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International Development of Traditional Medicine / Complementary and Alternative Medicine Research – What Can Europe Learn?

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Summary
Background: The aim of this study was to analyse global research and development (R&D) strategies for traditional medicine (TM) and complementary and alternative medicine (CAM) across the world to learn from previous and on-going activities. **Methods:** 52 representatives within CAMbrella nominated 43 key international stakeholders (individuals and organisations) and 15 of these were prioritised. Information from policy documents including mission statements, R&D strategies and R&D activities were collected in combination with personal interviews. Data were analysed using the principles of content analysis. **Results:** Key stakeholders 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; whereas 10 years ago research focused mainly on exploring efficacy and mechanisms, today the majority of stakeholders emphasise the importance of a broad spectrum of research, including methodologies exploring context, safety and comparative effectiveness. **Conclusion:** The scarce public investment in this field in Europe stands in stark contrast to the large investments found in Australia, Asia and North America. There is an emerging global trend supporting a broad research repertoire, including qualitative and comparative effectiveness research. This trend should be considered by the EU given the experience and the substantial research funding committed by the included stakeholders. To facilitate international collaborative efforts and minimise the risk of investment failure, we recommend the formation of a centralised EU CAM research centre fostering a broad CAM R&D agenda with the responsibility for implementing the relevant findings of CAMbrella.

Introduction

While traditional medicine (TM) and complementary and alternative medicine (CAM) are widely used across the world, the research area of TM/CAM is relatively new. Although there is no apparent consensus regarding how TM/CAM research should be carried out, there is an emerging notion that research into CAM needs to be strategically developed. Consequently, a major goal of the EU-project CAMbrella was to propose a sustainable structure and pol-

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Table 1. Stakeholders and the type of organisation they represent

Name of stakeholder	Type of organisation
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
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 & 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

icy for CAM research and development (R&D) in Europe. The aim of the work package presented here was to analyse the global R&D situation for CAM to learn from previous and on-going CAM research initiatives and to inform the EU roadmap.

Material and Methods

Identification of Stakeholders

To identify global key stakeholders within TM/CAM R&D we sent out requests via e-mail asking for nominations of such individuals or organisations. 52 persons from the CAMbrella consortium and a selected group of external experts were contacted and asked to contribute nominations of individuals or organisations outside the EU playing a key role in TM/CAM R&D. Stakeholders from countries in which CAM R&D is integrated and publicly supported (e.g., US/Canada) were identified as well as stakeholders from countries where TM is widely used (e.g., China/India). 43 stakeholders (individuals and organisations) were nominated. These nominees were prioritised based on their international relevance as indicated by the number of publications, funded research projects and financial research allocations. 15 stakeholders were given first priority status (see table 1) and were grouped into 4 different organisational types: (i) government-funded departments or institutes; (ii) research organisations; (iii) research associations (with networking as primary goal); and (iv) global health organisations.

Policy Analysis

The analysis of TM/CAM policy was conducted in 2 main steps that involved data from documents, websites and interviews with selected stakeholders. A protocol for data collection was developed, partly based on the structure, process and outcome indicators published by the World Health Organization (WHO) used for the development of evidence-based national drug policies [1].

With guidance from this research protocol, we conducted interviews with 6 stakeholders selected on the basis of their representation of different types of organisations across the globe and their willingness and ability to participate in a face-to-face interview: KIOM (Korea), NCCAM/National Institutes of Health (NIH; USA), NICM (Australia), CCRAS/AYUSH (India), Samueli Institute (USA), NHPD/Health Canada (Canada).

Data from interviews and documents played a complementary role and were analysed using principles of content analysis [2, 3]. The first step in the analysis involved an exploration of descriptive data, e.g., stakeholders' funding, number of funded projects as well as an exploration of stakeholders' R&D strategies and mission statements, in addition to their testimonials during the interviews. The 5 categories of research approaches described by Fønnebø et al. [4] were used as a guiding framework for analysing R&D strategies.

While the analysis of the stakeholders' R&D strategies in step 1 aimed to show how stakeholders wanted their R&D practice to be implemented, step 2 of the analysis aimed to explore stakeholders' self-reported practice of CAM R&D. Self-reported activities were here defined as projects and publications that were mentioned by the stakeholders either on their website, in key R&D documents or listed as publications in PubMed. Completed and on-going projects were included. The websites and key R&D documents of stakeholders were extensively searched for any possible listings of research studies/publications. The goal was to find an abstract for each study. However, when this was not possible other information, e.g., the title, served as a basis for analysing the nature and content of the project.

Results

As described below in 3 separate sections, our findings point both to similarities and differences in stakeholders' TM/CAM R&D.

Descriptive Measures: Capacity and Funding

The 15 stakeholders vary greatly in capacity and funding (see table 2). Some Asian stakeholders began their work in the 1950s, while a number of stakeholders in high-income countries (North America and the Pacific region) date from the 1990s or 2000s.

Most of the financial support comes from public sources but, due to differences in the way budget figures are presented, it is difficult to compare budgets between stakeholders. For example, official fiscal budgets from 2010 range from almost €100 million to approximately EUR 5 million. The majority of stakeholders that conduct research also fund external research. Some stakeholders serve only as research networks (in table 2 referred to as research organisations) and do not have their own research budgets.

Mission Statements

By analysing the mission statements of 15 stakeholders, we have identified 4 main themes: i) The development of health care practice; ii) the scientific exploration of TM/CAM; iii) communication of TM/CAM-related research; and iv) TM/CAM focus areas. These themes represent both the expressed goals of the selected stakeholders and the means of achieving these goals. Although these themes overlap, they are distinct and not contradictory and are presented below under separate sub-headings. The excerpts presented in the results are used to illustrate the analytical points in each theme.

Development of Health Care Practice

The mission statements of a few stakeholders disclose a general goal to transform and improve health care and health of citizens:

'The mission of the Samueli Institute is to transform health care …' (Samueli Institute)

Other stakeholders express a similar goal if slightly different in terms of promoting integration between conventional health care systems and TM/CAM. The Osher Program for Integrative Medicine and the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), India Ministry of Health and Family Welfare are 2 such examples:

'… A third goal is to establish clinical treatment programs in which the knowledge and resources of integrative medicine can be used directly to help people as well as furnish training opportunities for medical students.' (Osher Program for Integrative Medicine)

'To mainstream AYUSH at all levels in the health care system…' (AYUSH).

The Scientific Exploration of TM/CAM

The most general and prevalent theme found in the mission statements concerns the scientific exploration of TM/CAM. Some stakeholders wish to increase the academic influence and interest in CAM by extending the evidence base and conducting rigorous science. This was exemplified by the mission statement of the Research Council for Complementary Medicine (RCCM) and National Center for Complementary and Alternative Medicine (NCCAM/NIH):

'Our aim is to develop and extend the evidence base for complementary medicine …' (RCCM)

'We are dedicated to exploring complementary and alternative healing practices in the context of rigorous science …' (NCCAM).

Communication of TM/CAM-Related Research

Another overarching goal expressed in the mission statements of many included stakeholders was to provide a communication platform for TM/CAM research. The specific focus of such communication activities ranged from providing a 'platform for information exchange' (e.g., ISCMR) to 'research translation and dissemination both to the public and professionals' (e.g., NCCAM):

'… and disseminating authoritative information to the public and professional communities. … A second goal is to reach out to the larger community with an emphasis on preventive care. The center seeks to educate both medical practitioners as well as the general public' (NCCAM).

TM/CAM Focus Area

Some stakeholders focused on specific areas of TM/CAM, such as a specific type of traditional medicine or natural product. Among the selected stakeholders there were examples of government-funded institutions focusing specifically on TM in China, India, Japan and Korea. Interestingly, the mission statements seem to indicate 2 lines of development: While KIOM, Korea, expressed striving towards modernisation and industrialisation of Traditional Korean Medicine, the mission statement of AYUSH, India, indicates that their intention for TM (in its present form) is to take a larger role within the general health care system:

'… to contribute to the improvement of human health through modernization and industrialization of TKM (Traditional Korean Medicine)' (KIOM).

'To mainstream AYUSH at all levels in the health care system; to improve access to and quality of health care delivery …' (AYUSH).

Interestingly, the Natural Health Products Directorate (NHPD) was the only selected stakeholder to explicitly emphasise the safety aspect in its mission statement:

Table 2. Descriptive measures for the included stakeholders. The figures are based on official documents and website information of the stakeholders

Stakeholder	Date established and time of operation	Budget estimates**	Financial support	Finances external research	Performs own research
Federal Ministry of Health (MoH), Brazil	1953–	total CAM investment (2003–2008): €4,740,596	federal	yes	yes
Natural Health Products Directorate (NHPD), Health Canada	2003–2008	total investment (2003–2008): €2,378,010 [NHPD, 2008]	federal	yes (~11.5% of budget for partnership)	no
Samueli Institute	2001–	€12,582,080 (2010) €10,437,973 (2009) €9,479,370 (2008)	private, not-for-profit	yes	yes
Osher Centers	centres in the USA (Harvard, 2001 & UCSF, 1998) and in Sweden (KI, 2005)	official budget figures not found	private, not-for profit	yes.	yes
The Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)	1995–	€142,645,082 (2010–2011) €127,699,902 (2009–2010)	federal	no	yes
CCRAS (AYUSH)	1978–	€19,574,744 (2010–2011) €20,342,381(2009–2010)	federal	no	yes
World Health Organization (WHO), Traditional Medicine (TRM)	date of establishment not found	not found	member state support; private/public funding	not been found	no
Research Council for Complementary Medicine (RCCM)	1983–	N/A	charity	no	no
Korean Institute of Oriental Medicine (KIOM)	1994–	€29,149,799 (2011) €19,944,599 (2010) €15,341,999 (2009)	federal	yes (~10% budget goes to external research projects)	yes
National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health (NIH)	1998–	*€101,260,265 (2011 planned); €98,795,573 (2010); €93,352,232 (2009)	federal	yes	yes
Integrative Medicine (IM) Consortium	1999–	N/A	memberships and philanthropic support	no	no
International Society for Complementary Medical Research (ISCMR)	2003–	N/A	non-profit organisation with membership finances	no	no
Japan Society of Oriental Medicine (JSOM)	1950–	official budget figures not found	non-profit organisation	not found	yes
China Academy of Traditional Chinese Medicine (CATCM)	1955–	official budget figures not found	federal	not found	yes
National Institute of Complementary Medicine (NICM)	2007–2009	€6,044,748 (2009)	€1,380,780 (2009) from federal support, and €4,663,968 from universities and other collaborative partners	no	yes

*This represents approximately half of the budget of research into CAM. The other half is primarily represented by the National Cancer Institute (NCI).
**Budgets are estimates derived from electronic sources which have not been confirmed by the stakeholders, and hence should be taken as pointers of investment and not be misinterpreted as actual spending.

'The mission is to contribute to improved knowledge of NHPD to enable Canadians to make informed choices about their safe and effective use' (Health Canada).

Stated R&D Strategies and Self-Reported Actual R&D Activities

In the analysis of the selected stakeholders' R&D strategies and activities, we found 3 main themes that seem to direct their R&D strategies: i) type of research; ii) utilisation; and iii) impact on society.

Type of Research: Stated R&D Strategies

A strong trend was a development, over the last decade, from a focus on biological mechanisms and component efficacy to a broader focus on the investigation of complex interventions with multiple and mixed methodology. The director of CCRAS, for example, referred to this trend as 'reversed pharmacology'. This broad focus on all research methods also applies to the newly established centre, NICM, in Australia. NCCAM, USA, also emphasised a broader mixed methods research focus. 1 exception to this trend was KIOM, Korea, who expressed a main focus on component efficacy and biological mechanisms.

Type of Research: Self-Reported R&D Activities

The analysis of stakeholders' self-reported activities revealed that their R&D activity largely depended on their organisational type. Firstly, it was found that government funded departments or institutes as well as research organisations openly reported most of their R&D activities. Research associations with networking as their primary goal and global health organisations did not report having R&D activities of their own. Secondly, it seemed that the type of reported R&D activities prioritised by government-funded research organisations cover the whole range of research categories as described by Fønnebø et al [4]. Thirdly, it was found that among the stakeholders that did have R&D activity, their mission statements were in general consistent with their self-reported R&D activities. Hence, no apparent theory-practice gap among the analysed stakeholders was found.

Utilisation

The analyses indicated that to some stakeholders utilisation was an important factor directing R&D strategies, whereas to others utilisation did not seem to explicitly direct R&D policy. In general, there seems to be a difference between stakeholders focusing on CAM compared with those focusing on TM. All stakeholders focusing on CAM (e.g., NCCAM, NICM, NHPD) seemed to include prevalence figures as an influencing factor in prioritising research activity. CCRAS and KIOM focusing on TM, however, did not explicitly mention prevalence as directing their R&D strategy. In summary, utilisation of TM/CAM may influence R&D strategies in 2 different ways through: (i) the popularity of a certain TM/CAM, and (ii) the disease burden related to the condition for which a particular TM/CAM is used, as exemplified by NICM and NCCAM:

'… high burden of disease where preliminary evidence is strong and demonstrates likelihood of positive impact' (NICM, Australia).

'extent and nature of practice and use…' (NCCAM, USA).

Impact on Society

The potential role of TM/CAM R&D for the society seemed to be an important factor directing R&D policy. 2 such examples involved collaboration with regulatory authorities and the natural health products industry. Many research initiatives funded by the NHPD were connected to the development of regulatory functions. Moreover, NICM-prioritised research projects involved collaboration with the natural health products industry. For stakeholders focusing on TM (e.g., CCRAS), the issue of intellectual property rights was mentioned but not considered to be an obstacle, thanks to different initiatives including the Traditional Knowledge Digital Library.

Discussion

R&D strategies and activities among the selected stakeholders range from providing professional networks to having a comprehensive R&D policy and communication agenda. Despite this heterogeneity, 2 issues were of common priority to most stakeholders: (i) How to set priorities for CAM R&D and (ii) how to conduct CAM R&D.

Directing the Research – Types of Research and Prioritisation

A strong trend that was found was a development, over the last decade, from a research focus on biological mechanisms and component efficacy to a broader focus on the investigation of complex interventions with a broad range of research methodologies. This was favoured by most stakeholders and supported also by data from the interviews with the representatives of the WHO. This development is also reflected in the scientific literature both in medicine (e.g., Thorpe et al. [5]) and CAM (e.g., Witt et al. [6]). The importance of researching contextual factors in relation to CAM, and applying qualitative methodology can be illustrated by the research conducted by Kaptchuk et al. [7]. This trend provides an important recommendation for CAMbrella and the EU given the experience and size of research funding committed by the included stakeholders.

The issue of strategic CAM R&D was a difficult topic to discuss for various reasons, including the inherent national political nature of specific CAM modalities. For example, we found a spectrum of critical opinion regarding the NCCAM-funded research in the USA. At 1 end of the spectrum were

claims that CAM approaches are inherently implausible and justified only by 'pseudoscience' that peer-review processes are inferior and that the research agenda is driven by political pressures rather than scientific considerations, etc. At the other end of the spectrum were claims that NCCAM research fails to evaluate CAM as it is actually used in 'real-world' practice settings, that the field is dominated by reductionist scientific approaches or inappropriate methodology, and that there has been insufficient focus on health and wellness. In general, such contrasting views and opinions are likely to be common in many countries, including the EU member states, and may impact substantially on any CAM R&D initiative, pointing to the need for independent, public investments in the field. The NIH has in fact increased their expenditure on CAM research from approximately USD 100 million in 1999 to USD 520 million in 2010 [8]. The investment of the NIH in the NCCAM, and a number of similar public institutions around the world, as shown in this paper, stand in stark contrast to the European public investments in the field – despite the prevalent use of CAM among European citizens and the fact that many researchers in the field are based in Europe. This critique has also previously been pointed out in individual European countries such as the UK (e.g., [9, 10]), where public investments in CAM research have been showed to constitute 0.08% of the total research budget [11].

The contrasting views and opinions about CAM research found in our analysis could possibly explain why several of the stakeholders expressed aiming towards a balance between the many types of research methodology. This was also confirmed by our analysis of the actual CAM R&D projects carried out. This, however, seems to apply mainly to initiatives in high-income countries. In contrast, in China and South Korea, the focus appears to be predominately on component efficacy and biological mechanisms. However, India seems to support a shift of focus from efficacy towards 'real world' comparative effectiveness research, stated by the director of CCRAS, as a 'reversed pharmacology' research approach. Despite the aim of many stakeholders to invest in a broad spectrum of research methodologies, priority setting is vital for any organisation given the limited R&D funding available. Priority setting was suggested to occur for both NICM and NCCAM considering the popularity of a certain CAM and the disease burden.

The lack of R&D focus with regard to safety of CAM indicates that the reasons or lack of reason behind this should be studied further. It should be noted that, for example, the Uppsala Monitoring Centre, a WHO Collaborating Centre, has for a long time had systems for reporting and analysis of adverse events following herbal product use [12]. Given the extensive use of TM/CAM products across the world, the low number of reported adverse events published in the scientific literature is notable. Such findings may challenge funding of costly general regulation of CAM products and therapies that have a broad therapeutic application and that have been used extensively among populations for many years. On the contrary, reports on, e.g., high levels of heavy metals in Ayurvedic preparations (e.g., Saper et al [13]) point to the need for targeted regulation.

Impact on Society and Intellectual Property Rights

Moreover, our results indicate that some stakeholders support health care reform with the aim of including TM/CAM where this is compatible with their current national health legislation. While the KIOM works for modernisation and industrialisation of TKM, CCRAS/AYUSH, India, aims for TM to take a larger role within the general health care system in its present format. The issue of intellectual property rights was raised by stakeholders focusing on TM as an obstacle to R&D efforts. Stakeholders pointed out that this was because most TM modalities cannot be patented, and indigenous knowledge may, hence, be exploited for commercial purposes without any benefit to the nation or indigenous population.

Methodological Considerations

To our knowledge the presented study is the first stakeholder analysis on this topic. The data on which these results are based are largely dependent on the level of transparency of the included stakeholders. The views of individuals representing an organisation may sometimes differ from the organisation as a whole. However, the triangulation of different data sources was a way of reducing this. The limitations of drawing conclusions from mission statements should also be considered, since mission statements may not reflect current thinking and activities of the stakeholders. In addition, our approach to review actual practice by the stakeholders reflects the totality of the stakeholders' engagement, which may not be reported through such sources. However, the coherence between theory and practice in R&D indicates that R&D activities were justly reported. Finally, we have not been able to include stakeholders from the Africa or Middle-East, and this is a limitation to our conclusions.

Conclusion and Recommendations

The conclusion and recommendations from this study could be summarised as follows:

- A broad range of mixed methods research strategies should be used to investigate CAM within the EU. 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.
- The CAM research strategy for Europe should be based on the popularity of a specific intervention and be related to the national or regional public health needs and disease burden.
- We recommend the formation of a centralised and academically supported EU CAM research centre with responsibility for operationalising CAMbrella strategy for the EU.

The inherent complexity and political nature of the CAM field may negatively influence any CAM R&D initiative in general, and on the CAMbrella roadmap in particular. Our recommendation includes the formation of a centralised EU CAM research centre with the responsibility of operationalising the CAMbrella recommendations in collaboration with selected EU member states and academic institutions. This would facilitate collaborative efforts and would increase synergies and minimise the risk of duplication of R&D investments internationally.

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