

# chapter 2

## Clinical issues associated with the use of complementary and alternative medicine

### Overview

**In this chapter the following is provided:**

- a discussion of the routes by which complementary and alternative medicine (CAM) advice is provided
- a list of the conditions most usually treated with CAM
- a discussion of the types of evidence for CAM and an explanation given of difficulties in conducting and assessing research in CAM
- an account of the safety issues associated with CAM
- a description of how CAM is used in veterinary medicine.

### CAM treatment providers

#### Regulatory control

Aromatherapy, homeopathy and other popular complementary therapies are to be regulated for the first time in the UK under a government-backed scheme in 2008. The announced Natural Healthcare Council will be able to strike off errant or incompetent practitioners. It will also set minimum standards for practitioners to ensure that therapists are properly qualified. Patients will be able to complain to the council about practitioners and the new body will be modelled on the General Medical Council and other similar statutory bodies.

Chiropractic and osteopathy are already subject to statutory control.

The provision of CAM services may be by the following groups:

#### Healthcare providers

- Qualified members of the statutorily controlled health professions may offer advice and prescribe complementary medicine exclusively, or more likely as an adjunct to their orthodox practice (e.g. physicians, nurses, pharmacists).

- Trained professional CAM practitioners (e.g. herbalists, homeopaths) may also offer advice and treat.

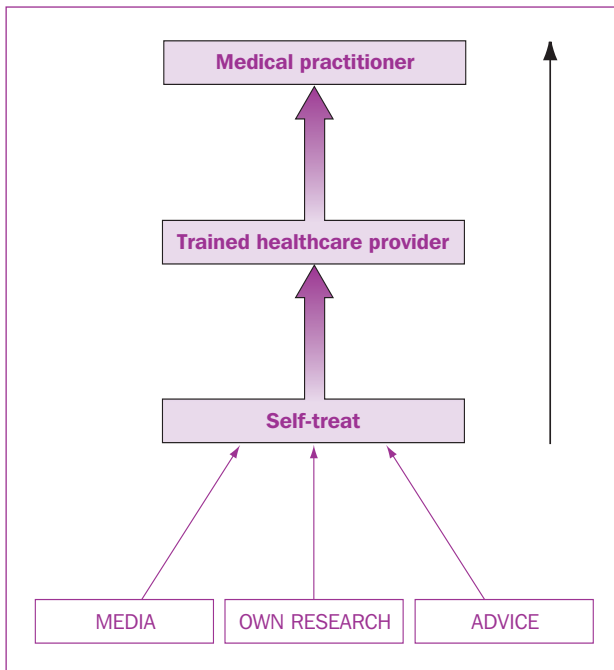
### Other providers

- practitioners without formal training (lay practitioners)
- family and friends.

### Self-treatment

- People who become ill typically follow a pathway known as a *hierarchy of advice*. It is summarised in Figure 2.1. This may begin with self-medication following personal research and/or consultation with relations, friends or lay practitioners, then more self-medication, and finally consultation with a healthcare provider and medical practitioner. However, this illustration is highly simplified, for people do not always follow a logical pathway, particularly in cases of more severe illness, when they may go straight to their pharmacist or general practitioner (GP). They may return to previous treatments if later ones fail, may try different methods simultaneously or may consult CAM practitioners along the way. This makes the assessment of certain treatment outcomes extremely difficult.

Figure 2.1 Hierarchy of advice.



- Self-treatment regimens may encompass proprietary drugs, patent medicines, aromatherapy oils, herbal or homeopathic medicines as well as changes in diet or lifestyle. Increasingly, government policy is to drive patients away from the National Health Service (NHS) for simple self-limiting-type conditions and encourage self-treatment. The switching of certain high-powered drugs from a prescription-only category to allow sale in a pharmacy has facilitated this. In the UK about 75% of abnormal symptoms are dealt with outside the NHS. The GP sees around 20% of patients, 16% take no action, 63% self-medicate and 1% go directly to hospital. Thus the influence of the pharmacist or health shop assistant is often important in recommending what remedies patients should purchase.

## The CAM treatment process

The procedure to be followed in the choice and provision of a CAM intervention is summarised in Figure 2.2 and comprises the following eight steps:

1. obtaining basic information on the condition being presented
2. taking a decision on whether to treat or to refer
3. taking a decision to treat with CAM or orthodox medicine
4. gathering supplementary information
5. deciding on a particular intervention
6. establishing a treatment regimen
7. providing the treatment
8. follow-up.

### Step 1: gathering basic information

In order to take the decision on treating a particular case in an informed manner, some basic information is required and the questioning process described by the well-known acronym WWHAM may assist the amplification of information proactively supplied by the patient.

#### WWHAM

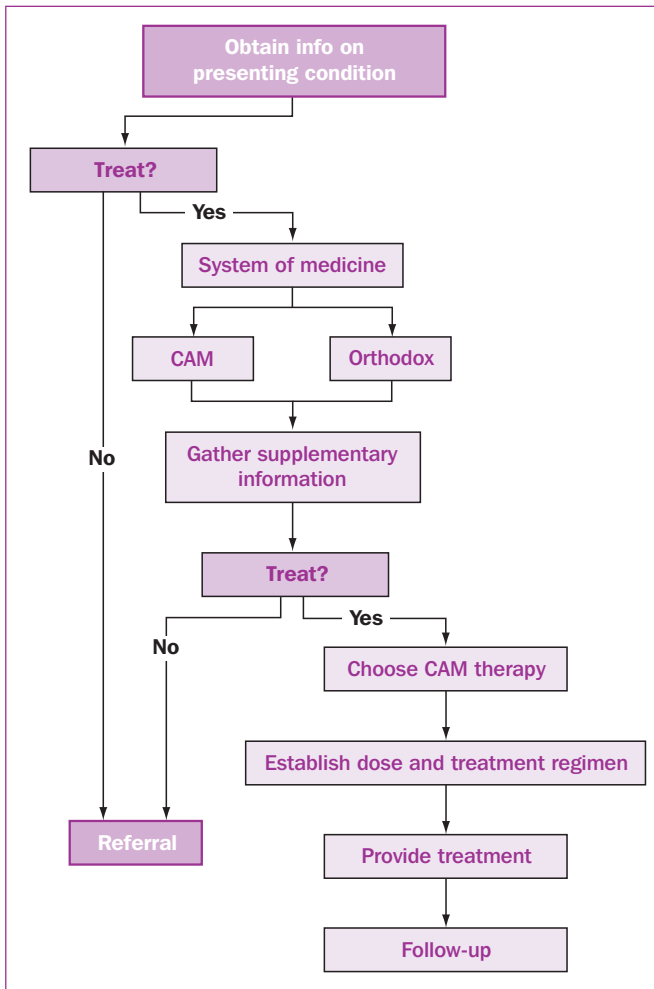
- Who is the medicine for?
- What is the medicine for?
- How long have the symptoms been present?
- Any action already taken?
- Medicines currently being taken for other reasons?

**Tip**

### Step 2: deciding whether to treat or refer

With experience, and within the bounds of one's competency, the decision to treat using orthodox medicine or CAM or to refer may be taken without an indepth investigation. It will be based on a variety of factors, including the severity and type of symptoms being presented, the length of time during which symptoms have been experienced and the patient's health status.

**Figure 2.2** Treating with complementary and alternative medicine (CAM) therapies.



### Examples of conditions most often associated with use of CAM

- allergies
- arthritis
- cancer management
- depression
- influenza
- insomnia
- musculoskeletal conditions
- neurological and psychological disorders
- pain.

### Step 3: deciding on orthodox medicine or CAM

Having decided to treat, the next question is whether to treat with CAM or allopathic (orthodox) methods. The patient might express a strong wish to be treated by a particular CAM therapy due to a dissatisfaction with orthodox medicine (see Chapter 1) or there may be no suitable orthodox treatment available. For example, requests for help with examination nerves or morning sickness in pregnancy can be effectively met by homeopathy.

### Step 4: gathering supplementary information

Before one can choose an appropriate medicine to counter-prescribe, information must be gained from:

- the patient – signs and symptoms. A useful acronym to use when assessing the signs and symptoms displayed in a case is provided by the letters *LOAD*, standing for listen, observe, ask and decide
- the practitioner's observational and listening skills
- the practitioner's own knowledge and limits of competency
- searching the evidence-based literature for the answer to a clinical question (see below).

### Tips

#### LOAD

- *Listen* to what the patient tells you about his or her symptoms.
- *Observe* the patient's general demeanour, appearance and temperament.
- *Ask* the patient appropriate questions to learn more about the condition.
- *Decide* what to do next after assessing the information provided.

### Step 5: deciding on a particular therapy

If all the preparatory work in step 4 has been carried out assiduously then choosing a therapy is not as daunting as might first appear. Given the restrictions on resources in most pharmacies and health stores, it is not possible to pursue extended consultations. This means that the conditions being treated are likely to be restricted to simple self-limiting conditions although some chronic conditions may be tackled as experience grows.

There is another acronym that might be found useful here. ACT stands for assess, confirm, talk.

### Tips

#### ACT

- *Assess* – with all the requisite information one can choose an appropriate therapy.
- *Confirm* – having chosen the therapy it is advisable to discuss the decision with the patient to confirm that the proposed course of action meets with the patient's approval.
- *Talk* – it may also be appropriate to give some general information on CAM and the specific therapy chosen, particularly if the intervention is being advised proactively rather than reactively in response to a request.

**Step 6: establishing a treatment regimen**

The choice of treatment regimen may be influenced by a number of factors, including the severity of the condition and the status of the patient's general health.

**Step 7: providing the treatment**

The provision of treatment may involve the administration of an appropriate remedy or carrying out a procedure.

**Step 8: follow-up**

Following up the patient's process and a re-evaluation of the treatment if necessary complete the treatment cycle.

**Evidence base**

It is important that CAM practitioners adopt the principle of evidence-based medicine (EBM) sooner rather than later. It promotes the idea that for each form of treatment the evidence regarding clinical effectiveness should be systematically reviewed and the results implemented into practice.

However, the relationship between EBM and complementary medicine may become unbalanced, and the proponents of one system ignore or dismiss the values of the other. This lack of cross-paradigmatic respect is the wellspring for division and suspicion that is currently permeating the arranged marriage between CAM and EBM.

**Definition**

EBM is defined as 'the conscious, judicious use of current best evidence in making decisions about the care of individual patients'.<sup>1</sup> It is about getting the best therapeutic outcomes for patients, by integrating clinical expertise and knowledge with patients' needs and preferences, using the most current information available in a systematic and timely way.

**Overview of CAM research**

Evidence associated with the use of CAM therapies is discussed in detail in the chapters dealing with specific therapies. Here a brief overview of CAM research is given.

- There is no doubt that many CAM disciplines suffer greatly from an inability to provide robust evidence acceptable to orthodox observers. In particular, homeopathy, which commonly uses dilutions of medicine that are well beyond Avogadro's number, is the subject of much scepticism. At this dilution level there are no molecules of drug left in solution – at least none that can be measured with methods currently available.

- Historically, there has been little scientific research into CAM, largely because of its place as a 'fringe' profession.
- Complementary medicine in general is deeply rooted in a tradition where experience comes first and science second. The arguments usually claim that hundreds of years of experience on thousands of patients are innumerable stronger than scientific studies which normally only include a few patients and are far removed from 'real life' anyway.<sup>2</sup>
- In the UK most research is funded by private-sector interests who might see the economic benefit of a certain procedure or product. The research culture that has developed has been one that emphasises an evidence-based approach to establishing the efficacy of single herbs and nutrients, overlooking the way that complementary therapists use these substances.

### **Types of outcome measure**

There are two terms commonly used to describe the outcome of any given treatment: efficacy and effectiveness.

#### **Efficacy**

Efficacy is measured under standard scientific conditions (usually a randomised controlled trial (RCT)). It is the normal requirement before regulatory authorities will consider granting a licence for the release of a medicine to the market.

#### **Effectiveness**

This is based on a patient-oriented outcome determined under field conditions. Thus, if a homeopathic medicine is given to a patient who is then seen to improve, one would say the medicine was effective rather than efficacious. Theoretical justification is not usually an issue. The perception that an intervention is 'effective' differs widely between patients, and in many cases between patient and prescriber too. Part of this divergence may be due to the fact that it is possible to identify two treatment outcomes. The first, an improvement in the clinical characteristics of the condition being treated, can be assessed in terms of any or all the following:

- resolution of symptoms
- reduction in severity of symptoms with less discomfort
- a need to take less medication
- better quality of life.

The second outcome concerns the patient's overall feeling of wellness. This is largely subjective and may vary from day to day. Patients differ in their ability to deal with disease and this may be reflected in the success or otherwise of treatment.

Objective outcome measurements have been developed to obtain some idea of the extent of positive or negative outcome.

Examples include the Visual Analogue Scale, the Overall Progress Interactive Chart and the Glasgow Homoeopathic Hospital Outcome Scale. These measures were developed for use in studying outcomes resulting from homeopathic treatment and will be mentioned again in Chapter 4.

Some CAM disciplines are more difficult than others to assess; determining a mechanism of action may be impossible. This topic will be discussed further when each therapy is described in future chapters.

### Range of evidence

The value of stringently conducted RCTs is undisputed because they have great internal validity. However, their results may not have relevance to everyday decision-making. In RCTs patients are randomly assigned to standard and investigational arms and are followed up over a defined period. The final results of the randomised groups are often compared, irrespective of whether the positive result of one treatment arm was induced in part by using the alternative-treatment principle (the intent-to-treat principle) as a result of cross-over. The best and most appropriate evidence for each outcome is required from the perspective of both healthcare provider and patient. This cannot be provided by a single-outcome study. An RCT is not the best way to determine rare side-effects of a treatment: a case-control or observational study is better. Research into causes of illnesses and prognoses is usually best done with cohort studies – lower in the hierarchy of levels of evidence but vital to an understanding of disease. A balanced portfolio of research across several layers of the hierarchy of evidence is preferable.

### Tip

An eight-point hierarchal continuum exists to rank the quality of evidence. This leads from strictly controlled randomised trials, systematic reviews and meta-analyses at one end (efficacy) to observational studies, including anecdotal case reports, case series and comparison with historical groups (effectiveness), at the other end.

The widespread use of hierarchies of evidence that grade research studies according to their quality has helped to raise awareness that some forms of evidence are more trustworthy than others.

### CAM research – the problems

Research into CAM is hampered by a number of factors.

#### Financial resources

Probably the most acute problem is a lack of funding – at least in the UK.<sup>3</sup> Funding bodies are often unwilling to make grants in unorthodox areas.

A second problem with research into CAM in the UK is that much of it is performed without prioritising those projects with the best chance of success.

In the USA the National Center for Complementary and Alternative Medicine

(NCCAM) provides research funds for projects that currently include:

- mechanisms of action
- exploratory clinical studies and phase I and II clinical trials
- areas of special interest
- areas subject to a short 'pause' in new funding.

### **Lack of research skills**

Many early clinical trials investigating CAM have had serious flaws. Research is not included in many homeopathic courses, although attempts are being made among educationalists to interest students in this important aspect of CAM.

### **Research design**

#### **Lack of a suitable hypothesis to test**

Most scientific research sets out to provide evidence for or against a hypothesis. Most CAM research does not have a formal hypothesis to test.

#### **Placebo design**

There are difficulties in designing placebo for many CAM disciplines to enable placebo-controlled trials. For example, sham acupuncture or sham reflexology is extremely difficult to achieve. Research design is further confounded by the wide variation in how many forms of CAM are practised. For instance, there are many different approaches to the practice of chiropractic and acupuncture.

#### **Inappropriate extrapolation of results**

Despite the emphasis on multimodality treatment regimens in many CAM disciplines, most research has examined only one, or perhaps two, interventions taken from a whole treatment system. For instance, there are hundreds of small studies examining the efficacy of acupuncture needling alone for treating asthma, pain, hypertension or nausea. Yet, in practice, acupuncture needling would be just one of a portfolio of interventions used by an acupuncturist, including herbal medicines, dietary changes and exercise therapy (see Chapter 5). This makes it difficult to form an opinion in isolation as to the effectiveness of a particular intervention.

#### **Standardisation**

The number and length of treatments and the specific treatment used may vary both between individuals and for an individual during the course of treatment. For example, when designing an RCT for acupuncture, the investigator is faced with choices concerning the selection of points, the depth of needle insertion

and the frequency and scheduling of treatment. Lack of standardisation of herbal medicines also makes comparisons between trials difficult.<sup>4</sup>

### **Lack of patients**

There is an unfortunate catch-22 situation where lack of evidence means lack of patients from the NHS means lack of evidence. Other problems include difficulties in retaining patients.

Despite these complexities, rigorously designed clinical trials are possible, including pragmatic studies of complete CAM systems. The quantity of applied health research on complementary medicine is growing rapidly, and the quality is improving. The number of randomised trials of complementary treatments has approximately doubled every 5 years,<sup>5</sup> and the Cochrane Library now includes nearly 50 systematic reviews of complementary medicine interventions.

### **CAM research – the criticisms**

The stance of many orthodox practitioners is illustrated in the following editorial from the *Lancet*:<sup>6</sup>

If a claim of clinical efficacy cannot be put in a way that allows it to be corroborated or refuted, and its efficacy is challenged by a substantial group of well-informed observers, that claim belongs to the world of metaphysical discussion rather than medical practice.

It has been made clear that claims of clinical effectiveness will only be universally accepted when interventions have been subject to the same rigorous tests as those required in orthodox medicine. The main criticism applied to CAM in general concerns the quality of the research.

### **Outcome measures**

Many of the studies demonstrating the clinical benefit of complementary techniques have reported improvements in subjective measures of disease activity. Subjective improvement in symptoms or an increased sense of well-being are valid therapeutic goals, just like objective improvements. In fact, objective benefits might not actually be perceived by the patient. Despite this, such outcome measures are frequently considered to be invalid by the orthodox scientific community.

### **Statistical significance**

Much of this evidence involves small numbers of patients and is of poor methodological quality. However some high-quality

systematic reviews of complementary medicine have recently been published which provide a reliable basis for making healthcare decisions.

### **Inappropriate focus**

Much of the research effort in CAM is in the form of treatment  $x$  for disease  $y$ .<sup>7</sup> Almost no systematic research is taking place on the delivery, organisation and financing of different integrative healthcare models or on the appropriateness, quality, availability and cost of CAM modalities in the current healthcare system.

### **Publishing bias**

CAM practitioners often complain about bias against their research, with mainstream journals ignoring positive outcomes.

The location of papers in terms of journal type and impact factor (a measure of the publication's status or importance) should be taken into account when the literature on CAM is being consulted.

### **Source of evidence on CAM**

In a review of recent advances in the status of CAM, Vickers states that the quantity of applied health research is growing rapidly and the quality is also improving.<sup>8</sup> The number of randomised trials of CAM has approximately doubled every 5 years and the Cochrane Library now includes over 50 systematic reviews of CAM interventions.

The evidence currently available may be considered under four headings: (1) RCTs; (2) clinical audit; (3) observational studies; and (4) anecdotal evidence.

### **Randomised clinical trials**

The RCT is far from being a gold standard, as stated above. Most – but not all – results come from large groups of people and cannot easily be used to assist prediction of an outcome in any given individual. Others, including chemotherapeutic agents, may be  $n = 1$  trials. There are few paediatric trials. It is difficult to design a suitable placebo for physical interventions such as exercise therapy, massage or acupuncture. Patient (and operator) blinding is difficult in such therapies. Studies involving relaxation or meditation provide similar difficulties.

### **Clinical audit**

This is the systematic evaluation of clinical activity – the effectiveness of a particular intervention. It involves the identification of a problem and its resolution as part of an audit cycle. Audit is about ultimately improving a procedure

### Observational studies

Patient-oriented outcome measures such as those mentioned above may contribute to evidence of effectiveness of CAM interventions.

### Anecdotal evidence

This type of evidence is the basis of many CAM procedures. It usually refers to a collection of single-episode case reports collected in the literature over many years. This traditional bibliographical evidence may be acceptable to regulatory authorities in support of certain licensing procedures. CAM reports rarely include great detail and tend to be statistically non-significant because of the small sample size.

### Searching the literature

The evidence-based approach seeks to gather the information necessary to support clinical intervention.<sup>9</sup> It involves three stages:

1. formulating a clear clinical question to be investigated
2. searching for the evidence
3. appraising the evidence.

## Tips

### Formulating a clinical question

The well-built clinical question has four elements, summarised by the acronym PICO:

- Patient, population or problem – a description of the discrete group of patients and/or the problem being investigated. (e.g. depression in menopausal women)
- Intervention, prognostic factor or exposure – what is the main intervention, prognostic factor or exposure? (e.g. use of St John's wort)
- Comparison or intervention (if appropriate) – what is the main alternative to compare with the intervention? (e.g. use of orthodox drug)
- Outcome you would like to measure or achieve – what can I hope to accomplish, measure, improve or affect? (reduction in symptoms)

These elements may be used to formulate a question on which a search strategy can be built. Given the examples above this might be 'In pregnant women suffering from depression, does the use of St John's wort, when compared with an orthodox drug, provide a reduction in symptoms?' This in turn facilitates organised database searching to find the most relevant highest-quality evidence that can inform a particular clinical decision.

There are some limitations to the procedure, including occasions when evidence is unavailable or insufficient to answer the question effectively and when practitioner skills are inadequate to interpret the literature. However, it may be particularly useful where the practitioner has some gaps in his or her knowledge that need to be filled.

The relatively small number of robust studies on CAM in the literature precludes firm recommendations on one or more sources of reliable data. A range of different sources is required for identifying relevant studies. Examples include:

- Cochrane database of systematic reviews (<http://tinyurl.com/yqcvgr>)
- PubMed, Medline (<http://tinyurl.com/2gjcwh>)
- Research Council for Complementary Medicine (<http://tinyurl.com/ywcry8>)
- HerbMed (<http://www.herbmed.org/>)
- Complementary and Alternative Medicine Specialist Library (<http://tinyurl.com/q86oe>)
- internet search engines (e.g. Google <http://www.google.com/>).

### Appraising the evidence

When critically appraising the literature there are three key issues:

1. validity – are results of the study valid?
2. importance – do the results matter clinically?
3. relevance – are the results likely to assist in caring for my patient?

Two resources that can help with the appraisal process are Critical Appraisal Skills Program (CASP) provided by the UK NHS at <http://tinyurl.com/2qkkn3> and the Oxford Centre for Evidence Based Medicine site (CEBM) at [www.cebm.net](http://www.cebm.net).

Other tools and guides are available through Google.

Having obtained answers to the PICO questions, the prescriber may then move on to the second stage in gathering information and integrate all the data into clinical practice.

### Safety

As stated in Chapter 1, it is generally perceived by the public that CAM is entirely safe. In fact many interventions have the potential to do harm if used inappropriately. For example, herbalism has remedies with a potential risk of intrinsic toxicity as well as possible dangerous interactions with orthodox drugs being taken concurrently. Certain manipulative therapies can also cause damage if not performed correctly. The general dangers of using CAM may be categorised under two headings: direct risks and indirect risks.

#### Direct risks

- allergic reactions or other adverse reactions to remedies or diagnostic agents used during the practice of CAM
- use of adulterated or poor-quality preparations
- interaction between CAM medicines and existing medication
- manipulative or other damage caused by inexperienced practitioners.

### Indirect risks

- patient's condition deteriorates due to inaccurate diagnosis and/or inappropriate treatment
- serious illness not detected through lack of knowledge or experience of practitioner
- discontinuation of prescribed orthodox medication without permission (or knowledge) of patient's doctor
- application of alternative approach to CAM preventing consideration of other orthodox procedures
- patient attempts to self-treat in response to media pressure when professional advice should be sought.

### CAM and veterinary medicine

The Veterinary Surgeon's Act 1966 states, subject to a number of exceptions, that only registered members of the Royal College of Veterinary Surgeons (RCVS) can practise veterinary surgery in the UK.

Veterinary surgery is defined as:

encompassing the art and science of veterinary surgery and medicine which includes the diagnosis of diseases and injuries in animals, tests performed on animals for diagnostic purposes, advice based upon a diagnosis.

The exceptions include:

- veterinary students and veterinary nurses – governed by various amendments to the Veterinary Surgeons Act
- farriers – although farriers have their own Farriers Registration Acts, they are also governed by the Veterinary Surgeons Act and are not allowed to perform acts of veterinary surgery
- owners can treat their own animals.

The other exceptions (including CAM) are governed by the Veterinary Surgery (Exemptions) Order 1962. With the movement of complementary therapies into the field of animal treatment, this order was introduced to amend the Veterinary Surgeons Act to take such legitimate therapies into account.

As far as complementary therapies are concerned, this order refers to four categories:

1. Manipulative therapies: this covers only physiotherapy, osteopathy and chiropractic and allows these therapies where a vet has diagnosed the condition and decided that this treatment would be appropriate.
2. Animal behaviourism: behavioural treatment is exempt, unless medication is used where permission must again be sought from the vet.

3. Faith healing: according to the RCVS *Guide to Professional Conduct*, faith healers have their own Code of Practice, which indicates that permission must be sought from a vet before healing is given by the 'laying on of hands'.
4. Other complementary therapies: according to the RCVS *Guide to Professional Conduct 2000*, section on treatment of animals by non-veterinary surgeons (available at the RCVS website: [www.rcvs.org.uk](http://www.rcvs.org.uk)): 'It is illegal, in terms of the Veterinary Surgeons Act 1966, for lay practitioners however qualified in the human field, to treat animals. At the same time it is incumbent on veterinary surgeons offering any complementary therapy to ensure that they are adequately trained in its application.'

Thus, apart from the manipulative therapies, behavioural treatment and faith healing, all other forms of complementary therapy are illegal in the treatment of animals in the UK when practised by non-vets.

In the UK herbal and homeopathic medicines registered by the Veterinary Medicines Directorate under the Veterinary Medicines Regulations are available for use in both companion animals and food-producing animals without the need for a veterinary prescription.

## Self-assessment

### Case studies

1. A regular patient of yours has just been diagnosed with a 'delicate' problem his doctor calls benign prostatic hypertrophy (BPH). The patient's GP wants to start him on treatment with an orthodox medicine but the patient is worried about side-effects. He asks you about a herbal product called Saw palmetto which a friend of his takes.

Explain how you would go about gathering the necessary information to allow an informed response to be made.

How would you respond to the following scenarios?

2. A man of about 40 wearing paint-spattered overalls comes in and asks for 'something alternative' for diarrhoea that 'comes and goes'. You notice he has a limp.

## Tips

- In most cases the healthcare provider's problem will be lack of relevant information. Case 1 encourages you to investigate problem-solving techniques with respect to addressing gaps in knowledge on the use of CAM.
- There is no definitive answer to this question because there are too many unknowns.
- This case prompts you to follow a structured approach to gathering the necessary information to enable you to make an informed response. You should use the PICO system and make a list of the questions to be asked to generate the required information.
- You may find it useful to discuss this question with a colleague or colleagues.

## Tips

- Scenarios 2–6 are designed to encourage the thought processes leading to the choice of appropriate treatment, by listening, observing and asking the right questions.
- The actual choice of medicine is not important here, although possible choices are given in some of the answers.
- Look for an integrated approach that may involve orthodox medicines or other measures too to demonstrate the complementary approach.
- Use the acronym LOAD, standing for listen, observe, ask and decide action, and deal with each scenario using this as a template.
- Again, there is no outright answer to these scenarios. You should reflect on your response to each situation.

3. A teenager asks for something to help her sleep. You note she has bloodshot red eyes.
4. An elderly man visiting from the north of Scotland asks what he should do about troublesome diarrhoea.
5. A burly rugby-player comes to you complaining of the 'collywobbles'. Can you help?
6. A woman in her 50s has just lost her mother to breast cancer. In her consultation she is crying. You know she is diabetic with the usual complications.

## Exercises

Answer true or false to the statements below.

1. **The hierarchy of advice:**
  - a. depends on the condition being treated.
  - b. represents a pathway by which patients seek advice on healthcare.
  - c. means patients always go to their GP first.
  - d. means a patient only self-treats after consulting a healthcare provider.
  - e. is always strictly followed by people seeking advice on healthcare.
2. **Evidence for CAM:**
  - a. EBM is about getting the best therapeutic outcomes for patients.
  - b. There is an extensive evidence base for most CAM therapies.
  - c. CAM therapies are mainly evaluated using measures of efficacy.
  - d. The Visual Analogue Scale provides a subjective measure of effectiveness.
  - e. RCTs may not have relevance to everyday decision-making.
3. **Research in CAM:**
  - a. Methodological inadequacies affect the quality of the evidence base for CAM.
  - b. Trials on multimodality treatments provide good-quality results.
  - c. A main criticism applied to CAM is that its research is lacking in statistical rigour.
  - d. Mainstream medical and scientific journals only publish positive results for CAM outcomes.

- e. A clinical question may be formulated using the mnemonic PIOC.
- 4. Source of evidence on CAM:**
- a. RCTs are the only method of gathering evidence of effectiveness.
  - b. No RCTs are available for CAM therapies.
  - c. Clinical audit measures the effectiveness of an intervention.
  - d. Observational studies may contribute to evidence of effectiveness of CAM interventions.
  - e. Anecdotal evidence may be acceptable to regulatory authorities.
- 5. Safety:**
- a. There may be an indirect risk due to an allergic response associated with the use of CAM diagnostic agents.
  - b. CAM medicines may interact with orthodox medicines.
  - c. Orthodox medicines should always be discontinued when CAM is commenced.
  - d. All CAM medicines are totally safe.
  - e. Patients may self-treat with CAM under all circumstances.
- 6. Veterinary:**
- a. There are no registered CAM medicines for veterinary use.
  - b. CAM in animals may only be provided by Veterinary Surgeons.
  - c. The Veterinary Surgeons Act 1966 allows all healthcare providers to treat animals.
  - d. Owners are legally allowed to treat their own animals.
  - e. Registered homeopathic veterinary medicines may be used in food-producing animals.

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### Further reading

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- Kayne S B, ed. *Complementary and Alternative Medicine*, 2nd edn. London: Pharmaceutical Press, 2008.
- Lewith G T, Jonas W B, Walach H. *Clinical Research in Complementary Therapies: Principles, Problems and Solutions*. London: Elsevier Churchill Livingstone, 2002.

### Useful resources

Bandolier Complementary and Alternative Medicine:  
<http://tinyurl.com/3deesr>

CAM Research Institute:  
<http://www.camresearch.com/>

Complementary and Alternative Medicine Specialist Library:  
<http://www.library.nhs.uk/cam/>

Complementary and Integrated Medicine Research Unit:  
<http://www.cam-research-group.co.uk/>