

More On BMA's Approval Of Acupuncture

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We may be in danger of bribing volunteers

EDITOR—Christie's news article has highlighted an important inconsistency in the World Medical Association's fifth revision of the Declaration of Helsinki.¹ This fundamental document, first adopted by the association in 1964, defines the ethical and moral responsibilities of physicians and others participating in research on human subjects.

The document insists that all subjects should be volunteers, having freely given informed consent to the research proposed. The latest revision is also particularly concerned with protecting the rights of economically or medically disadvantaged populations, typified by those in developing countries. Paragraph 29 identifies the concept of testing new treatments against the best existing treatment, where such exists, rather than against placebo. Paragraph 30 takes this theme further by saying that, at the conclusion of the study, every patient entered into the study should be assured of access to the best proved prophylactic, diagnostic, or therapeutic method identified by the study. Christie interprets these statements to mean that people in developing countries would at least get access to the best

current treatment if they agreed to take part in research into new treatments.²

Economically or medically disadvantaged populations are those in whom the best or most up to date medical services may not be available. If the principles in the revised declaration are put into practice, then those participating will clearly not have freely consented and will not be volunteers (according to *Collins Dictionary of the English Language*, a volunteer is a person who does some act without being promised any remuneration³). By promising treatments either during or at the conclusion of a research study that would otherwise be inaccessible to the local population, those organising the study would be tempting or coercing subjects into participation. This is precisely what the Declaration of Helsinki is designed to prevent. Although revision and updating of the declaration is important to ensure that it remains up to date, we must be careful not to stray too far from its original goals.

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- 1 World Medical Association. Declaration of Helsinki. Ethical principles for medical research involving human subjects. www.wma.net/e/policy/17-c_e.html (accessed 8 Dec 2000).
- 2 Christie B. Doctors revise Declaration of Helsinki. *BMJ* 2000;321:913. (14 October.)
- 3 Hanks P, McLeod WT, Urdang L, eds. *Collins dictionary of the English language*. 2nd ed. Glasgow: Collins, 1986:1700.

More on BMA's approval of acupuncture

BMA replies to correspondence

EDITOR—Moore et al and Kovacs and Gil del Real criticise the BMA's report on acupuncture.^{1,2} Our review of the evidence base of acupuncture rested heavily on the comprehensive work of Ernst and White, which summarised the clinical evidence for and against the effectiveness of acupuncture.³

The conclusion of this work is that acupuncture seems to be more effective than sham acupuncture or other control interventions for some conditions, including nausea and vomiting, back pain, dental pain, and migraine. However, for smoking cessation, weight loss, and a range of other conditions the present evidence is unclear. We discussed the problems introduced in basing conclusions on poor quality studies or reports.

Our survey of general practice throughout the United Kingdom showed that acupuncture is the complementary therapy most used by general practitioners, with most patients being referred for pain relief and musculoskeletal disorders. Acupuncture is now reported to be used routinely ahead of physiotherapy and drug delivery systems in 86% of chronic pain services.⁴

The thrust of our recommendations seems to have been missed. The BMA calls for substantial research funding, the production of guidelines, and a formal appraisal of acupuncture. Kovacs and Gil del Real should note that our recommendation about availability of acupuncture in the NHS was subject firstly to having policies, guidelines, and mechanisms for making this treatment generally available—hence the need for appraisal by the National Institute for Clinical Excellence (NICE). Improvements in training and regulation of non-medical practitioners are required, and doctors need to know the basics of complementary and alternative medicine so that they are better able to advise patients. Our detailed review of safety and adverse reactions to acupuncture should reassure Moore et al that the treatment is comparatively safe—the more important risk is likely to arise through misdiagnosis and the withholding of orthodox treatment.

There are more than 5500 acupuncturists in the United Kingdom, of whom over 3500 are statutory health professionals, an increase of 51% in two years.⁵ Acupuncture treatment has flourished despite a lack of widespread knowledge of its efficacy, and without comprehensive guidelines for either general practitioners or patients. Recommendations clarifying whether acupuncture should be used in the NHS are urgently needed.

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- 1 Correspondence. BMA approves acupuncture. *BMJ* 2000; 321:1220. (11 November.)
- 2 BMA. *Acupuncture: efficacy, safety and practice*. Amsterdam: Harwood Academic, 2000.
- 3 Ernst E, White A. *Acupuncture: a scientific appraisal*. Oxford: Butterworth Heinemann, 1999.
- 4 Clinical Standards Advisory Group. *Services for patients with pain*. London: Department of Health, 1999.
- 5 Mills SY, Budd S. *Professional organisation of complementary and alternative medicine in the United Kingdom*. Exeter: Centre for Complementary Health Studies, University of Exeter, 2000.

BMA report is not wrong

EDITOR—The letter by Moore et al denouncing the BMA report on acupuncture is couched in strong language, but their account of the report is selective and misleading.¹ They ignores its recommen-

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dation that acupuncture is effective for nausea and vomiting (particularly postoperative symptoms in adults), for which there is a sound body of evidence.²

Moore et al misrepresent the BMA's position on smoking cessation; in fact, the report states clearly that "at present there is no evidence to support any role for acupuncture in the management of smoking cessation."⁷

Moore et al state: "There is evidence that it [acupuncture] harms" without reference; in fact, current evidence shows that the incidence of adverse reactions to acupuncture is low.³

The evidence remains equivocal on the use of acupuncture for chronic pain. The most recent systematic review found that acupuncture is better than no treatment (waiting list controls) but that it is premature to draw conclusions about the effectiveness of acupuncture compared with placebo or standard care.⁴

Performing double blind placebo controlled trials of acupuncture is exceptionally difficult. Pending such gold standard evidence, the BMA accepted the task of dispassionately evaluating the available literature to define an appropriate role for acupuncture in the NHS. Its report is not "quite simply wrong," and such dogmatism does not serve our patients or enhance the quality of debate on this important subject.

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- 1 Moore RA, McQuay H, Oldman AD, Smith LE. BMA approves acupuncture. *BMJ* 2000;321:1220. (11 November.)
- 2 Lee A, Done ML. The use of nonpharmacological techniques to prevent postoperative nausea and vomiting: a meta-analysis. *Anaesth Analg* 1999;88:1362-9.
- 3 Norheim AJ, Fonnebo V. Adverse effects are more than occasional case reports: results from questionnaires among 1135 randomly selected doctors and 197 acupuncturists. *Complementary Therapies in Medicine* 1996;4:8-13.
- 4 Ezzo J, Berman B, Hadhazy VA, Jadad AR, Lao L, Singh BB. Is acupuncture effective for the treatment of chronic pain? A systematic review. *Pain* 2000;86:217-25.

Acupuncture techniques should be tested logically and methodically

EDITOR—Neither the BMA in its report on acupuncture nor the comments of Moore et al are entirely right or wrong.¹ Lack of evidence for efficacy does not equal evidence for lack of efficacy. Obtaining evidence of efficacy for acupuncture has been hampered by methodological problems unique to this kind of manual therapy, particularly that of finding a credible, truly inactive, control procedure. There are now credible sham acupuncture procedures in which skin penetration in the control group is avoided, and the first trial to use such a procedure indicates a specific effect for acupuncture.²

Systematic reviews of acupuncture for back pain include trials that use different techniques and control procedures. These would usually be considered far too heterogeneous to be included in a review. The highest quality trials compare needling of classic acupuncture points with control procedures that entail exactly the same type of needling at other points. The intragroup effects in

these trials nearly always indicate a noticeable improvement after needling, but, inevitably, the difference between what is described as real acupuncture and what is described as placebo is rarely significant. As discussed by Moore and McQuay, the controls used in blinded studies of acupuncture for chronic back pain were 50% effective.³ These controls entailed skin penetration, so one form of acupuncture was compared with another. A 50% response rate is typical of effective treatments for acute and chronic pain.⁴

In their drive for academic rigour, reviewers are distracted from taking a logical overview of the subject. There is no evidence that acupuncture points exist, so subjecting acupuncture points to rigorous testing is unlikely to be rewarding. There is a wealth of evidence, however, that somatic sensory stimulation can modulate pain.⁵ Needle penetration of tissues is a potent form of sensory stimulation. It is on this basis that the British Medical Acupuncture Society trains doctors in an evidence based approach to dry needling therapy. Safety issues are important, but for general practitioners or pain specialists acupuncture is still probably one of the safest of the physical or pharmacological interventions they use.

There is a dearth of randomised control trials with positive results, but this may be due more to methodological difficulties than a lack of efficacy. The positive results in lower quality trials may not be attributable solely to bias. The pain community would be done a disservice if acupuncture techniques were not tested in both a logical and methodologically sound manner.

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- 1 Moore RA, McQuay HJ, Oldman AD, Smith LE. BMA approves acupuncture. *BMJ* 2000;321:1220. (11 November.)
- 2 Kleinhenz J, Streitberger K, Windeler J, Gussbacher A, Mavridis G, Martin E. Randomised clinical trial comparing the effects of acupuncture and a newly designed placebo needle in rotator cuff tendinitis. *Pain* 1999;83:235-41.
- 3 Moore RA, McQuay HJ. Bias. *Bandolier* 2000;7:1-5.
- 4 McQuay HJ, Moore RA. *An evidence-based resource for pain relief*. Oxford: Oxford University Press, 1998.
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Avoidance of ingestion of anti-inflammatory drugs in dyspepsia is confounding variable

EDITOR—Langman et al in their paper on the effect of anti-inflammatory drugs on overall risk of common cancer describe a method using coded data from the general practice research database to support their hypothesis that anti-inflammatory drugs may protect against oesophageal and gastric cancer.¹ The study reported the association between a reduction of coded cases of cancer of the oesophagus, stomach, colon, and rectum in a subpopulation who had

received at least seven prescriptions in the 13-36 months before diagnosis.

This conclusion seems to be ambitious as aetiologically it seems unreasonable to anticipate that the use of a drug in the 36 months before diagnosis will halt a neoplastic process that may have begun many months or years before. Gastrointestinal cancer (particularly of the oesophagus and stomach) is often associated with abdominal pain and dyspepsia. Patients and their attending clinicians will avoid the use of anti-inflammatory drugs in the presence of such dyspepsia. Thus the reported association between the use of anti-inflammatory drugs near the time of diagnosis is more elegantly explained by the confounding avoidance of these drugs in dyspepsia associated with malignancy.

Langman et al also describe a possible dose effect, and once again this is equally well explained by the greater avoidance of these drugs in patients with increased dyspepsia rather than by invoking a hypothetical mechanism of gut epithelial protection. One of the great advantages of collecting clinical information in a coded format is that new associations may be discovered by using a variety of techniques including knowledge discovery in databases (P J B Brown and V Raymond-Smith, unpublished data).² If such exploitation of repositories of data is to gain recognition and acceptance in medicine vigilance is needed in interpreting these associations and a full consideration of possible confounding factors is essential before proposing new theories.

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- 1 Langman MJS, Cheng KK, Gilman EA, Lancashire RJ. Effect of anti-inflammatory drugs on overall risk of common cancer: case-control study in general practice research database *BMJ* 2000;320:1642-6. (17 June.)

Risk of torsades de pointes with non-cardiac drugs

Prolongation of QT interval is probably a class effect of fluoroquinolones

EDITOR—Yap and Camm emphasise the risk of torsades de pointes associated with non-cardiac drugs that prolong the QT interval.¹ They comment on the fluoroquinolone antimicrobial agents grepafloxacin and sparfloxacin causing QT prolongation but also the apparent lack of this effect with levofloxacin. We recently cared for a patient who developed torsades de pointes while taking levofloxacin, which prompted us to examine retrospectively paired electrocardiograms in other patients to compare QTc intervals before and after they started treatment with this drug.

Twenty three patients who received a standard dose of 500 mg levofloxacin daily had cardiograms that could be compared for QTc prolongation. Prolongation of > 30 ms was found in four patients and of > 60 ms in