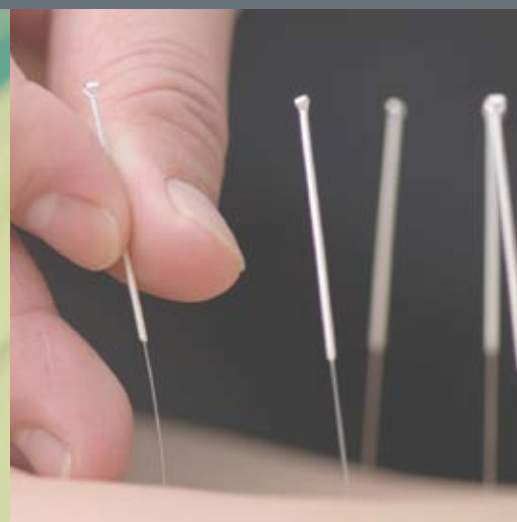


EICCAM

European Information Centre for
Complementary & Alternative Medicine



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Executive Summary

The worldwide use of CAM (Complementary and Alternative Medicine) has grown considerably in the past 20 years. Analysing surveys done over the past ten years the general conclusion can be made that 20% of EU citizens have a clear preference for CAM healthcare, and another 20% are regular users of CAM. More than 100 million citizens in the EU make use of CAM today. The most commonly used CAM therapies in Europe are Homeopathy, Acupuncture, Phytotherapy (= herbal medicine), Anthroposophic medicine, Naturopathy, Traditional Chinese Herbal Medicine, Osteopathy and Chiropractic.

According to the WHO, “it is extremely important to create the conditions for the correct and appropriate use of CAM which, if used correctly, can contribute to the protection and the enhancement of citizens’ health and well being.” This can only happen if the public at large and EU decision makers receive suitable information on CAM and actual CAM research. The outcome of research on complementary medicine undertaken by research centres and working groups is usually presented only in scientific journals and to fellow scientists. Thus, the information rarely reaches the group of policy and decision makers on European health policies.

Another problem is that publications are usually conceived in a specific format and that the language used is scientific terminology, which means that they are often difficult to read in the short period of time available to decision makers. Consequently there is a communication gap to be bridged and scientific news on CAM therefore needs to be adapted or “translated” in order to reach the target groups.

Our vision is to create an Information Centre starting first at a modest level focusing on communication and to develop it later to a position as the first interlocutor on European scientific CAM affairs, making the scientific voice of CAM heard and understood in Europe.

The aim of this “European Information Centre for Complementary and Alternative Medicine (EICCAM)” should be the communication of scientific and health care related information on CAM to the media, politicians, legislators and other stakeholders in a way that is appropriate to the needs of these target groups. This information should be independent, comprehensive, understandable and quality assured in order to contribute to informed decision-making.

The Information Centre has been set up as a public foundation, with a Management Board and a Scientific Board. Both boards will jointly decide on actions and activities while the Scientific Board will select the information input and output and, most importantly, ensure its independence.

The worldwide use of CAM has grown considerably in the past 20 years.¹⁻³ In line with the global figures of the WHO, the resort to CAM in the EU has extended similarly.^{4,5} Utilisation levels of CAM in the Member States varied from 20 to 70 percent of the population in 1998.⁶ Analysing surveys done over the past ten years the general conclusion can be made that 20% of EU-citizens have a clear preference for CAM healthcare, another 20% are regular users and another 20% are occasional users of CAM. This means more than 100 million citizens in the EU make use of CAM. Based on these figures one can conclude that from the perspective of EU citizens CAM is a condition sine qua non for modern healthcare in the European Union. The most commonly used CAM therapies in Europe are Homeopathy, Acupuncture, Phytotherapy (= herbal medicine), Anthroposophic medicine, Naturopathy, Traditional Chinese Herbal Medicine, Osteopathy and Chiropractic. The popularity of the individual therapies, however, differs widely between countries.

As CAM frequently forms part of a healthy lifestyle, it may have positive impacts on public health in general. A recent study for example showed that children with an anthroposophic lifestyle have fewer problems regarding allergies than children from other backgrounds.⁷ More studies have to be done to confirm the positive relationship between healthy lifestyle and use of CAM. In any case, in several Member States of the European Union this has led to decisions by growing numbers of national health services to reimburse CAM Health service and products. Several countries in Europe currently run activities promoting CAM as an essential part of primary health care.

The WHO points out that the popularity of CAM is partially triggered by needs for cost-effectiveness and the dissatisfaction with the effectiveness and/ or higher risks connected to conventional biomedical interventions. Last but not least - CAM could be a means to combat pollution generated by the increased consumption of medicines that are excreted by humans and animals and subsequently end up in the environment.⁸

Being aware that traditional, complementary, or alternative medicine has many positive features, and that traditional medicine and its practitioners play an important role in treating chronic illnesses, and improving the quality of life of those suffering from minor illness or from certain incurable diseases (WHO Resolution on Traditional Medicine 2003).⁹

3.1 NEED FOR PROPER INFORMATION

According to the WHO, “it’s extremely important to create the conditions for the correct and appropriate use of CAM which, if used correctly, can contribute to the protection and the enhancement of citizens’ health and well being. One such condition is the need to make sure that consumers are better informed and aware of CAM strategies and treatments so as to enable them to make appropriate decisions on how to improve their health. The long-term goal is to maximise the benefits and minimise the risks of CAM use by empowering consumers to become active participants in health care and to make informed choices”.¹⁰

WHO suggests that general consumer information regarding CAM may include the following key issues:

- The importance of the need to take charge of one’s own health by being an informed consumer.
- The need for all providers, both conventional health care providers and CAM practitioners, to be aware of the major CAM and conventional therapies in use in order to promote the best treatment strategy to meet the patient’s specific needs and prevent potentially dangerous interactions.
- The importance of ensuring that the provider is competent and provides CAM services and products of quality.
- Where relevant, the need for consumers to find out about standard charges and possible health insurance coverage for CAM therapies.

Approaches in the USA where ‘seed’ funding and dedicated funding for research were available provided impetus to establish and continue an effective CAM research program there. In the USA in 1998 the Congress established the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health that is charged to ‘conduct basic and applied research (intramural and extramural), research training, and disseminate health information and other programmes with respect to identifying, investigating, and validating CAM treatments, diagnostic and prevention modalities, disciplines and system’. To date the NCCAM had funded 10 university-based centres for research on CAM. The example of the NCCAM shows that, if funds are there, experienced researchers will apply for them, and with sufficient investment high-quality research in non-conventional medicine can be achieved.

Rigorous research on CAM, training programs for researchers in CAM, and the dissemination of information to public and professional areas are the main tasks of the institute, which holds a budget of U\$117.7 million (!!) a year.

By way of contrast in Europe, foundations, organisations, academic institutes and private persons mostly execute CAM scientific research projects. There are around 50 research centres on CAM at the moment.

The outcome of research on complementary medicine undertaken by these centres and working groups is usually presented in scientific journals, to fellow scientists and at scientific events with participation of a mostly informed audience. Thus, the information rarely reaches the group of decision makers on European health policies.

Another problem is that publications are usually conceived in a specific format and that the language used is scientific terminology, which means that they are usually difficult to read in the short period of time available and even the abstracts are often not clear enough for a layperson. It appears that scientific news on CAM therefore needs adapted written 'translation' in order to reach the target groups. This problem is not systematically taken care of by the organisations and institutes presently active in the field of CAM research. Consequently there is a communication gap to be bridged. As long as the latter exists, it will be difficult to convey the message to the political decision makers, namely that substantial and good quality research in CAM exist and does show potential for much improved public health care.

3.2 INITIATIVES TAKEN SO FAR

The need for more and better information on CAM has become apparent on various occasions such as in the European Open Health Forum and the European Health Forum Gastein (2005).

During work to ensure that CAM is represented in FP7 the same lack of information became apparent. As a result an international multidisciplinary Working Group was established to set up this information centre.

3.3 AIM

The vision is to start at a modest level focusing on communication and to extend towards a position as the first interlocutor on European scientific CAM affairs, which could make the scientific voice of CAM heard and understood in Europe.

The objective of the EICCAM: to further free and informed choice of CAM therapies, through the provision and dissemination of understandable, objective and high-quality information on their safety, effectiveness and efficiency to decision makers and the media in Europe.

3.4 AREAS OF WORK

- Collection and updating on a regular basis of scientific information on CAM
- Converting the scientific information into summarised information that is understandable by the educated non expert public
- Monitoring the input and output of information
- Networking with the scientific community
- Networking with all stakeholders
- Organising or participating in scientific events on CAM
- Taking initiatives and leading in critical times

3.5 STRUCTURE AND ORGANISATION

The Information Centre has been set up as a public foundation, with a Management Board and a Scientific Board. Both boards will jointly decide on actions and activities while the Scientific Board will select the information input and output and, most importantly, ensure its independence.

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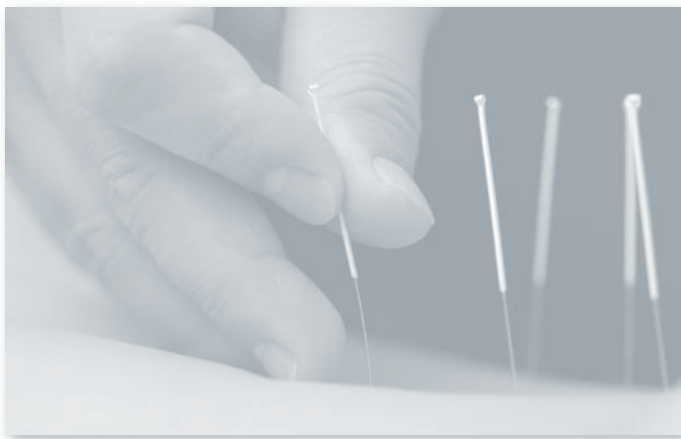
What is CAM?

In the international context the term CAM is used as an abbreviation for Complementary and Alternative Medicine.

The Cochrane Collaboration defines CAM as “a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being. Boundaries within CAM and between the CAM domain and that of the dominant system are not always sharp or fixed”.¹¹ CAM includes amongst other medicinal therapies such as Phytotherapy, Homeopathy, Acupuncture, Anthroposophic medicine, Naturopathy, Traditional Herbal Chinese Medicine and bodily treatments including Osteopathy, Chiropractic, and Shiatsu.¹²

The basic characteristics of CAM are:

- an individualised and holistic approach to health
- restoring patients’ own natural systems for fighting disease as well as restoring and maintaining health with the aid of medicines, bodily treatments, modification of lifestyle, dietary change and health psychology approaches
- salutogenesis versus pathogenesis.



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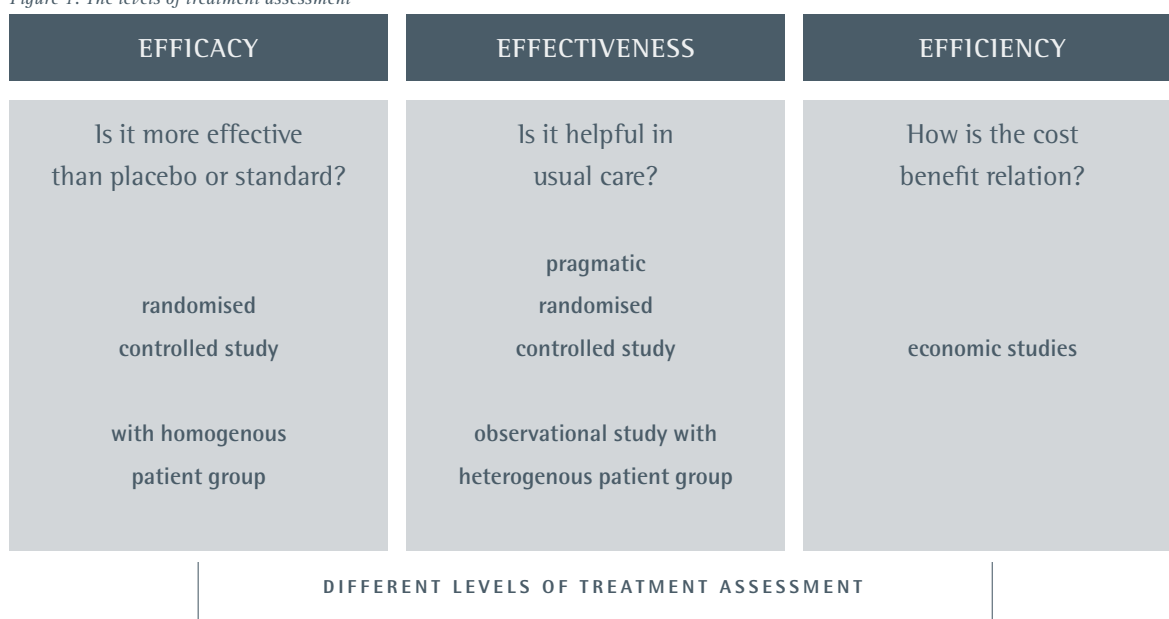
CAM Research

CAM treatment should be based on practical experience as well as research evidence. Regardless of the kind of treatment, or whether it is a conventional or non-conventional method, research has to answer the same questions:

- Which patients are treated?
- What spectrum of treatments is applied?
- Is the investigated treatment effective?
- Is it cost-effective?
- Is it safe?
- Can we explain the treatment mode of action?

The answer to the last question calls for basic research, whereas all other questions have to be addressed through epidemiological and clinical studies. In the field of conventional health care, medical decisions are increasingly based on results of randomised controlled studies. According to the standards of Evidence Based Medicine such studies provide the highest grade of evidence, followed by non-randomised controlled studies, observational studies, case reports, and expert opinions. Evidence Based Medicine thus allows for a broad spectrum of study types, so that various research questions such as “Is homeopathy more effective than placebo?” or “Is acupuncture treatment in addition to usual care more effective than usual care alone?” can be tackled with appropriate study designs (see Figure 1). In addition to quantitative research methods qualitative studies could be used to answer questions such as practitioner-patient relationships and patient satisfaction which are both important aspects of the treatment process.

Figure 1: The levels of treatment assessment



The aim of Evidence Based Medicine is to provide a rational basis for medical decisions. This basis can, however, be distorted by taking into account only such studies that deliver evidence of the highest level i.e., randomised controlled trials. RCTs are mainly performed in experimental, and to a certain degree artificial, settings, and include highly selected patients. Their enormous advantage is the exclusion of other (confounding) factors that can influence the results and distort the effect of the investigated factor. Often, however, the results lose some of their validity when they are transferred to the average real-life patient, who in many cases is older, has more than one disease, takes more than one medicine, or is perhaps less compliant. Therefore, results that have been obtained under ideal conditions must be supported with studies that reflect the reality of everyday health care and can help to assess the effectiveness of a treatment in everyday care. These observational studies, on the other hand, cannot answer the question of causality.

For CAM, several types of studies have been published. But the typical overviews, like systematic reviews or meta-analyses, represent only a part of the research because they take only randomised controlled studies into account. Consequently, the question of CAM effectiveness in normal care settings is completely neglected and more generally, the value of high quality observational studies is often underestimated.

This is exemplified by two studies: A study by Concato¹³ in the New England Journal of Medicine compared the results of randomised controlled studies and observational studies for 5 indications and found comparable outcomes. In the same issue of this journal, Benson¹⁴ analysed 136 studies for 19 different treatments. For 17 treatments the results of randomised controlled studies and observational studies had been very close. Thus it appears necessary to give the results from observational studies more weight in Evidence Based Medicine. Excluding all results from observational studies from reviews or decisions would dismiss an important source of relevant information.

In the field of CAM, to date most systematic reviews try to answer the question if a CAM treatment is different from placebo or a conventional standard treatment. But many patients use CAM treatment in addition to conventional treatment, so it is important for decision makers to know whether this is beneficial for these patients or not, and for what costs. A few pragmatic studies on CAM in recent years assessed the effectiveness in normal care,¹⁵⁻¹⁷ but more are needed.

Health Technology Assessments such as those performed by NICE in the UK, by the BAG in Switzerland¹⁸ or by the SBU in Sweden have aimed to summarise all available evidence for a treatment, including randomised controlled studies, observational studies, case reports and expert opinions. Unfortunately, a full Health Technology Assessment takes a long time to complete, and so it is often outdated at the time of publication. Therefore decision makers often have to resort to more recent scientific publications. But these are usually difficult to understand outside the experts' community, and increasingly sophisticated statistical procedures contribute to the lack of understanding. There is a growing need to make new and up-to-date scientific medical information available in a comprehensible manner.

In more and more countries, decision making increasingly takes not only the efficacy or effectiveness of a treatment method into account, but also its cost-effectiveness. For this very reason at the end of the 19th century German Sick Funds paid for homeopathic and naturopathic treatment.

Introducing a new or additional treatment into normal care usually entails additional expenditures, and the most relevant question is whether the benefits of the new treatment will justify its costs. To provide sound data here, the number of economic evaluations in CAM has increased in recent years. Up to 2004 more than 50 economic evaluations have been published and about half of them have found lower costs for CAM than for conventional care.¹⁹ For homeopathy, two economic evaluations have recorded the outcomes and costs of treatment by German and French General Practitioners (GPs) who integrate homeopathy in their practice, and compared them with GPs who do not.^{17,20} The results of both studies are congruent: GPs who integrate homeopathy in their practice achieve better results for similar costs.

In the UK studies for spinal-manipulation and acupuncture were performed²¹ and the incremental costs for one additional year of perfect quality of life (1 QALY) due to the CAM treatment have been found to be about 15,000. During the last three years the cost-effectiveness of acupuncture according to international benchmarks was determined for headache, low back pain and neck pain.²²⁻²⁴

For the non-expert reader, scientific publications of cost-effectiveness studies are as hard to understand as studies in clinical research; the methods that are similarly complex and sophisticated stand in the way of drawing easy conclusions. Further problems arise from the fact that the EU members' health systems are quite different so that economic study results from one country cannot be easily transferred to another country.



6 CAM & Regulation

CAM provides a tough challenge for regulators because of its growing use among patients and healthcare providers. Key problems in this regard are the fundamental differences in characteristics and traditions compared to conventional or allopathic medicine, and the “internal” differences between the therapies under the CAM umbrella. At this moment, the practice of CAM is not specifically regulated on an EU level. As a consequence, national rules and practices in this regard differ significantly.^{25,26} With respect to CAM products (medicinal products, medical devices, and food supplements) the first steps towards EU-wide harmonisation have been made.

6.1 LEGISLATION APPLICABLE TO CAM PRODUCTS

Directive 92/73/EEC²⁷ on homeopathic medicinal products (now part of Directive 2001/83/EC)²⁸ was the first EU legal instrument concerning CAM. Subsequent Directives were adopted for traditional herbal medicinal products,²⁹ and food supplements.³⁰ The aim of these Directives is to improve the quality and safety of these products, while maintaining an extensive right of product access.³¹ Therefore, special licensing procedures are provided which should be better suited for the assessment of CAM products.

Previous studies on the licensing of homeopathic medicinal products in the EU have concluded that the harmonisation effort for homeopathic medicines has not sufficiently materialised in practice.³² The main reasons for this are the highly differentiated implementations in the Member States with respect to technical standards and procedural requirements caused by the Directive’s ambiguous wording, and the considerable number of ‘old’ registrations and authorisations of homeopathic medicinal products, which are not covered by the Directive.

6.2 LEGISLATION APPLICABLE TO CAM THERAPIES

The absence of EU-wide rules regulating CAM practice maintains a situation in which the EU Member States have exclusive competences to regulate the provision of these types of therapies. However, the provisions on the free movement of people and services, and the freedom of establishment in the Treaty establishing the European Communities (hereinafter EC Treaty) can help to improve freedom of choice of therapy in the EU,³³ although such freedom has not been explicitly laid down in EU Law.

In practice this means that Member states can restrict CAM practice to medical doctors and/or qualified practitioners.³⁴ However, the Member States must remain compliant with the EC Treaty.³⁵ In other words, if a national rule restricts the free movement of services and persons, and/or the freedom of establishment in the EU, it must be justified on the basis of exemption grounds mentioned in the EC Treaty.

European citizens can relatively easily receive CAM treatment and related medication, as they are free to move to another Member State if the treatment or medicine³⁶ is not available. They may also order medicinal products for personal use from other Member States subject to some limitations.³⁷ In how far these possibilities safeguard freedom of choice of therapy remains unclear. It is however certain that patients need to make additional efforts to receive treatment or remedies of their choice outside of their own Member State.³⁸

6.3 FUTURE REGULATION OF CAM

‘Appropriate’ regulation of CAM therapies is mainly hindered by the absence of (sufficient) scientific data on possible risks and benefits related to CAM.^{39,40} Not surprisingly, therefore, both the World Health Organisation⁴¹ and the House of Lords in the UK⁴² have stated that research in safety, efficacy and cost-effectiveness should be the main priorities in CAM research. In line with this, the EU has provided new funding opportunities for research in CAM⁴³ in its recently adopted 7th Framework Programme.⁴⁴

The zero-risk regulatory strategies such as those currently applied to specific homeopathic medicinal products⁴⁵ impose a cost on society that is too high. This is basically because it is impossible and inefficient to strive for medicines that are completely “risk-free”.⁴⁶ Risk is moreover a relative concept: the abolition of one risk can easily lead to the occurrence of another,⁴⁷ and perception of risk is subjective.^{48,49} Future CAM regulation may therefore be increasingly guided by efficiency criteria which establish a proper balance between the cost of regulation on the one hand, and the expected risk associated with the use of CAM on the other hand.

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- 45 • For example, a non-scientific approach to specific routes of administration and allowed concentrations under Article 14(1) of Directive 2001/83/EC, lead to prohibitive requirements for injectables and certain dilutions (under D4 or C2)

- 46 • Supra note 16. See also: E. Ernst, *Risks of herbal medicinal products*, 13 *Pharmacoepidemiology and Drug Safety* 2004, pp. 767-771

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