



Universitas 21

University of Nottingham
September 13th – 14th 2006



**“Complementary and Alternative
Medicine should definitely be
incorporated in healthcare systems on
the basis of cost effectiveness and health
effectiveness evaluations”**

To present an argument
against this motion.

Professor Kenneth Muir





Areas to consider

- Homeopathy
- Herbal Chinese Medicine
- Acupuncture



'The main weakness of the methods is that it does not take a scientific approach and can therefore be lacking in rigour'

- Results are not generalisable.
- Replicating the study might not be possible. This is largely because of its flexible approach that is determined by circumstance and organisational needs.
- It does not produce statistical data which might make arguing for increases resources and presenting results problematical.
- Results are not objective and are reliant on the interpretation of the individual carrying out the audit. This means that it relies heavily on the skills of the evaluator who may be carrying out the evaluation with little or no assistance from others.



The problems of RCT for TCM



Herbal drugs have been used by ethnic Chinese for more than 3,000 years but seems to be lack of systematic clinical evaluation on safety.

- Conventionally TCM decoctions are prepared at home by the patient or the family. Therefore quantitative and qualitative control become a problem.
- Decoction is prepared in an unscientific way, e.g. various amounts of water used, different temperatures and duration of boiling, the "age of the plant," (for plants and herbs, there is no expiry date).
- The patients invariably end up receiving different dosages of medicine each time, seriously affecting the therapeutic effect.
- It was postulated that in TCM many active ingredients work together, rather than one single ingredient
- Another difficulty encountered in the study of herbal medicines is that the actions of herbs are multiple.
- In TCM, one plant product is considered a single item in the prescription. But one plant product contains multiple pharmacological agents or chemical compounds
- Most people have little understanding of the proper way of preparing TCM. There are differences in the water soluble and oil or alcohol soluble decoctions.
- Some chemical contents in the plant vary in different plant cycle. Such characteristics render the study of herbs difficult. The dispensers in the herbal store should be aware of this, for better quality control.



Does acupuncture work?



- For acceptance in western medicine RCTs are normally required
- Several acupuncture treatment have now been evaluated by RCTs
- Problems remain for evaluating acupuncture in trials as the exact therapy is tailored individual patient
- **Please note** that RCT's are about 50 years old, while Chinese Medicine is 4500 years old, and there has only been adequate funding sources for alternative medicine research in the last 4 or 5 years.





Main things said by CAM and TCM practitioners

- “Can’t evaluate” - clinical judgement
- “Individual” patient
- Choice of products varies
- Combinations



National Health Service

“It is available to the whole population, and not only is it available to the whole population freely, but it is intended, through the health service, to **generalise the best health advice and treatment. It is intended that there shall be no limitation on the kind of assistance given**”

Aneurin Bevan





Reality now - limited

- Rationing
- Post code lottery
- Hospital trusts overdrawn
- Laying off front line workers
- New effective drugs can't be prescribed



Problems

- Herceptin
 - Proven efficacy
 - Expensive - £25k for 12 months treatment
 - NICE – issued guidance recommending Herceptin for early breast cancer.
 - Elisabeth Cooke, launched an appeal to get Herceptin on the NHS.



National Institute for Health and Clinical Excellence



- Looking at wasteful western medical procedures.
- Prescribing of unnecessary drugs.



Against the previous background



- Add CAM and TCM
 - No/limited evidence of efficacy
 - No evidence of cost effectiveness
 - Not even able to test

Researcher

Gross Salary: £1950 pm

Tax and NI: @ £507 (26%)

Therefore Net salary: £1443 pm



Does CAM increase or decrease the expenditure of the health service system ?

- Potential "harms" to the NHS?
- Who are the practitioners? Are they medical trained or under strict regulations?
- Delay conventional treatments?
 - e.g., chronic disease/ cancer patients



Problems of Advocacy

- Doctor prescribes
- Litigation from America



Legal Issues regarding CAM

- Legal responsibility for GP
 - if practitioners are negligent or without full indemnity insurance?
 - Other medical conditions caused by CAM referral?
e.g., Patient receive initial pain relief through osteopathy, then later suffer from a slipped disc



Herbal Medicine–Safety Issues

- Patients may fail to use more appropriate conventional treatments
- Each product may contain different amounts of active ingredients
- Products may contain toxic ingredients which need to be removed to allow safe application
- Negative interactions with medications
 - Anti-coagulants in St John’s wort or horse chestnut
 - Anti-platelet agents in ginko biloba
 - Other unknown interaction?

“It is the part of the cure to wish to be cured”

Seneca, Hippolytus, 249

“The treatment of the disease may be entirely impersonal; the care of the patient must be completely personal”

*Frances Weld Peabody (1891-1927)
The Care of the Patient*



"Lack of scientific evidence and the absence of regulation "

-- *Strengths, weaknesses, and development of traditional Chinese medicine in the health system of Hong Kong: through the eyes of future western doctors. Wong et al., 2006*

AUTHORS' REPLY, - Our wonder is how the editor found our paper under the heap of statistician led studies, the dementing effect which is spreading into clinical research like the acquired immune deficiency syndrome.

The idea that you cannot detect any clinically important effect in an open study of 13 patients is at best a statistical scotoma and at worst an economy of truth. If you sharpen your question and refine your measuring technique you can detect the effect of drugs in as few as 6-10 patients.

But very many more patients would have been required had we left the definition of response in the statistically acceptable but scientifically soft reaches of clinically assessed acne, urticaria, sweating and psoriasis. The ability to detect change is a function of method, which is why we prefer to design and use objective methods of measurement.

Statistics is a small part of methodology; it says more about what you cannot do than what you can do and is rarely creative. It cannot therefore be allowed to dictate the needs of clinical science; we have too many studies with a reliable statistical provenance and negligible biological future. The impending season of good will should help as the hard line statistical Cassandras are replaced by user friendly software packages on the Christmas tree.

Martina Daly, Sam Shuster

The Lancet



"When you can measure what you are talking about and express it in numbers you know something about it, but when you cannot measure it, when you cannot express it in numbers, your knowledge is a meagre and unsatisfactory kind: it may be the beginning of knowledge, but you have scarcely in your thoughts, advanced to the stage of science.

William Thompson, Lord Kelvin.

Public lectures and addresses
1891-1894

Conclusions

1. CAM's are a limited proven efficacy.
2. As a whole they add a further significant financial burden to the NHS.
3. Compete with other spending priorities.
4. Have significant safety concerns.
5. Have important issue about advocacy and litigation.