

**NUFFIELD  
COUNCIL<sup>ON</sup>  
BIOETHICS**

**BACKGROUND PAPER**

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**Complementary Medicine: ethics**

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**Forward Look  
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# NUFFIELD COUNCIL <sup>ON</sup> BIOETHICS

*Forward Look*  
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## **Complementary Medicine: ethics**

### **Background Paper**

#### **Summary**

- 1 This paper looks at some of the issues raised by the use of complementary and alternative medicines in the UK. It outlines some of the policy, regulatory and legal issues raised by this area of medicine, including ethical considerations relating to patient autonomy and consent, the doctor-patient relationship, paternalism, fairness and the proper use of public resources.

#### **Background**

##### *Terminology and examples*

- 2 There is no universally agreed-upon definition of complementary medicine. Common to many characterisations of complementary medicine is the notion of therapeutic treatment which falls outside the mainstream health institutions within which standard or conventional medicine is practised. Sometimes the difference between conventional and complementary medicine is expressed by appeal to the holistic or 'individualistic' nature of complementary therapies, many of which purport to interact with features of the patient other than physiological features. A definition proposed in a 2003 BMJ article, subsequently widely adopted by others writing in the field, defined complementary medicine as the "diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual frameworks of medicine".<sup>1</sup>
- 3 Much of the literature and discussion on this topic refers, rather than to 'complementary medicine', to 'complementary and alternative medicine' or 'CAM'. 'Complementary medicine' is sometimes thought of as a set of treatments and therapies which patients choose to have in addition to conventional medicine, whereas 'alternative medicine' can be used to refer to treatments and therapies intended to replace conventional medicine. This distinction, however, does not map onto any particular division amongst the different treatments making up the set of CAM therapies, and the expression

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<sup>1</sup> Ernst E, Resch K-L, Mills S, et al. (1995) Complementary medicine: a definition *British Journal of General Practitioners*: 506

'CAM' is more often used to refer to the group of relevant therapies as a whole. Sometimes the terms 'unconventional' or 'traditional' medicines are used to describe the same group of treatments and therapies.<sup>2</sup>

- 4 There are a very wide range of therapies which fall into the category of CAM. More commonly used examples include acupuncture, homeopathy, chiropractic, osteopathy and medical herbalism. Activities such as yoga, reiki, shiatsu and aromatherapy are also sometimes used as CAM therapies. Less well known CAM therapies include autogenic training and therapeutic ultrasound, as well as a range of others. Annex 1 shows a table of some CAM therapies and brief descriptions of each.
- 5 The range of conditions and diseases that CAM may be used to treat is also wide. CAM therapies may be used to promote general wellbeing, to prevent specific illnesses, to remedy minor ailments or injuries, or to address symptoms of a range of short or long term conditions. CAM is commonly used, for instance, for pain relief in a variety of contexts and is widely used for a range of other problems including migraine, IBS, menstrual pain, and less severe mental health conditions, such as anxiety or stress. People also make use of CAM therapies to treat symptoms of a wide range of serious diseases, including cancer, stroke, dementia and Parkinson's disease.
- 6 Some CAM therapies and techniques are used for other than purely medical purposes. A number of CAM therapies purport to improve general wellbeing, or promote relaxation, and many people find activities like yoga, aromatherapy, tai chi and meditation to be enjoyable activities in themselves. For such areas of CAM, many practising them may choose to do so for more general exercise or leisure purposes, rather than to address specific health problems.
- 7 CAM treatments are often delivered by therapy-specific practitioners, but can also be performed or arranged by doctors, nurses or other practitioners from conventional health settings. Professional bodies and associations provide training and accreditations for CAM therapists, and training in CAM for doctors and nurses is made available by through some of the Royal Colleges and universities.
- 8 The wide range of CAM therapies, and uses to which they are put, may raise a question about the usefulness of classifying this diverse set of therapies, practices and activities as a single enterprise of 'CAM'. Issues relating to regulation, law, function, safety and efficacy are not identical across each areas of CAM and it might be argued that conceptualising the set of CAM treatments as one discrete area of medicine obscures important differences in the policy and ethical issues raised by distinct CAM therapies.

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<sup>2</sup> Zollman C and Vickers A (1999) ABC of complementary medicine: what is complementary medicine? *BMJ*

## Information on use of CAM in England

- 9 Statistics suggest that in England CAM therapies are popular and that use is increasing. A paper published in 2001, using data from 1998, showed substantial use of CAM in the English population. The study looked at use of acupuncture, chiropractic, homeopathy, hypnotherapy, medical herbalism and osteopathy, and found that 10.6% of adults had visited a therapist providing one of these services in the preceding 12 months. The report also estimated that 22.1% of adults had purchased homeopathic or herbal remedies over the counter within the same period.<sup>3</sup> A later report, published in 2010 using data from the 2005 Health Survey for England found that 12.1% of people in England had consulted a CAM practitioner in the preceding 12 months.<sup>4</sup>
- 10 The 2010 study found that a range of demographic variables were associated with use of CAM. Women, university educated people, those with anxiety, depression or poor mental health and those with lower levels of perceived social support were all significantly more likely to have used CAM.<sup>5</sup>
- 11 Current estimates suggest that annual total expenditure on CAM in the UK as a whole is around £1.6 billion. The majority of this money comes from individuals personally funding their own privately provided CAM treatment.<sup>6</sup> Some CAM use, however, is funded by the state. There are several NHS homeopathic hospitals in the UK, and acupuncture, osteopathy and chiropractic are also made available to NHS patients, in certain areas of the country.<sup>7</sup>
- 12 CAM arouses considerable controversy in the UK and there is entrenched disagreement over whether and how it may exert any effects on those who use it. CAM therapies have not been tested to the same extent as licensed drugs or approved treatments in conventional medicine and there is dispute over whether research claiming to provide evidential support for CAM is conducted according to recognised scientific standards. Moreover, for some CAM treatments, the mechanisms by which they purport to exert their positive effects do not fit neatly into the established scientific understanding of human physiology, biochemistry and medicine more broadly. Support for CAM is sometimes denounced as pseudo-science and vociferous critics have accused CAM of promoting 'quackery' and bogus treatments.<sup>8</sup> Proponents of CAM insist that it can be an effective and beneficial tool in the treatment of

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<sup>3</sup> Thomas KJ, Nicholl JP and Coleman P (2001) Use and expenditure on complementary medicine in England: a population based survey *Complementary Therapies in Medicine*

<sup>4</sup> Hunt K J, Coelho HF, Wider B, Perry R, Hung SK, Terry R Ernst E (2010) *Complementary and alternative medicine use in England: results from a national survey*

<sup>5</sup> The earlier 2001 study found that use of CAM therapies were significantly higher amongst women than in men.

<sup>6</sup> Wellcome Trust, 'Complementary medicine for pain' microsite

<http://www.wellcome.ac.uk/en/pain/microsite/medicine1.html>

<sup>7</sup> For example, the Bristol Homeopathic Hospital and the Royal London Hospital for Integrated Medicine. [http://www.nhs.uk/explore-by-career/wider-healthcare-team/careers-in-the-wider-healthcare-team/clinical-support-staff/complementary-and-alternative-medicine-\(cam\)/](http://www.nhs.uk/explore-by-career/wider-healthcare-team/careers-in-the-wider-healthcare-team/clinical-support-staff/complementary-and-alternative-medicine-(cam)/)

<sup>8</sup> Professor David Colquhoun, whose Improbable Science blog purports to expose 'quackery' and Simon Singh, whose 2008 article 'Beware the Spinal Tap' accused The British Chiropractic Association of promoting bogus treatments, are two high-profile sceptics

many areas of health and appeal to widening use and a large body of positive patient reports to defend use of CAM.<sup>9</sup>

- 13 Much of the contention centres around disputes over the quality of evidence claiming to support the beneficial effects and safety of CAM, the degree to which it is appropriate or necessary to assimilate testing of CAM into the assessment structures applied in conventional medicine, and how far observed positive outcomes are due to placebo effects.

#### *Controversies surrounding the use of CAM in the UK*

- 14 Over the last 10 years, increased use of CAM and more vigorous public debate have given rise to greater scrutiny of CAM in the UK. This is particularly the case with homeopathy, which is currently available to patients in some parts of the UK on the NHS.
- 15 High profile science journalist and doctor, Ben Goldacre, published numerous articles between 2003-11, in the Guardian and on his Bad Science blog, criticising the evidence purporting to support the use of alternative medicine, and homeopathy in particular. His 2008 book *Bad Science* argues for the need for blind testing and randomisation in clinical trials testing the efficacy of CAM.
- 16 The subject received widespread attention in the mainstream media around this time with debate centring on whether CAM should be available on the NHS. In 2006 a group of 12 senior doctors and scientists wrote a letter, published subsequently in The Times, to senior managers within the NHS requesting that policy on the use of alternative medicine be reviewed, appealing to the need for robust evidence to justify public expenditure.<sup>10</sup> A freedom of information request made in 2009 by the Channel 4 News programme revealed that £12m had been spent on homeopathy between 2005 and 2008.<sup>11</sup> The total £286.6 billion spent by the NHS within the same period (89.6 billion, 94.7 billion, 102.3 billion in each subsequent year)<sup>12</sup> was not widely reported alongside this figure.
- 17 In 2010 the Science and Technology Committee in the House of Commons published a report, as part of its “Evidence Check” work looking at how the UK Government makes use of evidence, to devise and review policy into the use of homeopathy.<sup>13</sup> The report concluded that there is no good evidence for the efficacy of homeopathy and recommended that it should not be available on the NHS. The report also concluded that the MHRA should not have responsibility for licensing homeopathic medicines since, the Committee argued, this gives the public the misleading impression that those medicines

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<sup>9</sup> A 1999 BMJ article found that around 80% of users of complementary medicine were satisfied with the treatment they received.

<sup>10</sup> <http://www.senseaboutscience.org/pages/letter-from-professor-baum-and-other-scientists-to-nhs-trusts.html>

<sup>11</sup> <http://news.bbc.co.uk/1/hi/uk/8489019.stm>

<sup>12</sup> Harker R (2012) NHS funding and expenditure *House of Commons Library*

<sup>13</sup> <http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/45.pdf>

are efficacious.<sup>14</sup> The report notably focused not only on cost-effectiveness but also on the patient trust issues raised by seemingly legitimising homeopathy by making it available through state health institutions.

- 18 The Government response to the Science and Technology Committee report rejected its conclusion that the availability of homeopathy on the NHS created serious public trust issues and declined to remove access to homeopathic treatments on the NHS, arguing that making quality information available to commissioners, doctors and the public was the most effective way of dealing with the issues raised by the report.<sup>15</sup> Though the Department of Health official stance is that it has no position on particular CAM treatments, homeopathy remains available on the NHS in principle, with local NHS organisations retaining powers to take independent decisions about whether to give patients access to it.<sup>16</sup>
- 19 Other well known critics of the CAM include Professor Edzard Ernst and Dr Simon Singh, who's 2008 popular book *Trick or Treatment* looked at a range of evidence on the effects of homeopathy, chiropractic and medical herbalism, critiquing the evidence claiming to support these areas of CAM and arguing that there are significant safety issues with a number of CAM therapies. Simon Singh was unsuccessfully sued for libel by the British Chiropractic Association in 2009 for claiming that the organisation had made bogus claims about the effects of the therapy.
- 20 Currently, homeopathy, chiropractic and other forms of CAM treatment continue to be available to patients, through parts of the NHS and private practice. CAM continues to be the subject of close scrutiny in the UK, with critical articles appearing regularly in the print and broadcast media.

#### *Outside the UK*

- 21 The trend for increasing use of CAM is also reflected outside of the UK. The European Information Centre for Complementary and Alternative Medicine say that 20% of EU citizens, over 100 million people, are regular users of CAM therapies.<sup>17</sup>
- 22 Whilst CAM is widely used in Europe, regulation exists in only 18 of the 29 countries. Other than for herbal and homeopathic medicines (paras 47 & 50) there is little EU legislation on the use of CAM and the majority of European countries do not have national policies or local regulation of the field.<sup>18</sup>

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<sup>14</sup> This report went further than a 2000 House of Lords Science and Technology Select Committee report looking at complementary and alternative medicine as a whole, which made a range of recommendations around regulation, training and information in CAM, but concluded that both statutorily regulated and effectively self-regulated CAM therapies should be made available on the NHS.

<sup>15</sup> Department of Health (2010) *Government Response to the Science and Technology Committee report 'Evidence Check 2: Homeopathy'*

<sup>16</sup> <http://www.nhs.uk/Conditions/homeopathy/Pages/Introduction.aspx#available>

<sup>17</sup> <http://www.eiccam.eu/home.php>

<sup>18</sup> The European Public Health Alliance *What is CAM – Complementary and Alternative Medicine – an overview* <http://www.epha.org/spip.php?article4004>

- 23 The EU recently funded a major project aiming to facilitate more and improved research into CAM. The 1.5 million euro European Commission CAMbrella project ran between 2010 and 2012 and aimed to develop a research network and knowledge base within CAM to inform further work.<sup>19</sup>
- 24 According to the World Health Organisation (WHO), global use of CAM is also growing.<sup>20</sup> WHO argue that use of CAM, worldwide, typically follows one of three patterns. In developing countries, for instance, where access to conventional medicine may be limited, CAM can be the primary source of healthcare for many people. In Africa the ratio of CAM practitioners to people is 1 to 500, whereas the ratio of doctors of conventional medicine to people is 1 to 40,000. This kind of use is contrasted with use of CAM for cultural or historical reasons, as in Singapore and Korea, and use in the developed world, where use of CAM may be used to supplement other forms of conventional medicine.
- 25 WHO published a *Traditional Medicine Strategy 2014- 2023* at the end of 2013, replacing its *Traditional Medicine Strategy 2002-2005* and the traditional medicine components of the WHO medicines strategy in the intervening years.<sup>21</sup> WHO regard parts of CAM favourably, seeing the potential for its use in more mainstream medical contexts. The strategy aims to harness the potential contribution of traditional and complementary medicine (TCM) to health, wellness and people-centred health care and promote the safe and effective use of CAM, regulating, researching and integrating CAM in health systems, where appropriate. Objectives of the strategy include not only developing guidance on the use of CAM, but also to 'increase the availability and affordability' of TCM, with an emphasis on access for poor.

## Evidence

- 26 There is a perception in parts of the public and scientific community that very little scientific work has been conducted on outcomes associated with CAM. However, the situation is more complex. For some time there has been a considerable number of dedicated journals and organisations focused on publishing, funding or coordinating research into CAM. A range of studies and research projects are currently underway, and the volume of work studying the effects of CAM is steadily growing in size.<sup>22</sup> Proponents of CAM say that there are now areas for which scientific studies do provide robust support and this perspective is, to some degree, reflected in mainstream health provision. The National Institute for Health and Care Excellence (NICE), which issues

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<sup>19</sup> The CAMbrella website provides information on CAM research projects <http://www.cambrella.eu/home.php>

<sup>20</sup> *WHO Traditional Medicine Strategy 2014-2023*

<sup>21</sup> The WHO document uses the expression 'traditional and complementary medicine' or 'TCM' throughout to refer to CAM therapies.

<sup>22</sup> A number of universities have dedicated centres and research groups looking at CAM, such as the Complementary and Integrated Research Unit at the University of Southampton University, the CAM group at University of Birmingham and the EASTmedicine research centre at the University of Westminster in the UK, and the University of Maryland Centre for Integrative Medicine. The EU CAMbrella project (see paragraph 23) is a further example.

clinical guidance to practitioners based on the best available evidence, now recommends that osteopathy and chiropractic be considered as options in the treatment of lower back pain.<sup>23</sup> Debates which acknowledge the increasing focus on evidence in CAM instead centre on the quality and quantity of evidence purporting to demonstrate efficacy, the need for scientific evidence to justify use of CAM, the distinction between efficacy and effectiveness and the safety of CAM treatments.

### *Status of scientific evidence in CAM*

- 27 In spite of the appetite for increased testing in CAM, some practitioners have claimed that the normal standards of evidence of efficacy, as applied in tests of conventional medicine, are not appropriate for the assessment of CAM therapies. CAM does not work in the same way as conventional medicine, operating in many cases, proponents maintain, holistically and individualistically on the psychological and spiritual features of patients, as well as on their physical features. Since CAM works through means other than those underlying conventional medicine, transcending mere physiological effects, they claim that lack of success in randomised control trials cannot show that CAM therapies do not work and seeking evidential support in this manner is not appropriate for CAM.<sup>24</sup>
- 28 Critics of this view insist, however, that evidence for the efficacy of CAM must be supplied if it is to be shown that CAM can provide genuine benefits and improved outcomes to patients. Arguments appealing to the differences between CAM and conventional medicine, it is said, in fact rely on a misunderstanding about the nature of scientific assessment. It has been proposed that agreement on models for testing can be reached by carefully articulating the goals and methodology of the tests.<sup>25</sup>
- 29 Whether or not tests for CAM which advocates and sceptics alike can accept may be devised, many maintain that conventional scientific standards must be imposed on research supporting CAM, if it is to be funded by the state.<sup>26</sup> Health practitioners and institutions are widely encouraged to practice 'evidence-based medicine'.<sup>27</sup> Much of the criticism attracted by CAM continues to focus on the lack of evidence of efficacy and it is more usual for

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<sup>23</sup>National Institute for Health and Care Excellence *Low back pain: Early management of persistent, non-specific low back pain* <http://publications.nice.org.uk/low-back-pain-cg88>

<sup>24</sup> Wellcome Trust, 'Complementary medicine for pain' microsite <http://www.wellcome.ac.uk/en/pain/microsite/medicine1.html>

<sup>25</sup> Wellcome Trust, 'Complementary medicine for pain' microsite <http://www.wellcome.ac.uk/en/pain/microsite/medicine1.html>

<sup>26</sup> Both recent Parliamentary reports on this area agreed for this conclusion. The House of Lords Committee on Science and Technology report into complementary and alternative medicine stated explicitly that use of CAM therapies in the NHS could not be supported unless convincing research on efficacy demonstrated that any benefits to the patient were superior to those brought about by placebo. (HoL Science and Technology Committee, 2000) The 2010 Science and Technology report on homeopathy argued similarly that efficacy should be the main criterion on which decisions about whether to make homeopathy available to NHS users should be made (Science and Technology Committee, 2000)

<sup>27</sup> Regulatory guidance for doctors published by the GMC requires that they "provide effective treatments based on the best available evidence" (paragraph 16b *Good Medical Practice* (2013) General Medical Council)

advocates to defend CAM by arguing that it *is* efficacious, rather than denying efficacy is an appropriate test.<sup>28</sup>

### *Studies of efficacy of CAM*

- 30 Many advocates of CAM do accept that demonstrating that CAM works is important and, for most, this means demonstrating efficacy rather than mere effectiveness. This distinction is sometimes expressed as a difference between how a drug or treatment works in 'ideal' as compared to 'real world' conditions.<sup>29</sup> Treatments can have effects in ideal conditions that they would not have on patients in the real world (because the patient experiences side effects, for instance) and, conversely, can also have effects in the real world which would not obtain in idealised conditions (because of the placebo effect (see paragraph 31)). Efficacious treatments are those that are effective in ideal conditions and whose outcomes are not explained by placebo effects. Treatments which are merely effective may explain improvements in a patient's symptoms when used in clinical practice, but are not efficacious because they would not have these effects in idealised conditions. Discussions around whether or not CAM treatments offer genuine benefits to patients often focus on whether CAM treatments are genuinely efficacious and thereby produce positive outcomes going beyond mere placebo effects.
- 31 There is disagreement over how best to define the placebo effect. Placebo effects are positive health outcomes experienced by some patients when taking a 'sugar pill' – the placebo - which cannot be attributed to any active agents in the substance. The placebo effect is well-documented but the phenomenon is not currently well understood. Whilst both critics and advocates agree that CAM can have this type of effect on patients, and therefore be *effective* for those patients in treating certain symptoms, most maintain that in order for CAM to be shown to work, efficacy, rather than effectiveness, must be established.
- 32 In spite of the relative lack of evidence for the efficacy of CAM as compared with conventional medicine, there are nevertheless growing numbers of individual studies, systematic reviews and research projects aiming to establish greater knowledge about the effects of CAM therapies. Dedicated journals, such as the *Journal of Alternative and Complementary Medicine* and the *Alternative Medicine Review* publish work on CAM therapies, and a number of bodies aiming to provide scientific support for the use of CAM now exist. The Scientific Review of Alternative Medicine, for instance, publishes exclusively on these topics and a number of therapy-specific organisations, such as the Society of Homeopathy and the Institute of Chinese Medicine describe research and evidence gathering as part of their aims.
- 33 The NHS choices website also publishes information on clinical trials being conducted worldwide in a range of areas, and lists numerous examples of

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<sup>28</sup> The Society of Homeopathy, British Acupuncture Council, and British Chiropractic Association all dedicate sections of their websites to information on research, referring to systematic reviews and clinical trials looking at outcomes.

<sup>29</sup> Department of Health (2010) *Government Response to the Science and Technology Committee report 'Evidence Check 2: Homeopathy'*

studies on CAM therapies, including osteopathy, chiropractic and homeopathy.<sup>30</sup>

- 34 The Cochrane Collaboration, whose systematic reviews of evidence in the biomedical sciences survey a wide range of studies on a given area, discarding poorly designed trials, and aim to draw robust overall conclusions about the body of evidence on a given topic, currently has a CAM work stream.<sup>31</sup> The Cochrane CAM Field was established in 1996 and is based within the University of Maryland Centre for Integrative Medicine. The Cochrane library now has reviews of evidence on a wide range of commonly used CAM treatments including acupuncture, the Alexander technique, aromatherapy, homeopathy and others. The programme has also conducted reviews of less well known and less used CAM treatments, such as therapeutic ultrasound and electromagnetic therapies. The total number of systematic reviews of CAM techniques the Cochrane Collaboration has listed on its website is 639.<sup>32</sup>
- 35 Looking at one example, acupuncture, the Cochrane Library has 45 published systematic reviews of evidence on its use for a range of conditions, including vascular dementia, acute stroke, IBS, ADHD and rheumatoid arthritis.<sup>33</sup> Of these studies on acupuncture, only two reviews, looking at the effects of acupuncture in the treatment of migraine prophylaxis and in tension-type headache, recommended that acupuncture be considered by health practitioners as an option in clinical treatment.<sup>34</sup> Many of the reviews conclude by stating that no firm conclusion can be drawn about the treatment in question either way, on the basis of existing evidence.
- 36 There are areas of CAM which are, nevertheless widely considered to be efficacious for certain kinds of condition. Many take there to be good evidence that osteopathy and chiropractic are both efficacious in the treatment of lower back pain, for example, as evidenced by their inclusion in NICE guidelines. It is possible that some of the criticism that these therapies continue to attract is due to less well-supported claims about the range of conditions which can be treated by these therapies. Some chiropractors, for instance, claim to be able to treat asthma, headache, high blood pressure and gastrointestinal disorders - conditions for which there is thought to be no reliable evidence that chiropractic offers benefit. And even the use of such therapies in the treatment of specific conditions where good outcomes are

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<sup>30</sup> Searching for clinical trials by therapy yields, for instance, 665 trials underway round the world for osteopathy <http://www.nhs.uk/Conditions/Clinical-trials/Pages/clinical-trial.aspx>

<sup>31</sup> <http://www.thecochranelibrary.com/details/browseReviews/1238739/Complementary--alternative-medicine.html?page=5>

<sup>32</sup> <http://www.compmed.umm.edu/cochrane/reviews.asp>

<sup>33</sup> <http://www.thecochranelibrary.com/details/browseReviews/1238739/Complementary--alternative-medicine.html?page=5>

<sup>34</sup> Linde K, Allais G, Brinkhaus B Manheime, E, Vickers A and White A (2009) Acupuncture for migraine prophylaxis *Cochrane Database of Systematic Reviews*; and Linde K, Allais G, Brinkhaus B Manheime, E, Vickers A and White A (2009) Acupuncture for tension type headache *Cochrane Database of Systematic Reviews*

thought to be better established, there has been continued criticism of the reliability of the evidence purporting to show efficacy.<sup>35</sup>

### *Studies on safety*

- 37 Historically, efforts to assess evidence on CAM have focused on forming conclusions about its efficacy and what, if any, positive outcomes on health it may have. However, the emphasis has changed more recently, with more attention being focused on issues around safety.<sup>36</sup>
- 38 Whilst there is a perception amongst parts of the public that CAM is 'natural' and therefore safe, the growing body of work on CAM has shown that there are areas where significant negative effects have been associated with its use. Evidence on the Wellcome Trust's work looking at the use of 14 fields of CAM in the treatment of pain showed some evidence of adverse effects was available for seven of the 14, with serious adverse effects being reported, to differing extents, in three fields.<sup>37</sup>
- 39 Debates concerning the safety of different CAM techniques must take account of the very large number of CAM therapies and treatments, which are unlikely to perform identically in studies measuring safety. The Wellcome Trust work, for instance, has found no evidence of safety issues with a number of techniques, including the Alexander technique, reflexology, homeopathy and Yoga and it may be that further research goes on to show that some fields of CAM are completely safe whilst others are not. As with efficacy, the current levels of evidence do not seem to be substantial enough to enable firm conclusions to be drawn about safety of a number of CAM fields either way.

### *Need for further research*

- 40 The literature on CAM is replete with calls for further research into the effects of CAM to be conducted. A high proportion of the Cochrane CAM reviews conclude that more and better evidence is needed in order to be able to formulate robust views about the effects of CAM, in terms of both efficacy and safety.
- 41 The Wellcome Trust position statement on CAM similarly advocates further research into CAM.<sup>38</sup> The Trust held a workshop in 2000 looking at the issues prevalent in CAM research which made recommendations for the future of research in the field. They propose that greater collaboration between clinical researchers and CAM practitioners be cultivated, so that research skills and knowledge of scientific methods be shared and that CAM practitioners be

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<sup>35</sup> Orrock PJ and Myers SP (2013) *Osteopathic intervention in chronic non-specific low back pain: a systematic review* and Posadzki P and Ernst E (2011) *Osteopathy for musculoskeletal pain patients: a systematic review of randomized control trials*

<sup>36</sup> Pilkington K and Boshnakova A (2013) Complementary medicine and safety: Is there a standard for producing systematic reviews *Complementary Therapies in Medicine*

<sup>37</sup> Wellcome Trust microsite on pain, Table 1: Examples of complementary medicine used for pain control [http://www.wellcome.ac.uk/en/pain/microsite/Ernst\\_table1.pdf](http://www.wellcome.ac.uk/en/pain/microsite/Ernst_table1.pdf)

<sup>38</sup> Wellcome Trust (2000) Policy on complementary and alternative medicine <http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002760.htm>

routinely trained in research methods. It also recommended that a single body overseeing research activities across CAM techniques be established. The Royal Society have also argued in the past that further research into CAM should be conducted with an emphasis on conducting randomised clinical trials.<sup>39</sup>

- 42 Some have argued that there is a bias against funding of research into the effectiveness of CAM. Since funders typically make decisions about allocating money to research projects on the basis of existing evidence, the current relative lack of evidence in CAM, as compared with other areas of medicine with which CAM competes for funding, creates an obstacle to developing the evidence base. This issue may be exacerbated by other factors including lack of academic infrastructure, which means limited access to library facilities, academic supervision and experience in writing grant applications.<sup>40</sup>
- 43 If it is the case that research funding into CAM is harder to secure than in other areas of medicine then unfavourable comparisons with the evidence base for conventional medicine may not fairly represent the CAM field. Systematic reviews are only able to survey existing evidence, which may fall short in certain areas (methodological issues relating to relating to size of trials, incomplete blinding and bias have been raised by Cochrane reviewers). Disappointing results from systematic reviews may therefore contribute to an impression that CAM is fundamentally unscientific in the eyes of funders, making it harder still to obtain support for well-designed trials capable of making reliable findings.
- 44 The Research Council for Complementary Medicine, formed in 1983 and coordinated through London South Bank University, exists in part to address these issues. The organisation's stated aims are to facilitate research into CAM, developing a network of researchers and disseminating research findings on CAM to the public, practitioners and governments. It may be that further initiatives to address a relative lack of funding into CAM research are appropriate to enable a full comparison with conventional medicine.

## Regulatory issues

- 45 Levels of regulation and oversight in the UK vary across different areas of CAM. Some fields of CAM practice are regulated by bodies with statutory functions whereas others operate with little or no regulation. Similarly some of the products used in CAM are regulated by the MHRA, whilst others sit outside of any regulatory framework. For a number of CAM fields, advice on good practice, teaching and training is provided by professional bodies, which serve to represent and support, rather than regulate, the relevant profession.
- 46 Osteopathy and Chiropractic are two areas of CAM over which there is now statutory regulation. The General Chiropractic Council (GCC)<sup>41</sup> and the

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<sup>39</sup> The Royal Society (1999) Complementary and Alternative Medicine: Response to the House of Lords inquiry into complementary and alternative medicine

<sup>40</sup> Ernst E, Cohen M H, and Stone J (2004) Ethical problems arising in evidence based complementary and alternative medicine *Journal of Medical Ethics*

<sup>41</sup> <http://www.gcc-uk.org/>

General Osteopathic Council (GOsC)<sup>42</sup> are two of the nine UK health regulators, overseen by the Professional Standards Authority, who maintain statutory registers of practitioners for whom a licence to practice is required. The Osteopaths Act 1993 and the Chiropractors Act 1994, alongside secondary legislation, create powers for the GCC and the GOsC to maintain their registers, give advice on good practice and take action to against practitioners for poor performance. Practitioners in these fields are legally required to be registered in order to practice and the titles 'chiropractor' and 'osteopath' are protected in law, such that it is an offence for a person to use either title unless he or she is registered with the appropriate council. The GCC and GOsC have the same powers as medical regulators, such as the General Medical Council and the General Dental Council, and are able to remove practitioners from registers and withdraw a practitioner's licence to practice if they have reason to believe their fitness to practice is impaired.

- 47 Homeopaths are not statutorily regulated in the UK, though EU legislation requires that use of homeopathic medicines through Europe be regulated.<sup>43</sup> In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) register homeopathic medicines for use.<sup>44</sup>
- 48 In homeopathy, as in other areas of CAM, professional guidance and advice on practice standards is nevertheless issued by organisations which do not have regulatory powers and whose primary remit is to represent practitioners in the field. The role of these organisations differs substantially from those of statutory regulators, such as the GMC, which does not purport to represent the medical profession, and whose role is not, in the main, to support doctors. The Society of Homeopaths, for instance, is a professional body representing homeopaths, which also maintains a register of practitioners and publishes guidance on good practice. The British Homeopathic Association, a charity providing information on homeopathy, performs a similar function. In both cases, though, registration is voluntary and neither organisation has any statutory powers to take action against poor performance or conduct. Anyone may call themselves a homeopath and sell their services to the public.
- 49 Acupuncture is similarly self-regulated through The British Acupuncture Council, which provides guidance on good practice, accreditation, education and funds research into the effects of acupuncture as well as representing acupuncture practitioners.<sup>45</sup> Again, registration is voluntary and whilst the Council is at liberty to remove practitioners from its own register, it has no statutory powers to investigate practitioners about whom complaints have been made or stop them from practicing. Acupuncture practitioners are, however, required to register with their local authority under the Local Government (Miscellaneous Provisions) Act 1982).<sup>46</sup>

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<sup>42</sup> <http://www.osteopathy.org.uk/index.php>

<sup>43</sup> European Directive 92/73/EC

<sup>44</sup> Homeopathic medicines:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Homeopathicmedicines/>

<sup>45</sup> <http://www.acupuncture.org.uk/public-content/about-the-bacc/what-we-do.html>

<sup>46</sup> <http://www.legislation.gov.uk/ukpga/1982/30> This legislation makes the same requirement of tattooists and practitioners in ear-piercing and electrolysis.

- 50 As with homeopathy, whilst medical herbalists are not subject to statutory regulation, the use of substances prescribed by medical herbalists is currently regulated in European law. The EU *Directive on Tradition Herbal Medicinal Products*, which has been in force in the UK since 2011, prohibits the sale of unlicensed herbal medicines throughout most EU states. However, there have been complaints in the UK that the directive is disproportionately obstructive and there are currently proposals to consider the introduction of statutory UK-specific regulation for medical herbalists.<sup>47</sup> For practitioners, the National Institute of Medical Herbalism in the UK gives advice on good practice to practitioners and makes information available to the public on the locations of registered members, but plays no role in education.
- 51 A number of concerns have been raised about the lack of regulation in CAM therapies.
- 52 The lack of research into the effects of using CAM techniques presents a number of issues from a regulatory perspective. In the absence of strong evidence in favour of the safety of CAM (regardless of whether or not CAM is efficacious) there may be questions around whether practitioners are able to safely recommend or administer CAM treatments to patients. This is especially relevant in light of evidence suggesting that there may be some areas of CAM which may have serious adverse effects. This may constitute a serious problem from a patient welfare perspective and present a strong reason in favour of increased regulation.
- 53 The issues around efficacy of CAM treatments may themselves present regulatory issues for some practitioners who are subject to regulation, even if a given CAM therapy were established to be safe. Doctors for instance are required in guidance issued by the GMC to “provide effective treatments based on the best available evidence” and make “good use of the resources available” to them.<sup>48</sup> It is not clear that doctors would be acting in line with good practice guidance in providing or arranging treatments for which there are serious questions around efficacy and evidence.
- 54 It has been pointed out that lack of medical knowledge amongst those practising CAM techniques may also create risks around patient safety.<sup>49</sup> Even if CAM practitioners are well trained in their own disciplines, a lack of broader medical understanding, and knowledge of human anatomy, physiology and biochemistry may present patient safety issues. It could mean, for instance, that CAM practitioners may not fully appreciate how a treatment they administer could impact on a patient’s wider overall health, or that there may be difficulties in effectively communicating with their patient’s other care providers about them.
- 55 It may also be in the interests of CAM practitioners themselves that the field be better regulated. Increasing public interest in and use of CAM therapies

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<sup>47</sup> Barber, S (2014) Regulation of Herbal Medicines *House of Commons Library*

<sup>48</sup> See paragraphs 16b and 18 of *Good Medical Practice* (2013) General Medical Council

<sup>49</sup> Ernst E, Cohen, M H, and Stone J, *Ethical problems arising in evidence based complementary and alternative medicine* (2004) *Journal of Medical Ethics*

creates competition, and doctors and other healthcare professionals are now administering CAM. For those areas of CAM for which there is no formal regulation or statutory registration, anyone is able to sell CAM services and the quality implications of an unregulated market also pose a threat to the credibility of the field as a whole. Improved education, training, certification and professional guidance would benefit and improve the CAM field as a whole, distinguishing the useful treatments and competent practitioners from those that do not offer genuine benefits to patients.<sup>50</sup>

## Ethical considerations

- 56 Ethical issues relevant to the use of CAM treatments relate to consent, patient autonomy and the role of the state, fairness and the ethics of private healthcare, the doctor-patient relationship and use of public resources. Key themes across the relevant arguments involve establishing differences between CAM and conventional medicine, and highlighting ethical issues distinctive to CAM that do not apply to conventional medicine.

### *Patient autonomy and consent*

- 57 Taking account of patient autonomy, it has been said, requires that doctors respect their patients' decisions and wishes about their own treatment.<sup>51</sup> GMC guidance requires that doctors discuss with patients their treatment and care, and must listen to patients and respect their views about their health. Regard for patients' autonomy and right to self-determination may therefore require that they be enabled to access CAM treatments if that is what they prefer.
- 58 Other considerations may seem to support this approach in the UK. Recent reforming initiatives in the NHS emphasise the value of patient choice and patient-centred care, which aims to put individuals at the centre of decision-making around their own treatment options. England is a multicultural society in which patients' varied backgrounds may give rise to quite diverse views about what kind of care is desirable and it could be argued that Government policy and professional conduct guidelines should be sensitive to this. The Government response to the Science and Technology Committee report on homeopathy appealed directly to this idea when citing the 'geographical, socioeconomic and cultural diversity in England' which they argued made it appropriate to consider factors beyond efficacy when assessing the appropriateness of making homeopathy available to patients.
- 59 Nevertheless, given that obtaining consent from patients to undergo treatment requires equipping them with sufficient information about the likely effects of a proposed treatment, there may be difficulties for practitioners in meeting the requirement to obtain patients' valid consent when providing or arranging CAM therapy. In light of ongoing questions around the effects and safety of CAM it may be difficult or impossible for doctors and other health care

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<sup>50</sup> Haynes B (1999) Commentary: A warning to complementary medicine practitioners: get empirical or else *BMJ*

<sup>51</sup> Ernst E (1996) The ethics of complementary medicine *Journal of Medical Ethics*

professionals to ensure that their patients are appropriately informed about the risks and benefits, as is required by guidance.<sup>52</sup>

- 60 Issues around consent may raise separate problems in cases involving children, particularly in situations where a parent requests a CAM treatment for a child lacking capacity. Parents or others making decisions about medical treatment on behalf of children lacking capacity must do so in their best interests, though in light of the incomplete information about the effects of CAM therapies it may be difficult for the practitioner to make a well-informed decision about whether a CAM treatment would be clinically appropriate or not. Best interests 'checklists' in medical ethical guidance also include appeal to a range of considerations in addition to what is clinically indicated, including parents' views and values.<sup>53</sup> These kinds of situation will present challenges for doctors and other practitioners attempting to weigh the clinical considerations, the views of parents and their cultural or religious or other values or beliefs when making decisions about using CAM to treat children.
- 61 Advocates of CAM may, however, respond to these arguments by pointing out that similar criticisms apply to areas of conventional medicine. We do not have a complete understanding of the full effects of many drugs used widely in mainstream medicine. Full clinical trial data, for instance, is not made available routinely to doctors or others making decisions about using drugs in patient care. Doctors will frequently not, therefore, be in a position to provide their patients with full information about the likely effects of the drugs they prescribe, with obvious implications for gaining valid consent. Discussions around these issues, advocates argue, should ensure that CAM is not compared to a 'gold standard' model of mainstream medicine which may be actualised only rarely in the real world.
- 62 A separate concern relating to CAM and consent may be that in addition to the relative lack of scientific evidence available to the medical community, there is also a lack of accessible, reliable information covering what *is* currently known about CAM available to the public, as compared with information about conventional medicine. Access to information about treatment options, and what they involve, is often facilitated through a range of sources including patient organisations, medical charities, and GP surgeries.<sup>54</sup> Organisations such as the European Information Centre for Complementary and Alternative Medicine aim to address this gap by translating knowledge around science on CAM into accessible information for patients<sup>55</sup> and the patient advice website 'Medline for the Public' funded by the US National Institutes for Health has a set of pages on CAM.<sup>56</sup>

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<sup>52</sup> *Consent: patients and doctors making decisions together* [http://www.gmc-uk.org/static/documents/content/GMC\\_Consent\\_0513\\_Revised.pdf](http://www.gmc-uk.org/static/documents/content/GMC_Consent_0513_Revised.pdf)

<sup>53</sup> See guidance on assessing best interests in *Protecting children and young people: the responsibilities of all doctors* (2012) General Medical Council

<sup>54</sup> Organisations like Macmillan Cancer Support or the MS Society provide illness-specific information about health treatments, and online resources like NHS Choices contain comprehensive information about treatment options for a wide range of conditions.

<sup>55</sup> <http://www.eiccam.eu/home.php>

<sup>56</sup> <http://www.nlm.nih.gov/medlineplus/complementaryandalternativemedicine.html>

- 63 Nevertheless doctors may be concerned that patients tend to be less well-informed about CAM and this may exacerbate issues around ensuring that patients can give their valid consent to CAM treatments. Notably, such a conclusion would not establish any fundamental difference in the ethics of use of CAM as contrasted with conventional medicine, but may instead constitute strong reason to address gaps in public understanding of, and knowledge about, CAM therapies.

*Beneficence, non-maleficence, autonomy and paternalism*

- 64 Assuming it is possible for patients to consent to CAM therapies, it may still be argued that access to them be restricted. The medical ethical principle of beneficence requires that practitioners act to benefit their patients. Those who believe that evidence suggests CAM doesn't truly benefit patients may argue that practitioners should not administer, prescribe or refer patients for CAM therapies, whether or not patients genuinely consent to them, as providing or arranging CAM treatments does not respect the principle of beneficence.
- 65 More generally, the principles of beneficence and autonomy conflict in medical ethics when a patient autonomously chooses, and consents to, a treatment which the practitioner believes would not be of benefit to them. Practitioners may not be able to fully respect both principles in such cases. Those who believe that the principle of beneficence may override patient autonomy in certain circumstances are sometimes said to be committed to a form of medical paternalism.
- 66 Many view paternalistic policies as illiberal, on the whole, holding that people should be allowed to make their own choices, whether or not these are likely to result in the best outcomes for them. As indicated above, the trend in medical ethics over the last few decades has been to give the patient more control over their treatment, with guidance on consent taking a stronger focus on giving the patient more control over their own care. Guidance to doctors makes clear that they must respect patients' decisions to accept or refuse treatment options for "a reason that may seem irrational to the doctors, or for no reason at all".<sup>57</sup> Nevertheless, there is debate over how far the principle of autonomy should extend and what it requires of clinicians in terms of providing – as opposed to withholding or withdrawing - treatment.
- 67 However any conflict between autonomy and beneficence in CAM be resolved, a stronger line of argument claims that use of CAM may breach the principle of non-maleficence. This principle is often expressed as the notion that doctors should not act in ways that harm their patients. The uncertainty around the risks attached to CM may mean that practitioners cannot be confident of respecting the principle of non-maleficence when providing CAM. It has been argued that these direct risks, as well as the risks associated with poorly performing, unregulated practitioners, may create ethical concerns about use of CAM, in the absence of professional standards and oversight.<sup>58</sup>

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<sup>57</sup> See paragraph 5c of *Consent: patients and doctors making decisions together* (2006) General Medical Council

<sup>58</sup> Ernst E (1996) The ethics of complementary medicine *Journal of Medical Ethics*

68 As with issues around obtaining valid patient consent, however, defenders of CAM may protest that similar considerations bear on areas of conventional medicine. For example, use of mainstream medicine in the treatment of children quite commonly involves the prescription of medicines ‘off licence’, where doctors and other healthcare practitioners may have incomplete information about the likely effects of using those medicines in children. Perceived ethical issues around running clinical trials in children mean that many treatments have not been rigorously tested in children, and there is not, consequently, conclusive evidence about efficacy or safety of use in children for many drugs. Nevertheless, prescribing off licence for children is quite common in paediatric medicine, and does not, in principle, contravene professional guidelines.<sup>59</sup> A combination of practitioner-knowledge and other less structured means of assessing patient outcomes may instead be used by practitioners to guide decisions about their use. Whether or not this is considered appropriate, the example shows that differences between the ways that treatment is arranged in conventional medicine and CAM may be less pronounced than the previous argument suggests.

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### *Honesty, deception and the doctor-patient relationship*

69 Even if evidence supporting the use of CAM could only demonstrate positive outcomes consistent with mere placebo effects – if CAM were merely effective rather than efficacious – it may be thought that use of CAM could still be worthwhile since it could benefit patients by exerting positive effects. To go further, restricting patients’ access to CAM may wrongly deprive patients of these perceived improvements in health, which genuinely make them feel better.

70 This idea is not unique to CAM and has been discussed in the context of clinical use of placebos more broadly. Whilst there is debate over the mechanism by which placebos work, it is thought that time spent with a practitioner, having the opportunity to talk and be listened to, may play a role in explaining their effects. There is work currently underway exploring in greater depth the positive health effects that placebos can have on patients. Some researchers in this area have argued that the medical community should be exploiting this effect and using it to patients’ advantage.<sup>60</sup>

71 Key ethical questions here concern honesty, deception and the practitioner-patient relationship. Whilst it is unclear what mechanisms explain the positive effects associated with placebos, it is generally held to be important that the patient be unaware that the substance they take is not efficacious.<sup>61</sup> This would seem to imply that a practitioner prescribing or arranging a placebo, or any non-efficacious treatment, would need to deceive their patient about the nature of the treatment and its mode of action. One of the fundamental

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<sup>59</sup>See paragraphs 67-70 of *Good practice in prescribing and managing medicines and devices* (2013) General Medical Council

<sup>60</sup>The Program in Placebo Studies and Therapeutic Encounter project is one example of a project exploring the effects of placebos and how they may contribute to the improvement of patient outcomes. <http://programinplacebostudies.org/>

<sup>61</sup>Shaw D (2009) Prescribing placebos ethically *Journal of Medical Ethics*

principles in medical ethics concerns honesty; being open and truthful with patients is a core responsibility for practising doctors and other healthcare professionals.<sup>62</sup> Making use of the positive placebo effects associated with CAM in clinical medicine may therefore require that practitioners breach professional guidance and fundamental ethical principles by deceiving their patients.

- 72 Ethicists in this field have offered a number of objections to this view. It has been argued, for instance, that use of placebo in clinical practice need not entail deceiving patients. This response depends, in part, on the particular conception of deception that is held – it has been proposed, for instance, that deception requires promoting one’s own self-interest and that prescribing a substance with placebo effects for the benefit of a patient does not meet this condition.<sup>63</sup> It has also been pointed out that practitioners are able to truthfully make a range of statements about the placebo they prescribe to their patient e.g. ‘I am prescribing to a pill which research suggests will benefit you’ or ‘I have reason to believe this pill work for your condition’ etc. These kinds of considerations may suggest use of the placebo does not require deception, or alternatively that deception of this nature is not morally problematic, and that it may therefore be morally permissible for doctors to make use of placebos in clinical practice.<sup>64</sup> Others maintain, that the primacy and importance of autonomy and valid consent in modern medicine mean that more complete information must be provided to patients.<sup>65</sup>
- 73 Relatedly it has been pointed out that failing to provide full information need not involve deception. We would not normally expect doctors give their patients every piece of information about each drug they prescribe, or its underlying mechanisms, unless this were specifically requested or were thought to be significant for the patient in making a decision about using it. By way of illustration, a high proportion of the effectiveness of antidepressant medication, between 30 and 100%, can be attributed to the placebo effect<sup>66</sup> – a disclosure we may not expect doctors to make before prescribing such drugs, or at any rate would not view as a deception to withhold.
- 74 It has also been argued that objections to the use of placebo rely on an unduly narrow conception of doctoring, specifically that only through pharmacology can doctors help patients.<sup>67</sup> Instead, this argument goes, doctors and other healthcare professionals aid patients in a range of ways, including through reassurance, encouragement and the resolution of uncertainty. Use of the placebo may sit comfortably within this more textured

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<sup>62</sup> GMC guidance to doctors says that they must “respond honestly” to patients’ questions (paragraph 31), must be “honest and trustworthy in all...communication with patients...” (paragraph 68) and must make sure that their conduct “justifies patients’ trust in [them] and the public’s trust in the profession” (paragraph 65) *Good medical practice* (2013) General Medical Council

<sup>63</sup> Gold A and Lichtenberg P (2014) The moral case for the clinical placebo *Journal of Medical Ethics*

<sup>64</sup> Gold A and Lichtenberg P (2014) The moral case for the clinical placebo *Journal of Medical Ethics*

<sup>65</sup> Shaw D (2010) Homeopathy is where the harm is: five unethical effects of funding unscientific remedies *Journal of Medical Ethics*

<sup>66</sup> Khan A, Faucett J, Lichtenberg P, *et al* (2012) A systematic review of comparative efficacy of treatments and controls for depression *PLoS One*

<sup>67</sup> Lichtenberg P Heresco-Levy U and Nitzan U (2004) The ethics of the placebo in clinical practice *Journal of Medical Ethics*

notion of medical practice. Acknowledging that illness does not always reduce to mere biomedical effects may itself make room for the use of placebo in clinical practice.

- 75 Accordingly, defenders of the use of placebo in clinical settings suggest that they may be permissibly prescribed, as long as other principles or guidelines constraining their use be employed. Proposals for such principles include, for instance, that practitioners prescribing placebos should do so only where there is evidence to suggest they may be effective for the patient, when there are no other medications likely to be more effective and should withdraw the placebo immediately if it proves ineffective.<sup>68</sup> Adoption of similar guidelines may also make room for the ethical use of CAM.
- 76 A separate defence of use of the placebo challenges the idea that in order for a placebo to work, the patient must be unaware that they have been prescribed a placebo.<sup>69</sup> These studies found that the placebo effect can be present even when those using them are aware that they are taking non-efficacious substances. If such conclusions were general, applied in the context of CAM, ethical concerns relating to honesty and deception would not arise, as practitioners would be able to make inefficacious CAM treatments available to their patients without misleading them about the likely source of any improvement in their condition.

#### *Legitimation of CAM*

- 77 CAM is frequently administered by therapy-specific practitioners, such as homeopaths, osteopaths or chiropractors. However, increasingly, CAM treatments may be recommended, prescribed or administered by doctors, or patients may be referred to CAM therapists by doctors. In 1999 it was believed that 39 % of GP practices then made CAM therapies available to their patients.<sup>70</sup> This figure is likely to be considerably higher now that some CAM therapies have been assimilated into clinical guidance by NICE.
- 78 It is possible that the use of some forms of CAM therapy by doctors, whether through the NHS or not, may be seen by some patients as an endorsement of CAM. In the absence of reliable, robust sources of patient information, this association may legitimise the use of CAM in the eyes of some patients, which, in light of ongoing controversies around the efficacy of CAM, some find problematic. The Government Chief Scientific Advisor has argued along similar lines in questioning the continued use of homeopathy in the NHS,

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<sup>68</sup> Lichtenberg P Heresco-Levy U and Nitzan U (2004) The ethics of the placebo in clinical practice *Journal of Medical Ethics*

<sup>69</sup> Kaptchuk TJ, Friedlander E, Kelley JM, *et al.* (2010) Placebos without deception: a randomized controlled trial in irritable bowel syndrome. *PLoS ONE*; Amanzio M, Benedetti F (1999) Neuropharmacological dissection of placebo analgesia: expectation activated opioid systems versus conditioning activated specific subsystems *Journal of Neuroscience*; Park LC, and Covi L. (1965) Non-blind placebo trial. An exploration of neurotic patients' responses to placebo when its inert content is disclosed *Archives of General Psychiatry*

<sup>70</sup> Zolman C and Vickers A (1999) ABC of complementary medicine: What is complementary medicine? *BMJ*

pointing out that if a therapy is available on the NHS patients are likely to infer from this that it is efficacious.<sup>71</sup>

- 79 A similar argument has been made about widening the regulation of CAM. Licensing products used in homeopathy, for example, may carry connotations of efficacy which, the current scientific view holds, would be misleading.<sup>72</sup> Parallel points have been made about osteopathy and chiropractic, both regulated by statute in the UK.

#### *Risks associated with omission of conventional medicine*

- 80 Another key issue relates to the potential harm done to patients who may seek CAM as a substitute to conventional medicine. When CAM is available, patients may choose to forgo conventional medicines, for which there may currently be better evidence of positive effects on health outcomes, because they instead choose to undergo what may be inefficacious CAM remedies.<sup>73</sup> The negative consequences of this effect may be particularly pronounced in cases where patients elect to treat life-threatening conditions such as cancer with exclusively CAM remedies.
- 81 Again, this may be especially problematic in situations where parents are making decisions for children who lack capacity. A high profile instance of such a case was covered extensively in the UK media in 2012, when a mother refused to allow her young son to receive chemotherapy and radiotherapy treatment for a brain tumour, choosing instead to seek treatment from a CAM practitioner.<sup>74</sup>
- 82 Broader public health issues may also arise in cases where CAM is substituted for conventional medicine. It has been proposed that a measles outbreak in Germany in 2003 was traceable to a school subscribing to CAM philosophies which had discouraged parents from vaccinating their children.<sup>75</sup> Public health considerations like these may raise distinctive moral questions since harm may be experienced by those who do not, themselves, choose to undergo CAM.

#### *Fairness and public resources*

- 83 Putting aside the issues around evidence, and assuming that there are genuine benefits associated with the use of CAM, the current state of CAM provision may raise questions around justice. If it is the case that some patients experience improved health outcomes from use of CAM treatments

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<sup>71</sup> The Chief Scientific Advisor's concerns were raised in the *Government Response to the Science and Technology Committee report 'Evidence Check: Homeopathy* where it was also argued that effective communication with the public about the scientific status of homeopathy was vital.

<sup>72</sup> Department of Health (2010) *Government Response to the Science and Technology Committee report 'Evidence Check: Homeopathy'*

<sup>73</sup> Shaw D (2010) Homeopathy is where the harm is: five unethical effects of funding unscientific remedies *Journal of Medical Ethics*

<sup>74</sup> In this case the High Court ultimately made a ruling that conventional treatment was in the child's best interests and this was enforced.

<sup>75</sup> Ernst E (2011) Anthroposophy: Risk Factor for Noncompliance With Measles Immunization *The Pediatric Infectious Disease Journal*

the fact that they are available in the UK predominantly on a private basis may be perceived to be unfair. Those with less means to pay for CAM therapies will be less able to make use of them.<sup>76</sup>

- 84 It is possible, however that the opportunity costs involved in making CAM available to patients on the NHS may outweigh the benefits. There are necessarily limited funds available for state-funded health services, and decisions around provision must weigh up the relative benefits of making CAM available to patients, in the context of general resource provision in the NHS.
- 85 A parallel point may apply to funding. Whilst there have been many calls for research into CAM to be increased, the finite resources available for medical research mean that decisions to support research into CAM also have opportunity costs. Where research is conducted into CAM, research into something else must be forgone. Some may argue that the use of public funds to research therapies and substances for which there is currently minimal evidence of efficacy and, in some cases, for which there appears to be no viable mode of action compatible with our best understanding of science, is not a good use of public money.<sup>77</sup> However, if it is the case that there is a bias against funding research into CAM (see paragraph 42) relying on the existing evidence base to make an assessment of this kind may not be warranted.

### *Conflict of interests*

- 86 Plausibly, many of the principles underpinning ethical conduct in conventional medicine apply also in CAM.<sup>78</sup> Good practice in CAM would seem to require adherence to principles of confidentiality, consent, maintaining boundaries and others set out in good practice guidance applying to doctors, nurses, dentists and others.
- 87 For those areas of CAM that are not statutorily regulated, there may be ethical issues concerning private practice and conflicts of interests. Since patients seeking CAM are treated and advised directly by the practitioners whose services they are purchasing, practitioners have a financial interest in starting treatment with a patient, or continuing treatment beyond the time for which it would be beneficial to the patient. This conflicts with the practitioners' interest in the wellbeing of the patient and the medical ethical principle to 'make the patient one's first concern'.
- 88 This issue is not unique to CAM since it arises for doctors or other health practitioners selling their services within private practice – however, the existence of statutory regulation means that practitioners in these fields are

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<sup>76</sup> Ernst E, Cohen M H, and Stone J (2004) Ethical problems arising in evidence based complementary and alternative medicine *Journal of Medical Ethics*

<sup>77</sup> This was the conclusions of the Committee on Science and Technology's report into homeopathy, wherein it was argued that sufficient testing of homeopathy had been conducted and in the face of strong competition for research funding, further research would not be justified.

<sup>78</sup> Ernst E, Cohen M H, and Stone J (2004) *Ethical problems arising in evidence based complementary and alternative medicine Journal of Medical Ethics*

subject to mandatory good practice guidelines and can be penalised for deviating from them. This is not the case for unregulated CAM practitioners working in private practice.

- 89 Once again, this conclusion would not establish a fundamental ethical concern intrinsic to CAM and there are currently key differences across the different CAM fields in how problematic such an issue might currently be. Good practice guidance osteopaths, for instance, says explicitly that they should not prolong treatment unnecessarily or put their own interest above their patient.<sup>79</sup> The issue may instead support a case for increased regulation and the introduction of mandatory practice standards within other CAM fields.

### **Questions to consider**

- To what extent do patients elect to undergo CAM therapies instead of, rather than in addition to, conventional medicine? What are the effects of this?
- Does the existing evidence base fairly represent the CAM sector?
- Is there an unfair bias against funding research into CAM therapies? If so, how might further research into CAM be encouraged?
- Is there a lack of research expertise in the CAM sector? If so, how could this be addressed?
- Alternatively, are there ethical issues with the state funding further research into CAM?
- Should regulation of the CAM sector widened?
- Does increased regulation legitimise CAM in the eyes of the public? If so, what effects does this have?
- Should health practitioners be able to prescribe inefficacious treatments to give rise to positive placebo effects? How would this impact on the doctor-patient relationship?
- Are there distinctive questions around use of CAM in children?

### ***A possible role for the Nuffield Council?***

- 90 In selecting topics for future work, the Council must take account of its Terms of Reference which require it to “identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern”. Selection criteria developed by Council include the following factors:

- Is the topic associated with recent advances in biological and medical research and/or are there ‘new’ reasons for looking at longstanding issues or revisiting issues covered in previous Council reports?
- Does the issue raise complex ethical questions?
- Would input from the Council be timely?
- Could the Council make a distinctive contribution?
- Would action by the Council anticipate or respond to public concern?
- Is there sufficient reason to consider this topic over others?

*Anna Wilkinson, April 2014*

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<sup>79</sup> *Osteopathic Practice Standards* (2012) General Osteopathic Council

Annex 1 – Table of some common complementary medicines and descriptions

Therapy	Description	Used to treat
Acupressure	Stimulation of acupoints with heat, pressure or needles	Range of pain symptoms, cancer, fertility, nausea, stroke and other conditions
Acupuncture	Application of pressure to parts of the body	Pain symptoms, headache
Alexander technique	Education in lessening use of muscles in daily activities	Back pain, asthma and Parkinson's Disease
Applied kinesiology	Diagnostic technique for identifying illness by testing muscles	n/a
Anthroposophic medicine	Massage, exercise, counselling and imbibing of diluted substance	Range of conditions
Aromatherapy	Use of plant materials by aerial diffusion, inhalation or topical application	Altering mood, cognitive function and general health
Autogenic training	Relaxation technique involving 'visualisations'	Digestion and bowel health, high blood pressure and immune system
Chiropractic	Manipulation of spine	Back pain, asthma, headache, high blood pressure, gastrointestinal disorders and others conditions
Herbal medicine	Imbibing of substances made from plants or plant extracts	Range of conditions
Homeopathy	Imbibing of highly diluted substances	Range of conditions
Hypnotherapy	Use of induced sleep-like state to alter behaviour, attitudes and feelings	Depression, anxiety, eating disorders and stress
Meditation		
Nutritional therapy	Application of nutrition science to redress nutritional imbalances	Range of chronic conditions and general wellbeing
Osteopathy	Manipulation, stretching and massage of muscles	Back, neck, shoulder and limb pain
Reflexology	Application of pressure to feet, hands or ears	Stress and pain symptoms
Reiki	Palm or 'hands-on healing'	Nervous, respiratory, circulatory, digestive and other disorders, injuries and general wellbeing
Relaxation and visualisation	Use of imagination to visualise desirable outcomes	Stress and pain symptoms
Shiatsu	Application of finger and palm pressure, stretching and massage	Promotion of wellbeing
Therapeutic touch	Positioning of therapist's hands on or near patient to manipulate patients' 'energy field'	Pain and anxiety
Yoga	System of low impact physical exercises	Pain, stress and depression