

World Health Organisation: Clinical research in traditional and complementary medicine

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CLINICAL RESEARCH IN TRADITIONAL AND COMPLEMENTARY MEDICINE

WHO definitions:

- **Traditional medicine** is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

(www.who.int/medicines/areas/traditional/definitions/en/)

CLINICAL RESEARCH IN TRADITIONAL AND COMPLEMENTARY MEDICINE

WHO definitions:

- **Complementary medicine or alternative medicine** refers to a broad set of health care practices that are not the country's own tradition or conventional medicine and are not fully integrated into the dominant health care system.

(www.who.int/medicines/areas/traditional/definitions/en/)

USE OF TRADITIONAL AND COMPLEMENTARY MEDICINES

- Commonly used in less developed countries and increasingly in more developed countries
- Developed countries, people who have used CAM at least once:
 - US ~42%
 - Canada ~50%
 - France ~75%
 - Australia ~48%
 - Belgium ~31% (Fisher P, Ward A 1999 Health Canada WHO)

USE OF TRADITIONAL AND COMPLEMENTARY MEDICINES

- Developing countries, use of traditional medicine for primary health care:
 - Uganda 60%
 - Tanzania 60%
 - Rwanda 70%
 - India 70%
 - Benin 80%
 - Ethiopia 90%
- » (WHO TM strategy 2002-2005)

ISSUES

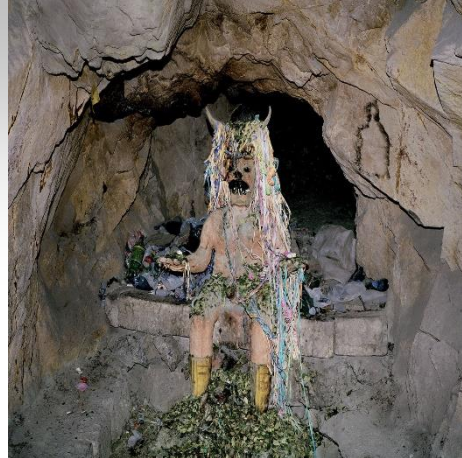
- How much do we know about them?
- How many different traditional and complementary medicines are there?
- What do they aim to achieve?
- What do they do?
- How safe are they?

ISSUES

- How are practitioners trained?
- How are they regulated?
- How do they update their knowledge?
- How or are standards maintained?
- How do they 'monitor' effectiveness?
- How do they 'monitor'safety?



DIFFERENT TYPES OF MEDICINE



CLASSIFICATION

- **Alternative medical systems**
 - Alternative to conventional medical systems evolved from systems of theory or practice
- **Mind body interventions**
 - Techniques to enhance the mind's capacity to affect and or cope with conditions
- **Biological based therapies**
 - Use of substances (herbs, food, vitamins etc) to enhance healing or prevent illness
- **Manipulative and body based methods**
 - Based on manipulation and or movement of body parts
- **Energy therapies**
 - Based in fields and flow of energy and manipulation of these

<http://www.medscape.org/viewarticle/464731>

WHO EFFORTS IN PROMOTING SAFE, EFFECTIVE AND AFFORDABLE TRADITIONAL MEDICINE

The World Health Organization launched its first ever comprehensive traditional medicine strategy in 2002-2005. The strategy is designed to assist countries to:

- Develop national policies on the evaluation and regulation of TM/CAM practices;
- Create a stronger evidence base on the safety, efficacy and quality of the TAM/CAM products and practices;
- Ensure availability and affordability of TM/CAM including essential herbal medicines;
- Promote therapeutically sound use of TM/CAM by providers and consumers;
- **Document traditional medicines and remedies.**

WHO EFFORTS IN PROMOTING SAFE, EFFECTIVE AND AFFORDABLE TRADITIONAL MEDICINE

The World Health Organization launched a second traditional medicine strategy in 2014-23. The strategy is designed to assist countries to:

- to support Member States in harnessing the potential contribution of T&CM to health, wellness and people-centred health care and to promote the safe and effective use of T&CM through the regulation of products, practices and practitioners.

WHO Traditional Medicine Strategy 2014 – 2023

[http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf?ua=1]

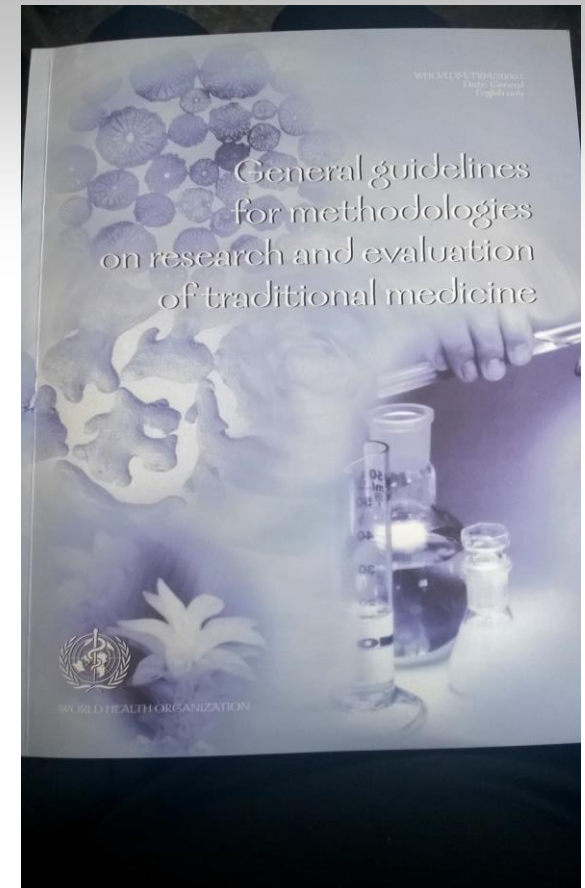
WHO EFFORTS IN PROMOTING SAFE, EFFECTIVE AND AFFORDABLE TRADITIONAL MEDICINE

By:

- 1) Building the knowledge base and formulating national policies;
- 2) Strengthening safety, quality and effectiveness through regulation; and,
- 3) Promoting universal health coverage by integrating T&CM services and self-health care into national health systems

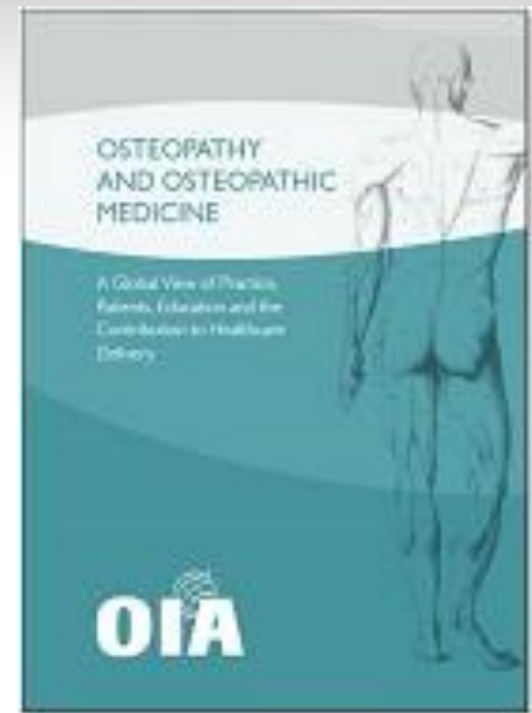
RESEARCH CHALLENGES

- Funding
- Priorities
- Politics
- Appropriate methodologies
- Acceptable and credible methodologies
- Robust and rigorous studies
- Skills base in the professions



OIA GLOBAL REPORT 2012: OSTEOPATHY

- Defining the therapy
- Defining scope of practice / what we do?
- Defining the population we treat
- What do we treat?
- Training?
- Standards and regulation?
- Safety and effectiveness?



OIA GLOBAL REPORT 2012:CHALLENGES

- Defining osteopathy
- Obtaining data
- Regional differences
- Proving effectiveness
- Proving safety

CHALLENGES IN RESEARCH FOR TRADITIONAL AND COMPLEMENTARY MEDICINES

- Non standard therapies and therapists
- Person centred / individualised / bespoke treatments (that may be adapted over time) to treat the same conditions
- Finding methodologies that produce robust evidence
- Blinding / replication / protocols /
- Fidelity (is what is said to be delivered actually what is delivered?)
- Quality for example of herbal products and devices

- For effectiveness (does it work?)
- For efficacy (mechanisms of action, how does it work?)
- For safety (risk of harm)

The hierarchy of evidence is applied to effectiveness studies ONLY

Randomised controlled trials

Issues:

- Double blinding (bias)
- Protocolised interventions
- Comparison groups (usual care not seen as good enough)
- Cochrane GRADE criteria and quality appraisal checklists

Solutions:

- Pragmatic randomised controlled trials
- Cluster randomised controlled trials

Mechanisms of action: How does it work?

- Laboratory
- Qualitative studies
- Theory and hypotheses testing / Iterative studies

RESEARCH METHODOLOGIES: SAFETY

- Surveillance
 - active
 - passive
- Prospective cohort studies

RESEARCH METHODOLOGIES: OTHER AND PATIENT CENTRED OUTCOMES

- Patient Reported Outcomes
 - Evidence of outcome (numerous domains can be measured)
- Patient Reported Experience
 - Evidence of satisfaction /experience / quality/ global change
- Audit
 - Scope of practice
 - Description of practice

RESEARCH METHODOLOGIES: OTHER AND PATIENT CENTRED OUTCOMES

- Qualitative studies
 - Exploring
 - Understanding
 - Models of care
 - Models of mechanisms
 - Explanatory models of behaviour

- Resources
 - People
 - Money
 - Expertise
 - Leadership
 - Time