Original article

Complementary and alternative medicine (CAM) professional practice and safety: A consensus building workshop

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Abstract

The use and practice of complementary and alternative medicine (CAM) may have potential safety issues. These may relate to practitioner competence, product quality, interactions with medication and non-compliance with conventional medicine. Safety is central to all healthcare practitioners and is an area where CAM groups should work together to achieve consensus.

With many CAM professions in the UK moving towards regulation, the Research Council for Complementary Medicine (RCCM) recognised the need for consensus between professions on the best way forward for collecting and using safety data. A 3 hour consensus workshop of UK CAM professional body representatives was convened. Results highlighted the importance of, and challenges inherent in, collecting CAM safety data. The definition of safety was discussed, in particular variation in adverse effects between therapies and recognition of both practitioner and product safety issues. A range of methods of collecting safety data were suggested, with triangulation of many approaches felt to be most useful. The main problem in recording adverse event data within practice was identified as the barrier of distrust. However, three examples of safety data collection projects were cited, which were all well received by practitioners, suggesting that developing such a scheme across CAM professions is a valuable endeavour. It is important to demonstrate the benefits or ‘rewards’ of collecting such data to practitioners, rather than ‘punish’ non-collection.

We suggest that new schemes are piloted with a small, local groups of practitioners, and supported by their professional organisations. Feedback from the professional bodies represented at the workshop was very positive and suggests that in the UK they are keen to move forward with the safety agenda. We would welcome comments from other countries on the safe practice of CAM.

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Introduction

This article reports the results of a consensus workshop between representatives of the main complementary and alternative medicine (CAM) professional bodies in the UK. The workshop focussed on the safety of practitioner-based CAM and how safety data could be collected, managed and acted upon. Safety is central to all healthcare practitioners and is an area where CAM groups should work together to achieve consensus in terms of data collection and data sharing. Systems for reporting safety issues are important as a vehicle for obtaining information, but should also be utilised as a tool to facilitate learning, advance quality improvement and to ultimately minimise the rate of the occurrence of errors linked to patient care [1]. Evidence of safety is an urgent priority for CAM as a growing number of CAM professions achieve statutory regulation or voluntary regulation, e.g. in the UK through the Complementary and Natural Health care Council (CNHC)1 or the Health Professions’ Council (HPC).2 This workshop was organised by the Research Council for Complementary Medicine (RCCM), a UK charity which provides a forum to bring together the various CAM professions to develop and share research evidence.

The workshop was initiated in response to the following developments in the UK:

- The key objectives of the RCCM’s most recent strategy, published in 2009 [2].
The publication of the 2009 King’s Fund report ‘Assessing Complementary Practice: building a consensus on appropriate research methods’ [3].

The increasing move towards regulation and the need for professional bodies to work together on research evidence and safe practice.

Background

The potential safety risks of complementary and alternative medicine (CAM) include intrinsic adverse effects (related to errors in treatment via a practitioner or self-medication), interaction with pharmaceuticals/other CAM and extrinsic effects due to lack of standardization, contamination, substitution, adulteration, incorrect preparation/dosage or inappropriate labeling [4–6]. Many CAM are also subject to risks arising from lack of quality control, licensing, regulation and misrepresentation [4]. Further risks may arise when CAM is used as an alternative to medical treatment [4].

An issue commonly of concern is the risk of interaction between CAM and conventional medication, especially for herbal medicines and supplements, often aggravated by lack of communication between clinicians, CAM practitioners and patients [4].

Much of the recent CAM safety data has focused on herbal medicines [7], acupuncture [8] and spinal manipulation [9]. There is also some data on adverse events in specific subpopulations such as children [10] and the elderly [11]. A brief overview of available data for some specific therapies suggests that the risk of major adverse events with manual therapy, acupuncture and homeopathy is low [8,12–15]. Evidence suggests that adverse effects in acupuncture are declining, perhaps due to more rigorous training and practice [8].

However, there is a lack of standardised, routine and widely available data on safety across the CAM professions. The workshop and this article aim to report how we in the UK are beginning to address this issue. We would welcome comments from other countries on the safety of CAM.

The workshop

The workshop aimed to reach consensus amongst the UK CAM professions on how safety data can be collected, managed and acted upon.

CAM professional bodies who were either already statutorily regulated or working towards statutory or voluntary regulation were invited to send a member (preferably a research lead) to represent their professional group at the workshop, held on December 16th 2010.

This event aimed to bring together the professional bodies to focus on what evidence they had as professions, how to build the evidence base and explore ways of working together in identifying research priorities.

Professions represented included: acupuncture, chiropractic, osteopathy, craniosacral, hypnosis, herbal medicine, naturopathy, nutrition, shiatsu, massage and reflexology, as well as representatives of NHS Evidence CAM specialist collection and the Universities of Southampton, Brighton, London South Bank, Westminster and Cambridge.

Pre session reports of the current available evidence from each professional group suggested that the most useful focus for this first workshop should be safety.

Although this workshop aimed to reach consensus, it should be noted that safety issues vary between therapies, in particular whether treatment involves manipulation or ingestion of products. Also, the level of involvement of the practitioner in safety varies between therapies, which is in turn dependent on practitioner regulation and training.

The 3 hour workshop commenced with an open discussion to clarify and define the issues surrounding safety in CAM. The discussion was opened by Prof Robinson, facilitated by Prof Lewith and transcribed by Dr Lorenc. This was followed by small group discussions with feedback to the group on specific areas of safety. Consensus was reached through discussion, and subsequent review of the workshop report by those present. However, the views expressed are those of the representatives from the professional bodies and as such may not be shared by all members of professional groups, particularly those who were not in attendance.

The workshop was hosted by the RCCM with the aim of providing a non-threatening environment. The RCCM is an impartial organisation and, as such, is able to bring a range of different professions together.

What is safety?

The Medicines and Healthcare Regulatory Agency (MHRA) provide a definition of an adverse drug reaction, however, this is specific to ingested products:

‘An unwanted or harmful reaction experienced following the administration of a medicine or combination of medicines under normal conditions of use and is suspected to be related to the medicine’

There was discussion about the definition of an adverse effect or event, which has been defined as [16]:

- Adverse event: An unfavourable outcome during/after an intervention but not necessarily caused by it.
- Adverse effect: An adverse event where the causal relation between intervention and event is a reasonable possibility.

It was recognised that the types and severity of adverse effects vary depending on type of therapy. The variation in perception of types of adverse events or ‘negative responses’ in CAM has been discussed in other papers [17,18].

Andrew Long et al. [17] developed a typology of ‘negative responses’: Type 1: Responses unconnected to the CAM modality; Type 2: Transitional effect (client-perceived and theory-consistent); Type 3: Transitional effect (theory and experientially consistent); Type 4: Undesired, but not unsafe event or effect; Type 5: Potentially adverse event or effect and possible risk to client safety.
It was recognised that some minor after-treatment effects with some worsening may occur for some therapies. Encouraging active, regular feedback of these to an external body may cause unnecessary alarm. Practitioners, in terms of their duty of care to the patient, would monitor the progress and feedback between treatments themselves and advising the client accordingly.

Workshop delegates agreed that safety of CAM has two main components: the safety of an individual practitioner (achieved through regulation, registration, competency) and the safety of the therapy itself.

Practitioner safety

The skills required for good clinical practice within a consultation and in management of patients are generic to all therapies, and a core part of high quality professional training. Competency should be covered by each professional association’s terms of acceptance onto professional registers, and assured through education. The components of competence identified are given in Box 1

The same standards apply to all health professions both orthodox and CAM:

1. Education – safe practice starts with education; independent accreditation of courses is a cornerstone of high quality education.
2. Post-qualification – continuing professional development (CPD) from accredited provider and recognised by the professional body.
3. Fitness to practice – Indemnity insurance, first aid, professional code of conduct, Vetting and Baring Scheme with criminal records check requirement.
4. Safety – agreement on standards within the profession
5. Complaints – dealt with by the regulator, e.g. CNHC, BAAB, and BRA.

Intrinsic safety of the therapy/treatment

CAM fits broadly into three categories [19]: manipulative approaches (e.g. acupuncture, osteopathy), mind-body medicine (e.g. hypnosis, meditation) or natural products (e.g. herbs, homeopathy and nutritional supplements). The different therapies deliver a wide variety of techniques or products, and many provide a package of care which includes advice and education about lifestyle and disease prevention or maintenance of health. Particular differences in therapies which may affect safety data include:

- Where and how the intervention is delivered.
- Standardisation of preparations/interventions.
- Awareness, if applicable, of product safety.
- Acknowledging the ‘whole package’ – education, lifestyle.
- Adverse effects/events.

Collecting data

Routine collection of patient data on outcomes was at an early stage of development for most professions, as were adverse event recording systems, some of which are currently being tested. A range of methods for collecting safety data on CAM were identified, including:

- Public reporting
- Whistleblowing by colleagues who suspect bad practice
- Regular reporting from professionals
- Routinely asking about and recording outcomes within patient consultations
- Case note review

Regular reporting from professionals is the system used in medicine in the UK, via the ‘yellow card’ system.3 This is a useful method, but relies on practitioners self-reporting and requires a centralisation of data. Public reporting may also be useful, but relies on the public knowing what is expected and recognising something unusual. Given the issues associated with each of these methods, triangulation using a range of methods may be the best method to capture this information.

Any system of routine safety data collection will require a central organising body. Professional regulatory bodies can be responsible for collecting safety data. The benefits are that patients/practitioners trust them and they will have a specialist understanding of the therapy in question. However, practitioners may prefer an independent body, as combining regulation, insurance and adverse event reporting may be problematic. Government regulatory bodies such as the MHRA (Medicines and Healthcare products Regulatory Agency) in the UK could be used, as they already collate safety data about possible side-

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3 http://yellowcard.mhra.gov.uk/.
Effects/reactions to conventional medication via their ‘Yellow Card’ scheme, including herbal medicines. However, they are unlikely to be sympathetic to specific CAM. Manufacturers are also an important repository of safety information, but are likely to be biased by commercial interests.

Examples of CAM safety data collection

Three systems of safety data collection were presented, for physiotherapy, osteopathy and chiropractic.

A project headed by Ann Moore, Professor of Physiotherapy, University of Brighton, asked private physiotherapists to volunteer to collect data. Volunteers were sent a memory stick which contains a standardised data collection ‘tool’ which facilitated data collection on progress of treatment and outcomes. Providing this pre-prepared ‘tool’ has proved very useful in obtaining the most useful information. Results from this experience suggest that local branches of the physiotherapy association are encouraged via their Head Office to ask members to collect data from clients [personal communication].

For osteopathy, data collection has included data on practice profiles, outcomes, patient profiles, symptoms, treatment and management strategies, responses to treatment, as well as adverse effects; a total of 65 variables. A snapshot data collection project began in 2009 to pilot a data collection tool developed by members of the profession through a consensus process. The recording of the selected variables was seen as constructive by osteopaths. These results are now being disseminated and the system has demonstrated its use to the osteopathic profession [20].

The Chiropractic Patient Incident Reporting and Learning System (CPIRLS) is a web-based system which allows the reader to leave comments regarding the reported incident or in response to other comments. The administration of incident reporting is independent, secure and anonymous (secure access with a universal password available only to chiropractors via the membership areas of their association websites). Therefore practitioners have nothing to fear by sharing their experiences [21,22]. Submitted reports are published in outline form on the website, monitored by CPIRLS team members who can edit inappropriate matter and access/download all data for future thematic analysis [21]. This system is positively perceived by chiropractors, who understand it as a tool that could help the profession achieve accountability and openness, and improve patient safety [21].

Reasons identified for under-reporting included fear of retribution, being too busy and insufficient clarity on what to report. Learning from this system highlights the need for reporting and learning systems to make clear the objectives, resources and capacity of the organisers. Experts for analysing adverse effects and a comprehensive strategy for national implementation must be in place [1].

Problems in collecting safety data

The main problem in recording adverse event data within practice was identified was the barrier of distrust. There is a need for a culture of accountability and policies to encourage professionals to collect safety data. Potential methods for achieving this are given in Box 2.

Box 2. Ideas to encourage professionals to collect safety data

- The idea of a ‘reward and penalty’ or ‘carrot and stick’ policy was discussed.
- There is a need to demonstrate the benefits of collecting safety data to practitioners, i.e. providing a ‘carrot’. Examples of the benefits of collecting safety data are:
  - To improve National Health System buy-in e.g. access to working in NHS by providing information for commissioners
  - To make obtaining funding for providing treatments and research easier
  - Encouraging reflexivity within practice
  - Obvious benefits for patients
- ‘The stick’: For professions with compulsory regulation, registering bodies could require collection of safety data in order to register. However, practitioners may be unwilling to report safety data to a registering body – a ‘neutral’ professional body trusted by the members may be more successful.
- Collecting data relevant to the individual therapy
- Convincing practitioners that collecting data of interest can endorse the power of the individual practitioner, their knowledge and their practice (particularly in terms of audit)
- Reporting to a trusted body, e.g. their own professional organisation may provide a CPD opportunity
- Collecting data of interest to the profession such as potential identification of ‘out of the ordinary occurrences’ for future

Other challenges included:

- Personal response to treatment and adverse effects vary for individual patients.
- Collecting data from patients directly after treatment may increase the response rate, but is dependent on recall and report by patients. There are also time issues in consultation and patients may query the benefits for them.
- Patients may not return for follow up treatments due to side-effects, making them an important source of data on adverse effects. However, collecting data from this group would require follow up which could be challenging and unethical.
- Collecting data on self-administered CAM could be problematic as there is no professional to collect data. In addition
consumers are often unaware of exactly which products they are using, for example distinguishing between herbal products, homeopathy and nutritional supplements.

- Many patients use or are prescribed many therapies simultaneously
- There is a lack of consensus on therapy-specific warnings given to patients. Professional bodies may need to take ownership for this, and it could be further explored or developed by auditing practice if not already established.
- The need to collect details of products, including brand, dosage, etc.
- Funding for safety data collection.

**Using data**

There are benefits to collecting safety data from CAM professions as it can be used to:

- Produce internal reports to CAM practitioners
- Identify gaps in education
- Identify gaps in research
- Monitor large data sets to identify problems and take prompt action
- To improve the educational training

**Conclusion and recommendations**

This report has illustrated the challenges inherent in identifying, collecting and collating safety data on CAM. Safety data collection systems need to: emphasise the benefits of collecting safety data; be fully supported by professional bodies; provide clear guidance on data collection; ensure anonymity and trust of practitioners. We suggest that any new schemes are initially piloted with a small, local group of practitioners, perhaps supported by professional organisations. Existing provision should be utilised, such as student clinics, as simple audits can produce very interesting data. Free, online data collection systems could be used.

Feedback from the professional bodies represented at the workshop and from the examples of data collection systems was very positive and suggests that in the UK CAM professionals are keen to move forward with the safety agenda.

Specific recommendations arising from the workshop include:

- Developing a network of UK CAM professional organisations, using the RCCM as a conduit.
- Guidelines on what is an adverse effect/event in CAM, and which terms should be used.
- Sharing of tools for and experience of collection of safety data between CAM professions.
- Advising CAM practitioners and professional bodies on access to resources for safety evidence.
- Further workshops to include outcome data collection, identifying the evidence gaps and developing research methodology/strategy.

We would encourage CAM professional organisations from other countries to share their experience and recommendations regarding the collection of safety data, through forums such as EuJIM.

**Conflict of interest**

Professor Robinson is the Chair and a trustee of the RCCM.

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**References**


