Experimentering
Models of CAM integration
in health systems

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What’s new?

an increasing number of CAM treatments* now have a considerable evidence base for safety and effectiveness**

* E.g.: acupuncture for chronic pain and headaches; antenatal perineal massage for reducing perineal trauma during labour; Hypericum for mild – moderate depression; etc.

** The ongoing 2° Regional Experimental Program of Emilia Romagna, including observational and randomized studies, was launched in 2009 in order to evaluate the effectiveness and feasibility of some CAM treatments.
Equity

As soon as the evidence base reaches a critical level (“considerable”)…

…it becomes necessary to experiment with integration of CAM into health systems / services in order to ensure equity in access to safe and effective care.
Premise:
CM-CAM* integration is not an event…

… not even adding a certain amount of “unconventional” to the “conventional” routine care…

… but an individual and social process of change, which develops in the minds and behaviours of patients, providers and stakeholders in very different contexts of care

• “Integrative Medicine”, rather than a pre-defined entity, is an objective that should be pursued in an experimental way…

• …we think that a possible way is studying models of CM-CAM integration for prevention or care of selected health problems

NB: CM = Conventional Medicine
CAM = Complementary and Alternative Medicine / Unconventional Medicine

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Definition *

“A **model of integrated health care** is a potentially generalizable organisational modality of interaction between providers, between services, and between providers and services, resulting in the coordinated supply of conventional and unconventional (CAM) treatments /procedures appropriate for prevention and / or care of a specific health condition.

The model of integrated health care can include single treatments or packages of treatments in standard diagnostic and care courses;

it has to be developed as a research project and evaluated on the basis of pre-planned quantitative and qualitative outcomes”.

* Adopted by the OMnCER for the 3° Unconventional Medicines Experimental Program of Emilia Romagna Region, Italy, 2012
Models’ features:

• potentially generalizable

• coordinating conventional and unconventional (CAM) approaches

• complex

• experimental
CAM integration in a Health Service / System is a complex innovation

In principle it could be similar to what happens in conventional medicine whenever any innovation (a new drug, device, or procedure) is brought into the usual routines.

In reality, CAM integration has peculiarities that can hamper the reciprocal adaptation (of the “new” practice to the Health service and vice-versa), because of:

• cultural differences, which are a primary cause of difficulty in the dialogue between the providers

• different levels of complexity of the “new” procedure, varying from the simple prescription of a dietary supplement to the complex and time consuming procedure of a TCM or homeopathic diagnosis and treatment.

So, CAM integration in the Health Services is a particularly complex process at both cultural and practical level. Researching and evaluating models of CAM integration requires a complex approach.

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Researching models requires:

- **different types of research** (on effectiveness, safety, cost-effectiveness, patients’ preferences and satisfaction, health services studies, etc.)

- **methods for reaching consensus** and implementing changes.

In fact, ideally, an efficient integrative medicine model entails a **coordinated, interactive and pragmatic process of change** whose main actors are the Health Service workers and attending patients.
# Research methods for studies on integrative care models*

<table>
<thead>
<tr>
<th>Evaluation of:</th>
<th>Suitable research methods:</th>
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<tbody>
<tr>
<td>Effectiveness</td>
<td>Comparative effectiveness (pre-post case series, pragmatic RCT, comparison between services, etc.)</td>
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<tr>
<td>Safety</td>
<td>Observational studies</td>
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<tr>
<td>Patients’ and providers’ knowledge, motivations, preferences, attitudes</td>
<td>Quantitative methods (surveys or interviews with questionnaire)</td>
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<tr>
<td></td>
<td>Qualitative research methods (case report, narrations, interviews, focus group, Delphi process, consensus conference, etc.)</td>
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<tr>
<td>Cultural and operational difficulties of the integration process</td>
<td>Qualitative research methods (see above, in particular: focus group)</td>
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<td>Health services research (survey)</td>
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<td>Methods for promoting change (action research, participatory research)</td>
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<td></td>
<td>Quality improvement (audit)</td>
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<tr>
<td>Economic issues</td>
<td>Costs observation, services comparison, cost-effectiveness analysis</td>
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This part will be examined more in depth in the afternoon round table Green Hall, h 17.00
Work done by the OMnCER
Observatory on Unconventional Medicines of Emilia Romagna Region

2011 - Writing, discussion and approval of the policy document
(available – in Italian - for the interested colleagues at the afternoon session on Models, Green Hall 17.00)

December 2011 – 2012 - the OMncER worked intensively for setting up the III°CAM Experimental Programme, by:

- **Prioritizing the clinical conditions** on which to experiment models of integrated care

- **Selecting the CAM treatments / modalities** worth to be included in such models on the basis of their considerable evidence base

- **Identifying other CAM treatments / modalities** with preliminary interesting data or other features (for example high prevalence of use) which make them worth to be studied as well

- **Setting up the methodological framework** for experimenting models of integrated care
2012: designing the III° Experimental Program Unconventional Medicines

3 OMnCER working groups:

- Chronic non cancer pain
- Patient with cancer
- Women’s health

... selected the research topics using 4 main criteria:

- evidences in the literature,
- relevance of the health problem,
- experiences in the 2° Experimental Programme *
- feasibility of an integration course

* Ongoing studies of the 2° Experimental Programme with positive results and pertinent to the topics of the III° Programme will be included in it.

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CAMbrella

The OMnCER initiative for the III° Exp. Program has been developed in parallel with the setup of the *Roadmap for future clinical research in CAM* by the EC-FP7 CAMbrella project *(soon to be published)*

NB: the Health and Social Agency of Emilia Romagna Region (ASSR-ER) is one of the partners of the EC-FP7 CAMbrella project
### Topics of the 3° Regional Experimental Program:

<table>
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<tr>
<th>Fields</th>
<th>Topics</th>
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<tbody>
<tr>
<td>Pain (not due to cancer)</td>
<td>Chronic pain with particular attention to: headache and low back pain</td>
</tr>
<tr>
<td>Patients with cancer</td>
<td>Quality of life and prevention / reduction of adverse events due to cancer therapies, with particular attention to symptoms as fatigue and nausea</td>
</tr>
<tr>
<td>Women’s health</td>
<td>Pain during labour</td>
</tr>
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</table>
Next steps

Regional call to the Local Health Agencies (ASL) of the Regional Health Service (SSR) for multicenter projects, whose main objective is the setup and evaluation of models of CAM integration for 3 relevant health conditions

• by a multidisciplinary approach

• in health services with adequate CAM research capacity

• with the participation of both: CAM experts and patients recipient of the included care modalities
What does “multidisciplinary approach” means?

• quantitative evaluation of effectiveness (when needed), safety, cost-effectiveness of the CAM treatments included in the project

• qualitative-quantitative evaluations of preferences, compliance, satisfaction and meanings attributed to CAM by involved patients and providers

• methods fit to involve health workers and make them actors of the process of CAM integration
What does “adequate CAM research capacity” mean?

• experience in planning and implementing clinical studies, access to databases, statistical support, etc.

• availability of human resources expert in CAM interventions included in the projects and motivated to integrate them
Does this course overlap with clinical and health service research in Conventional Medicine?

CER – Comparative Effectiveness Research

PCOR – Patient Centred Outcome Research

* This part will be examined more in depth in the afternoon Round table, Green Hall, h 17.00
The CER challenge

What’s Comparative Effectiveness Research?

«Comparative effectiveness research (CER) identifies what works best for which patients under what circumstances».

Congress, in the American Recovery and Reinvestment Act (ARRA) of 2009, tasked the IOM to recommend national priorities for research questions to be addressed by CER

CER - comparative effectiveness research

The continuous and unsustainable raise of health expenditures emphasizes the need of comparative research on the different possible alternatives in the “real world”…

Atkins D. QUERI, Washington (USA) –
Annual meeting of Italian Cochrane Network 2009

The “new” treatment:
• works ≥ < in respect of the present standard?
• for which indications?
• in which patients?
• do its benefits overcome risks…
• … and justify costs?

“Despite trials that are conducted each year around the world, there is still a surprisingly large gap between what we know and what we need to know to provide optimal care.”

— Jim King, M.D.
AAFP Board Chair

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What’s Comparative Effectiveness Research?

“..the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care.

The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels."
The Patient-Centered Outcomes Research Institute (PCORI) established by Congress through the 2010 Patient Protection and Affordable Care Act

PCORI aim:

• “Defining methodological standards and a translation table to guide healthcare stakeholders towards the best methods for patient-centered outcomes research (PCOR). Better methods will produce trusted information and lead to better healthcare decisions, and ultimately to better health.

• The standards offer an approach to align the research agenda with questions that underlie patients’ and clinicians’ uncertainty about what works best, for whom, under what circumstances”.
Patient-Centered Outcomes Research

PCOR typical questions:

• “Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?”

• “What are my options and what are the potential benefits and harms of those options?”

• “What can I do to improve the outcomes that are most important to me?”

• “How can clinicians, and the care delivery systems they work in, help me make the best decisions about my health and healthcare?”

• etc.
What are healthcare interventions?
Treatments, tests, and any other strategies used in the prevention, diagnosis, treatment, and management of illness or injury. The legislation lists them (Appendix E-1):
- protocols for treatment
- care management and delivery procedures
- medical devices
- diagnostic tools
- pharmaceuticals, including drugs and biologicals
- integrative health practices
- any other strategies or items being used in the treatment, management, diagnosis, or prevention of illness or injury in individuals.
What Business Are We In? The Emergence of Health as the Business of Health Care


“… while much of recent U.S. medical practice proceeds as if health and disease were entirely biologic, our understanding of health's social determinants has become deeper and more convincing. An enormous body of literature supports the view that differences in health are determined as much by the social circumstances that underlie them as by the biologic processes that mediate them.

…the evidence does suggest that health care as conventionally delivered explains only a small amount — perhaps 10% — of premature deaths as compared with other factors, including social context, environmental influences, and personal behavior.

If health care is only a small part of what determines health, perhaps organizations in the business of delivering health need to expand their offerings...

...in the future, successful doctors, hospitals, and health systems will shift their activities from delivering health services within their walls toward a broader range of approaches that deliver health”.

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Conclusion

• Health Services **NEED** innovative approaches to health care, and can be a fertile terrain for experimenting integrative care courses.

• The Emilia Romagna III° CAM Experimental Programme is focused on projecting and evaluating integrative care courses, in order to offer to the citizens better health care for some relevant health problems…

• … and to contribute to a worldwide movement for transforming health care…

• …aware that both, Conventional Medicine and CAM have limits, and can do better for the patient by working together rather than working alone…
In fact, if we listen what many patients say, it’s not rare that …

… in the ocean of human suffering, apparently simple approaches can catch the fish of relief, and help as much as the most powerful and sophisticated technologies …
CAM integration in health systems: experimenting models

Round Table – Green Hall, h 17.00

Co-chairmen:
Elio Rossi, Francesco Cardini

Participants:
• Benno Brikhaus – Charité, Institute for Social Medicine (Berlin – Germany)
• Terje Alraek - NAFKAM (Bergen & Tromso - Norway)
• Guido Giarelli - University of Magna Grecia (Catanzaro - Italy)
• Cinzia Colombo - Istituto Mario Negri - Progetto Partecipasalute (Milano – Italy)
• Torkel Falkenberg - Karolinska Institutet (Stockholm – Sweden)
KEY FEATURES
FOR CLINICAL RESEARCH IN CM / CAM
(included research on integrative care models)

• PATIENT’S CENTRED *

• INVOLVING ALL RELEVANT STAKEHOLDERS
  (patients / researchers / providers / health care managers)

• INDEPENDENT (= non market-driven)

* Dr. Cinzia Colombo will examine this issue more in deep
Research methods should adapt to this new perspective

- **Mixed Methods** (quantitative / qualitative / methods for promoting change)
  - Dr. Giarelli and Dr. Falkenberg will examine this issue more in depth

- Rational sequences of research methods

- **Priority of Pragmatic research designs**
  - because they are more patient-centred
  - because they are more relevant for clinicians
  - because CAM have to be studied as they are practiced in the real world
  - Dr. Benno Brinkhaus will examine this issue more in depth
Including innovation

In order to be integrated in the health care courses offered by a Health Service, a “new” treatment or modality of care should have a “reasonable amount” of evidences of being:

• effective in clinical practice for groups of patients large enough;

• safe, or at least with a positive risk-benefit ratio;

• preferred, or at least accepted by population groups large enough;

• practiced in the best way * by motivated providers working in the service or linked to it, and accepted (or at least not hindered) by their colleagues;

• economically sustainable (cost-effective).

* Dr. Terje Alraek wil examine this issue more in depth