Research in primary care complementary and alternative medicine provision: an integral part of NHS clinical governance activity.

Jane Wilkinson
David Peters

School of Integrated Health

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Research in Primary Care Complementary & Alternative Medicine Provision

An Integral Part of NHS Clinical Governance Activity

Jane Wilkinson & David Peters

The 1997 UK government white paper "The New NHS: Modern, Dependable"[1], introduced a legal requirement for the NHS to provide accountable and quality assured services. Clinical governance was described by Scally and Donaldson (1998) as the "... system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish." An organisational culture that "...creates a working environment which is open and participative, where ideas and good practice are shared, where education and research are valued.... is likely to be one where clinical governance thrives."

Importantly, the latter part of this quote implies that research will underpin clinical governance (CG) activities. To a lesser degree, other CG targets including the development and impact of Continuing Personal and Professional Development (CPPD), service redesign and even the implementation of CG activities will themselves need to be monitored and reviewed. Clearly, the research methodologies appropriate to these different areas will need to be wide-ranging.

Research Governance (RG) has also rapidly developed over the last few years, especially post the publication of the 2001 Department of Health (DoH) Research Governance Framework for Health and Social Care[2] and subsequent changes to the way research ethics committees work. As Kerrison et al[3] explain:

"The research governance framework sets in place mechanisms for ensuring that research complies with all professional, ethical, legal, and scientific standards... From April 2004, all research conducted in care organisations must have a research sponsor... The primary role of NHS trusts in the framework is as care organisations. Care organisations must ensure that all research on NHS patients... NHS staff and research carried out in NHS premises, is conducted according to the framework."

Directives from the European Union also bring in new guidance and rulings on best practice in research. An example of this is Directive 2001/20/EC on Good Clinical Practice in Clinical Trials[4], which will is due to come into legal force in all EU member states on May 1st 2004.

NHS modernisation has given Primary Care Trusts (PCTs) unprecedented autonomy, but it also makes them accountable for any services they commission. Therefore, if Complementary and Alternative Medicine (CAM) services are to be integrated into the NHS, the development of CG (with its imperatives and processes for ensuring accountability and quality improvement) will be a crucial consideration for PCTs developing CAM services. Being able to demonstrate CAM's benefits, cost-savings and effectiveness would validate those who proclaim the advantages of integrated healthcare in the NHS. Among these advantages is the potential to help PCTs meet key targets in the government's modernisation agenda (i.e. a more primary care-led NHS, with fewer secondary care referrals and reduced prescribing rates). It will require a great deal of sound and highly efficient research to determine these outcomes.

As CAM integrates with the NHS, several factors relevant to the clinical governance of CAM are likely to influence policy formation in PCTs. Research conducted by the Medical Care Research Unit (MRCU) at the University of Sheffield[5] identifies a number of key overlaps as being crucial to commissioning CAM services:

- Equity of access
- Cost effectiveness
- Local priorities
- Adequacy of the evidence base for CAM
- Availability of appropriate quality assurance indicators

The Government's response to the House of Lords Select Committee scientific report on CAM[6] reinforces this idea: "CAM can also play a part in treating NHS patients. But if it aspires to be an equal player with other forms of NHS treatment, it must meet the same standards required of them. And it must be clear and realistic about the contributions it can make."[7] The headline NHS priorities (e.g. waiting lists, national priority conditions, and National Service Frameworks) will also influence, for better or worse, the development of CAM services.

The Department of Health (DoH) and the King's Fund have funded a three-year project, based at the School of Integrated Health, University of Westminster to address the issue of clinical governance for CAM NHS primary care services. Part of this work is to facilitate the process of developing consensus on best practice. Several important CG areas were prioritised at an initial stakeholder event and were subsequently addressed in a series of six seminars, hosted by the King's Fund. The first seminars addressed key issues relating to evaluation and research, and this was followed later in the series with a seminar on economic evaluation.

The seminars were attended by a broad range of stakeholders who heard presentations on current thinking by relevant experts followed by groupwork on specific topics, with the aim of drafting guidance on how to apply CG activities to CAM practice, as well as identifying the necessary steps and resources needed to help the process evolve.

Following the seminars, a modified Delphi technique[8] was used to generate 'expert' feedback on the seminar outputs. The results of this process are being published in a consultation document[9] this month. Over 1500 individual stakeholders are being included in the consultation.

Evaluation & outcomes

One of the most interesting outputs from the series of seminars was the development of a pilot series of Broad Evidence Synthesis Topic on CAM (BESTCAM) reports, which was proposed by Kate Thomas, Deputy Director of the MCRU. Widely cited sources of evidence (such as Cochrane, York University, and Bandolier), which pull together the available evidence, focus exclusively on RCTs and frequently conclude that there is "no good evidence" relating to CAM. Kate Thomas and Dr Michael Dixon (Chair of the NHS Alliance) both made the case for returning to the original definition of evidence-based medicine (EBM): "the integration of the best research evidence and evidence gleaned from clinical experience and influenced by patient values and preferences". The true intention of EBM will be lost if decision-makers focus exclusively on randomised controlled trials as the only definitive source of evidence.

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Randomised controlled trials into the efficacy of CAM are rather sparse and the results of their systematic review inconclusive. Because this evidence is so under-developed and so much at variance with the impression of those who use CAM, there will be value in incorporating evidence on applying CAM in practice.

Efficacy vs effectiveness

The efficacy versus effectiveness debate is concerned with the discrepancy between the results of controlled clinical trials and more pragmatic evaluation of practice as it happens in the clinical setting. Efficacy is high on internal validity at the expense of generalisability; effectiveness is high on external validity at the expense of careful controls. The research community favours efficacy while the practice community prefers effectiveness. The disparity has practical consequences in that healthcare delivery is influenced increasingly by the development of practice guidelines based on research data. It is entirely proper that evidence should be the foundation of effective healthcare delivery. The debate has to do with what constitutes the best evidence for clinical decisions. The BESTCAM reports aim to address this issue by incorporating a range of effectiveness studies of alongside the efficacy evidence.

The debate on EBM continues to be a hot topic for GPs[11]: "...the evidence-based medicine movement is evolving. It retains the fundamental premise that the efficacy and safety of interventions should be assessed in population-based research studies using the

tools of objective scientific measurement, with special status rightly accorded to the randomised controlled trial. But it increasingly recognises three additional areas of interest, which might be termed the 'interface zones' between evidence-based medicine and the real world, and which, I contend, require the research methods of the social sciences as well as (and sometimes instead of) those of biomedical science.

The three 'interface zones' are:

1. The "... historical, political, economic and cultural" context within which "clinical research trials are planned, funded, undertaken (or abandoned), analysed, discussed, published (or withheld from publication) and disseminated." These must be "defined and understood."
2. The "large gap between established evidence of efficacy research trials and delivering effective practice requires attention to both clinical outcomes and socio-cultural aspects of professional behaviour and organisational change."
3. "The clinical encounter...must be separately studied by appropriate techniques... [as it] is an interpretive and creative act that goes beyond objective scientific enquiry."

Examining different types of evidence

Pooled RCT evidence on CAM is patchy, making it hard to draw definitive conclusions; yet decisions are usually made on this basis. A different approach is therefore required, as Kate Thomas pointed out in the first CG seminar[12]: "We cannot move forward if we require the highest level of proof of effectiveness [for every therapy in relation to every patient condition]. We will deny patients the benefit if we insist on that."

Discussion in the seminars focused on the value of non-RCT data in informing best practice, the development of new services, and the application of methodologies for assessing good quality research and reviewing non-RCT data in a robust and systematic way. Ways of supporting good practice in clinical governance for CAM services will need to be found, primarily in the generation of Performance Indicators (PIs).

Pilot BEST CAM Report

Participants at the DoH/King's Fund seminar favoured broadening both the types of evidence and the methodologies employed, including:

- Effectiveness of service delivery
- Impact on prescribing rates
- Secondary care referrals
- Waiting times for orthodox treatments
- GP and other primary care practitioners' consultation rates
- Workload
- Accessibility

Cost-effectiveness, benefits, and safety were also considered important. It was also generally acknowledged that a wide set of health outcomes should be included (quality of life, well-being, early return to work, etc.) Patient experience and satisfaction were high on agenda, as was acceptability to patients and referring GPs. Patient-led research was also identified as important.

The reports would cover either single treatment modalities or multiple treatment options for specific conditions. Priority conditions were those that are traditionally expensive to treat in terms of finance and resources, are related to National Service Frameworks (NSFs), or address other local and national priorities:

- Patient choice, access, and safety
- Demand management
- Perceived effectiveness gaps within orthodox medicine
- Unmet or poorly met needs

Delegates were pragmatic about how BEST CAM reports should develop over time, the initial priority being those conditions and treatments where relevant evidence is available. As a result of this work, a pilot BEST CAM report is being developed by the CG team for the treatment of low back pain, in tandem with the pilot development of an integrated therapeutic pathway.

Performance indicators

The generation of PIs is an example of applied research in CG, central to service evaluation and development. More crucially, services will not be funded without them. They need to be realistic and have a clear rationale, (e.g. evidence that a certain service delivered to x number of patients can reduce secondary referrals).

Delegates agreed that PIs should be generated in four key areas:

- Safety
- Effectiveness and efficacy
- Delivery
- Value for money

Areas relating to safety included: adverse events, risk assessment, and health and safety procedures. Indicators were seen as essential for specific and non-specific conditions, and for a range of health outcomes including symptomatic relief, functional improvement, well-being, patient enablement and health promotion in chronic disease, lifestyle changes and the impact on patients' ability to cope, their improved productivity, and impact on family life. Patient feedback, expectations and satisfaction were also considered highly relevant.

Economic evaluation

Valid economic evaluations of all health and social care interventions, including CAM, are absolutely essential. In many ways, economic evaluation of CAM is no different from that of conventional medicine, and the same could be argued for its clinical evaluation. Yet the challenges involved raise questions about how best to evaluate not only CAM but conventional care too!

The imperative of the 'single metric' in economic evaluation is at the heart of the problem: economists would like to produce generalisable outcomes, so they can assess whether CAM is doing something different when compared to other treatments - to see, for instance, whether treatments for back pain are better value for money than treatments for knee pain. Feedback is needed from economists on how separate empirical evidence from speculation. There is a great deal of intuitive understanding about 'expanded benefits' from CAM, but how do we measure different kinds of benefit, and, more importantly, explore the relative value that patients attach and their preferences for different outcomes?

Discussion, both in the seminars and through the ensuing Delphi process, revolved around the potential for evaluating the cost-effectiveness of CAM. Among the diverse strands of current economic thinking and research, there are examples of ways to take into account wider outcomes and associated costs. An example of this would be to track patients with low back pain with and without CAM interventions, and to compare this with orthodox treatment. The longer-term and wider implications would then be assessed (e.g. time off work, dependency on other family members, social benefits due to incapacity to work, the impact of early intervention on prevention of acute chronic recurrences, and so on). As Dr Mike Dixon, Chair of the NHS Alliance pointed out[14]:

"Integrating CAM is not just about introducing a new treatment, it is about changing the way we view ourselves and our capacity for self healing. That is the added benefit CAM could bring to the NHS, but it is one that is difficult for the health economists to quantify... Unless we look at the whole picture – the culture, population, community regeneration, the individual consultation – we will continue to view it solely in conventional terms. We need to get away from this reductionist approach, which characterises modern medicine today."

The cost/benefit analysis of CAM will make no sense unless we bear in mind the wide range of perceived benefits, and the patient's perspective on the benefits they would like to receive. This raises the issue of whether the NHS ought to be providing those kinds of benefits, and what an NHS-appropriate definition of health might be? This last question is perhaps the most central. Four domains of benefit call for immediate study:

- Health status
- Well-being
- Process utilities
- Health behaviours (which would include the dis-benefits of conventional treatment side effects)

Delegates proposed that the scope of evaluation should be widened, leading to the development and application of more appropriate and

relevant research methodologies. Whilst recognising a need to incorporate current orthodox practice in the evaluation of CAM (in particular through the application of innovative models, such as Program Budgeting and Marginal Analysis - PBMA[11]), there was a consensus that any research should ask questions that are both relevant to CAM and appropriate to commonly associated outcomes. As well as more direct health gain, these might include longer-term evaluations of the impact on the individual and their immediate family, and wider costs to the social system as a whole. Examples include early return to work, maintaining family cohesiveness (especially where carers are concerned) as well as claims on the benefits system. This also relates to the prevention of clinical sequelae and the possibility that a CAM consultation can contribute to a person's empowerment for health promotion and self-management. National and local priorities around patient-choice and health promotion mean exploring methodologies that could measure outcomes related to these initiatives.

Networks for CAM research

Networks for CAM researchers are already evolving across the UK, some with online facilities[15]. The Integrated Healthcare Network[16] is a site dedicated to professionals with an interest in developing CAM primary care services, including clinical governance and related research. It is jointly run as part of the Clinical Governance Project, University of Westminster and the Prince of Wales's Foundation for Integrated Healthcare.

In conclusion

There is a developing ethos of CG supporting research across conventional and complementary medicines. A three-year programme of DoH/King's Fund seminars and other activities is working to develop an approach to research that teases out the complexities of efficacy versus effectiveness, and varied methodologies whilst accommodating the growing demands for economic justification of treatment funding.

Jane Wilkinson (cgcam-net@wmin.ac.uk) is Senior Research Fellow and Manager of the Clinical Governance for CAM in Primary Care project at the School of Integrated Health. Professor David Peters is Clinical Director of the School, University of Westminster.

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9 Copies of the consultation document (which also details the CG project) can be obtained by members of the Integrated Healthcare Network www.ihn.org.uk or by e-mailing cgcam-net@wmin.ac.uk.
10 The Research Capacity Development Programme has invested in developing CAM-related research capacity. It is a national programme, which provides personal awards & funds academic infrastructure to support research capacity development within the NHS. It is funded by the Department of Health's R&D Programme, and is administered by the National Coordinating Centre for Research Capacity Development (NCCRCD). www.dh.gov.uk/Home/fs/en select R&D/ Call for proposals/ Complementary and Alternative Medicine

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13 We would like to acknowledge the contribution to this discussion made by: Kate Thomas (Deputy Director, MCRU, University of Sheffield), Dr Michael Dixon (Chair, NHS Alliance), Professor Nancy Dennis (Professor in Health Economics, Department of Economics, City University) and Richard Little (Senior Research Fellow, Centre for Health Planning & Management, Keele University) in talks given at seminar 5: See White, Wilkinson and Peters et al 2003.
14 White C, Wilkinson J, Peters D et al. (2003): "Clinical Governance for CAM in primary care: Seminar 5: Building consensus on the evaluation of CAM in primary care" King's Fund Seminar.
15 CAM related research networks:
- ACCoRD Prince of Wales' Foundation for Integrated Healthcare - www.fihealth.org.uk
- The Alternative and Complementary Healthcare Research Network (ACHRN) - www.users.globalnet.co.uk/~duerden/achrn/aaseries.htm
- Alternative and Complementary Therapies Research Network (ACORN) - www.ihs.ox.ac.uk/acorn
- The Complementary and Alternative Medicine Researcher Network (CAMRN) - www.rccm.org.uk/camrn/CAMRN_intro.aspx (RCCM - www.rccm.org.uk)
- The Scottish Complementary/Alternative Medicine Research Network (CAMRen) within the Complementary/Alternative Medicine (CAM) Forum - www.man.ac.uk/rcn/scotland/camren.htm

16 Integrated Healthcare Network - www.ihn.org.uk