Le medicine non convenzionali
Tra prove di efficacia, rischi e stregoneria

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1. Differenze tra CAM e CM

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<th>Conventional</th>
<th>Unconventional</th>
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<tr>
<td>Mainstream</td>
<td>Alternative</td>
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<td>Orthodox</td>
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<td>Scientific</td>
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<td>Evidence based</td>
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<td>Allopathic</td>
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<td>Western</td>
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The most compelling (and most “inflammatory”) label is that conventional medicine is scientific and that unconventional is unscientific.

1. CAM is predominantly private medicine, not reimbursed within the healthcare system.
2. Providers of CAM often lack medical training, and often are not physicians.
3. The effectiveness and safety of many forms of CAM is not proven, according to the EBM standards.

4. The research funds for CAM are currently scarce, much more so than in CM.
5. CAM lacks a tradition or culture of modern, scientific research comparable to CM.
6. CAM is claimed to be holistic and its benefits of CAM are thought to be mental, psychological, spiritual, and social, thus they can be less tangible or measurable than those of CM.

“Conventional” and “Unconventional” Medicine Can they be integrated?

Arch Intern Med 1998;158:2179-81
**CM & CAM: Can they be integrated?**

**CM**
Conventional Medicine

**CAM**
Complementary and Alternative Medicine

**EBM**

**Tonelli MR, Callahan TC**

**Why alternative medicine cannot be evidence based**

*Acad Med 2001;76:1213-20*

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**La gerarchia delle prove di efficacia**

1. Revisioni sistematiche di RCTs
2. Trials controllati e randomizzati
3. Trials controllati non randomizzati
4. Trials non controllati
5. Studi osservazionali analitici
6. Studi osservazionali descrittivi
7. Opinioni, fisiopatologia

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**Mason S, Tovey P, Long AF**

**Evaluating complementary medicine: methodological challenges of randomised controlled trials**

*BMJ 2002;325:832-4*

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- CAM should be evaluated as rigorously as conventional medicine to protect the public from charlatans and unsafe practices, but many practitioners of CAM are reticent about evaluation of their practice.

- In defence, many CAM practitioners argue that research methods dissect their practice in a reductionist manner and fail to take into account complementary medicine's holistic nature leading to invalid evaluation.
CAM: Where is the evidence?

- CAM cannot be evidence-based in the conventional sense of the word.
- Softer types of evidence need to be taken into consideration as well.
- Placebo effects must not be dismissed as nonbeneficial.
- The healing encounter includes significant factors that may never be quantifiable.
- The scientific method cannot measure hope, divine intervention, or the power of belief.
- Research in CAM must consider social, cultural, political, and economic contexts.

Quali fattori confondenti negli studi non controllati?

- Effetto reale del trattamento
- Effetto placebo
- Aspettative ottimistiche
- Effetto Hawthorne
- Miglioramento spontaneo

Soddisfazione dei pazienti

Trials non controllati e studi osservazionali

Nella CM il loro ruolo è limitato a:
1. Malattie rare
2. Studi di fase II
3. Quando sussistono tutte le condizioni seguenti:
   - malattia ad esito sfavorevole/fatale
   - drammatica efficacia del trattamento
   - effetti sfavorevoli accettabili
   - assenza di trattamenti alternativi
   - presupposti fisiopatologici convincenti

Trials non controllati e studi osservazionali

- Vitamina C (scorbuto)
- Insulina (coma diabetico)
- Antibiotici (polmonite pneumococcica, endocardite batterica)
- Vitamina B12 (anemia perniciosa)
- Appendicectomia (appendicite perforata)
- Trapianto di fegato (epatite acuta fulminante)
- Inibitori della colinesterasi nella myastenia gravis
- Alcuni antidoti negli avvelenamenti
- Defibrillatore esterno nell’arresto cardiaco

Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials
Problems in testing CAM

- The average size of the overall therapeutic effect associated with CAM is usually modest and the NNT are often high (statistically significant but of debatable clinical relevance)
- Even minor adverse effects would therefore critically disturb the delicate balance of risk and benefit.

RESULTS

- During the period 1996-2002, a total of 20,209 articles about CAM were published
- Approximately 50% of CAM articles appeared on journals with no IF.
- The proportion of clinical trials was 7.6% of total CAM articles.

CONCLUSIONS

- We believe there is an urgent need to conduct rigorous research in the field of CAM in order to support, for the need of the public, an evidence-based approach to these therapies.

1. Differenze tra CAM e MC
2. Efficacia delle CAM
3. Rischi delle CAM
4. CAM ed EBM
5. La posizione del GIMBE®
3. Rischi delle CAM

1. Direct harm
   - Harm results from a side effect of a CAM
     - Herb-drug interaction
     - Toxicity of herbs
     - Vertebral artery dissection or nerve damage after chiropractic manipulation
     - Needle penetrating the lung during acupuncture

2. Indirect harm
   - Results from the delay of appropriate treatment for a medical condition due to misinformation about unrealistic treatment of a condition.
   - Indirect harm is often seen with cancer treatments.

3. Economic harm
   - Many CAMs are marketed directly to the public through advertising and testimonials in the press, the internet, television, and through multi-level marketing.

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Complementary medicine and the Cochrane Collaboration

JAMA 1998;280:1628-30
| 193 Cochrane Reviews related to CAM  
(Issue 2, 2005) |
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<td>• Bandolier</td>
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<td>• Evidence-Based Complementary and Alternative Medicine</td>
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<td>• Journal of Evidence-based Dental Practice</td>
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**Shekelle PG, Morton SC, Suttorp MJ, et al.**

**Challenges in systematic reviews of complementary and alternative medicine topics**

*Ann Intern Med 2005;142(12 Pt 2):1042-7*

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**Vickers AJ**

**Message to complementary and alternative medicine: evidence is a better friend than power**

*BMC Complementary and Alternative Medicine 2001;1:1*

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- There are no good reasons to suggest that EBM is incompatible with CAM, or that it works to CAM's disadvantage.
- Were the CAM community to reject EBM, its future would be decided in the closed-off back rooms of power.
- By placing CAM on an equal footing with conventional medicine - what matters for both is evidence of effectiveness - EBM provides an opportunity for CAM to find an appropriate and just place in health care.
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.

The Navajo have integrated “unconventional Western medicine” - provided by the Indian Health Service - into their centuries-old conventional health care, which is provided by native healers.

5. La posizione del GIMBE®

SI’
- Favorire l’integrazione tra CM e CAM
- Identificare le problematiche metodologiche - diverse nelle varie tipologie di CAM - che esistono per la valutazione dell’efficacia delle CAM.
- Diffondere la metodologia della ricerca nelle CAM.
- Finanziare la ricerca per valutare l’efficacia e la sicurezza delle CAM.
- Rimborsare le CAM di documentata efficacia.

5. La posizione del GIMBE®

NO
- Diffusione indiscriminata delle CAM
- Pratica delle CAM da parte di professionisti non medici
- Legittimazione delle CAM solo per il fatto che è praticata dai medici.
- Spingere i pazienti ad abbandonare CM di provata efficacia in favore di CAM dall’incerto profilo beneficio-rischio.