appraisal of the evidence, in reaching their conclusions. Such judgements relate to the extent to which each of the components of the evidence base is ‘fit for purpose’. Is it reliable? Does it appear to be generalisable? Do the intervention’s benefits outweigh its harms? And so on. Decision makers have to be teleoanalysts. Although techniques such as Bayesian statistics will undoubtedly assist they will not be a substitute for judgement. As William Blake (1757–1827) observed: ‘God forbid that truth should be confined to mathematical demonstration’.”

A graphic example of the *reductio ad absurdum* of such an approach is demonstrated by an assessment of procedures employed in dentistry using 260 Cochrane reviews published in 2012. This concluded that on the basis of Cochrane systematic reviews *“the overall quality of evidence can be regarded as low or non-existent for most of the dental procedures assessed.”*[[4]](#footnote-4)

On the basis of this, would anyone seriously suggest that the Charity Commission should cease to support measures to advance the skills and procedures of dentists? If the answer is ‘no’, should CAM be treated differently?

It is evident that there are increasing concerns among the scientific and medical community about the way that evidence based medicine is being employed because it may:

* Undervalue clinical expertise and experience presenting a theoretical rather than ‘real world’ approach to clinical practice.
* Ignore patients’ values and preferences
* Promote a cookbook approach to medicine in which a particular treatment is promoted for a specific condition regardless of the individual presentation of that condition or the individual needs of the person seeking treatment. Although doctors have historically made care decisions on the basis of their own knowledge and experience, they are under growing pressure to adhere to guidelines as a way to improve and standardize care.
* Favour research over clinical experience whereas both are a valid means of coming to a decision about treatment. In truth, there are few trials for which the evidence is incontrovertible.
* In the absence of evidence from randomized trials, there is a tendency for patients to experience ‘therapeutic nihilism’ that fails to provide practical help based on clinical experience or emotional support.
* Fail to provide a holistic approach - taking account of the overall needs, circumstances and lifestyle of patients. Clinical guidelines providing evidence based medicine are designed to meet the needs of ‘average’ patients yet few patients fit such a description. Randomized clinical trials, held to be the scientific gold standard, often under-represent or exclude certain groups, such as minorities, children, the elderly and people with several coexisting medical problems. It is questionable as to whether such evidence should be used as the basis for establishing broad treatment protocols.

**Evidence for herbal medicine**

Herbal medicine has been practised by all peoples across the world since prehistoric times. This extraordinary wealth of experience amounts to a vast knowledge base stretching back millennia. Today the contribution of plants to disease treatment and prevention remains impressive. At the start of 21st century, 11% of the 252 drugs considered as basic and essential by the World Health Organisation were exclusively of flowering plant origin.[[5]](#footnote-5) Researchers also noted that, 80% of 122 plant derived drugs had a traditional medicine use identical or related to the current use by the pharmaceutical sector of the active elements of the plant.[[6]](#footnote-6) It is in the light of this historical experience that the European Traditional Herbal Medicinal Products Directive (2004/24/EC) recognises the validity of long traditional herbal use allowing “the registration of herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy, provided that there is sufficient evidence of the medicinal use of the product throughout a period of at least 30 years, including at least 15 years in the Community.”

There is a vast amount of research on herbal medicines published worldwide. As an example, Medline (Pubmed), shows over 50,000 citations for the search term “herbal” demonstrating the ongoing scientific interest in plant medicines. The mechanisms by which plant medicines achieve clinical effect are becoming increasingly clear. Scientific analysis reveals herbal medicines to contain a wide range of active constituents (e.g. polyphenols, saponins, alkaloids, tannins, essential oils, fatty acids, vitamins and trace elements) and it is through the agency of these naturally occurring compounds that herbal medicine takes effect. These constituents provide reliable plausibility for the use of plant medicines in helping to treat disease and maintain optimum health.

Published research demonstrates the potential of herbal medicines. A few examples are mentioned here:

* A recent (2017) meta-analysis (gathering together the overall results) of studies carried out on St John’s wort for depression reviewed 27 clinical trials with a total of 3808 patients, comparing the use of St John's wort and Prozac type antidepressants (SSRIs). The researchers found that St John’s wort has comparable efficacy and safety to SSRIs.[[7]](#footnote-7)
* Rosemary has been associated with memory enhancement since ancient times, a belief referred to by Shakespeare in Hamlet where Ophelia says, “There’s rosemary, that’s for remembrance.”(Hamlet, iv. 5.) A 2003 study demonstrated that rosemary oil and lavender oil could radically affect the memory of subjects who breathed in these aromas. While rosemary oil produced a significant enhancement of memory in the study’s participants, lavender exerted precisely the opposite effect.[[8]](#footnote-8) This 2003 study on the effect of these aromatic oils and memory was repeated in 2015 by doctors in the popular TV programme “Trust me I’m a doctor” with the same outcomes.[[9]](#footnote-9)
* A meta-analysis of the herb echinacea demonstrated a markedly positive response concluding “Evidence indicates that echinacea potently lowers the risk of recurrent respiratory infections and complications thereof.”[[10]](#footnote-10)

In the light of this we would submit that there is both plausibility and specific evidence for the use of herbal medicine in treating the sick and maintaining health. Charities that support the advancement of research and the practice of herbal medicine in its various traditions (Phytotherapy, Chinese herbal medicine, Ayurveda and Tibetan medicine) should be supported by the Charity Commission. A review comparing the quality and results of trials of Western phytotherapy (herbal medicine) and conventional medicine challenges the widely held belief that the quality of the evidence on the effectiveness of herbal medicine is generally inferior to the evidence available for conventional medicine.[[11]](#footnote-11)

Question 2: Can the benefit of the use or promotion of CAM therapies be established by general acceptance or recognition, without the need for further evidence of beneficial impact? If so, what level of recognition, and by whom, should the Commission consider as evidence?

We consider that the case we have made in answer to question 1 provides the sufficient level of evidence for the beneficial impact of herbal medicine to enable the Commission to support the development of herbal medicine practice.

Question 3: How should the Commission consider conflicting or inconsistent evidence of beneficial impact regarding CAM therapies?

As we have pointed out above there is conflicting and inconsistent evidence in evaluating conventional medicine treatments. Since these are supported by charitable foundations, CAM modalities in general and herbal medicine in particular should be treated in the same way and accorded similar support.

Question 4: How, if at all, should the Commission’s approach be different in respect of CAM organisations which only use or promote therapies which are complementary, rather than alternative, to conventional treatments?

Herbal treatment can sometimes be complementary and other times alternative. For example, there is evidence that herbal medicines can spare the use of conventional antibiotics in treating mild and moderate infections. A paper presenting data highlighting this potential was presented to the House of Commons Select Committee on Antimicrobial Resistance and can be accessed on the EHTPA website (<http://www.ehtpa.eu/>). In this case, herbal medicine is alternative treatment and provides a means of reducing the very real threat of antimicrobial resistance. The Charity Commission should support herbal medicine to help combat the growing menace of antimicrobial resistance as well as its potential in treating a range of other long-term conditions not particularly well managed by conventional medicine. Scoping documents outlining the evidence for herbal medicine to be used for a wide range of common conditions can be found on the EHTPA website (<http://www.ehtpa.eu/>).

Question 5: Is it appropriate to require a lesser degree of evidence of beneficial impact for CAM therapies which are claimed to relieve symptoms rather than to cure or diagnose conditions?

Symptomatic treatment seeks to alleviate the signs and symptoms of a medical condition for the comfort and well-being of the patient. However, it also may be useful in reducing consequences and development of the signs and symptoms of the disease. Relieving symptoms can oftentimes enable the natural homeostatic mechanisms of the body to bring about a cure. For this reason demarcation between symptomatic treatment and curing a disease appears an artificial construct. Herbal practitioners treat the whole person taking into account all relevant aspects of lifestyle and diet to help bring about resolution of an illness and to maintain health. Herbal practitioners undertake years of training which enables them to diagnose their patients and know when to refer on in the case of serious illness requiring conventional medical treatment.

Question 6: Do you have any other comments about the Commission’s approach to registering CAM organisations as charities?

No.

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