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Reducing the risk of complementary and alternative medicine (CAM): challenges and priorities

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Abstract

Introduction

The safety of health care is increasingly prominent concern of the public, applying to complementary and alternative medicine (CAM) as well as conventional treatment. In 2009, a group of academic and clinical CAM researchers held a workshop to discuss the constraints, methodology and priorities of research into CAM safety. This group here report their discussions on constraints and priorities in safety research, and offer collaboration with practitioners internationally with the aim of improving patient safety for CAM practices and products.

Discussion

The researchers reached a consensus that the first priority for CAM safety research is active surveillance, or the measurement of actual harm from CAM. The second priority is research into beliefs and attitudes of practitioners, public and professional organisations, and what influences those attitudes; the final research area covers the procedures used to ensure safe practice, and their effectiveness. Research into the safety of healthcare is challenging at many levels, including definitions of terms where a recent WHO initiative is significant. Particular difficulties that must be addressed in planning CAM safety research include: the apparently low incidence of harmful incidents; the limited regulatory setting for CAM practice including the omission of CAM interventions from most mainstream adverse event reporting schemes; the widespread perception of CAM as natural and safe; the complexity of CAM therapies; interactions between CAM and conventional care; professional complacency; and the special challenges unique to specific CAM therapies such as the concept of a ‘healing crisis’.

Conclusions

International collaboration between experts in the field, including practitioners and researchers, may be the best way to achieve the required levels of expertise.

Keywords: Safety; Epidemiological monitoring; Complementary therapies; Adverse events; CAM, adverse effects; Safety management;

Introduction

The central aim of health care is to benefit its recipients; yet widespread experience has shown that healthcare itself causes harm that is a major cause of worldwide morbidity and mortality. [1] The World Health Organisation (WHO) designated safety of health care as a global priority in 2002, and established a Patient Safety initiative which published a conceptual framework [2] describing the steps necessary for improving safety in practice (box 1).

Box 1 **WHO Patient Safety Research: research sequence**

Measuring harm
Understanding the causes
Developing solutions
Learning from implementation
Evaluating impact
Translating improvements into policy and practice

Complementary and alternative medicine (CAM) has been defined as a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine (http://nccam.nih.gov/health/whatiscam accessed 21 Nov 2012). Although debate rages about the clinical effect of CAM interventions, surveys from many parts of the world have consistently documented that a high proportion of the population uses CAM. [3] CAM thus forms a common component of health care choice globally, and must meet patients' demands for effectiveness and safety.

Recently, a report of a workshop of UK practitioners on CAM safety was published, focussing on building the evidence base and exploring research priorities. [4] The report describes practitioner competencies and identifies a range of methods for collecting safety data, citing three examples of surveillance. The report specifically invites comments from practitioners and researchers in other countries.

In 2009, an international workshop of academic and clinical researchers with a special interest in CAM safety was held in Tromsø, Norway under the auspices of NAFKAM (National Research Centre in Complementary and Alternative Medicine). Discussion focussed on priorities, methods and constraints of research into CAM safety. The benefits that this type of group of academic researchers could offer to any collaboration include: a range of experience in the field; theoretical understanding; consistency of terminology, definitions and research methods; and identification of methodology and constraints on research.

The first author drafted and circulated the the workshop report, which was based on notes and flip-charts and evolved further in response to the group's comments. . Discussion included the constraints to researching CAM safety, and the need to establish research priorities. An email consensus was used for the latter. The group considered it timely to report their conclusions on both constraints and research priorities in this special issue of *EuJIM,* aiming to promote a merger of the practical

approaches of practitioners with the theoretical and literature-based underpinning and international dimension provided by academia.

Definitions of terms

Any discussion of healthcare safety is complicated by inconsistencies in terminology and definitions, as well as differences in key concepts such as how to classify adverse events. For example, definitions produced in Australia, Canada and Europe are not consistent. The World Alliance for Patient Safety, as part of the WHO initiative on Patient Safety, reached a consensus on a new International Classification of Patient Safety (ICPS) [5 6]. This classification includes a set of standardised safety definitions that were intended to be clear and unequivocal and to reflect the colloquial use of terms, as well as being consistent with the WHO Family of International Classifications. The advantage of such a universal system should be obvious in relation to collecting, classifying and analysing safety data.

Some of the more relevant definitions are set out in box 2. One important change is the renaming of 'adverse event' to 'harmful incident', which is intended to avoid the common confusion between the terms 'adverse event' and 'adverse reaction'.

Box 2 Preferred terms and definitions: WHO ICPS[6]

Safety: the reduction of risk of unnecessary harm to an acceptable minimum (note: some forms of harm are necessary, such as an incision in surgery)
Event: something that happens to or involves a patient
Incident (in full, Patient safety incident): an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.
Harmful incident (formerly adverse event): an incident that resulted in harm to a patient.
Side effect: a known effect, other than that primarily intended, related to the pharmacological properties of a medication.
Adverse reaction: unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.
Incident type: a descriptive term for a category made up of incidents of a common nature, groups because of shared, agreed features

*the word 'unnecessary' recognises that errors, violations, patient abuse and deliberate unsafe acts occur in health care and are unnecessary acts[6]

The WHO have identified different forms of classification of risk for different purposes, and the ICPS presented a classification of thirteen incident types [6], such as 'clinical administration', 'clinical process', and 'behaviour', that aims to be universally applicable. All incident types except one ('oxygen/gas/vapour') seem potentially relevant to CAM.

The author group has agreed that this set of definitions is relevant and applicable for use in research on CAM safety.

Special challenges in CAM safety research

The study of the harmful incidents associated with CAM does not necessarily require a different research approach from conventional health care; indeed it is important to apply the knowledge and expertise already gained. But the research team must include people with specialist knowledge of CAM. The taxonomy for collecting reports on errors should be based on theoretical error concepts and should include information on system factors [7]. There are, however, special factors that might impede a research project into CAM safety. These challenges, though presented here primarily in relation to surveillance projects, also raise secondary research questions of their own.

Low incidence of harmful incidents

Serious CAM-related risks appear to be rare. To take acupuncture as an example, several large, prospective surveys have established its safety in Japan[8], the UK[9 10] and Germany [11 12]. The data from about 2.2 million treatment sessions suggest the maximum risk of serious harmful incident is 1:76,000 patients treated [12]. Similarly, a prospective survey of 50,276 cervical manipulations identified no serious harmful incidents [13]. These data suggest the risks of CAM could be ranked as 'very low', according to one classification [14]. In particular, homeopathic products are highly diluted and appear to present little risk [15]. Therefore large sample sizes, possibly requiring international collaborations, are required if precise inferences are to be made from surveillance studies.

Lack of regulatory setting of CAM practice

In many countries CAM practice is provided outside the national healthcare systems and practised by non-regulated personnel. CAM may therefore not be monitored by the safety mechanisms and reporting systems incorporated into mainstream regulatory and legislative frameworks. Even those CAM practices and products that are regulated rarely have adequate systems in place for reporting, assessing and acting on harmful incidents.

Where care overlaps or is shared, conventional health care practitioners often have little knowledge of CAM products or therapies [16], and are often unaware that their patients are seeking CAM providers or use their products [17]. Interactions with drugs are thereby less likely to be identified and reported.

Even when national surveillance systems have the capacity to collect information about CAM-related harmful incidents (as is the case with many adverse drug reaction registries such as the yellow card system in the UK[18]), few patients or practitioners (CAM or conventional) appear aware of this [19]. This constitutes specific challenges for CAM in addition to the challenges already inherent in the majority of established passive surveillance systems for safety in conventional medicine.

The different forms of self-regulation and the lack of regulatory bodies or professional organizations for some CAM practices and products make it difficult to conceptualize who might undertake to systematically identify risk associated with CAM. Robust new surveillance systems will need to be developed, together with an exploration into how

the concept of risk in CAM can be established in the professions in a way that enables the full and accurate reporting of the harmful incidents.

Perceived as safe due to being "natural"

The philosophy of CAM therapies generally emphasises their mode of action in ‘mobilising self-healing’ which implies they must be perfectly safe. Up to 90% of patients regard CAM as safe and so often do not even consider the possibility that treatment may have side effects [20]. Patients might be less likely to report harmful incidents that may be associated with natural products than with conventional pharmaceuticals, suggesting this may be related to preconceived ideas about the inherent safety of natural products [21].

Homeopathic remedies are generally considered safe so patients may increase the dose, risking overdose with non-homeopathic ingredients, such as ‘non-active’ solvents, up to toxic levels [22]. Furthermore, risk may arise from ‘mistaken identity’, where e.g. herbal and other medicines are described as homeopathic to make them look safer [23]. Deliberate contamination during preparation constitutes another risk [24].

These factors makes it less likely that CAM-related harmful incidents will be identified and reported, particularly via the passive surveillance systems currently in place for conventional treatments, which are themselves subject to serious underreporting. These factors also raise research questions about how the public can be educated to understand that CAM practices and products may be associated with harmful events, without causing unnecessary alarm.

Complex interventions

For some CAM treatments it is often easy to identify the component responsible for the harmful incident (for example, the acupuncture needle), but a large proportion of CAM interventions constitute complex treatments. Researchers need to determine whether they should pursue a search for a harmful component or address safety at a systematic level. Little experience is available at the present time with regard to this matter.

Medicinal products used in CAM such as plant extracts are likely to be pharmacologically complex and so have multiple physiological effects which may represent a beneficial synergy or harmful interaction, depending on the specific context. This problem is exacerbated by the common practice of combining many compounds in one product making it difficult to identify potential harmful incidents or interactions with other products.

Interactions with conventional medicine

The research situation becomes even more complicated when taking into account that many patients using CAM simultaneously use conventional practices and drugs. Although there is some high-quality research about herbal medicine-drug interactions, this research has mainly been carried out on single standardised herbal medicines. Broadening this field into interaction in general creates many challenges [25].

Information given to patients by conventional or by CAM practitioners might adversely influence belief in or uptake of the other type of therapy, including for example failure of CAM practitioners to refer patients when more effective conventional treatment is available for their condition [26].

Complacency

Discussion of safety can be interpreted by CAM practitioners as confrontational and an insult to their professional integrity. For example, a systematic review of reported harmful incidents of acupuncture [27] first generated a defensive response before professional acupuncturists came to consider safety as a legitimate topic of research, [28] and subsequently became active research collaborators [29].

Complacency is a likely cause of under-reporting for all passive surveillance systems [21 30]. In conventional medicine, estimates suggest that as few as 6% of all harmful incidents are ever reported [31], but there is evidence that the problem may be even worse for CAM products [30].

A specific challenge will be to develop methods to circumvent the complacency present among some CAM traditions with regard to potential harm of their treatments.

Special challenge: 'healing crisis'

One risk-related issue that is relevant to the safety of some CAM therapies is the so-called healing crisis, also known as a 'therapeutic aggravation'. This event is particularly linked to homeopathy, but may be reported with other CAM therapies. It has been defined as: 'Temporary worsening of existing symptoms following the administration of correctly chosen homeopathic prescription, which indicates a favourable response to treatment'[32].

CAM practitioners regard a healing crisis as a positive sign that predicts subsequent improvement in the condition as it is seen to be a sign that the body's self healing potential has been activated. There are only few examples of research into this concept [33], although the phenomena has been widely reported for centuries [34].

The healing crisis meets the usual definition of a harmful incident (box 2). Practitioners might argue that the healing crisis is a desired event and therefore not adverse, but until it has been demonstrated that the healing crisis is an important component of treatment effectiveness, then we regard it as a harmful event. A similar example from conventional medicine would be the fever and localised inflammation associated with immunizations: this may be evidence of an immunological response, but is still harmful and patients must be informed about the risk. We need to understand the associated effectiveness, the frequency in different therapies and different cultures, the predictability, and the relationship to different therapists, of the so called 'healing crisis'.

Priorities for research

The NAFKAM workshop provided a forum for an initial sharing of ideas and experiences, and subsequently attendees agreed to conduct an email consensus

(modified Delphi method) exercise to establish research priorities. First, 14 potential research topics were identified by the lead author from notes and flip-charts of the meeting combined with a survey of safety literature. The topics related to five areas: practitioner training, professional regulation, public belief and attitudes, registry, and surveillance. Each topic was then expressed in the form of one, or sometimes two, generalised research aims (for example, the topic of professional regulation naturally led to the research aim: 'Review the operation of organisations responsible for overseeing CAM safety'). In the first round, the seven participants were asked to comment on the relevance of the topics and aims, and to suggest revisions and improvements to the wording. Their comments were summarised and presented back to participants with revised research aims, in a second round. Participants were invited to rate their top five priorities, in order. The resulting research priorities, with mean scores of ratings, were as follows (1 is most important, 5 least important):

1. Active surveillance projects including vulnerable patients and concomitant use of conventional care; score 1.2.
2. Attitude to safety among CAM practitioners (i.e. the extent to which safety is integral to clinical practice); score 2.7
3. Influences on, and changes in, public and patient beliefs and attitudes to CAM safety; score 3.5
4. Attitude to safety in CAM professional organisations (i.e. the extent to which safety is considered integral in all thinking and decisions); score 3.2
5. Procedures (and their effectiveness) that CAM professional organisations use to ensure continued safe practice by their members; score 4.2.

Conclusion

In a period of increasing societal interest in safety of health care, the CAM professions and individual practitioners have a responsibility to question and enhance the safety of their products and practices. A number of challenges exist. To reduce the risk, the harmful incidents associated with various CAM products and practices should first be documented, particularly where data are sparse.

Research should also be undertaken into diminishing risk where appropriate, especially how to enhance the safety culture among the stakeholders representing different products and practices. These projects need international collaboration to develop and provide specialised resources and avoid duplication, and to provide sufficiently large datasets in sufficient diversity of practice to be meaningful.

More information is needed about the incidence of these events in different settings and population groups. The extensive range of harmful incidents potentially associated with CAM, as well as the range of activities that are described as CAM practice along with the number of organisations involved in training or overseeing practitioners constitute a significant problem for research in this area. These issues need to be considered carefully to facilitate further understanding of the events as well as the prospective design and evaluation of strategies to reduce the future risk.

Authors statements:

Authors: All research done by the authors

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