The Roadmap for European CAM Research

An Explanation of the CAMbrella Project and its Key Findings

cambrella

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Foreword

CAMbrella is an EU funded project that looks into the situation of Complementary and Alternative Medicine (CAM) in Europe as it presents itself in 2012. The acronym brings together the terms "CAM" and "umbrella" to stress the project's effort both to harmonize existing knowledge and to determine the knowledge gaps in this field. Both parts come together in recommendations to the European Commission and the European Parliament on the way forward in Europe for research into CAM – the "Road-map for European CAM research".

The European Commission took the decision to fund a project under the 7th Framework Programme (FP7) because to date there has been no proper evaluation of the situation of CAM in Europe: this applies to almost all member and associate EU countries, with the noticeable exceptions of UK, Switzerland and Norway. No other countries have investigated the topic, nor has the European Commission, i.e. Directorates-General Research and Health.

CAMbrella is therefore a pioneer project, which has sought to establish a scientific base from which to answer questions such as these:

- What is CAM in Europe?
- Where do we stand with regard to CAM?
- What do citizens and patients expect as potential CAM users?
- What are the national and European regulatory settings of CAM?
- How are the safety needs of patients and citizens met? How about freedom of informed choice in health care for European citizens – are their wishes taken into account by regional, national and European regulations?
- How about the provision of CAM? Who practises it and how does education in CAM work?
- How is the European situation viewed from outside, by experts in the field from USA, India and China?
- Where should Europe go in terms of CAM research? What are the most urgent questions here?

This booklet provides an explanation of how we went about our work, and an overview of CAMbrella's findings. Eight work packages focussed on the topics mentioned above (and more). Here is a summary of the work of the project and the conclusions we reached – we do hope you find it interesting to read.

Yours sincerely,

Bettina Reiter
Project communicator

Wolfgang Weidenhammer
Project Coordinator

Project Rationale

The goal of this collaboration project was to look into the present situation of CAM in Europe in all its relevant aspects and to create a sustained network of researchers in the field that can assist and carry through scientific endeavours in the future. Research into CAM – like any research in health issues – must be appropriate for the health care needs of EU citizens, and acceptable to the European institutions as well as to national research funders and health care providers. It was CAMbrella's intention to enable meaningful, reliable comparative research and communication within Europe and to create a sustainable structure and policy.

The CAMbrella network consists of academic research groups which do not advocate specific treatments. The specific objectives were to:

- develop a consensus-based terminology widely accepted in Europe to describe CAM interventions
- create a knowledge base that facilitates our understanding of patient demand for CAM and its prevalence
- review the current legal status and policies governing CAM provision in the EU
- explore the needs and attitudes of EU citizens with respect to CAM
- develop an EU network involving centres of research excellence for collaborative research.

Based on this information, the project created a roadmap for research in CAM in Europe. The roadmap sums up and streamlines the findings of the whole project in one document that aims to outline the most important features of consistent CAM research at European level. You can find a summary of these findings in the final section of this booklet.

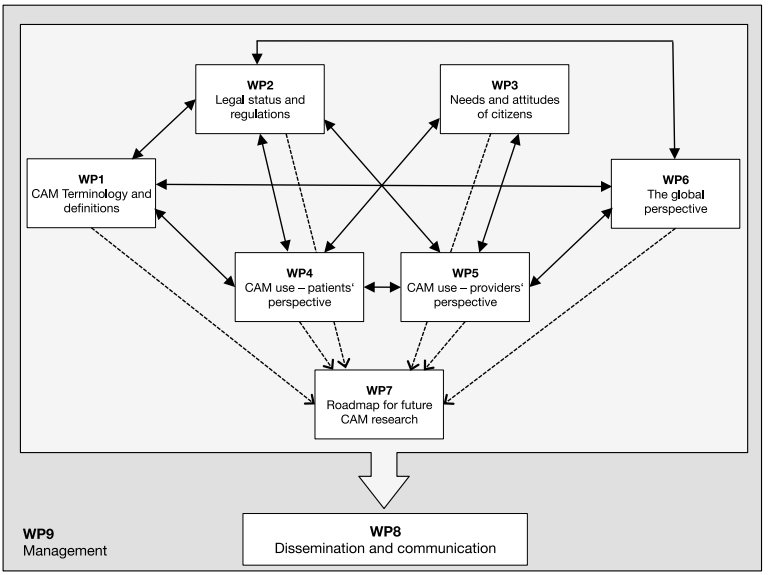
Geographical scope

The project was intended to review the situation in the 27 EU member states plus the 12 associated countries.

Work Packages

To facilitate this coordinating action, the project worked in nine independent but interrelated work packages (see below), coordinated by a Management Board and directed by a Scientific Steering Committee (consisting of the work package leaders and the project coordinator) with the support of an Advisory Board. The Advisory Board represented the main CAM stakeholders, including citizens, practitioners, clinical providers, and manufacturers of CAM medicinal products.

Interrelations between the work packages in the cambrella project



Work package 1

Terminology and definitions of CAM methods

Leading beneficiary
Universität Zürich (UZH)

Work package leader
Prof Dr Dr Bernhard Uehleke

A pragmatic definition of CAM:

CAM, as utilized by European citizens, represents a variety of different medical systems and therapies based on the knowledge, skills and practices derived from theories, philosophies and experiences used to maintain and improve health, as well as to prevent, diagnose, relieve or treat physical and mental illnesses. CAM therapies are mainly used outside conventional health care, but in many countries some therapies are being adopted or adapted by conventional health care.

Objectives

The overall aim of this work package was to develop a pragmatic definition of "Complementary and Alternative Medicine" (CAM), that is acceptable Europe-wide, and could be used systematically to research the prevalence and legal status of CAM in Europe, as well as to investigate the citizens' demands and providers' perspectives related to CAM in general and within the CAMbrella coordinating activities.

The specific objectives were to:

- identify and analyse the existing terms and definitions of CAM used in scientific publications of researchers and by organisations (e.g. World Health Organisation – WHO)
- integrate aspects of terms and definitions of CAM used in surveys about its use or prevalence and publications of stakeholders
- provide a core set of CAM disciplines and methods used consistently all over Europe and an additional list of country specific CAM disciplines and methods to take into account the different traditions and cultures of the EU member states
- develop a practical pan-European definition of CAM, its disciplines and respective methods.

Description of work

WP1 carried out a detailed search in the data base PUBMED for various lead terms such as "alternative medicine" linked to "definition" without any restriction to language or date of publication. It also screened a large amount of (nationally published) scientific literature about CAM terminology for provision of definitions. Definitions from the home pages of relevant CAM organisations were also incorporated.

In order to develop a rough estimate for a core set of disciplines used across Europe, the WP developed a questionnaire about the awareness, knowledge and use of major disciplines for each country to be answered by national experts in the field. It soon became evident that there are few experts with a broad enough overview of the many disciplines in their country; thus the WP was not able to identify experts for all 27+12 European countries and had to stick to the participant countries in CAMbrella (12).

Findings

Worldwide, the terms used for defining CAM, CAM methods and procedures, or therapies related to CAM vary greatly. A certain method, procedure or therapy might be regarded as part of CAM in one country while in other countries the very same procedure might not be related to CAM, but to normal life style, conventional medicine, psychology or philosophy. There is a huge variety of definitions which is impractical, both as concerns research purposes and with regard to EU conformity.

There are numerous other terms which are widely used as synonyms for "CAM", along with terms used outside the scientific literature, including, for instance "experience-based medicine" (Erfahrungsheilkunde), "holistic medicine" (Ganzheitsmedizin), "natural medicine" (medicina naturista, Naturheilkunde), and "other medicine" (médecine deuxième). Other terms include "traditional medicine (TM)" and "person-centred medicine."

There is a great variety of classification systems for the many disciplines and methods covered by CAM and it is almost impossible to place them into a hierarchy. No real operational definition is available to determine which of them would relate to CAM. In our definition (see above) we addressed the issue of an overlap between CAM and conventional medicine.

The following seem to be among the most important CAM disciplines in the EU (in alphabetical order): acupuncture (various methods), anthroposophic medicine, herbal medicine, homeopathy, manual therapies (chiropractic, massage, osteopathy, reflexology), natural medicine (including aromatherapy, herbal medicine, nutrition, food supplements, exercise, lifestyle advice and psychological techniques), and Traditional Chinese Medicine (various methods and related techniques). Some of the presumed country-specific disciplines/methods are classified as conventional medicine rather than CAM in other countries, e.g. balneology, which is related to physical medicine in Germany and elsewhere.

There are examples which might be considered as relevant country-specific disciplines (not exhaustive): Austria: energetic medicine; Denmark: visualization; France: mesotherapy; Germany: breath therapy, neural therapy (according to Ferdinand Huneke), hydrotherapy or water therapy according to Sebastian Kneipp; Hungary: dance therapy; Sweden: naprapathy, Rosen method. It seems that with regard to a range of methods, the patterns of use are similar in certain groups of culturally related countries like Scandinavia, the Mediterranean nations and German-speaking countries.

Work package 2

Legal status and regulations

Leading beneficiary
University of Tromsø (NAFKAM)

Work package leader
Prof Dr Vinjar Fønnebø

The European Union has decided that the organization and regulation of health care is a national responsibility, while medicinal products are regulated at the Union level.

The situation with regard to CAM regulation can be summarized in three points:

- **There is no common approach to the regulation of CAM practice in Europe. All 39 countries that were studied do it their own way.**
- **Market authorization of herbal and homeopathic products are regulated similarly in each country in accordance with EU Directives.**
- **Several EU Directives and other legal and informal documents have a direct and indirect influence on how patients, practitioners and researchers can relate to CAM in Europe.**

Although diversity in health care regulation and legislation enables a wider choice of options with regard to CAM aspects of health care, the same diversity seriously hampers any efforts to establish EU-wide predictable conditions for both treatment and research.

Objectives

The objectives of WP2 were twofold: firstly to review and describe for each member or associated state the legal status of CAM, the regulatory status, governmental supervision and reimbursement status of CAM practices, and the reimbursement status and regulation of CAM medicinal products; and secondly to review the status of and potential obstacles for EU wide regulation of CAM practices and medicinal products.

Description of work

The country-specific status has been described with reference to the date of project start. This work generated the first subreport, building partly on the report entitled "How are European patients safeguarded when using complementary and alternative medicine (CAM) jurisdiction, supervision and reimbursement status in the EEA area (EU and EFTA) and Switzerland" published by NAFKAM in 2005. The regulatory status of CAM medicinal products constituted the second sub-report, while the third subreport on EU-wide regulation and potential obstacles to such regulation could partly build on the 2005 NAFKAM report and other published work in the area.

The primary data has been publicly available regulatory and legal documents for each country as well as the EU. Health ministries have been contacted by letter, e-mail and phone. Some countries have been visited in person. The draft description of each country has been submitted back to the health ministry in some countries to double-check the information presented about that country.

The sub-report on the status with regard to the regulation of CAM medicinal products was developed following the same methodology. The primary data for sub-report number three on status of and potential obstacles for EU wide regulation of

CAM practices and medicinal products were the same as for the other two sub-reports. These primary data were supplemented with personal meetings with relevant information sources in Brussels.

Findings

The regulatory environment determines how a provider can be educated, certified and offer services. The organisation and regulation of health care is a national responsibility within the European Union. There is no common approach to the regulation of CAM practice in Europe. This results in a considerable variety in regional, national, European and international legal regulations, which make any comparison of CAM practice and provision in any respect almost impossible.

Medicinal products are regulated at the EU level. Market authorization of herbal and homeopathic products are regulated similarly in each country in accordance with EU Directives. As regards legislation of CAM, 19 of the 39 countries have a general legislation, of which eleven have a specific CAM law and eight have sections on CAM included in their health laws (such as "Law on health care" or "Law on health professionals"). In addition to general CAM legislation, some countries have regulations on specific CAM treatments.

Several EU Directives and other legal and informal documents have a direct and indirect influence on how patients, practitioners and researchers can relate to CAM in Europe. However, the heterogeneity of the legal status and regulations for CAM in Europe creates the following obstacles:

For patients: when patients cross borders in search of CAM treatment, they may encounter substantial differences in the professional background of apparently identical CAM providers, who in addition tend to work under completely different

reimbursement systems. This situation influences CAM patients' rights, access and potential safety, and constitutes a challenge to a harmonized national and European follow-up of the new patients' rights according to the cross-border health care Directive 2011/24/EU.

For practitioners: when practitioners cross borders they will encounter a substantial variety of CAM practice in Europe. While CAM professions in some countries are tightly regulated, the same professional categories in other countries are totally unregulated, meaning that it is almost impossible to establish professional common ground.

For researchers: when researchers cross borders they will experience that practices and practitioners are not comparable across national boundaries, and any observational or experimental study can therefore be generalised only within a narrow national or cultural context.

Work package 3

Needs and attitudes of citizens

Leading beneficiary
University of Southern Denmark (SDU)

Work Package leader
Prof Helle Johannessen, PhD

Many citizens in Europe have positive attitudes to CAM although their attitudes and needs have not been consistently researched across Europe.

In addition they

- **wish to have access to increased and diverse CAM provision**
- **need easily accessible and trustworthy information regarding CAM**
- **require the transparent regulation of CAM and the training of those who practise CAM.**

More research in this field is needed.

Objectives

The objectives of WP3 were to identify cross-European indicators for population based needs and attitudes regarding CAM, and to identify, map and provide information on the needs of European citizens with respect to CAM, and their attitudes towards CAM.

Description of work

A purposeful sample of stakeholders was selected, taking account of the wide geographical range (EU, regional and national) and the diversity of knowledge and/or interests (e.g. academic, non-governmental, governmental) in CAM in Europe.

These stakeholders attended a workshop (Vienna, 24–25 June 2010) which sought to:

- identify how to explore the needs and attitudes of EU citizens to CAM
- share relevant sources of information about CAM
- identify how citizens' needs and attitudes to CAM can be measured and compared across the EU.

The workshop resulted in initial suggestions concerning relevant sources of information and participants identified three key issues regarding citizens' needs and attitudes to be considered in the systematic literature search:

- independent and easily accessible information about CAM, based on the strength of available evidence to support informed decision making
- quality of care that comprises CAM services, providers and products
- equal access to CAM services

These three central issues were transformed into literature search terms that broadly reflect a range of indicators for needs.

WP3 then carried out a systematic review of literature concerning EU citizens' needs and attitudes using the search terms mentioned above in the main relevant databases (PubMed, Web of Science, CINHAL, AMED, PsycINFO/Articles). These searches identified a broad range of quantitative and qualitative literature, and the reporting quality of the identified articles was assessed using acknowledged quality assessment.

Findings

It was only possible to research the attitudes and needs of citizens in Europe concerning CAM in 18 of 39 European countries; substantial research based knowledge is only available from the UK.

Nevertheless, the following tendencies can be reported:

- Citizens in the EU wish to have access to increased and diverse CAM provision: Studies indicate that citizens wish CAM to be available as part of their options for health care, for example in hospital and general practice care. They also wish CAM provision to be delivered not only by medical doctors and/or doctors trained in CAM specialities, nurses or other conventional health care providers, but also by CAM providers with therapy specific training. There is a wish for more, and more diverse, CAM provision.

- Barriers in the access to CAM: EU citizens seem to meet considerable barriers in the access to CAM: CAM treatments are predominantly paid for privately and are difficult to access due to lack of availability and limited accessibility.

- Citizens express a wish for more support and acknowledgement regarding their CAM use: CAM use is often not disclosed by patients in other treatments because of the assumed or known hostile attitude of the medical professionals towards CAM treatments.

- Citizens need easily accessible and trustworthy information: European citizens wish to have access to reliable and trustworthy information that can support an informed decision about treatment options.

- Citizens require transparent regulation of CAM practice and training: Citizens' confidence in the provision of CAM would be supported by public frameworks regulating the practice of CAM and by CAM being provided by members of professional CAM organisations that ensure educational as well as ethical standards.

Work package 4

CAM use – the patients' perspective

Leading beneficiary
University of Southampton (US)

Work package leader
Prof Dr George Lewith

The data available from our systematic review are inconclusive and of very variable quality. Many of the studies are of poor methodological quality. There are reliable data in a few countries but in the majority of the 27 EU member states there is no data.

However, use of herbal medicine was the most frequently reported use of CAM. Musculoskeletal problems were the most reported condition.

Objectives

The objectives of WP4 were to:

- address the prevalence of CAM use in Europe, taking into account regional and national variations, and creating a summary of current information about prevalence of CAM use and its trajectory
- identify the major conditions treated with CAM, based on existing literature as well as suggesting future research strategy to overcome relevant evidence gaps
- explore the reasons why patients choose CAM through a systematic review of survey material and existing databases
- identify a standardised questionnaire for CAM use in at least 3 European languages that will provide a consistent EU approach to a widespread, but clearly defined range of CAM.

Description of work

WP4 used a developed systematic review protocol in order to perform the original literature searches, so as to evaluate the use of CAM by EU citizens. They identified over 5,500 papers from the peer review literature. They removed duplicates and excluded opinion pieces, editorials or letters, guidelines, reviews, pharmacological, historical or geographical studies, effectiveness or efficacy studies and ethno botanical research, qualitative studies pertaining to the attitudes of CAM patients, CAM practitioners or CAM education and any studies of CAM use in disease specific populations. This left 190 papers potentially containing CAM use prevalence in general population surveys. Full papers were retrieved from the publishing journals, and further papers were excluded that did not meet the inclusion criteria. In the end we found 87 studies that reported the prevalence of CAM use, that were included in the final analysis.

These study inclusion criteria meant that for 25 EU member states (64%) no general population data on CAM use was located. The main characteristics of the included studies were that:

- the studies were generally of poor quality
- in 32% of papers, CAM was not defined to survey participants
- only 29% reported pilot studies of the questionnaire used and 79% reported data collection strategies that were subject to recall bias (recall over 12 months or more).

A standardised European Questionnaire (I-CAM-Q) was translated from English into German, Italian, Spanish, Hungarian, Romanian and Dutch. Country specific instructions were added as some terms differ across countries, e.g. the term chiropractor does not exist in Romania and would be poorly understood. We translated it as "manual therapist" with a descriptive explanatory note. It was also noted that there were differences in provider qualifications between countries, and with respect to education (MD or non MD). The translation of terms with explanations was also used on a country specific basis. A protocol was piloted with 50 people (40 people completed the questionnaire alone and returned it by post, and 10 completed it with a researcher). Analysis identified common problems across countries including a "hard to read" layout, misunderstood terminology and uncertainty in choosing response options. Quantitative analysis confirmed that a substantial minority of respondents failed to follow questionnaire instructions and some questions had substantial rates of missing data. As a self-complete questionnaire, the I-CAM-Q has low face validity, low acceptability, and is likely to produce biased estimates of CAM use if used in England, Romania, Italy, Netherlands or Spain.

Findings

There is a lack of reliable data on the prevalence of CAM. However, use of herbal medicine was the most frequently reported use of CAM. Musculoskeletal problems were the most reported condition.

While there are a few rigorous prevalence studies that are based on nationally representative samples, the vast majority are small and of poor quality. Most EU countries do not have any data at all. Reported prevalence rates of CAM use were between 0.3% and 86%. We were unable to calculate the overall prevalence rate for herbal medicine, homoeopathy, chiropractic, acupuncture or reflexology by either country or across the EU or to differentiate between practitioner (doctor) based prescriptions and over the counter purchases of homeopathic and herbal medicines.

Prevalence rates of the main therapies in use were reported as follows:

- Herbal medicine (31 studies): prevalence rates varied from 5.9 – 48.3% of the population studies. However herbal medicine was not well defined (it may be included in naturopathy, folk medicine or traditional Chinese medicine) and variously categorised as medical herbalism, herbal remedies, herbal teas, phytotherapy. Some specific herbs were reported by name such as St John's Wort.
- Homeopathy (25 studies): prevalence rates varied from 2 – 27% of the populations studied.
- Chiropractic (17 studies): sometimes reported as "Chiropractic or osteopathy" (1 study), as one of a group of CAMs (4 studies) and as "manual or manipulative treatments" (2 studies). Prevalence rates were 0.4 – 20.8% of the populations studied.
- Acupuncture (14 studies): was poorly defined. Prevalence rates were 0.44 – 23% of the populations studied. Eight further studies reported acupuncture as part of groups of CAMs.

- Reflexology (11 studies): and in a group of CAMs in one other study. Prevalence rates varied from 0.4 – 21% of the populations studied.
- Dietary supplements: calcium supplement use was reported in 9 studies. Use of all other dietary supplements, vitamins, minerals, fish oils, glucosamine and other products was reported heterogeneously in groups, singly or combinations of supplements in 28 papers. It was not possible to distinguish whether the dietary supplements were bought over the counter or prescribed at consultations.

As regards a reliable method to measure CAM prevalence:

- We have piloted an existing questionnaire (the I-CAM-Q) in 4 EU member states.
- We need a questionnaire-based tool to measure the prevalence of core CAM practices and to obtain reliable population based data.
- Unfortunately the I-CAM-Q in its present form has many weaknesses and will require major revision before it can be widely utilized for this purpose.

Work package 5

CAM use – the providers' perspective

Leading beneficiary
Universität Bern (UNIBE)

Work package leader
Dr Klaus von Ammon

No common approach can be identified as regards the provision of CAM practice in Europe. Both medical and non-medical practitioners play an important role in the provision of CAM within the healthcare system in Europe. Teaching and certification are subject to international, national or in some countries even regional regulations. There is a complete lack of coherence in training, education and provision of CAM.

CAM provision in Europe requires the:

- **transparent harmonisation of CAM training, medical education and certification**
- **standards of the regulation and registration bodies for both therapists and products to be open to the public.**

Objectives

WP5 sought to identify the different models of CAM provided by registered physicians and CAM practitioners (including non-medical providers with no academic background) by country within European public health systems.

It aimed to:

- review literature addressing the providers' perspective of CAM use in Europe, find out how many providers offer CAM and which different CAM methods are provided
- identify the health problems for which CAM is utilised (with WP4)
- explore how CAM research and the relevant evidence base are integrated into CAM practice
- describe the impact of research results on health care practice.

Description of work

There are few peer reviewed publications that deal with this topic and present reliable data. For physicians, registration bodies enable data sampling in a more or less reliable manner through internet searches, whereas non-medical practitioners are rarely organised and thus much less accessible through the internet. With decreasing "levels" of professional organisation the precision and accuracy of the available data diminishes.

As regards physicians, four of the five most provided CAM therapies were clearly identified: acupuncture, manual therapies, homeopathy, and herbal medicine are represented in almost all EU27+12 countries. A population based ranking of the next 5 to 15 therapies demonstrates decreasing accuracy with decreasing order due to lack of reliable data, mostly in the new EU member states and some of associated countries. For some of the professionally organised non-medical practitioners, web-

derived data of varying reliability are available. However, even for some western EU countries, including France, Germany, Italy, Portugal and Spain, this data must be gathered from the "yellow pages". In summary, there is a North to South and West to East decline concerning the reliability of data for both medical and non-medical CAM providers.

WP5 tested various forms of communication and meeting formats to understand and develop appropriate research methods, and identify the national approaches to medicine and health care barriers. Research was restricted to registered CAM practitioners, both medical and non-medical, and further contributions from NGOs were included in the final deliverable. Together with WP4, WP5 identified the health problems for which CAM is used and contacted national registration bodies for information to allow cross-referencing of data for physicians and non-medical practitioners. The data obtained were displayed in tables and country and discipline specific maps.

As regards education and training, three levels of qualification and certification were identified:

- medically trained professionals like dentists, pharmacists, physicians (MD) veterinarians and sometimes midwifes, fully trained in both, conventional medicine and CAM, according to national (MD) and international CAM standards with national diploma and registration, continuous medical education (CME) and repeated certifications
- non-medical practitioners with full CAM training of various levels according to national or international standards (e. g. ECCH diploma), and
- MDs and non-medically trained practitioners who receive a lower level of education within their chosen CAM discipline.

No specific data were obtained for impact of research on education and practice, but we assume no differences compared to conventional medicine, where scarce data is available. WP5 also

identified a lack of information regarding CAM products. Hence, the European Coalition on Homeopathic and Anthroposophic Medicinal Products (ECHAMP) and the Association of Natural Medicine in Europe (ANME) were asked for their specific and, where available, general data concerning the market for CAM products.

Findings

CAM provision in Europe comprises health care practitioners and physicians with different healing attitudes, medical background, training, certification, and practice. Data are only available if they are registered in any specific body open to the public, and are therefore scarce, scientific publications are almost lacking completely.

Both medical and non-medical practitioners play an important role in the provision of CAM within the healthcare system in Europe.

CAM provision in the EU27+12 is maintained by more than 150,000 registered medical doctors (MDs) with additional CAM certification and more than 180,000 registered and certified non-medical CAM practitioners. This suggests up to 65 CAM providers (35 non-medical practitioners and 30 physicians) per 100,000 inhabitants, compared to the EU figures of 95 general medical practitioners per 100,000 inhabitants.

Acupuncture is the most frequently provided method (53% of all practitioners) with 80,000 physicians and 16,000 non-medical practitioners trained in the therapy, followed by homeopathy (27% – 45,000 and 4,500, respectively). These two disciplines are both dominated by physicians. Herbal medicine and manual therapies are almost exclusively provided by non-medical practitioners.

Naturopathy, on the other hand, is dominated by 15,000 (mostly German) physicians, as is anthroposophic medicine (4,500) and neural therapy (1,500).

CAM provision in Europe has not yet gained governmental interest at large; state funded research based knowledge is mainly available for Denmark, Germany, Norway, Switzerland, and the UK. This calls for more research in this field throughout the EU and associated countries.

Public demand can be noted for the following:

- the transparent harmonisation of CAM training, medical education and certification
- that the standards of the regulation and registration bodies for both therapists and products to be open to the public.

Work package 6

The global perspective

Leading beneficiary
Karolinska Institutet (KI)

Work package leader
Prof Dr Torkel Falkenberg

High quality research requires independent peer reviewed funding and experienced medical research networks: both should be fostered by a European institutional structure comparable to the National Centre for Complementary & Alternative Medicine (NCCAM) in the United States.

A centralised EU CAM centre could make operational the CAMbrella recommendations in collaboration with selected EU member states and appropriate (worldwide) academic institutions to enable evidence-based health sector reform with appropriate CAM interventions in the EU.

Objectives

The aim of WP6 was to map the international position and status of CAM within health care policy so as to view the EU situation in context. This approach was founded on the WHO Global strategy for Traditional Medicine (TM) and/or CAM, and its main objectives were to:

- incorporate experiences from countries in which CAM Research and Development (R&D) is integrated and publicly supported (US/Canada), while exploring its use as TM in developing countries (China/India)
- understand the pros and cons of CAM R&D internationally addressing issues of patient rights and need, cost, regulation (of practitioner and product), evidence base and research policy/strategy
- consider the risks of over harvesting medicinal plants and the protection of traditional inherited knowledge of traditional medicine used within CAM
- identify the strategies we need to address from an EU perspective, as well as develop an understanding of how the EU might relate to international developments.

Description of work

Through a nomination and prioritisation process, fifteen global R&D stakeholders were identified based on their international relevance as indicated by number of publications, funded research projects and financial research allocations:

Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), India
State funded department / institute
Central Council for Research in Ayurveda & Siddha (CCRAS), AYUSH, India
State funded department/ institute
China academy of Traditional Chinese Medicine, China
State funded department / institute

The Consortium of Academic Health Centers for Integrative Medicine (here referred to as IM consortium) (CAHCIM), North America
Research association
Federal Ministry of Health / Complementary and Alternative Medicine, Brazil
State funded department / institute
International Society for Complementary Medicine Research (ISCMR), international
Research association
Japan Society of Oriental Medicine, Japan
Research organisation
Korean Institute of Oriental Medicine, Korea
State funded department / institute
National Center for Complementary and Alternative Medicine, National Institutes of Health, USA
State funded department / institute
National Institute of Complementary Medicine (NCIM), Australia
Research organisation (partly state funded)
Natural Health Product Directorate, Health Canada, Canada
State funded department / institute (time limited initiative)
Osher Program for integrative medicine, located centers in USA and Sweden
Research organisation
Research Council for Complementary Medicine, international, UK based
Research association
Samueli Institute, USA
Research organisation
World Health Organization, Traditional Medicine, international
Global health organisation

WP6 developed a protocol for data collection, partly based on structure, process and outcome indicators published by WHO, to facilitate the development of evidence based national policies on medicinal products. The main topics in the protocol included the mission statement, R&D activities, and explicit or implicit R&D strategies.

We collected information from policy documents from the prioritised stakeholders and carried out personal interviews with them, selecting documents on the basis of their relevance in answering the questions in the research protocol, including policy

documents and information on websites. Although documents were available for all prioritised stakeholders independent of the interviews, the interviews proved to be very valuable for finding the most relevant, accurate and up to date documents.

An international meeting in Chengdu, China, was arranged so as to benefit from a wider audience of CAM researchers present at the large international research meeting ICCMR 2011. At this meeting the WP6 results were presented and participants were invited to comment on the findings. In addition, separate interviews were arranged with high level Korean and Chinese experts.

WP6 analysed the interviews with key stakeholders and documentary information collected from all stakeholders using principles of content analysis. Data of descriptive character included the budget, source of funding, number of funded research projects, and focus area (e.g. TM/CAM vs. specific therapies). The explorative analysis included data from both documents and interviews concerning mission statements and R&D strategies. Preliminary findings indicate that activities of key stakeholders vary greatly in terms of capacity, mission, and source of funding (private/public). R&D activities among selected stakeholders ranged from a mere provision of research funding to a comprehensive R&D and communication agenda.

R&D strategies could be categorised as follows:

- context, paradigms, philosophical understanding and utilization
- safety status
- comparative effectiveness
- component efficacy
- biological mechanisms.

The lessons from this analysis of CAM R&D amongst international stakeholders provided valuable input into the EU CAM research roadmap.

Findings

Key stakeholders on the global arena of CAM R&D vary greatly in terms of capacity, mission, and funding source (private/public). They ranged from only providing research funding to having a comprehensive R&D and communication agenda. A common shift in R&D strategy was noted. Where ten years ago research focused mainly on exploring efficacy and mechanisms, the majority of stakeholders today emphasise the importance of a broad spectrum of research including methodologies exploring context, safety and comparative effectiveness of whole systems of care.

Europe lags well behind other regions such as North America, Asia and Australia in terms of the level of investment in CAM research and the integration of research results into health policy and health regulation.

An emerging trend among many of the stakeholders was to prioritise studies focusing on clinical effectiveness of whole systems of care.

The choice of method(s) for any particular project or experiment should be based on the specific scientific question and should focus on delivering safe and effective health interventions to EU citizens.

In line with our findings, the CAM research strategy for Europe should be based on the popularity of a specific intervention and related to the national or regional public health needs and disease burden. The work of WP6 supports a formation of a centralized and academically supported EU CAM research centre.

Work package 7

The Roadmap for CAM research in Europe

Leading beneficiary
Charité – Universitätsmedizin Berlin (Charité)

Work package leader
Prof Dr Benno Brinkhaus

- **CAM is a neglected area of research in the EU – it needs active encouragement**
- **An EU research strategy for CAM must prioritise a European wide approach that reflects the needs of the citizens and providers of CAM**
- **Research methods must reflect the real-world settings of health care in Europe**
- **A centralised and academically supported EU CAM centre should make this EU research strategy operational**

Objectives

The main objectives of WP7 were to:

- analyse the research methods already applied to CAM in the EU
- develop research methods and strategies for CAM that take into account the needs and attitudes of EU citizens and providers
- develop research strategies and a research roadmap to enable future clinical and epidemiological research in the field of CAM regarding prevalence of use, effectiveness, efficacy, cost effectiveness and safety.

Description of work

WP7 collected data and expert opinions on research into CAM. We conducted a literature review on the main methodological issues, problems, priorities and strategies in CAM research. Furthermore, methodological aspects of WPs 3, 4 and 5 were reviewed. Based on these findings, we organised a workshop with international, distinguished experts. The workshop developed methodological recommendations in a consensus process. These recommendations were formulated into the Roadmap for CAM research in Europe within Work Package 7 and approved by the CAMbrella final consensus conference and CAMbrella's scientific steering committee.

Findings

There is too little knowledge about the current state of CAM in Europe:

- about the prevalence of use of CAM in most European countries
- about the needs and attitudes of EU citizens, patients and providers regarding CAM
- about the types and modi of CAM provision

In the past, the majority of clinical trials have assessed the efficacy rather than the effectiveness of CAM, meaning:

- there is a lack of data on the clinical outcomes of CAM treatments in comparison with conventional treatments in real-world settings
- unspecific effects seem to have significant value in CAM treatments
- reliable data about safety and adverse effects of CAM in real-world settings are scarce.

There is considerable heterogeneity within CAM in the EU and these differences have hampered the development of combined European research efforts. The challenges now are to:

- gather comparable information about the real situation as regards provision, use and regulation of CAM in all countries of Europe
- identify and address the areas in which CAM could play a role in the improvement of health care to European citizens
- Establish a scientific knowledge base that enables all stake-holders including policy makers, researchers, health care providers and citizens to make informed decisions about CAM.

Conclusions and recommendations

In order to consider employing CAM as part of the solution to the health care challenges we face in 2020, it is vital to obtain reliable information on its prevalence of use, effectiveness, safety and cost in real world settings. This research strategy aims to provide the EU and its citizens with valuable scientific information for stakeholder decisions about CAM treatments.

1. CAM is a neglected area of research – it needs active encouragement

European research in the field of CAM is limited and our knowledge about CAM is very poor. There is almost no significant investment in any EU country in a CAM research structure or strategy. The CAM industry is small and there are no major financial or/and industrial interests driving research efforts in this field. Scientific bias hampers the free exchange of ideas, concepts, treatment techniques and comparison of clinical outcomes. CAM is organised mostly in private provider settings (medical and non-medical), thus the academic experience among CAM providers is scarce and there are few academic centres of research, resulting in a substantial lack of funding for research programmes. Career opportunities in an academic setting are rare.

In order to pay proper attention to the real situation of use and provision of CAM in Europe, and to understand why CAM is so popular within the EU, structural and sufficient financial support is needed at all levels: private, university bound, national and European.

2. An EU research strategy for CAM must reflect the needs of the citizens, patients, providers and other stakeholders

CAM is frequently employed in prevention, health literacy and self-management of chronic long-term conditions. Therefore it could contribute to the upcoming health care challenges in Europe.

Foremost, it is needed to:

- establish a European-wide approach to assess the prevalence of use of core CAM disciplines
- address the diversity of training, education and provision of CAM across Europe
- identify the most promising CAM treatment options for the most prevalent health conditions in Europe (obesity, chronic diseases like diabetes, cancer, musculoskeletal problems, healthy ageing and others)
- quantify the economic effects of CAM in European health care

Stakeholders might have different views on CAM; these views should be taken into account in order to achieve meaningful research and allow stakeholders to make informed decisions for future health planning:

- identify the citizens' access to and preferences for CAM provision as well as their perspectives on education, training and practice of CAM providers
- determine how best to disseminate scientifically sound information about CAM to the European public, in line with the EU objective to enhance the ability of citizens to make better and informed decisions about their health care
- give clear guidance on CAM safety issues
- research and evaluate different models of CAM health care integration into routine care programmes

3. Research methods must reflect the real-world settings of health care in Europe

CAM should be considered along the same scientific lines that apply to medical research in general.

Everyone needs to know in what situation CAM is a reasonable choice. Therefore we recommend a clear emphasis on concurrent evaluation of CAM as an additional or alternative treatment strategy in real-world settings.

The strategy for the investigation of CAM should include a broad range of mixed-method research strategies including comparative effectiveness research, qualitative and quantitative designs. Stakeholders such as citizens, patients and providers should be closely involved to ensure real world relevance for the research.

Specifically, we recommend to:

- implement comparative effectiveness research (CER) and concurrent health economic evaluation of different treatment strategies including CAM
- put emphasis on the investigation of CAM safety in clinical contexts, e.g. by support of country-wide registers, observational studies, single case studies or case histories
- address the impact of context and meaning factors (generally known as non-specific effects and may include the "placebo effect") such as preferences and expectations in clinical research.

4. A centralised and academically supported EU CAM centre should make this EU research strategy operational

Currently there is little research on CAM in Europe and no structure through which research can be co-ordinated within the EU. There is a widely recognised need to ensure high quality research to enable scientific knowledge that is considered adequate for informed decision making by both providers and patients of CAM.

We propose that the EU actively supports an EU-wide strategic approach to facilitate the development of CAM research, through the funding of an EU centre for CAM that looks into the situation of CAM and gives research-based guidelines on how to address it. The aim of such a European centre for CAM would be to actively stimulate high quality research on CAM in the EU based on pan-European collaboration, through an independent research strategy aligned with EU health policy.

Work package 8

Communication and dissemination

Leading beneficiary
Viennese Academy for Integrative Medicine (Gamed)

Work Package leader
Dr Bettina Reiter

Communication in research is essential to ensure

- **and support capacities, coherence and collegiality of any multicentered research group**
- **a corporate identity for the collaboration and enhance its visibility**
- **the sustained dissemination of the results to the public at large and the stakeholder groups in particular**
- **to create a coherent message and slogan that can engage the public in a dialogue about scientific results**
- **translate the scientific results into public outreach for the general public**

Objectives

- to foster communication among the CAMbrella consortium members and between the consortium and CAM stakeholders including patient and public health care organizations
- to establish, host and maintain a website as the common platform for CAMbrella: **www.cambrella.eu**. The website will make all documents generated by the project publicly accessible.
- to identify CAM stakeholders and appropriate target audiences in Europe through which to disseminate information generated by the project
- to plan and organize the final CAMbrella conference

Description of work

WP 8 acted from the beginning of CAMbrella as the connecting / networking body within the group and at the same time developed the tools for sustainable dissemination during and after the completion of the project. We prepared proposals for a project logo already in advance for the kick off meeting in Munich in January 2010. The whole group discussed the image of CAMbrella given in the logo.

This resulted in the development and implementation of an appropriate Corporate Identity: Corporate Design, such as a Logo and guidelines for the graphics and work of all WPs, creating templates for spreadsheets and text processing; Implementation of Corporate Identity in the other WPs and their respective activities.

The next important step was to set up the project´s website providing all relevant information. A newsletter was launched that has sent out 12 issues of information about the project, but also about CAM in Europe, giving stakeholder portraits, reports about the CAM field in different European countries, pointing out relevant findings and other CAM related projects,

announcing conferences and scientific events etc. Via the website interested readers were able to subscribe to the newsletter, a feature which was used by about 750 readers.

We tried to invite and facilitate the dialogue with relevant stakeholders and the public at large in order to know more about their informational needs about CAM in general and research in particular. The website invited to register as a stakeholder in CAM. 53 institutions did so and have been contacted via letters. In an online questionnaire we approached international stakeholders in order to know more about their informational needs towards CAM. In turn the results of this online survey were the starting point for the discussion with international stakeholders at a workshop in Brussels, dedicated specially to the needs in terms of information about CAM.

The preparation and organization of the final conference with contributions from WP1 to WP7 was the major goal of WP8. It is a disseminative action that targets policy makers on the European level, especially the EU Commission, DG Health and Consumers (Sanco) and DG Research and innovation as well as interested stakeholders and the public at large.

Organising the final conference was made substantially easier by the kind support of Dr. Angelika Niebler, Member of the European Parliament, who was kind enough to invite her colleagues to a workshop devoted to the CAMbrella findings on November 28, 2012 inside the Parliament. The project was presented in a more comprehensive way on a full-day final conference the following day. This meeting was kindly hosted by the Bavarian representation in Brussels which proved very useful for all the backstage organisation a conference like this entails.

Disseminative actions and documents had to be established and prepared: A Policy Brief, the document that informs the EU Commission and policy makers about the findings and gives recommendations for future activities. The Policy Brief was

achieved in a consensus building process that involved all work packages and was given a final discussion and approval at a meeting of the Scientific Steering Committee. A Project Brochure that summarises the work of CAMbrella for the interested public, practitioners, laymen and stakeholders alike was prepared mostly by the autonomous input of the work packages, WP8 taking the editing role here. We were able to enhance the visibility of the scientific dissemination in pooling many of the papers in a supplement of Research in Complementary Medicine: Forsch Komplementmed 2012;19 (suppl 2).

In all public outreach WP8 always had the task to "translate" the scientific results into texts dedicated for the broader public, for example in the newsletter. WP8 acted as interface between the project and the interested audiences around. Differing interests in the target groups for the newsletter have to be considered in order to catch the attention of readers with different backgrounds.

The project's website was a state-of-the-art tool to connect with the stakeholders, to enable exchange with them, allow them some participation and interaction. In order to address a younger audience a facebook account was set up as well. To complete the project's presence in the Social Media media Twitter was added to our public outreach activities as well. All this formed part of the dissemination strategy.

In collaboration with the work package leaders WP8 created a unique project slogan compressing the key messages of all work packages:

CAMbrella – the Roadmap for European CAM Research

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SEVENTH FRAMEWORK
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