Complementary Medicine

Research and ethical issues in complementary and alternative care

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Introduction

Complementary and alternative therapies (CAM) represent a diverse range of health care options. They are an important part of many people's health care strategies. Health professionals (HPs) are increasingly interested in integrative medicine.1,2

To ensure safe and evidence-based health care, decisions should be based on the best available, relevant evidence. However, many conventional HPs question the evidence-base for CAM. For instance, a recent article by Professor John Dwyer on behalf of Friends of Science in Medicine (FSM) suggested CAM lacks evidence. FSM also wrote indicating they should not teach or encourage research into 'pseudo science' in their courses.

In fact, there is a great deal of quality evidence for some CAM. Likewise, it is imperative that HPs have a basic knowledge about CAM and are competent to critically appraise evidence and consider methodological and ethical issues.

Opposing views about CAM and its evidence base still prevail. Phelps' contends 'true friends of science would be open minded to the possibilities that lay outside the dominant paradigm... would encourage the exploration of health care modalities offering relief of suffering beyond the scope of current conventions'.

Research and ethics

All research should be conducted according to ethical principles and approved by appropriately constituted ethics committees.4 The role of research ethics committees is to protect human and animal study participants by considering the following core issues:

- Scientific quality.
- Researcher competence.
- Vulnerability of participants.
- Level of risk to participants.
- Potential benefits of the research.
- Level of risk to the researchers.
- Procedures for managing risk.
- Processes for obtaining informed consent.
- Participant ability to provide informed consent.
- Processes to protect anonymity.
- Indemnity insurance.
- Methods of storing and protecting data.

Some CAM practitioners argue research and ethical issues differ between CAM and conventional care. However, there are more similarities than differences, including the desire to provide the best possible care.

Some similarities and differences between complementary and conventional research

Access to safe, appropriate care

In most countries CAM is predominantly privately funded, although some health funds reimburse some CAM in some countries. Thus, access to beneficial, safe CAM may not be equitable or consistent with the ethical principle, justice. Significantly, CAM is an integral part of the health systems of some countries and is more accessible than conventional care.

Knowledge and competence

Evidence-based practice is a core competency for all HPs, including CAM practitioners but most CAM practitioners do not have sufficient training in critical appraisal skills, research or conventional care.6 Likewise, most conventional HPs are not competent to critically appraise research publications, most do not have sufficient CAM training and many are not trained in research processes.

Research suggests physicians, and possibly other HP disciplines, are more likely to ask colleagues for advice than access other sources of evidence.6 This is a concern for both CAM and conventional HPs if the colleagues providing advice have negative views about either paradigm, and could:

- Compromise communication and referral processes.
- Put people who combine CAM and conventional care at risk, especially people who do not disclose their CAM use.
- Raise questions about HP’s duty of care and their ethical and medico-legal responsibilities.

CAM therapies and practitioners are not regulated as rigorously as conventional HPs in most countries. In Victoria, Acupuncturists and Chinese herbal medicine practitioners must be registered with the Chinese Medicine Registration Board. Some CAM professional

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associations have rigorous self-regulation and continuing professional development requirements similar to non-regulated conventional HP associations such as dietitians.

**Safety and efficacy**

The safety and effectiveness of many CAM is under-researched according to the standards that apply to conventional care practices. Although randomised controlled trials (RCT) are seen as the ‘gold standard’, there is very little RCT evidence for some widely used conventional care.

Some care strategies in both paradigms are based on a long history of traditional use. Thus, a degree of uncertainty about the benefits and risk of some forms of care exist in both paradigms, but the level of uncertainty is regarded as greater in CAM.

**Funding and infrastructure**

Funding and infrastructure for CAM research is significantly lower than for conventional research in most countries. Consequently many CAM studies are of short duration, have small sample sizes and are rarely replicated. The first two criticisms can also be applied to many conventional studies.

The formation of the National Centre for Complementary and Alternative Medicine (NCCAM) and US government funding has attracted experienced researchers and increased CAM-related research output. NCCAM supports research training and plays a significant role disseminating information about safe, effective CAM. Recently, NCCAM released the Frontier Medicine Research Program, which addresses CAM areas with little robust evidence to support their use, for example Reiki in rehabilitation. The Office of Complementary Medicine in Australia plays a similar role but has less government funding, which compromises research training and promotes high quality CAM research and the need to develop HP research capacity.

**Evidence-based care**

The culture of evidence-based CAM is emerging, especially in integrative medicine, but is not as well embedded in CAM practice or training programs as it is in conventional care. CAM has not had an established research infrastructure or attracted experienced researchers. Consequently, CAM research often has significant methodological flaws, which makes it difficult to apply the findings to practice or to undertake systematic reviews to develop evidence-based guidelines.

**Beliefs and attitudes**

CAM practitioners often suggest conventional research methods are not suitable to CAM and that some CAM-related concepts are difficult to measure; for example holism, spirituality, person-centred care, and synergy and quenching. However, person-centred care, holism and spirituality are important concepts in conventional care and can be measured using valid tools and using qualitative methodologies.

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Table 1: Some reliable sources of information about complementary and alternative therapies.

<table>
<thead>
<tr>
<th>Source</th>
<th>Internet address or publication name</th>
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<tbody>
<tr>
<td>Alternative health News Online</td>
<td><a href="http://www.altmed.com">http://www.altmed.com</a></td>
</tr>
<tr>
<td>Quackwatch</td>
<td><a href="http://www.quackwatch.com">http://www.quackwatch.com</a></td>
</tr>
<tr>
<td>National Council Against Health Fraud</td>
<td><a href="http://www.ncaf.org">http://www.ncaf.org</a></td>
</tr>
<tr>
<td>American Botanical Council</td>
<td><a href="http://www.herbalgram.org">http://www.herbalgram.org</a></td>
</tr>
<tr>
<td>Cochrane database of Systematic Reviews</td>
<td><a href="http://www.cochrane.org">http://www.cochrane.org</a></td>
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<tr>
<td>Go to the Complementary health field</td>
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<tr>
<td>National Prescribing Service</td>
<td><a href="http://www.nps.org">www.nps.org</a></td>
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<tr>
<td><a href="http://www.library.uiuc.edu/archives/alasfa/1302014a.pdf">www.library.uiuc.edu/archives/alasfa/1302014a.pdf</a></td>
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<tr>
<td>World Health Organisation and Uppsala Monitoring Centre</td>
<td><a href="http://www.who-umc.org">www.who-umc.org</a></td>
</tr>
<tr>
<td>Complementary and Alternative Medicine Index (CAM): University of Maryland Medical Center</td>
<td><a href="http://www.umm.edu/altmed">http://www.umm.edu/altmed</a></td>
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</table>
The two research paradigms address different questions and must be rigorous and methodologically sound. However, measures of rigor in qualitative studies are different from quantitative studies, which are predicated on control.

Quantitative and qualitative studies answer different questions and make different contributions to the evidence: used together they provide a more holistic picture of clinically-based research. Thus, qualitative studies are no less valuable than RCTs.

Likewise, evaluation studies and audits also contribute important information.

**Reliable information**

Some HPs find it difficult to find reliable sources of CAM information, see Table 1, or to determine whether the information they access is credible. Some ways to determine the credibility of Internet information are referenced in Table 1.

**Publication issues**

Publication bias is a concern for both CAM and conventional HPs. Bias against publishing CAM research in conventional journals is decreasing, but still exists. One reason for the increased number of CAM publications is the fact that the science is improving and papers are more likely to meet rigorous peer-review processes.

In addition, the number of quality peer-review CAM journals is increasing. Significantly, all publications should meet the criteria for responsible publications, which apply to journal editors, reviewers, authors and publishers. In addition, authors should declare any conflicts of interest in the paper.

Another aspect of publication bias is the tendency for authors, research funders and journal editors to avoid publishing negative findings. Some experts regard not publishing or ignoring negative findings as a form of deception that misleads HPs and the public. The Australian and New Zealand Clinical Trials Register could help reduce some forms of publication bias in the future because it enables the progress and outputs of clinical trials to be monitored. However, it does not guarantee the research will or will not be published.

**Priority areas for CAM research**

The UK House of Lords Select Committee on Science and Technology Report on CAM (2000) recommended the Government should provide seed funding for CAM research and identified five main priority areas for CAM research:

1. The effects, efficacy, safety and cost-benefit of individual CAM.
3. Social research into CAM use.
4. Research to explore the reliability and accuracy of CAM diagnostic methods.
5. Translation and implementation CAM strategies shown to be safe and effective.

Bensoussa and Lewith (2004) suggested similar CAM research priorities for Australia, but acknowledged different stakeholders are likely to have different research priorities. For example, some stakeholders expect financial gains from sponsoring research.

Other important areas for CAM research include continuing to investigate:

- The safety and efficacy of the most commonly used herbal medicines.
- How to use CAM medicines and safely combine them with conventional care.
- Increasing the research capacity of CAM practitioners, including skills in evidence-based care.
- Improving the research basis for and credibility of CAM.
- Improving individual practitioner’s ability to identify and use the best available evidence to deliver optimal care.

Actual and theoretical interactions between herbal and conventional medicines need to be clarified. Accurate adverse event reporting makes a significant contribution to information about the safety and risk of CAM and conventional care processes. The utility of quality use of medicines as a framework for integrating CAM and conventional care is also worthy of further study.

**Summary**

Despite the concerns of many CAM practitioners, existing accepted research methods can be applied to CAM and encompass questions about CAM-related basic science, individual CAM therapies, social issues, epidemiology, service delivery, health promotion and prevention. In all research, the study question suggests the research method and forms the framework for the study protocol and the data analysis procedures. However, some specific CAM aspects do need to be considered. For example, CAM theoretical perspectives such as ‘the doctor within’, diagnostic systems, and the difficulty blinding some treatments such as acupuncture.

**References**


