

GIMBE®

Gruppo Italiano per la Medicina Basata sulle Evidenze

Evidence-Based Medicine Italian Group

Workshop

Evidence-based Medicine

Le opportunità di un linguaggio comune 3^a ed.

Como, 1-2 aprile 2006



Le medicine non convenzionali

Tra prove di efficacia, rischi e stregoneria

Conduce: Nino Cartabellotta

Discussant: Gianni Garozzo, Maurizio Mancuso,
Raffaele Pastore, Mara Ramploud

GIMBE® - Gruppo Italiano per la Medicina Basata sulle Evidenze

CM

Conventional
Medicine

CAM

Complementary and
Alternative Medicine

1. Differenze tra CAM e CM

Conventional

Mainstream

Orthodox

Regular

● Scientific

Evidence based

Allopathic

Western

Modern

Unconventional

Alternative

Unorthodox

Irregular

● Unscientific

Not evidence based

Naturopathic

The most compelling (and most “inflammatory”) label is that conventional medicine is scientific and that unconventional is unscientific.

1. Differenze tra CAM e CM

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.

1. Differenze tra CAM e CM

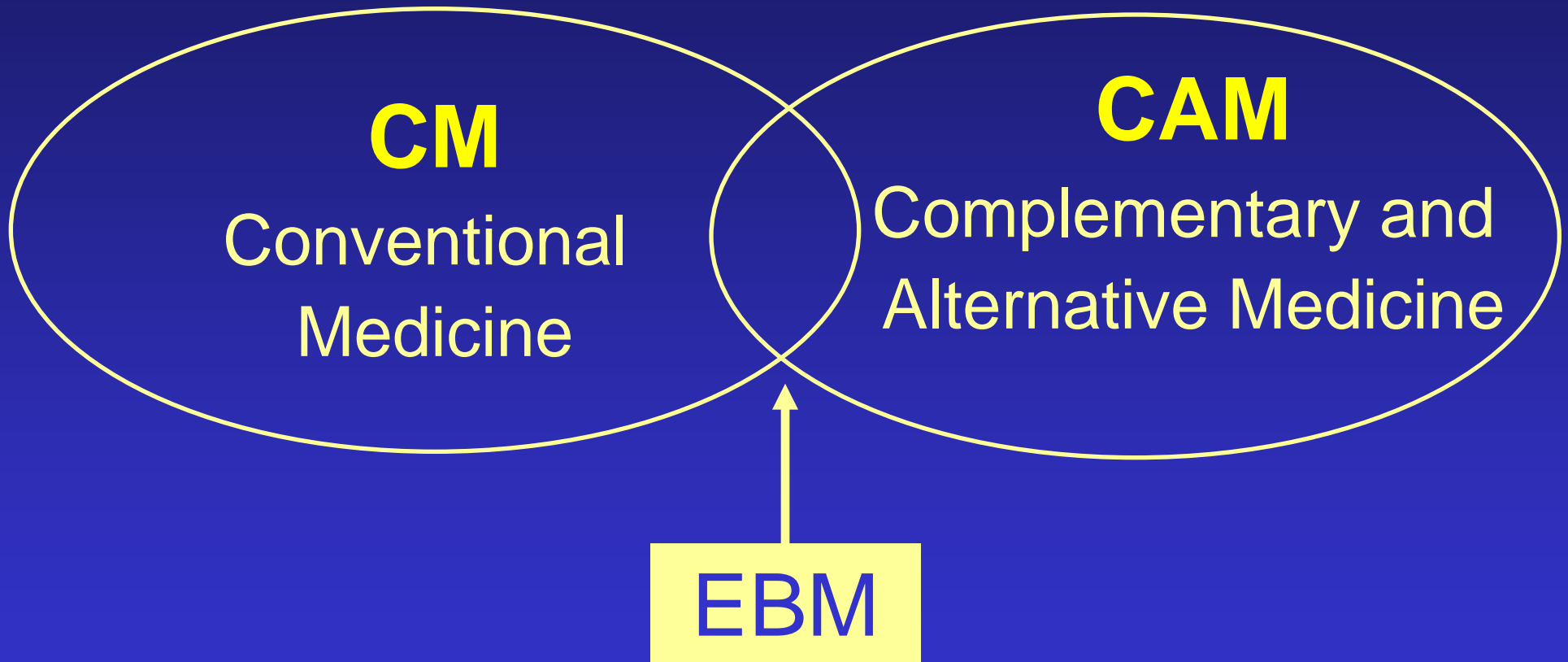
4. The **research funds** for CAM are currently **scarce**, much more so than in CM.
5. CAM **lacks** a tradition or culture of modern, scientific research comparable to CM.
6. CAM is claimed to be holistic and its **benefits of CAM** are thought to be mental, psychological, spiritual, and social; thus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

Dalen JE

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

Arch Intern Med 1998;158:2179-81

CM & CAM: Can they be integrated?



Tonelli MR, Callahan TC

Why alternative medicine cannot be evidence based

Acad Med 2001;76:1213-20

1. Differenze tra CAM e MC
2. **Efficacia delle CAM**
3. Rischi delle CAM
4. CAM ed EBM

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

Mason S, Tovey P, Long AF

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

BMJ 2002;325:832-4

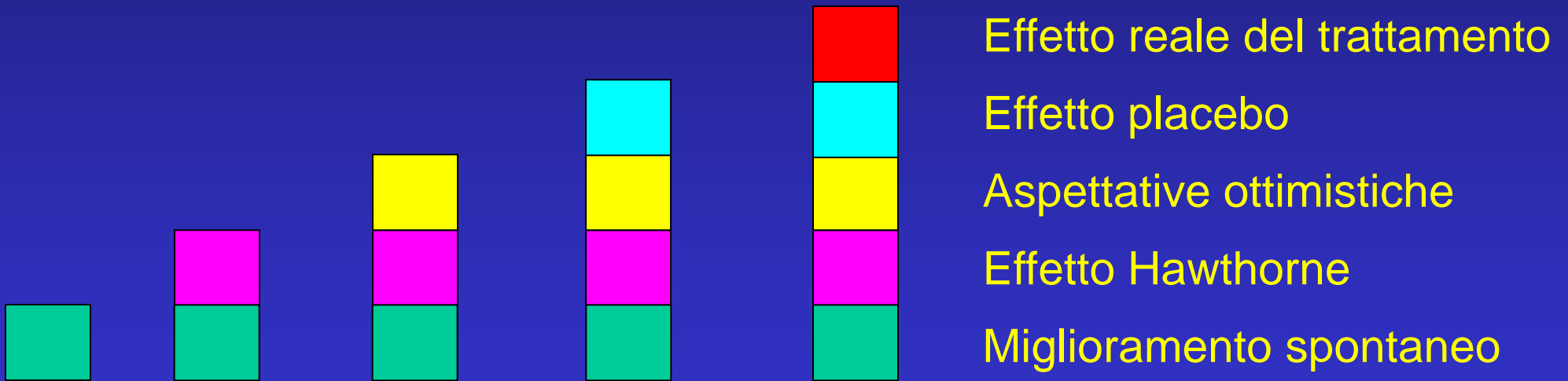
- CAM should be evaluated as rigorously as conventional medicine to protect the public from charlatans and unsafe practices, but many practitioners of CAM are reticent about evaluation of their practice.
- In defence, many CAM practitioners argue that research methods dissect their practice in a reductionist manner and fail to take into account complementary medicine's holistic nature leading to invalid evaluation.

CAM: Where is the evidence?

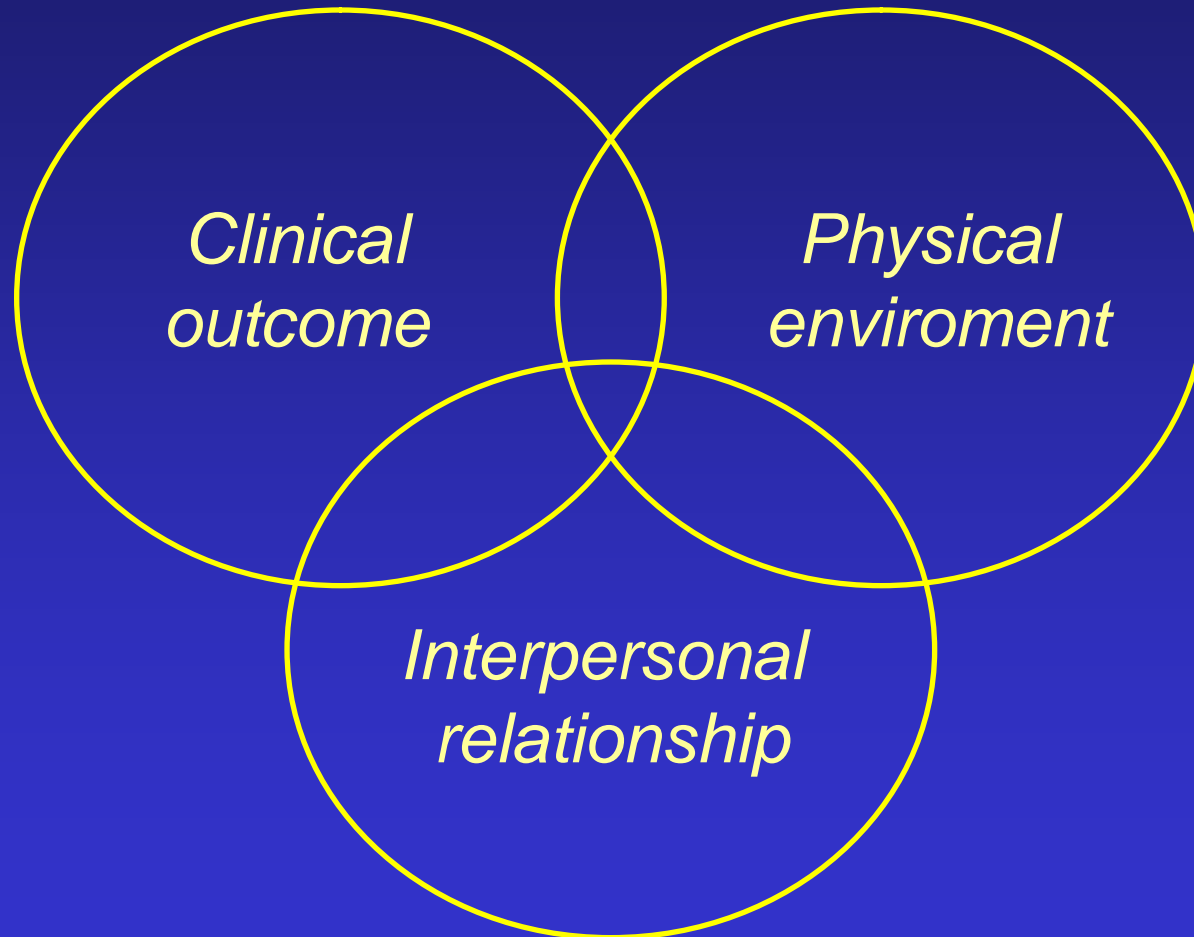
- CAM cannot be evidence-based in the conventional sense of the word.
- Softer types of evidence need to be taken into consideration as well.
- Placebo effects must not be dismissed as nonbeneficial.
- The healing encounter includes significant factors that may never be quantifiable
- The scientific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

Ernst E. J Fam Pract, 2003

Quali fattori confondenti negli studi non controllati?



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



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

Smith GCS et al. BMJ, 2003













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)
- Concentrati di fattore VIII e IX (emofilia)
- Inibitori della colinesterasi nella myastenia gravis
- Alcuni antidoti negli avvelenamenti
- Defibrillatore esterno nell'arresto cardiaco

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.

Table 1 Examples of techniques used in complementary and alternative medicine

Technique	Method	Indication (examples)	Serious risks (examples)	Benefits*	Risk benefit analysis
Acupuncture ²	Therapeutic /diagnostic	Chronic pain	Tissue trauma, infections (rare)†	No convincing evidence	Uncertain 
Acupuncture ³	Therapeutic /diagnostic	Nausea	Tissue trauma, infections (rare)†	Convincing evidence	Positive 
Aromatherapy ⁴	Therapeutic	Various	Allergic reaction, carcinogenic potential in some oils	Good evidence for relaxing effects	Uncertain 
Chelation therapy ⁵	Therapeutic	Intermittent claudication	Kidney damage, electrolyte imbalances†	No convincing evidence	Negative 
Chiropractic ⁶	Therapeutic /diagnostic	Back pain	Vertebral or carotid artery dissection†	Promising but not convincing evidence for acute or chronic back pain	Uncertain 
Herbalism ^{7 8}	Therapeutic	(St John's wort for depression‡)	Increased risk of bleeding, interaction with numerous drugs	Clear evidence that it is superior to placebo	Positive 
		(Ginkgo biloba for intermittent claudication‡)	Increased risk of bleeding, interaction with anticoagulants	Clear evidence that it is superior to placebo	Positive 
Homoeopathy ⁹	Therapeutic /diagnostic	Various	No serious direct risks of highly dilute remedies	No clear evidence for clinical effectiveness for any condition	Uncertain 
Iridology ¹⁰	Diagnostic	NA (diagnostic method)	False positive or false negative diagnosis	No convincing evidence	Negative 
Massage ¹¹	Therapeutic /diagnostic	Back pain	No serious direct risks	No convincing evidence	Uncertain 
Reflexology ¹²	Therapeutic /diagnostic	Various	No serious direct risks	No convincing evidence for clinical effectiveness for any condition	Uncertain 
Spiritual healing ¹³	Therapeutic /diagnostic	Various	No serious direct risks	No convincing evidence for clinical effectiveness for any condition	Uncertain 

*Evidence based on recent systematic reviews or meta-analyses.

†Fatalities have occurred.

‡As examples of one specific herbal remedy.

NA=not applicable

Ernst E, et al. J Med Ethics 2004

Raschetti R, Menniti-Ippolito F, Forcella E, Bianchi C.

Complementary and alternative medicine in the scientific literature

J Altern Complement Med 2005;11:209-12

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.

Raschetti R, et al. J Altern Complement Med 2005

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.

Raschetti R, et al. J Altern Complement Med 2005

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

Kotsirilos V. Aust Fam Physician, 2005

3. Rischi delle CAM

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.

Kotsirilos V. Aust Fam Physician, 2005

3. Rischi delle CAM

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.

Kotsirilos V. Aust Fam Physician, 2005

1. Differenze tra CAM e MC
2. Efficacia delle CAM
3. Rischi delle CAM
4. **CAM ed EBM**

Ezzo J, Berman BM, Vickers AJ, Linde K.

Complementary medicine and the Cochrane Collaboration

JAMA 1998;280:1628-30



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[The Cochrane Collaboration](#)

The Complementary Medicine Field is an international group of individuals dedicated to facilitating the production of systematic reviews of randomized clinical trials in topic areas such as acupuncture, massage, chiropractic, herbal medicine, homeopathy and mind-body therapy. The Complementary Medicine Field is coordinated by the University of Maryland Center for Integrative Medicine.

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The Center for Integrative Medicine

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193 Cochrane Reviews related to CAM (Issue 2, 2005)

The Cochrane Collaboration Complementary Medicine Field - University of Maryland School of Medi - Microsoft Internet Explorer

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Indirizzo http://www.compmcd.umm.edu/Cochrane/cam_reviews.html Vai

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The Cochrane reviews below are available in The Cochrane Library. Abstracts of the reviews can be viewed at no charge at the Collaboration's website (<http://www.cochrane.org/cochrane/revabstr/mainindex.htm>).

Cochrane Reviews Related to Complementary and Alternative Medicine (as of Issue 2, 2005) :

1. Acetyl-L-carnitine for dementia
2. Acupuncture and electroacupuncture for the treatment of RA
3. Acupuncture for acute stroke
4. Acupuncture for Bell's palsy
5. Acupuncture for chronic asthma
6. Acupuncture for depression
7. Acupuncture for idiopathic headache
8. Acupuncture for induction of labour
9. Acupuncture for lateral elbow pain
10. Acupuncture for low back pain
11. Acupuncture for shoulder pain
12. Acupuncture for smoking cessation
13. Alexander technique for chronic asthma
14. Alpha-lipoic acid for dementia

Internet

Publicazioni secondarie

- ACP Journal Club
- Bandolier
- Evidence-Based Medicine
- Evidence-Based Cardiovascular Medicine
- Evidence-Based Mental Health
- Evidence-Based Nursing
- Evidence-Based Healthcare & Public Health
- Evidence-Based Dentistry
- Evidence-Based Obstetrics and Gynecology
- Evidence-Based Ophthalmology
- Evidence-Based Gastroenterology
- **Evidence-Based Complementary and Alternative Medicine**
- Journal of Evidence-based Dental Practice



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THE CURRENT ISSUE



Volume 2 Issue 3 September 2005

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Evidence-based Complementary and Alternative Medicine (eCAM) is an international, peer-reviewed journal that seeks to understand the sources and to encourage rigorous research in this new, yet ancient world of complementary and alternative medicine.

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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

Vickers AJ

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

BMC Complementary and Alternative Medicine 2001;1:1

- 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.

Vickers AJ.

BMC Complementary and Alternative Medicine, 2001

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.**

Fontanarosa PB, et al. JAMA, 1998



The Navajo have integrated “unconventional Western medicine” - provided by the Indian Health Service - into their centuriesold 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.