Traditional Medicine

A global perspective

Edited by

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Preface

My good friend, Dr Gill Scott, and I were sitting in the gardens of the Mount Nelson Hotel (affectionately known as ‘The Nellie’) in Cape Town discussing Traditional African Medicine. We both thought that it would be good to bring descriptions of a representative number of traditional medical systems together in one text, aimed at academics, students and interested members of the public. I was delighted when Gill immediately agreed to contribute a chapter.

Over one-third of the population in developing countries lack access to essential medicines. Countries in Africa, Asia and Latin America use traditional medicine to help meet some of their primary health care needs. In Africa, up to 80% of the population uses traditional medicine for primary health care. The provision of safe and effective Traditional Medicine Therapies could become a critical tool to increase access to health care. Migration, both within countries and across continents, means that host communities, in particular health care providers working in multicultural environments, may well come into contact with unfamiliar practices. A compact yet wide ranging source of knowledge such as that provided in this book will help them understand the basics of medical systems that are being used by patients, often concurrently with western medicine. However, health care providers need more than just knowledge, for it is necessary to understand and effectively interact with people across cultures. In short, there is a need to develop cultural competence. With this in mind a method by which orthodox health care providers can approach patients using their traditional practices in a sympathetic manner is introduced in Chapter 3. Although it specifically refers to North American aboriginal medicine it can be adapted to other health care environments.

This book covers medical systems practised on five continents, chosen to offer readers an awareness of different approaches to health care around the world. For example, Traditional Chinese Medicine and Ayurvedic medicine, two complete health systems that form the basis of almost all Asian medicine, are covered in detail, using material derived from both observation and published literature. Medicine from the Amazonian region of Colombia is presented through a series of fascinating interviews with local healers that
emphasises the importance of ritualistic practice. In the African chapter the importance of using indigenous plants as remedies and the involvement of WHO are highlighted. Chapters on Japanese, Korean and Traditional Medicine in the Pacific provide an insight into the way other cultures have contributed to the development of their health care practices. Two chapters on folk medicine are also included: one covers the history and practice of secular and ecclesiastical practices with their origins across the continent of Europe, while the other seeks to demonstrate the wide ranging influence that a global religion can have on the health care of its believers.

I am grateful to my colleagues around the world for their generous support.

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This chapter describes the basic concepts governing the practice of traditional Chinese medicine (TCM) and then focuses on two of the most widely practised disciplines, acupuncture and Chinese herbal medicine (CHM), in greater detail. A brief overview of other similar traditional medicine practices is also included.

All healthcare providers, particularly those who practise in areas with substantial Chinese immigrant populations, will find it useful to have some background knowledge of this topic. However, the reader should appreciate that this chapter is designed only to be a brief introduction to what is a very wide-ranging and complex subject, and it will certainly not equip you to set up as a TCM practitioner!

**Traditional Chinese medicine**

**Definition**

TCM is a generic term used to describe a number of medical practices that originated in China but have now spread throughout the world. It includes not only acupuncture and CHM, but also a number of other disciplines such as dietary therapy, mind and body exercise (e.g. tai c’hi), and meditation.

**History**

The earliest Chinese medical treatise, *Huangdi Neijing*, is attributed to the highly esteemed Yellow Emperor (Huangdi) who, according to legendary history, ascended to the throne of China around 2698 BC.¹ The text, also known as *The Yellow Emperor’s Classic of Internal Medicine* or *The Yellow Emperor's Inner Canon*, is considered to be the highest authority on TCM.² It comprises two separate works:
1 *Suwen*, a book of simple questions

Written in the form of a discourse between Huangdi and his ministers on the nature of health, it contains a wealth of knowledge, including aetiology, physiology, diagnosis, therapy and prevention of disease, as well as an in-depth investigation of such diverse subjects as ethics, psychology and cosmology. It is likely that the book was developed by others over the centuries until a definitive version appeared in the first century BC, but it is, none the less, usually ascribed to Huangdi. The theories of medicine expounded in *Neijing* remain to this day the most authoritative guide to TCM.

Another significant influence on the development of Chinese medicine was produced in the first or second century AD. Entitled *The Classic of Difficult Issues*, it discusses the origins of the nature of illness, describes an innovative approach to diagnosis and outlines a system of therapeutic needling.

The origins of what might be called modern TCM can be traced back to Zhang Ji, who practised in the Qing Chang mountains close to Chengdu, Szechuan province, in the early years of the third century AD, although it was known to have existed in various forms for more than 1000 years before this date. Ji was described as the sage of medicine and probably used traditional methods of healing that were originally linked to Indian practices but were subsequently modified according to Chinese Taoist spiritual philosophy. Another of the famous masters of Chinese medicine active in the third century AD was Hua Tuo, a surgeon and practitioner of a range of therapies.

In the western world TCM, especially acupuncture and CHM, experienced its main expansion during the nineteenth and twentieth centuries as populations moved with developing means of transport. It diffused from immigrant families into host communities and was promoted by subsequent media exposure. The UK’s 100-year involvement in Hong Kong led to immigration from the colony and returning merchants, both spawning an interest in all things oriental.

In 1849 the Gold Rush in California brought a large influx of Chinese people to the western USA. They brought their traditional medicine with them and it proved to be popular among the prospectors and their families, particularly as western medicine was largely unavailable in these remote areas. The steady expansion of interest in TCM in the past 30 years in the USA has been attributed to media interest during President Nixon’s visit to the People’s Republic of China in the early 1970s (see Acupuncture below).

**Principles of TCM**

TCM is necessarily embedded in a complex theoretical framework that provides conceptual and therapeutic directions. Unlike the earliest Chinese
healing, which relied on supernatural guidance or altered states of consciousness, classic Chinese medicine relies on ordinary human sensory awareness. Its fundamental assertion, similar to the kindred philosophical systems of Confucianism and Taoism, is that contemplation and reflection on sensory perceptions and ordinary appearances are sufficient to understand the human condition, including health and illness. This assertion is fundamentally different from the western biomedical viewpoint, which gives privileged status to objective technology and quantitative measurement.

The Chinese approach to understanding the human body is unique. It is based on a highly sophisticated set of practices designed to cure illness and to maintain health and well-being. Ji is reputed to have said:

*The superior physician helps before the early budding of disease.*

These practices also represent an energetic intervention designed to re-establish harmony and equilibrium for each patient according to the holistic principle.

Whenever the practitioner uses acupuncture or herbal medicine, prescribes a set of exercises or proposes a new diet, his or her activities are all considered to be mutually interdependent and necessary to restore (or maintain) health.

Acupuncture and CHM are considered as separate therapies in this chapter but, in the West, it is common practice to treat patients using a combination approach. This differs somewhat to how Chinese medicine is practised in China where doctors tend to specialise in acupuncture, herbal medicine or tuina massage. This difference is probably due to the fact that there are far more practitioners in China than in the West.

TCM is as much a proactive process as a reactive one – that is to say, the principles of TCM may be applied to daily life to stimulate better health without the presence of an illness to initiate it.

Below is a brief description of the concepts that are fundamental to an understanding of how Chinese medicine is used:

- Yin and yang
- The five phases
- The five substances
- The organs
- The meridians or channels.

Although they are presented in discrete sections, they are all interlinked, like a jigsaw puzzle. In isolation each piece of the puzzle (concept) has little significance.

**Yin and yang**

According to Emperor Fu His, who lived in the Yellow River area of China, approximately 8000 years ago, the world and all life within it are made up of paired opposites, each giving meaning to the other. They may be viewed
as complementary aspects of the whole. Fu His formulated two symbols to represent this idea: a broken line and an unbroken line. These symbols depicted the two major forces in the universe – creation and reception – and how their interaction formed life. This duality was named yin–yang and represents the foundation of Chinese medicine. Thus, the meaning of night is linked to the meaning of day, the ebb of a tide to the flow, and hot with cold. Perhaps the most appropriate link might be that of health and disease, often thought of as being direct opposites. A different view might be that these are both facets of life, each necessary for the other, indeed each giving rise to the other.8 Thus disease may be thought of as a manifestation of health.

The relationship between the two elements is dynamic: nature constantly moves between the two. An analogy might be provided by considering a cup of coffee that starts as yang; as it cools the yang changes to yin, passing through an equilibrium that is just right for drinking. At any stage the application of heat will cause a flow back into yang. This element of change involving energy flows (see below) is seen as a fundamental quality of life.

Yin and yang are now reflected in the well-known entwined symbol (the tai ji symbol), depicted in Figure 6.1. Thus:

- Yin is a negative state associated with cold, dark, stillness and passivity: its symbol can be represented by the dark side of a mountain.
- Yang is a positive state associated with heat, light and vigour: its symbol can be represented by the sunny side of a mountain.

An example of the yin–yang principle in therapeutics may be provided by considering a patient who has a fever, i.e. an excess of yang. Only when the opposites are in equal balance is life in harmony. Too much or too little of either element results in disharmony. Treatment would therefore be seen as the ability to promote the conversion of excess yang into yin, allowing restoration of the equilibrium between the two and a consequent resolution of the fever.

As the organs of the body were discovered they were deemed to be yin or yang. Yang organs, including the heart, spleen, lungs, kidneys and liver, are hollow and normally referred to as the ‘fu’, whereas yin organs, including the stomach, intestines and bladder, are solid and referred to as ‘zang’.9 Each organ also has a yin and yang element within it, and it is the overall imbalance that leads to disease.

Figure 6.1 Yin and yang symbols.
Rather like the constitutional patient in homoeopathy, many ailments may be described as being yin or yang. Thus, a yin-deficient patient may be hot and feverish, restless and stressed out. A yang-deficient patient will feel cold and be pale and lethargic.

The basic principles of TCM are summarised in Figure 6.2.

**The five phases (wu xing)**

According to Chinese philosophy, the body organs are related to one of the five phases (or elements): wood, fire, earth, metal and water. These are said to represent the circle of life. The five phases have a flow in which they move, called the ‘generating cycle’ (Figure 6.3):

- Water generates wood (by nourishing trees)
- Wood generates fire (rubbed together to generate fire)
- Fire generates earth (ashes fall to support the soil)
- Earth generates metal (ore)
- Metal generates water (when molten resembles water).

The five phases are applied to the practice of TCM in a number of different cycles:

- In the sheng cycle, organs are considered to be in a familial relationship supporting each other, e.g. the kidney may be considered to be a fire organ (or ‘mother’ organ) and the liver an earth (or ‘son’)

![Figure 6.2 Basic principles of traditional Chinese medicine.](image-url)
organ. Treating the ‘mother’ organ might provide a route to improving the health of a deficient ‘son’ organ. This is more of a supportive role: the heart is considered to support the spleen, while the spleen supports the lungs, etc.

- The *ke* cycle implies a degree of control, as when water ‘controls’ fire. When an organ is weak it is unable to exert the control necessary to assist other organs. Thus, if the lungs are weak the liver may become too strong, leading to headaches or hypertension.

- The cosmological cycle (or sequence) considers water to be the most important element. As water corresponds to the kidney it reflects the importance that Chinese prescribers place on this organ. It is viewed as the centre of all yin and yang energy in the body and its health is therefore vital.

The five phases are in a complex relationship with other important elements of TCM as shown in Table 6.1.

<table>
<thead>
<tr>
<th>Table 6.1 Relationships of the five phases</th>
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<tr>
<td>Wood</td>
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<td>Seasons</td>
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<tr>
<td>Environment</td>
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<tr>
<td>Zang organs (yin)</td>
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<tr>
<td>Fu organs (yang)</td>
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<tr>
<td>Directions</td>
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<tr>
<td>Tastes</td>
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<tr>
<td>Senses</td>
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<tr>
<td>Tissues</td>
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<td>Emotions</td>
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The five substances

In TCM five substances encompass both tangible and intangible elements within the body. They are summarised in Table 6.2.

The first three substances, qi, jing and shen, are known as the ‘three treasures’ and are believed to be the essential components of an individual’s life. They include such qualities as energy and spirit.

The other elements, blood and body fluids, are rather easier to understand, although these also have essential intangible properties.

Qi (chee)

Qi is usually translated as simply ‘energy’ but there is no one English word that conveys its true meaning. It is considered to be a vital or life force and is carried round the body through the meridians (see below).

Qi is responsible for the following day-to-day body functions:

- Movement, both conscious (voluntary) and unconscious (involuntary)
- Transforming food and drink into blood, body fluids and energy
- Containment of organs, blood vessels and body tissues in their proper places
- Protection from external environmental factors including heat, cold and dampness
- Maintenance of body heat.

A number of qi disharmonies may be identified:

- A deficiency in qi will lead to debilitation, protracted recovery from illness, chronic colds, lethargy and other signs of weakness.
- Sinking qi is when qi can no longer perform its holding function and this is reflected in an organ prolapse.

<table>
<thead>
<tr>
<th>Basic substance</th>
<th>Main responsibility</th>
<th>Possible symptoms of disharmony (deficiency or excess)</th>
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<tr>
<td>Qi, Jing</td>
<td>Day-to-day functions</td>
<td>Debilitation, chronic colds, gastrointestinal problems</td>
</tr>
<tr>
<td>Shen</td>
<td>Development</td>
<td>Learning difficulties, kidney problems, ageing, weak constitution</td>
</tr>
<tr>
<td>Blood</td>
<td>Consciousness</td>
<td>Anxiety, insomnia, psychiatric problems, Paleness, stabbing pains, fever</td>
</tr>
<tr>
<td>Body fluids</td>
<td>Nourishes, moistens</td>
<td>Dryness of skin, dry cough; weeping rashes, productive cough (phlegm)</td>
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- Stagnation of *qi* is caused by an irregular energy flow or blockage; this may be the result of physical injury or emotional stress and its symptoms include indigestion and irritability or swelling and inflammation following a knock.
- Rebellious *qi* is when *qi* flow is in the wrong direction – e.g. in the stomach *qi* is considered to flow downwards; a reverse flow might cause nausea and vomiting.

An excess of *qi* is not considered to be detrimental unless it is blocked or it is over-acting on another organ system, e.g. in the case of a migraine headache, where the *qi* of the liver is blocked and, in excess, it invades the stomach and causes vomiting; with this release of energy the intensity of migraine symptoms is often reduced.

**Feng shui** is an ancient Chinese practice believed to use the laws of both heaven (astronomy) and Earth (geography), to help one improve life by receiving positive *qi*. Most of today’s feng shui schools teach that it is the practice of choosing a place to live or work, arranging objects and using colour to achieve harmony with one’s environment.

**Jing (essence)**
The concept of *jing*, similar to *qi*, is difficult to convey in a single English word. It may be translated as ‘essence’ and underpins all aspects of organic life. If *jing* is plentiful life itself is good, full of harmony and vitality. If *jing* is lacking then *qi* will be weak, life will be dull and the person will be susceptible to contracting disease. *Jing* differs from *qi* in that the former is responsible for the developmental changes associated with growth throughout life, whereas the latter is associated with day-to-day bodily functions. *Jing* governs fertility, sexuality and growth, and is believed to have 7-year cycles in men or 8-year cycles in women, during which development and ageing take place.

Jing is responsible for:

- governing growth, reproduction and development
- production of bone marrow
- promotion of kidney *qi*
- determining the basic constitutional strength.

Deficiency of *jing* is the only disharmony and is said to be more prevalent in men than in women. The following symptoms may be identified:

- Developmental disorders, including physical, mental and learning problems – as *jing* deteriorates with age, so symptoms of baldness, deafness, brittle bones and senility may result
• Kidney-related disorders
• Poor memory and concentration
• Constitutional weakness
• Low libido.

**Shen**

*Shen* is both mind and spirit. It is based in the heart and governs spiritual, mental and emotional health. It has been described as responsible for ‘the sparkle in one’s eyes’.

If there is a *shen* disharmony human thought may be disturbed and the eyes may be cloudy with insomnia, forgetfulness and, in the worse case, incoherent speech. With extreme *shen* disharmony the condition may lead to unconsciousness.

**Blood**

In TCM blood is much more than simply a physical transport system, as in western medicine. It is closely linked to *qi* and is considered to have the following important functions:

- It nourishes the body by carrying nutrients to all tissues and structures and in so doing it helps to fulfil the nutritive functions of *qi*.
- It has a moistening and lubricating action. It aids clear and stable thought processes.

Disharmony may arise from three imbalances:

- Deficiency shows in pale face, dry skin, light-headedness and emaciation.
- Stagnation produces stabbing pains, and purple lips and tongue.
- Excessive heat in the blood can cause bleeding, skin conditions and fever.

**Body fluids** (*jin ye*)

Body fluids include external light and watery fluids, such as saliva and tears (known as *jin*), and the dense thicker fluids that circulate inside the body, e.g. gastric juices and joint fluids (known as *ye*). The function of all the body fluids is to nourish and lubricate the body. They are essential for the maintenance of healthy *qi*.

Disharmony due to deficient body fluids results in dryness of the eyes, lips and hair, a dry cough and excessive thirst. Excess body fluids can lead to problems known as dampness and phlegm, characterised by productive coughs, weeping skin rashes and vaginal discharge.

The five substances are summarised in Table 6.2.
The organs (zang fu)
The organs detailed below have a special status in TCM, being the creators and storers of the five substances. They are considered to be closely related to specific emotions and virtues and, if their essential requirements are not fulfilled, ill-health will result. Two types of organs are recognised:

1  The solid organs
2  The hollow organs.

The solid organs (zang) are associated with yin and include the following:

- The heart is the centre of shen and also governs the circulatory system. It is positively associated with compassion, love and affection, and negatively with overexcitement. Symptoms of ill-health include insomnia and hyperactivity.
- The lungs relate to qi and require confidence to function effectively. They are positively associated with conscientiousness and negatively with sadness. Symptoms of ill-health include irregular breathing, coughs and susceptibility to colds.
- The liver ensures that qi flows smoothly. When the liver is in harmony, a person will feel relaxed and optimistic but, when out of balance, the person will feel irritable and unable to move forward positively. Symptoms of ill-health may be irregular periods, premenstrual syndrome (or tension), headaches, irritable bowel syndrome and a bad temper.
- The spleen creates qi. Its health depends on a good diet and a non-stressful lifestyle. It is positively associated with empathy and negatively with obsession. Symptoms of ill-health include poor appetite and diarrhoea.
- The kidneys store jing and are associated with long-term growth. Their positive emotion is courage and their negative emotion is fear. Symptoms of ill-health include lethargy, diarrhoea, infertility and oedema.

The hollow organs (fu) are associated with yang, and include:

- the gallbladder
- the large and small intestines
- the bladder
- the stomach
- the san jiao, also known as the ‘triple burner’ or ‘triple heater’. San jiao has no equivalent anatomical structure in western medicine,
although it roughly corresponds to the thoracic, abdominal and pelvic regions, including all the organs within. It coordinates transformation and transportation of fluids in the body. San jiao also helps move qi and maintains the ambient temperature in the body, a function from which the name ‘triple burner’ derives.

**The meridians or channels**

The word ‘meridian’ as used in TCM entered the English language through a French translation of the Chinese term jing-luo. Jing means ‘to go through’ and luo means ‘something that connects’. Meridians are the channels that carry qi and blood throughout the body. They form an invisible network close to the surface of the body, which links together all the fundamental textures and organs. Kaptchuk mentions 14 meridians in his book; other writers refer to different numbers ranging from 11 to 20. As the meridians unify all parts of the body and energy (qi) can pass along the channels, they are essential for the maintenance of harmonious balance. Set along the meridians are a number of points used by acupuncturists (see below).

The meridians are named for the organs or functions to which they are attached. Fulder explains the function of the meridians thus:

The meridian of the colon runs from a point on the nail of the index finger along the arm and over the shoulder and neck to the nose from whence it follows a deep pathway down to the colon. Because the meridian system connects the exterior of the body by pathways to the viscera, external factors can penetrate and produce symptoms such as abdominal pain, migraine, etc. Conversely, diseases of the internal organs will produce superficial symptoms that may appear along the lines of the meridians. Thus, kidney disease can induce back pain, while disease of the gall bladder can bring pain to the shoulder, these being areas through which the respective meridians pass.

**Practice of TCM**

**Diagnosis**

A diagnosis is achieved using four traditional methods:

1. Listening carefully to the sound and quality of the patient’s voice (auscultation) and evaluating any breath or body odours (olfaction).
2. Asking questions to ascertain the features of the illness (enquiry).
3. Observing the patient’s general demeanour, emotional state and shen, and assessing the quality and texture of the skin and the shape, colour and coating of the tongue (inspection).
4. Palpation of the pulses and body.
After taking a full history, pulses are read (Figure 6.4). Chinese medicine recognises up to 28 pulses, which are palpable on the right and left wrists. The right-hand pulses represent conditions of the lung, spleen and kidney yang, whereas the left-hand pulses represent conditions of the heart, liver and kidney yin. The pulse is assessed in seven criteria: depth, fluency, rhythm, size/shape, speed, strength and tension. The experienced practitioner can deduce much information on the patient’s past and present health status from reading the pulses and palpating the body.

The aim is to determine which organ(s) might be out of balance by considering all the elements outlined above, and to take appropriate action to rectify the problem according to the various principles outlined above. It appears to be a daunting task to the western healthcare professional, who is more used to making a decision on appropriate medication based on symptoms determined within a 3- to 5-min consultation.

**Treatment**

Treatment is by a range of different therapies; each is described below under the appropriate section headings.

**Evidence**

Many randomised controlled trials have been conducted in China to evaluate the effectiveness of TCM, but much of the information is either inaccessible to Western practitioners and/or may be flawed.

Tang et al. identified 2938 RCTs in 28 journals randomly selected from a total of 100 Chinese journals of TCM (4 national, 10 university, 10

![Figure 6.4  Reading the pulse.](image)
The first trials were published in the early 1980s. The number of trials had doubled every 2–3 years over the past 15 years. The number of RCTs published in all 100 journals by the end of 1996 was estimated to be around 7500. Comparison of trials searched for by hand with trials of TCM found in electronic databases (which hold journals of conventional medicine as well) shows that journals of conventional medicine in China published about a quarter of the number of RCTs published in journals of traditional Chinese medicine. Thus, almost 10 000 RCTs were published in China before 1997. Over 90% of the trials in non-specialist journals evaluated herbal treatments that were mostly proprietary Chinese medicines. The 10 most common diseases in the trials were ischaemic heart disease, stroke, chronic viral hepatitis, peptic ulcer, childhood diarrhoea, hyperlipidaemia, primary hypertension, upper digestive tract bleeding, diabetes mellitus and pneumonia. They accounted for a fifth of the trials.

Unfortunately much of the early research was considered to be inadmissible because of problems associated with:

- poor translation of studies
- the quality and design of the research not being up to western standards
- the use of unvalidated methods
- methodological difficulties of establishing control groups and sham procedures for the placebo arm of trials (e.g. it is impossible to ‘blind’ an acupuncturist)
- variations in what is understood by different terms.

From an initial sample of 37 313 articles identified in the China National Knowledge Infrastructure electronic database a study led by Wu of the Chinese Cochrane Centre at Sichuan University, found 3137 apparent randomized controlled trials on 20 common diseases published between 1994 and 2005. Of these, 1452 were studies of conventional medicine (published in 411 journals) and 1685 were studies of traditional Chinese medicine (published in 352 journals). Interviews with the authors of 2235 of these reports revealed that only 207 studies adhered to accepted methodology for randomisation and could on those grounds be deemed authentic randomised controlled. The reviewers considered that a randomisation sequence generated from a random number table, calculator, or computerised random number generator was authentic but that tossing a coin, drawing straws, or allocating a participant according to date of birth or hospital record number was not.

It is vital that correct plant species are used when researching traditional herbal medicine and that tests are carried out on material prepared according to ethnic methods. The choice of test system might also be
difficult because, particularly with traditional Chinese or Indian ayurvedic medicine, where the aim may be to correct imbalances in health, there is no outcome to measure in the same way that western medicine allows. For the same reason animal models are unlikely to provide applicable results. Practitioners frequently use mixtures of ingredients and testing standardised individual elements may not be appropriate. Another significant factor with ethnic medicine is the charisma and seniority of the practitioner, which introduces a significant element of placebo response that cannot be quantified.

The number of RCTs of TCM has increased in recent years. However, there have been few systematic assessments of the quality of reporting of these trials. Wang et al. concluded from an assessment of 7422 RCTs, published in mainland China from 1999 to 2004, that, although the quality of reporting of RCTs of TCM was improving, it still remained poor.19

**Modern Chinese medicine**

Since the 1950s, the Chinese government and the government of the Republic of Chinese Taiwan have put great efforts into promoting the modernisation of Chinese medicine. This has been in response to national planning needs to provide comprehensive healthcare services. Previously, TCM had been viewed as part of an imperial legacy, to be replaced by a secular healthcare system. Integration was guided by health officials trained in modern medicine; harmonisation with modern medicine was the goal. This was accomplished by a science-based approach to the education of TCM and an emphasis on research. There are now Chinese professionals trained in both TCM and modern western medicine, who conduct research on the development of Chinese medicine. Western science methodologies have been employed to analyse the effectiveness of herbs and treatment on various individuals. Many of the differences between TCM and western scientific practices are now being studied for their synergistic potential.

Tang has asked whether the current western model of research – trying out unknown treatments in animals – is suitable for studying treatments that have long been used in humans.20 Evidence-based medicine focuses on clinical research in humans. However, research in TCM has had a mechanism-centred approach. Despite occasional successes, such as in acupuncture,21 most questions, e.g. the nature of disease in TCM, have not been satisfactorily answered.

TCM research has been accused of being in disarray.22 A long history of use, traditions, faith, popularity and anecdotes is widely taken as evidence for the efficacy of traditional Chinese medicines. Some traditional therapies are undoubtedly effective but this does not mean that all are. These medicines have been used for thousands of years. Whether tested or not, they will continue to be used in places where TCM is officially recognised. Tang
suggests that there is a much greater need to determine whether Chinese medicinal herbs do work rather than how they might work. As traditional Chinese medicines are already in use, it would be better when studying them to start with showing efficacy in humans by RCTs.

Joint research projects have been undertaken in the USA involving research institutes such as Stanford University, the College of Physicians and Surgeons of Columbia University and the National Cancer Institute to evaluate the effectiveness of Chinese medicine and improve the classification and selection/prescription of formulae.

In 2008 the Department of Health and Human Services (HHS) of the USA and the Ministry of Health (MOH) of China concluded a Memorandum of Understanding on Collaboration in Integrative and Traditional Chinese Medicine research. (Full text available online at http://tinyurl.com/5tm79l – accessed 31 August 2009.)

However, the process of integration has resulted in the loss of important aspects of traditional theory and practice. Fewer acupuncture points are taught than in the classic system, and aspects of the theory of TCM have been de-emphasised.

Hospitals practising TCM still treat 200 million outpatients and almost 3 million inpatients annually. Overall, 95% of general hospitals in China have traditional medicine departments, which treat about 20% of outpatients daily.

**Acupuncture**

Acupuncture is a technique involving the insertion of fine needles into the skin at selected points over the body. Practitioners of acupuncture generally follow one of two broad approaches to the discipline, using either TCM with all its many ramifications for maintaining health, or the simpler symptom-oriented western acupuncture. This section gives an outline of both.

Acupuncture is used widely in western Asia, Australia, Canada and parts of Europe (Figure 6.5).

**History**

The theory that surrounds the practice of traditional acupuncture probably dates back as many as 4000–5000 years, although there are no reliable references in Chinese literature before the first century BC. Ancient works were generally written on bamboo strips and silk, and have not survived. The earliest physician reputed to be proficient in acupuncture techniques was Bian Que in around 500 BC.

The names and reputed functions of all the acupuncture points were established by about AD 259 when *The Classic of Acupuncture (Zhen Jiu Jia*
Figure 6.5 Global utilisation of acupuncture. (Adapted from WHO Global Atlas of Traditional, Complementary and Alternative Medicine, Map Volume Kobe, Japan: WHO Centre for Health Development, 2005: 50.)
Jing) was published. Acupuncture flourished in China throughout the Ming period (1368–1644). Subsequently, it went into gradual decline until 1822, when it was finally banned by Emperor Dao Guang, who disapproved of its practices. In the early part of the twentieth century acupuncture became part of the ongoing debate as to whether Chinese culture should be overtaken by western influences or maintain its own traditions. With the arrival of western medicine, acupuncture was increasingly relegated to rural and remote backwaters.

In the 1950s the discipline was reintroduced by the communist authorities, who saw TCM as a solution to the problem of providing healthcare to an ever-growing population. Acupuncture developed once again as people were quickly trained and pressed into service. Today it is practised alongside western medicine.

News of the success of acupuncture was brought to the west in 1683 by Dr Willen Ten Rhijn, a physician working for the Dutch East Indies Company in Japan. Dr Rhijn’s report was not the first, but it was the most reliable. Usage of the English word ‘acupuncture’ is attributed to him.

Acupuncture was widely practised in France in the late eighteenth century with Dr Berlioz, a Parisian doctor, becoming the first western practitioner of acupuncture in the early nineteenth century. John Churchill, the first British acupuncturist, used the technique in the treatment of rheumatism in 1821. Acupuncture was even mentioned in the first edition of The Lancet in 1823 as being chiefly used in ‘diseases of the head and lower belly’.

When China opened up to visitors shortly after President Nixon went to the country in 1971, physicians and others from the west made visits to witness how acupuncture was being used. Indeed in 1972 one of the authors of this chapter (SK) visited Nanjing and saw a surgeon directing her own abdominal operation, and observed several other minor operations and the delivery of a baby; all the procedures were performed with the aid of acupuncture needles to control the pain.

Acupuncture is now among the best-known complementary therapies in the UK. In Scotland, a random survey found that an impressive 94% of respondents in a random survey knew something about acupuncture and 25% said that they would consider using it, although in practice only about 6% had actually done so. It would be interesting to know why there was such a large discrepancy between the two figures.

**Principles of acupuncture**

In addition to the classic principles of Chinese medicine outlined above, there is one key aspect of practice still to consider. This is the theory of acupuncture points that are stimulated usually by the superficial insertion of
needles into the skin. Other methods of stimulation include the application of pressure and the passing of a weak electrical current (see below).

A basic 365 mapped acupuncture points are situated along the meridians. A further 1000 extra points and special use points may also be identified on the hands, ears and scalp. It is not known how these points were discovered—probably it was by observation over hundreds if not thousands of years—nor is it known exactly how many points were first identified. Pain points can be located anywhere on the body where there is a pain locus. Figure 6.6 shows an acupuncture doll with acupoints on the head and neck marked.

Acupoints cannot be identified by their appearance and no consistent features of their anatomy have been found that distinguish them from other tissues. It has been suggested that the points may be sites of tenderness. The methodology for investigating the tenderness of acupuncture points has been explored. The study of the acupoint known as spleen 6 found that there was no strong evidence to support the hypothesis that acupuncture points were more tender than control points.

Practice of acupuncture

There is archaeological evidence that shows that the earliest acupuncture needles date back to the Stone Age, when instruments called bian were thought to have been used in China. By the Bronze Age acupuncture was already well developed and needles were made of bronze. Needles were subsequently made of many different metals: gold, silver, copper, etc. Modern acupuncturists use solid sterile disposable needles of narrow bore, about 3 cm long (although longer needles may be used at different sites). Recently two novel acupuncture techniques have been reported. In the first
Wang et al. described the use of a needle that looks rather like a scalpel for the treatment of myofascial pain. The second is a new form of sustained stimulation by a plastic tube; this is introduced subcutaneously by a needle and left in situ for 24 hours before removal.

The patient is usually treated lying down to minimise any tendency to faint. As many as 15–20 needles may be inserted superficially at the appropriate point(s). The practitioner then gently introduces the needles a little more deeply into the muscle, rotating them between finger and thumb. Qi and blood flow throughout the meridians and this is where manipulation of the needle is critical in properly moving this flow. The arrival of qi called deqi is signified by a dull ache or tingling sensation and slight inflammation. Some practitioners may use electrical stimulation, connecting the needles to a small piece of equipment powered by batteries. Needles are left in place for up to 20 min: the patient is invited to lie back and relax. Occasionally a needle may be left in place for several days, normally situated in the ear; these so-called indwelling needles should not be used in patients with heart valve disease or who are immunocompromised.

A single course of treatment usually comprises 10–12 sessions. Two or three courses may be required for the treatment of chronic conditions. Acupuncture point selection may vary at each treatment, depending on the patient's response. If significant improvement is achieved, the patient will be discharged at the end of the treatment but will normally be instructed to continue with other elements of TCM, e.g. dietary control and perhaps exercises.

**Evidence**

The reader is referred to the comments made in the section on TCM above. Evidence of effectiveness is largely restricted to case studies, although RCTs are available for western acupuncture (see below). The findings of many of these randomised trials have caused much debate. Positive trials have been criticised because of inadequate blinding, and negative trials because the intervention was not administered by properly trained practitioners or control interventions may have had analgesic effects.

Cautious approval of some applications of acupuncture was given by the US National Institutes of Health consensus development meeting in 1997. The 12-member panel was asked to evaluate current evidence for the efficacy of acupuncture and concluded that there is ‘clear evidence’ of efficacy in the control of nausea and vomiting occurring in some patients postoperatively and in association with chemotherapy, and for the relief of postoperative dental pain. The panel said that acupuncture was ‘probably’ also effective in the control of nausea in early pregnancy. The British Medical Association reached a similar conclusion in their report on acupuncture. A
number of correspondents to the *British Medical Journal* criticised this support, claiming that the evidence was not sufficient to reach a positive conclusion.\(^\text{36}\)

There are problems with designing trials for acupuncture associated with the control arm of an RCT.\(^\text{37}\) The most usual placebo method is sham acupuncture, when needles are inserted outside acupuncture points with minimum interaction between practitioner and patient.\(^\text{38}\) It is argued that this is an incorrect method because it leads to a study of the importance of the acupuncture point rather than of acupuncture itself.\(^\text{39}\) Furthermore, as stated above, there are doubts about whether acupuncture points and non-acupuncture points can be identified. Even if they can, there is evidence that acupuncture at non-classic points, the so-called trigger points, may have analgesic effects.

Kaptchuk et al. investigated whether a validated sham acupuncture device had a greater placebo effect than an inert pill in people with persistent upper extremity pain due to repetitive strain injury.\(^\text{40}\) During the placebo run-in, participants assigned to the acupuncture group received two treatments a week with a sham acupuncture device that looked exactly like a real acupuncture needle but had a blunt tip and retracted into a hollow shaft handle. When the needle was ‘inserted into the skin’ participants saw and felt the needle penetration. Both sham and genuine needles were held in place with a plastic ring and surgical tape so the procedure looked identical. After the run-in period, the acupuncturists followed identical protocols for administering real or continued sham acupuncture. Participants in the pill group were instructed to take one capsule each evening to minimise daytime drowsiness. The placebo capsule contained cornstarch, and the amitriptyline capsule contained cornstarch plus 25 mg amitriptyline. The primary outcome was self-reported intensity of pain in the most severely affected arm during the preceding week measured on a 10-point numerical rating scale ranging from no pain (1) to the most severe pain imaginable (10). The sham device had greater effects than the placebo pill on self-reported pain and severity of symptoms over the entire course of treatment, but not during the 2-week placebo run-in. It was concluded that placebo effects seem to depend on the behaviours embedded in medical rituals.

Notwithstanding the difficulties highlighted above, a number of RCTs have been conducted, providing results that, with a few notable exceptions, are not conclusive.\(^\text{41}\)

Various methods of assessing clinically meaningful change associated with a course of acupuncture treatment have been studied.\(^\text{42}\) The most effective was the Measure Your Own Outcome Profile (MYMOP), in which patients were initially invited to rank up to three symptoms for which they were most interested in seeking treatment with acupuncture. This helped the acupuncturists formulate a treatment plan for each patient. Subsequently
they were asked to rate how much their clinical condition had improved or worsened over a specified period of time.

The BMJ Group has taken over the publishing of *Acupuncture in Medicine*, a quarterly title medical journal on acupuncture from 2009. This will be the first complementary medicine title that the BMJ Group has published and aims to build the evidence base for acupuncture.

**Safety**

A study that investigated the incidence and severity of acupuncture reactions has been carried out in Japan. In 1441 treatment sessions involving 30 338 insertions in 391 patients, 9 episodes of failure to remove the needle were reported and classified as negligence rather than an adverse reaction. The most common systemic reactions were tiredness and drowsiness (11%), aggravation of symptoms (2.8%), irritation (1%), vertigo (0.8%) and fainting (0.8%). The most common local effects were bleeding (2.6%) and pain (0.7%). The authors concluded that there were some adverse reactions associated with acupuncture, but that they were generally transient and mild. However, serious complications have been reported.

There is some evidence from a lack of recent cases in the literature that the situation is improving, i.e. the incidence of adverse reactions is decreasing, particularly in the west.

As fainting and drowsiness are commonly reported, patients should be advised not to drive immediately after treatment if affected, and to exercise particular care if any prescribed or over-the-counter (OTC) medication is being taken that might enhance these effects. It has been suggested that a fall in blood sugar could be involved and this might be a problem for patients with diabetes using insulin or oral hyperglycaemic drugs. Advice from a pharmacist on the rescheduling of administration would be appropriate.

The adverse effects that may be attributed to acupuncture have also been catalogued. Examples of potential dangers identified in the reviews include infection during needling and trauma.

**Infection during needling**

**Hepatitis**

Re-using needles with inadequate sterilisation has been the source of hepatitis in a number of patients, although the literature refers mainly, but not exclusively, to the 1980s and earlier.

**HIV**

Human immunodeficiency virus (HIV) infection has been linked to acupuncture. In one case a patient became HIV positive after a 6-week
course of acupuncture. In another case two acquired immune deficiency syndrome (AIDS) patients were strongly suspected of contracting their condition as a result of acupuncture. It must be stressed that due to lack of information a direct causal link in this case could not be established. There may also be some risk to the acupuncturist from treating a patient who already has HIV.

Other infections

Other infections reported include those due to *Pseudomonas* spp. and *Staphylococcus aureus*. A recent report describes an outbreak of post-acupuncture cutaneous infection due to *Mycobacterium abscessus* in Seoul, South Korea. The report details a large outbreak of rapidly growing mycobacterial infection among patients who received acupuncture at a single clinic and concludes that physicians should suspect mycobacterial infections in patients with persistent cutaneous infections after acupuncture, and infection control education should be emphasised for acupuncture practitioners.

Since the adoption of disposable needles and avoidance of touching the needle shaft before insertion, the incidence of infection during needling is likely to fall even more. It is no longer considered appropriate to use autoclaves to sterilise acupuncture needles due to the validation problems associated with bench-top autoclaves. The British Acupuncture Council (BAcC) has a comprehensive code of safe practice that, among other things, gives direction on clean needle technique.

**Trauma**

A number of cases of damage due to acupuncture needling, including pneumothorax, cardiac tamponade and spinal cord damage, have been reviewed. Five fatalities have been reported, although the evidence that acupuncture was solely to blame is compelling in only one of these cases, involving a 40-year-old Norwegian woman whose heart was pierced by a needle. A case of spinal cord injury from a broken, small needle-knife (known as *Xiaozendaos* in Chinese) insertion into the spinal cord with delayed onset of neurological symptoms has also been reported.

Local traumatic damage to blood vessels may produce a haematoma.

**Other adverse effects**

Other possible adverse reactions to acupuncture include cardiac arrhythmias, the triggering of asthma and the exacerbation of symptoms. Allergic reactions caused by the metal of the needles, particularly chrome and
nickel, are possible.\textsuperscript{61-63} There is some evidence that it might be inappropriate to use electro-acupuncture on patients with pacemakers.\textsuperscript{64} Some concerns have been expressed about the safety issues involved with electrostimulation and the possibility of tissue damage.\textsuperscript{65}

Accidental burns from moxibustion procedures (see below)\textsuperscript{66} or excessively warm acupuncture needles\textsuperscript{67} have been reported. Clinical misjudgement may give some cause for concern.

A summary of some of the complications of acupuncture is set out in Table 6.3, which gives a simple summation of the cases of each episode computed from a literature search. The results cannot be used to make deductions of the frequency of such events.

\textit{Contraindications}

Acupuncture is contraindicated or must be used with extreme care in patients who:

- are unwilling to be needled; they should not be pressurised to undergo treatment
- have a tendency to bleed excessively
- have a pacemaker; it might be affected by the electrical stimulation of acupuncture needles.

\begin{table}[h]
\centering
\begin{tabular}{|l|l|}
\hline
\textbf{Event documented} & \textbf{Number of cases in the literature} \\
\hline
Drowsiness, fainting & 1429 \\
Increased pain & 1129 \\
Nausea, vomiting & 540 \\
Infections & 228 \\
Pneumothorax & 129 \\
Hepatitis & 127 \\
Psychiatric complications & 112 \\
Convulsions & 80 \\
Cardiac trauma & 7 \\
\hline
\end{tabular}
\caption{Complications of acupuncture}
\end{table}
Precautions

A number of precautions may be suggested when practising acupuncture:

- Patients should lie down during treatment.
- Disposable sterile needles should be used.
- Needles should be counted before and after treatment so that all may be accounted for.
- Patients should be carefully observed for excessive bleeding.

Western acupuncture

Some general practitioners (GPs) and physiotherapists with orthodox backgrounds find it difficult to accept the intangible nature of traditional acupuncture, which relates to the flow of *qi*. Many dispute the existence of meridians or acupuncture points, preferring to link their practice to trigger points instead. Trigger points are small areas in muscle that have been strained or injured and have not healed. They may remain sensitive for many years, causing pain that may be experienced some distance away from the trigger point. Interestingly, the trigger points and pain referral sites appear to be similar in all people and, furthermore, many of the trigger points are identical to acupuncture points.

It is suggested that acupuncture works by stimulating the nervous system, leading to the release of opioid peptides (endorphins), compounds that are closely involved with the mechanisms by which the body controls its perception of pain. Thus, acupuncture is used in the treatment of intractable pain without the attendant traditional Chinese theory. This variant, which involves very brief needling lasting no more than a few seconds at trigger points, has been termed ‘minimal acupuncture’. Exponents of minimal acupuncture commonly treat musculoskeletal pain, arthritis and symptoms of stress, including tension headaches, gastrointestinal problems and nausea.

Applications of acupuncture

Therapeutic areas in which acupuncture has been used include the following.

*Pain*

**Back pain**

Many systematic reviews for back pain include trials that use different techniques and control procedures. However, the balance of evidence appears to suggest that acupuncture can be useful in the treatment of back pain...
when compared with placebo.\(^{74,75}\) A pilot study for an RCT of acupuncture in low back pain concluded that the results were ‘promising’ and worthy of further research.\(^{76}\)

A study was conducted as part of a major acupuncture research initiative by health insurance companies in Germany: 2807 patients with chronic back pain who attended over 1000 study centres were randomised to receive either acupuncture or no acupuncture in addition to whatever conventional care they chose to have. After 3 months of treatment, patients who received the acupuncture showed significantly greater improvements in back function and quality-of-life scores.\(^{77}\)

A short course of traditional acupuncture for persistent non-specific low back pain in primary care has been shown to provide a modest health benefit for minor extra cost to the UK NHS compared with usual care.\(^{78}\) Acupuncture care for low back pain appeared to be cost-effective in the longer term.

**Dental pain**

Most of the studies included in a systematic review of 16 trials of dental pain suggested that acupuncture does have a greater effect than placebo.\(^{79}\)

**Headache and migraine**

Four hundred and one patients with chronic headache were recruited from general medical practices in England and Wales and were randomly assigned to receive either standard care or acupuncture (12 treatments over 3 months). At 12 months after the onset of treatment headache scores in the acupuncture group fell by 34\% (compared with 16\% in the control group), with 22 fewer days of headache per year. They took 15\% less medication, made 25\% fewer doctor visits and took 15\% fewer days off work. The greatest improvements were found in patients with migraine.\(^{80}\)

A study investigated the effectiveness of acupuncture compared with minimal acupuncture and no acupuncture in patients with tension-type headache.\(^{81}\) The end-point was the difference in numbers of days with headache between 4 weeks before randomisation and 9–12 weeks after randomisation, as recorded by participants in headache diaries. The acupuncture intervention investigated in this trial was more effective than no treatment, but not significantly more effective than minimal acupuncture for the treatment of tension-type headache.

Vickers et al. determined the effects of a policy of ‘use acupuncture’ on headache, health status, days off sick and use of resources in patients with chronic headache compared with a policy of ‘avoid acupuncture’.\(^{82}\) Headache score at 12 months, the primary end-point, was lower in the acupuncture group (16.2, standard deviation [SD] 13.7, \(n = 161\), 34\% reduction from baseline) than in controls (22.3, SD 17.0, \(n = 140\), 16\% reduction from baseline). It was concluded that acupuncture leads to
persistent, clinically relevant benefits for primary care patients with chronic headache, particularly migraine and that expansion of NHS acupuncture services should be considered.

**Knee pain**
Patellofemoral pain syndrome is the leading cause of chronic knee pain in young adults and may affect up to 15% of young men in the US military service. The results of a controlled trial, which included a total of 75 patients with patellofemoral pain, led the authors to conclude that acupuncture may be beneficial as a treatment for the condition. A systematic review of high-quality RCTs also suggested that acupuncture can reduce pain and disability in people with chronic knee pain. Despite this evidence the role of acupuncture in the management of chronic knee pain is still unclear.

**Neck pain**
There is some evidence that acupuncture may be effective when it is used for neck pain, although a systematic review of 14 RCTs of this application concluded that existing data were insufficient to make a firm judgement.

**Pelvic girdle pain**
A randomised, single-blind trial at a hospital, and at 27 maternity care centres in Gothenburg from 2000 to 2002, showed that acupuncture and stabilising exercises were both efficient complements to standard treatment for the management of pelvic girdle pain during pregnancy, with acupuncture being superior.

**Pain after surgery**
A randomised trial of auricular acupuncture given for pain relief after arthroscopic knee surgery performed under general anaesthesia found that acupuncture reduced the need for ibuprofen after surgery more than an invasive needle control procedure. Interestingly, most patients in both groups believed that they had received true acupuncture and wanted to repeat it in future.

**Drug dependence**
In a randomised, sham-controlled open trial with one active and two control arms the use of acupuncture in cocaine dependence was investigated. The primary outcome was cocaine use assessed by three times weekly urine analysis. A total of 52 patients completed the study. Patients who completed a course of auricular acupuncture appeared to be more likely to abstain from using cocaine than either of the other two control groups. Another study showed that acupuncture could be of use in cocaine abusers stabilised on buprenorphine as a substitute. To combat the severe drug problem, the Chinese government has adopted the methadone maintenance treatment
programme, a multi-faceted therapeutic approach that aims to reduce the health and social problems induced by drug epidemics. In addition, TCM, including acupuncture and herbal therapy, is found both to be effective in the prevention of relapse and to cause few side effects, making it useful for the treatment of opiate addiction.93

**Gastrointestinal disorders**

Acupuncture has a long history of use for gastrointestinal disorders, including dyspepsia, ulcers and inflammatory bowel disease.94

**HIV**

Preliminary data from small numbers of participants in a pilot study using acupuncture for symptomatic relief have shown trends towards improvement in symptoms and quality of life.95

**Insomnia**

A systematic review of auricular acupuncture treatment for insomnia found 6 trials involving a total of 402 patients that met the authors’ inclusion criteria.96 Auricular acupuncture appeared to be effective for treating insomnia. However, as the trials were adjudged to be of low quality, it was concluded that further work involving better design, longer duration of treatment and longer follow-up should be undertaken.

**Nausea and vomiting**

For nausea and vomiting the P6 acupoint on the inner wrist is usually used. In a review of 29 trials in the literature that referred to nausea and vomiting from all causes, 27 gave positive results.97

**Osteoarthritis**

In a review of acupuncture in osteoarthritis, 13 studies were identified, of which 7 reported a positive and 6 a negative result.98 However, most of the positive trials were not placebo controlled so no conclusions could be reliably drawn. In a trial involving 352 adults aged 50 or more with a clinical diagnosis of knee osteoarthritis the addition of acupuncture to a course of advice and exercise delivered by physiotherapists provided no additional improvement in pain scores (measured on the Western Ontario and McMaster Universities osteoarthritis index [WOMAC] subscale).99 This finding agreed with an earlier trial that compared acupuncture with sham acupuncture given in addition to exercise in people with knee osteoarthritis.100 Small benefits in pain intensity and unpleasantness were observed in both acupuncture groups, making it unlikely that this was due to acupuncture needling effects.

Vas et al. analysed the efficacy of acupuncture as a complementary therapy to the pharmacological treatment of osteoarthritis of the knee, with
respect to: pain relief, reduction of stiffness and increased physical function during treatment; modifications in the consumption of diclofenac during treatment; and changes in the patient’s quality of life. Acupuncture plus diclofenac was found to be more effective than placebo acupuncture plus diclofenac for the symptomatic treatment of osteoarthritis of the knee.

A systematic review by Minns Lowe and colleagues assessed the effects of physiotherapy exercise programmes given after total knee replacement surgery in people with osteoarthritis. The review found a small-to-moderate effect of functional exercise on joint motion and quality of life at 3–4 months after surgery, but the effect was not sustained at one year.

Pregnancy

Among women in labour and women at various stages of pregnancy, systematic reviews and randomised trials have shown acupuncture to be safe, although limited sample sizes preclude definitive conclusions.

One hundred healthy women with singleton pregnancies took part in an RCT. The researchers were most interested in the impact of acupuncture on the speed of delivery, the length of the active phase of labour, the need for induction and the need for augmentation of labour with intravenous oxytocin. This small and preliminary study suggests that acupuncture has detectable beneficial effects on labour among women with spontaneous rupture of membranes at term. But as there was no active control (such as sham acupuncture), it is hard to say whether the benefits were due to the acupuncture itself or to the 20 minutes of personal attention received during treatment.

About 90% of all assisted reproductive treatment cycles result in the transfer of at least one embryo, but only about 25% of all cycles end in implantation of the embryo and live birth. Some preliminary evidence suggests that acupuncture given with embryo transfer may increase the odds of clinical pregnancy compared with control groups, although there is other evidence to the contrary: Wang et al. carried out a trial to determine if acupuncture performed during the follicular phase and luteal phase, but not on the day of embryo transfer, could improve the outcome following in vitro fertilisation pre-embryo transfer (VF-ET) compared with controls. The pregnancy rate was not improved.

Shoulder injury

Trials investigating the effect of treating shoulder injuries with acupuncture have yielded encouraging results.
Smoking cessation
A Cochrane review for smoking cessation included 18 reports, with 20 trials, that compared acupuncture with various other interventions.\textsuperscript{114} Acupuncture did not show any advantage over sham acupuncture.

Stroke
Systematic reviews and one RCT would appear to indicate that there is some effect of acupuncture on the rate of recovery of stroke patients.\textsuperscript{115–117}

Temporomandibular joint dysfunction
A small systematic review of three RCTs of acupuncture for temporomandibular joint dysfunction suggested that the treatment provided some symptomatic relief comparable with that provided by orthodox measures.\textsuperscript{118} A caveat of ‘more rigorous investigation needed’ was expressed by the authors.

Weight loss
Contrary to popular opinion, there is no firm evidence that acupuncture is effective in promoting weight loss.

The effects of pressing ear points at ear meridian points on obesity-related parameters including body weight, body fat, body mass index and waist:hip circumference was studied in two groups of non-obese healthy and obese volunteers.\textsuperscript{119} The authors concluded that further studies were needed with larger sample sizes and RCTs with both healthy and obese volunteers.

Other conditions
Conditions for which acupuncture has been used but for which there is no robust evidence include glaucoma\textsuperscript{120} and Bell’s palsy.\textsuperscript{121}

It would appear that acupuncture can be shown to be effective in the treatment of various forms of pain, and nausea and vomiting. Evidence for other applications is sparse and the Scottish verdict of ‘not proven’ would seem to be the most appropriate in these circumstances.

Availability of acupuncture

\textit{UK NHS}

Medical opinion
A questionnaire was sent to a random sample of 650 UK GPs selected from the BMA database and representing 1.6\% of the country’s GP population.\textsuperscript{122}
A number of questions relating to the provision of complementary and alternative medicine were asked in the survey. The response rate was 56%. The most popular therapy arranged for patients was acupuncture (47% of respondents). In almost half these cases the service was provided within an orthodox setting such as the GP’s own surgery. Pain relief and musculoskeletal disorders were the most frequently cited conditions treated; other applications included smoking cessation, stress and morning sickness.

When asked whom they thought should provide acupuncture, the GPs replied strongly in favour of registered medical practitioners, followed by physiotherapists and dentists. Less than half the respondents thought that TCM practitioners should be involved.

Reasons for not offering acupuncture were lack of demand (63%), lack of knowledge of the services available (63%) and lack of guidelines on how to assess the competence of practitioners.

The percentage of physicians who practise acupuncture in the UK has varied widely over the last 20 years, with estimates of 1% in Scotland\(^{123}\) from 3%\(^{124}\) to 21%\(^{125}\) in England, and from 4%\(^{126}\) to 5%\(^{127}\) in the country as a whole. This compares with the USA (1%)\(^{128}\) and New Zealand (Wellington 18%\(^{129}\) and Auckland 21%\(^{130}\)). In Australia the use of acupuncture by doctors has increased greatly since the 1984 introduction of a Medicare rebate for acupuncture. In 1996, 15.1% of Australian doctors claimed for acupuncture, with almost one million insurance claims being made.\(^{131}\)

In the UK the practice of acupuncture is not legally restricted to medically qualified doctors as it is in many other European countries (e.g. France, Hungary, Italy, Poland and Portugal), so the market may be partially satisfied by professional or non-medically qualified practitioners (NMQPs). There are more than 5500 acupuncturists in the UK, of whom 3500 are statutorily registered health professionals.

There are 3000 traditional acupuncturists in British Acupuncture Council, 5000 physiotherapists, 2500 GPs and about 3000 in other associations.

Cost-effectiveness studies of acupuncture
Cost-effectiveness studies of acupuncture have been mainly restricted to the treatment of pain. Wonderling et al. evaluated the cost-effectiveness of acupuncture in the management of chronic headache.\(^{132}\) The main outcome measure was incremental cost per quality-adjusted life-year (QALY) gained. Total costs during the 1-year period of the study were on average higher for the acupuncture group £403 (€460, US$663) than for controls £217 (€248, US$357) because of the acupuncture practitioners’ costs. The mean health gain from acupuncture during the 1-year trial was 0.021 QALYs, leading to a base case estimate of £9180 (€10,500, US$15,240) per QALY gained. This
result was robust to sensitivity analysis. Cost per QALY dropped substantially when the analysis incorporated probable QALY differences for the years after the trial. It was concluded that acupuncture for chronic headache improves health-related quality of life at a small additional cost; it is relatively cost-effective compared with a number of other interventions provided by the NHS.

Canter et al. systematically searched seven electronic databases, and included all prospective controlled studies carried out in the UK before April 2005, for rigorous cost-effectiveness studies of complementary treatments. Five studies, all randomised, met the criteria set and were included, one of acupuncture for chronic headache and four of spinal manipulation for different types of spinal pain. The provision of the treatments represents an additional healthcare cost in four out of the five studies considered. Estimates of cost per QALY from three studies compared favourably with other treatments approved for use in the NHS, but for spinal manipulation the health benefits were small to moderate and of questionable clinical significance. The authors acknowledged that estimates of cost-effectiveness may be less favourable in situations for which the complementary treatment is offered routinely rather than in the novel situation of a clinical trial.

Ratcliffe et al. have assessed the cost-effectiveness of acupuncture in the management of persistent non-specific low back pain. Lower back pain is a common ailment that places a considerable burden on society in terms of reduced quality of life and lost productivity. The study was based on a well-conducted pragmatic RCT, which found weak evidence of an effect of acupuncture on persistent non-specific low back pain at 12 months, but stronger evidence of a small benefit at 24 months.

**Availability of acupuncture in the USA**

Acupuncture has been increasingly embraced by practitioners and patients in the USA since the appearance of an article describing successful post-appendectomy pain management using acupuncture needles. California became the first state to license acupuncture as an independent healthcare profession in 1976. Since then, 40 states and the District of Columbia have adopted similar laws. Most states (27) allow herbal medicine within the scope of acupuncture practice; only a few states (10) require the supervision of a physician for the almost 11 000 practising non-physician acupuncturists. The number of acupuncturists is rapidly growing and is projected to quadruple by 2015. A National Health Interview Survey carried out in the USA revealed that 4.1% of the respondents reported lifetime use of acupuncture and 1.1% reported recent use. This utilisation of acupuncture was somewhat lower than expected given its significant national and international recognition and its visibility in the media, This may in part be a function of provider availability.
Variants of acupuncture

Acupressure
Acupressure is a form of acupuncture in which fingers, thumbs and elbows are used to stimulate the body’s acupuncture points. Acupressure relieves muscular tension, facilitating blood flow and therefore distributing more nutrients and oxygen throughout the body, as well as removing waste products. This helps to promote both physical calmness and mental alertness. The technique involves repeatedly pressing the acupuncture points for 3–5 seconds and then releasing the pressure. It is believed that the practitioner’s qi helps to strengthen the weakened qi of the patient. Thus it is important that the practitioner maintains a healthy body so that his or her qi is stronger than that of the recipient. As a result of these qi differentials, self-acupressure is not considered to be as effective as having a practitioner do it for you.

Acupressure has been used to relieve mental tension, for tired and strained eyes, headaches, menstrual cramps and arthritis, as well as to promote general healthcare. A trial to minimise motion sickness by intermittent pressure on the wrist point P6 with wrist bands found no reduction in symptoms. However, in a later study regular pressure was applied and, under these circumstances, a clear positive outcome resulted. Acupressure in sickness during pregnancy may also be helpful, although the use of the P6 point with wristbands as outlined above has not been successful in this context. A study to evaluate the effectiveness of acupressure in terms of disability, pain scores and functional status found that it was effective in reducing low back pain and that benefit was sustained for 6 months.

Acupressure should not be applied to an open wound, or to a place where there is inflammation or swelling. Areas of scar tissue, boils, blisters, rashes and varicose veins should also be avoided. Certain pressure points should be avoided during pregnancy and in patients with hyper- or hypotension.

Shiatsu
This is a deeply relaxing therapy originating in Japan that provides stimulation by using the fingers and palm of the hand to apply pressure and gentle stretches to the meridians. It consists of a whole body treatment, as it is believed that a disorder in one area can have effects elsewhere on the body. There are two main Shiatsu schools – one based on western anatomical and physiological theory and the other based on TCM (see Chapter 8).

Moxibustion
The tradition of moxibustion was originally developed in Mongolia and later incorporated into TCM and Tibetan medicine. It is similar to both
acupuncture and acupressure in its effects but uses a glowing wick instead of needles or fingertips as the source of stimulation for the acupoints. Traditionally moxa is the dried leaves of *Artemisia vulgaris* and *Artemesia argyi* and other species of mugwort, made into various forms including:

- punk – loose moxa, rather like green cotton-wool
- moxa rolls – similar to cigars in appearance
- moxa cones.

When lit, the moxa smoulders slowly. The glowing moxa rolls are held about 2 cm from the acupoint. Another method is for a small moxa cone to be placed on the blunt end of an acupuncture needle while it is in place. It is lit, transmitting the heat down the needle into the acupuncture point. A cone may also be placed directly on the skin over a slice of ginger. It is lit at its apex and burnt down until the patient is able to feel the heat; it is then removed. Cauterising moxibustion involves the burning of loose punk directly on the skin until blisters form; however, this technique is unlikely to be used in the UK.

Moxibustion tones, stimulates and supplements energy in the meridians. It is claimed to be an effective treatment for arthritis and menstrual problems.

**Chinese herbal medicine**

In the west it is quite normal to equate the word ‘herbal’ with something that grows in the garden. Certainly most Chinese herbal remedies are made from plant material, but others are of mineral or animal origin, e.g. gypsum (*shi gao*) is a cooling mineral ‘herb’ commonly used to treat conditions characterised by much heat. Oyster shells (*mu li*) may be used for hypertension. The use of animal parts is a controversial issue in western communities and it is currently illegal in the UK to use anything other than plant material in herbal decoctions. In China and other Asian countries the practice is still widespread, but it has been largely discontinued elsewhere after action by regulatory authorities with enthusiasm that may occasionally be misplaced. The famous highly aromatic salve marketed around the world known as Tiger Balm was once the subject of a dawn raid of Chinese herbalists by police in Manchester. They thought that they had uncovered the illegal use of parts from a protected wild animal. There were a few red faces when it was realised that the title merely referred to the nickname of the brand owner!

**History**

China’s greatest materia medica (*Pen Ts’ao*) was published by Li Shizhen in 1578.148 The culmination of 26 years’ work, it comprises 1892 species of
drugs of animal, vegetable and mineral origin, and includes no fewer than 8160 prescriptions.

Secret recipes (also known as ‘prepared medicines’) were the equivalent of modern patent medicines. They were first produced during the Song dynasty (AD960–1234) and were dispensed by government agencies such as the Imperial Benevolence Pharmacy. A variety of dose forms were available including pills, liquids and honey boluses. By the time of the Ming dynasty (1368–1644) more than 60 000 formulae had been recorded in the 1406 book entitled *Formulas of Universal Benefit* (*Pu Ji Fang*). In recent years many of these formulae have passed into public usage, but there may be as many as 5000 licensed patent medicines still circulating in China. The most famous factory is at the Tong Ren Tang pharmacy in Beijing, which has been operated by the same family since the late seventeenth century.

**Availability of CHM**

In the UK, Chinese herbalism is the most prevalent of the ancient herbal traditions currently being practised. About 500 different herbal materials are imported into the UK and are worth several million pounds each year. In addition an unquantified amount of material enters the country illegally by suitcase smuggling. There is ongoing concern about the lack of controls. In the USA legislation now allows the import of Chinese herbal materials, because the Food and Drug Administration (FDA) has lifted earlier restrictions that limited imports to ethnic groups. This has prompted the wider availability of prepared medicines.

There are now over 3000 clinics in the UK that prescribe Chinese herbal remedies for various disorders and the use of these remedies seems set to increase further, given the apparent success being reported, despite a lack of firm evidence of effectiveness in many cases. In the USA a survey of 575 users of CHM also showed an extremely high level of satisfaction.

**Practice of CHM**

Herbs are given to achieve eight general outcomes in TCM. These are:

- cooling
- diaphoresis
- elimination
- emesis
- mediation
- purging
- tonification
- warming.
Categorisation of Chinese herbs

Chinese herbs may be categorised according to:

- the four natures
- the five tastes
- the meridians.

The four natures

Similar to other TCM disciplines, CHM is based on the concepts of yin and yang and of qi energy. The herbs are ascribed qualities ranging from cold (extreme yin), cool, neutral to warm and hot (extreme yang), and are often used in combination according to the deficiencies or excesses of these qualities in the patient.

The five tastes

The five tastes are:

- Pungent: pungent herbs are often used to generate sweat and to direct and vitalise qi and the blood
- Sweet: sweet-tasting herbs are often used to tonify or harmonise bodily systems
- Sour: sour tasting herbs are most often used as astringents
- Bitter: bitter tasting herbs are used to dispel heat and purge the bowels
- Salty: salty tasting herbs are used to soften hard masses as well as purge and open the bowels.

The meridians

The meridians refer to which organs the herb acts upon, e.g. menthol is pungent, cool and linked to the lungs and the liver.

Formulation of Chinese herbal medicines

The unique characteristic of CHM is the degree to which it is formulated. In other forms of herbal medicine, especially western herbal medicine, herbs are often delivered singly or combined into very small formulae of herbs with the same function. In contrast, Chinese herbalists rarely prescribe a single herb to treat a condition. They create formulae instead. A formula usually contains from 4 to 20 herbs. They may also be combined with animal or mineral materials.

Examples of herbs from vegetable and animal origin are shown in Figure 6.7.
Medicinal substances are combined to:

- increase therapeutic effectiveness by synergy
- reduce toxicity or adverse reactions
- accommodate complex clinical situations
- alter the actions of the substances.

A typical Chinese herbal formula usually comprises the following components:\(^\text{154}\)

- The main ingredient, which treats the main disease
- The associate ingredient, which assists the main ingredient
- The adjuvant, which acts as an enhancer of the main ingredient, and moderates or eliminates the toxicity of other ingredients; it may also have an opposite effect to the main ingredient to produce supplementary benefits
- The guide ingredient (or envoy), which focuses the actions of the formula on certain meridians or areas of the body, or harmonises and integrates the actions of the other ingredients.
Presentation

When herbs are prescribed for individual patients the practitioner weighs out a day’s dosage of each herb and combines them in a bag. The patient is given a bag for each day that the herbal formula will be taken. The herbs are then boiled in water by the patient at home. The boiling process takes from 30 minutes to 60 minutes, and portions of the resulting decoction are consumed several times during the day.

A Chinese herbal dispensary and dispensing area are shown in Figures 6.8 and 6.9.

Another modern way of delivering herbs is through granulated herbs, which are highly concentrated powdered extracts. These powders are made by first preparing the herbs as a traditional decoction, after which the decoction is dehydrated to leave a powder residue. Practitioners can mix these powders together for each patient into a custom formula. The powder is then placed in hot water to recreate the decoction, which eliminates the need to prepare the herbs at home, but still retains much of the original decoction’s potency.

Example of a prescription

An example of the ingredients for a dried herb prescription is shown in Figure 6.10.
Chinese patent medicines

Pre-made formulae are available as pills, tablets, capsules, powders, alcohol extracts, water extracts, etc. Most of these formulae are very convenient because they do not necessitate patient preparation and are easy to take. These products are usually not as potent as the traditional extemporaneous
preparation of decoction described above. They are not ‘patented’ in the western sense of the word because there are no exclusive rights to the formula. Instead, ‘patent’ implies standardisation of the formula. All Chinese patent medicines of the same name have the same proportions of ingredients.

A medicine known as ‘four gentleman decoction’ (si jun zi tang) is an example of such a product. It is used for fatigue, reduced appetite, loose stools, pale tongue and weak pulse, which occur because of the deficiency of spleen and stomach qi and dampness in the digestive system. The formula comprises:

- Main herb: Radix panax ginseng (ren shen), to enhance spleen qi
- Associate: Rhizoma atractylodis macrocephalae (bai zhu), to strengthen the spleen and dry off the ‘dampness’
- Adjuvant: Sclerotium poriae cocos (fu ling), to assist the main and associate herbs
- Guide: Radix glycyrrhiza uralensis (zhi gan cao), to harmonise the other three herbs and regulate spleen qi.

The use of this formula is an example of tonification.

Regulatory affairs

Licensing of CHMs in China

Remedies used in TCM are subject to rigorous licensing procedures. The pharmacological, toxicological and clinical studies required by the regulatory authorities depend on the class of TCM product being licensed. Nine classes of medicines are recognised

- Single compound isolated from natural material(s)
- Newly discovered medicinal plants
- Medicines containing a substitute for a TCM raw material
- Medicines made from a medicinal plant part different to (and combined with) a plant part traditionally – used in TCM raw material
- Medicines containing effective fraction(s) isolated from natural material(s)
- A multi-ingredient TCM preparation
- Medicines involving a change in the route of administration
- Medicines involving a change in dose form
- Generic drug.

Under the Drug Administration Act 2001 post-marketing surveillance of adverse drug reactions is mandatory in China. Whenever an adverse reaction event occurs, the manufacturer, the medical institutions and the seller are obliged to report it.
Some examples of licensed Chinese herbal medicines are shown in Figure 6.11.

**Licensing of CHMs in Europe**

Most herbal medicines on the UK market are sold and supplied as unlicensed herbal remedies under the provisions of the 1968 Medicines Act (http://tinyurl.com/3yhq9p). The main legislation requires that medicines placed on the market must have a licence, which requires meeting standards of safety, quality and efficacy. These licensing conditions pose inappropriate demands on most herbal medicines, because plants are chemically complex and variable, active constituents are not always known and the huge costs cannot be recouped through patenting. Hence, there are very few licensed herbal medicines on the UK market.

Under the 1968 Act, herbal remedies are exempt from the licensing requirement if either the herbal remedy is made up on the premises from which it is supplied, after a one-to-one consultation (Section 6.1 of the Act), or it is an over-the-counter (pre-prepared) remedy, in which case no therapeutic claims can be made for it (Section 6.2 of the Act). These exemptions only apply to plant remedies, so medicines containing non-plant ingredients require a medicine licence.

In recent years these provisions, which provide no specific regulation for herbal medicines, have been considered inadequate to ensure their safety and quality. There are a number of reasons including: adverse effects from some herbal ingredients (natural does not mean safe); misidentification of some
herbs and occasional substitution of toxic for safe species; illegal inclusion of prescription-only drugs or heavy metals in some 'herbal' medicines; microbial contamination; and discovery of problematic herb–drug interactions. However, this situation is about to change.

For these various reasons a reform of the 1968 herbal provisions was undertaken. The UK law relating to the sale and supply of over-the-counter herbal remedies (Section 6.2 of the Act) has now been replaced by the European Directive on Traditional Herbal Medicinal Products of the European Parliament (2004/24/EC) and of the Council of 31 March 2004 amendment (available at http://tinyurl.com/2w9nfw). This establishes a registration scheme for industrially produced over-the-counter herbal medicines, under which manufacturers have to demonstrate safety and quality, but not efficacy. Quality is guided by European good manufacturing practice, and safety is protected by requiring evidence of at least 30 years of safe use, of which at least 15 years must be within the European Community. There is a lead-in time to allow manufacturers and suppliers to make the necessary adjustments, but after 2011 any over-the-counter herbal product that is not registered under this scheme will be illegal. This lead time is, however, only for products that were on the market before April 2004. All new herbal medicinal products must have a traditional use registration before being placed on the UK market. Further advice on the Traditional Herbal Medicines Registration Scheme is available at the UK Medicines and Healthcare products Regulatory Agency (MHRA) site at http://tinyurl.com/2ls8wm. By 3rd September 2009 a total of 88 THMR applications had been received by the MHRA of which 45 had been granted.

The European Directive leaves intact the UK exemption for herbal remedies made up by practitioners after a personal consultation, i.e. the exemption created by Section 6.1 of the 1968 Act. Such medicines will not have to be licensed and, because they are not industrially produced, will not have to be registered under the European Directive. There are, however, concerns about the quality and safety of herbal medicines supplied by this route. This is the context of the proposals for reform of Section 6.1 of the 1968 Act, published as a consultation document by the MHRA in March 2004, known as MLX 299 (available at http://tinyurl.com/3ctap2).

The issue is how to strengthen the public's protection while preserving their access to herbal medicines. This consultation document looked at a number of possible changes, including those discussed below:

- The statutory regulation (SR) of the herbal medicine profession provides the main mechanism, in a number of ways. First, members of the statutory register can be tied, through a codes of practice, to suppliers that have been audited and demonstrated satisfactory standards of quality assurance. The Register of Chinese Herbal
Medicine has provided a good model for such an arrangement through its Approved Suppliers scheme. Under SR an arrangement of this kind can be extended to all registered practitioners. As it will be illegal to practise under the title of herbalist or Chinese medicine practitioner without membership of the register, the public will have stronger assurance about the quality of Section 6.1 products than at present. Second, some more potent items in the materia medica can be restricted to use by registered practitioners. Third, SR provides a possible route for preserving access to so-called patent medicines (see below).

- At present practitioners have access to a wide range of Chinese medicine ‘patents’. These are unlicensed medicines that would be considered industrially produced and thus, once the European directive is in force, would have to be registered under that scheme in order to remain legal. However, it seems likely that most of these patents would be considered unsuitable for registration under the European directive, because even if they met the tough quality assurance standards, most would not be suitable for over-the-counter use. On the other hand, they are industrially produced, so they could not be supplied under the normal Section 6.1 conditions. One way in which access might be preserved is through the so-called ‘Specials’ regimen, a provision in European medicines law that allows authorised health professionals to commission a third party (who would have to possess a manufacturer’s license) to make up medicines according to a particular specification. As registered herbalists would be authorised health professionals, it would in principle be possible for herbalists to commission a range of products for the exclusive use of practitioners on the statutory register. This possibility was put forward by the MHRA.

- For acupuncturists to be able to commission specials they would also need to be designated ‘authorised healthcare professionals’ and able to demonstrate that they operate on a comparable level to herbalists in terms of the public’s protection. Under the new specials regimen, it is the practitioner who would be responsible for the formulation of any herbal patent medicine. Suppliers would not be able to advertise their products but would be able to advertise that they are able to provide a service.

- The current licensing exemptions apply only to plant remedies. The 1968 legislation was brought in when very little non-European herbal medicine was practised in the UK, and the question of non-plant ingredients did not arise. However, the use of CHM, in which mineral and animal ingredients play an important role, has grown rapidly in the UK since then. Although there have been no prosecutions to date arising specifically from the use of non-plant ingredients – hence the
law has never been tested in the courts – the wider concerns about the lack of regulation of herbal medicines have put this issue in the spotlight and it is clearly desirable to put this part of the materia medica onto a secure legal footing. The herbal community is therefore pressing for an extension of the licensing exemptions to non-plant medicines.

Licensing of TCMs in Australia
Chinese herbal products in Australia are regulated by the Therapeutic Goods Administration (TGA) and need to meet quality and safety standards.

Evidence
There is research that has demonstrated the usefulness of CHM in many disorders and supports its provision in state hospitals throughout China, alongside conventional medicine. It is suggested that, although the research is of variable quality, it should not be ignored. Some promising trials have been carried out in the west. Standardised oral herbal preparations that are monitored in a conventional western manner have been shown to be beneficial in eczema. CHM may also be effective in the treatment of primary dysmenorrhoea.

Other applications that have been studied include atopic dermatitis and the treatment of side effects associated with chemotherapy treatment.

Atopic dermatitis
A twice-daily concoction of an ancestral formula containing five herbs (CHM) was assessed as a treatment for atopic dermatitis (AD). After a 2-week run-in period, children with long-standing, moderate-to-severe AD were randomised to receive a 12-week treatment with twice-daily dosing of three capsules of either traditional CHM or placebo. The SCORing of Atopic Dermatitis (SCORAD) score, Children’s Dermatology Life Quality Index (CDLQI), allergic rhinitis score, and requirement for topical corticosteroid and oral antihistamine were assessed before and at weeks 4, 8, 12 and 16 after treatment. Adverse events, tolerability, and haematological and biochemical parameters were monitored during the study. The CHM concoction was found to be efficacious in improving quality of life and reducing topical corticosteroid use in children with moderate-to-severe AD. The formulation was palatable and well tolerated.

Treatment of side effects associated with chemotherapy treatment
Short-term side effects of chemotherapy include fatigue, nausea, vomiting, mucositis, and myelosuppression or neutropenia. These occur during the course of treatment and generally resolve within months of completion of
chemotherapy. A variety of Chinese medicinal herbs has been used for managing these side effects. A review by Zhang et al. has provided limited evidence concerning the effectiveness of Chinese herbs in alleviating chemotherapy-induced short-term side effects.162

Wei et al. assessed the efficacy and possible adverse effects of the addition of two Chinese medicinal herbs to treatment with radiotherapy or chemotherapy for oesophageal cancer.163 Only two studies of limited quality were included in their review and the results were inconclusive. CHM has been shown to have a significant impact on control of nausea experienced by patients with early stage breast or colon cancer who required postoperative adjuvant chemotherapy.164

Safety

Competence of practitioners

The use of CHM is increasing in the UK and fewer patients are now Chinese. This has led to problems, because most of those who seek treatment are unable to distinguish between adequately and inadequately trained practitioners.

Practitioners fall into three broad categories:

- Those who have had a full training in the discipline. This may be practitioners who have trained in China, normally for 5 years, or have graduated from a UK college or university, once again after a 4- or 5-year training to BSc or MSc level.
- Those who have received limited training in the UK or China.
- Those who have no training.

There are no data on exactly how many practitioners now offer Chinese herbal treatment in the UK, and only some of them will belong to a professional body. The main body is the Register of Chinese Herbal Medicine (RCHM), which maintains minimum standards of training and practice. Another organisation, the Association of Traditional Chinese Medicine (ATCM), also exists to represent mainly ethnic Chinese practitioners of both acupuncture and CHM. The RCHM and ATCM work in close collaboration in many areas and hold regular joint seminars and continuous professional development days in order to promote increased integration between the two groups.

Fully trained practitioners have training similar to that given to orthodox doctors in the west. They receive some training in western medicine and can distinguish those conditions that would be best treated by western medicine.
Intrinsic toxicity of herbs

Some CHMs have already caused serious health problems in the UK and other developed countries and, despite initiatives from both the MHRA and some representatives from the Chinese herbal medicine sector, problems with the quality of CHMs continue to arise.166

Large amounts of traditional medicines are imported into the UK, legally and illegally, and use of such medicines is frequently not admitted on occasions when serious illness forces patients to consult western medical practitioners. These medicines carry with them a risk of adverse reactions; the risk needs to be quantified and as far as possible minimised. A correspondent to the *Pharmaceutical Journal* has expressed concern that the availability of traditional CHMs in the western world will, at some time in the future, pose serious problems.167

A warning that there can be no guarantee of the safety or quality of traditional CHMs was issued by the MHRA in 2004 (http://tinyurl.com/2olbvg), following a similar warning 3 years before. The warning was circulated again in the light of clear evidence that problems with traditional CHMs containing toxic, and often illegal, ingredients persist, with the ingredients not always being declared on labels.

The MHRA said:

> There is no reliable way for the public to identify those CHMs which could be unsafe. In the light of this evidence we are unable to give the public any general assurances as to the safety of CHMs on the UK market. When buying TCMs people should always be aware of the possibility of low quality or illegal products. They should not take them if they are not labelled and [do not] include a list of ingredients in English. Even then, clear labelling is not in itself a guarantee of good quality standards.

Other general and specific safety warnings associated with the use of CHMs may be found at http://tinyurl.com/2p6rp4.

The herbs prescribed by practitioners of TCM in the UK are generally purchased from wholesale companies that specialise in this trade. These companies import herbs from the People's Republic of China either directly or through dealers in Hong Kong. The quality of imported herbs varies considerably, and great skill is needed to ensure that the correct herbs are provided to the practitioner. Some substitution of herbs is acceptable in China but can lead to problems if the wholesaler or practitioner is unaware of the substitution (see below). Confusion may arise over the precise identity of the herb being ordered; no standardised nomenclature exists for herbs. Fortunately, the best wholesalers and
properly trained practitioners are able to make fairly reliable checks, at least visually. Unrecognised contamination by other herbs, drugs and various chemicals (including heavy metals or insecticides) is another possible hazard.

In an effort to improve the provenance of Chinese medicinal herbs a field cultivation project has been set up in Germany.\textsuperscript{167} Herbs are grown under controlled and documented conditions, improving drug safety and material quality.

CHM has frequently been used as an alternative to orthodox therapies, especially where the latter have been considered to be ineffectual or have unacceptable side effects. One of the most popular uses of CHM in the UK is in the treatment of atopic eczema, particularly in cases resistant to orthodox therapy. As the herbal medicines are of natural origin, they are often perceived as being totally safe by consumers, but unfortunately many TCM remedies are potentially toxic when used in large doses and/or over extended time periods. Some examples of potentially toxic herbs are given in the following sections.\textsuperscript{168}

\textbf{Examples of toxic herbs}

It is estimated that there are 7000 species of medicinal plants in China and, of the 150 species most frequently used, 10 are toxic.\textsuperscript{165} In Hong Kong most cases of serious poisoning are related to the use of the roots of \textit{cao wu} (\textit{Aconitum kusnezoffii}), \textit{fu zi} and \textit{chuan wu} (\textit{Aconitum carmichaeli}). These herbs contain variable amounts of highly toxic alkaloids, including aconitine, which activates sodium channels and causes widespread excitation of cellular membranes. Several other herbal preparations containing aconitine alkaloids, e.g. monkshood (\textit{Aconitum} spp.), are commonly used in Chinese medicine to treat arthritic, rheumatic and musculoskeletal pain. The alkaloids have analgesic, antipyretic and local anaesthetic properties but they are potentially toxic. The toxic effects include severe cardiac arrhythmias, nausea, vomiting and general debility. Unfortunately there is only a small margin between therapeutic and toxic doses. Aconite species are currently classified as a prescription-only medicine (POM) in the UK for internal use, although they are allowed for use externally by herbalists.

Anticholinergic poisoning due to the flowers of \textit{yang jin hua} (\textit{Datura metel} L.) and \textit{nao yang hua} (\textit{Flos rhododendri mollis}) has been reported. These herbs, which are used to treat asthma, bronchitis and toothache, may contain hyoscine, hyoscyamine and atropine, and can cause flushed skin, dilated pupils, confusion and coma.

\textit{Ba jiao lian} (\textit{Dysosma pleianthum} [syn. \textit{Podophyllum pleianthum}]) is a species of the May apple that is used for the treatment of weakness and snake bites. The resin is extracted from the plant rhizome and is thought to
contain a toxin that can cause nausea, vomiting, diarrhoea and abdominal pain.\textsuperscript{170}

There are two species of senecio plants: \textit{Senecio scandens} (grown in China) and \textit{Senecio vulgaris} (grown in Europe). \textit{Senecio scandens}, used in TCM, contains eight times less pyrrolizidine alkaloids than \textit{Senecio vulgaris} and has little toxicity to the liver, whereas \textit{Senecio vulgaris} exhibits significant toxicity.

Hepatotoxicity is a feature of various Chinese herbal preparations. Between November 2003 and June 2004 four patients developed severe acute liver injury within 2 months of starting to take a slimming aid (\textit{Shubao}), widely available in the West Midlands of England.\textsuperscript{171} Three patients fully recovered on discontinuing the agent; one patient progressed to fulminant hepatic failure, requiring liver transplantation. Laboratory analysis showed adulteration with \textit{N}-nitrosofenfluramine, a recognised hepatotoxin. Warnings about taking slimming products have been issued by the MHRA (see below).

\textbf{Administration during pregnancy}

A number of herbs, e.g. pennyroyal (\textit{Mentha pulegium}, \textit{Hedeoma pulegoides}) and valerian (\textit{Valerian wallichii}) have abortifacient properties and should be avoided during pregnancy.\textsuperscript{172} Their action is thought to be due to the presence of volatile oils, which can induce uterine contractions.

\textbf{Administration to children}

Infants are at greater risk of possible poisoning from CHM than adults because of their inadequate biotransformation processes. Chinese infants are frequently given \textit{huang lian} (\textit{Coptis chinensis}) by their mothers to clear up ‘products of pregnancy’.\textsuperscript{173} The main alkaloid of this herb is berberine and it can displace bilirubin from its serum-binding proteins, causing a rise in free bilirubin concentration and a risk of brain damage. \textit{Yin-chen hao} (\textit{Artemisia scoparia}) is used for the treatment of neonatal jaundice and has a similar effect although it does not contain berberine.

\textbf{Concurrent use with orthodox medicines}

There are two problems here: an enhanced activity from the herbal medicine or the orthodox medicine, or both, and an intrinsic toxicity, real or threatened, from the allopathic ingredient.

\textit{Aristolochia} is an example of a herb that not only is toxic in its own right but also its administration concurrently with allopathic drugs in Chinese herbal preparations (albeit inadvertently) may potentiate its action, causing severe adverse reactions (see below).
There are several examples of the inclusion of illegal ingredients in Chinese medicines over many years and pharmacists should be aware of this possibility. In 1975, a herbal-based preparation called Toukuwan was manufactured in Hong Kong and widely promoted in the USA for rheumatism and arthritis. It was discovered that the product contained four orthodox medicines, including the prescription drug diazepam, and its continued import was swiftly banned by the FDA. More recently, the New Zealand Director General of Health advised consumers against taking a Chinese product known as *cheng kum* because it contained a pharmacy-only antihistamine that could cause drowsiness. The capsules have now been withdrawn from sale. They were advertised for use in the treatment of various conditions, including the promotion of joint mobility, healthy skin, as a support during menopause and of benefit while consuming alcoholic drinks. The Ministry of Health made the ruling following complaints from doctors about the product.

Another example is the intentional inclusion of steroids in oral and topical preparations used for the treatment of dermatological conditions. Following reports of positive clinical effects in the treatment of eczema, 11 Chinese herbal creams were analysed. Eight were found to contain dexamethasone in varying amounts. The mean value approximated to a proprietary brand of 0.05% betamethasone valerate, a commonly prescribed steroid ointment in the UK. None of the patients was aware that the creams contained a steroid. The authors concluded that the risk of adverse reactions with such potent steroids is increased by their inappropriate use and application to areas of thin skin and on the face.

It has been suggested that exported herbal remedies have been adulterated with synthetic drugs to improve their activity, and their popularity, in western countries. A dangerous evolution in the formulation of a Chinese herbal arthritis cure, *Chuifong Toukuwan*, manufactured by a laboratory in Hong Kong, has been described. The undeclared presence of phenylbutazone, indomethacin, hydrochlorothiazide, chlordiazepoxide, diazepam and corticosteroids was reported in the product, a mixture of 23 herbs.

Dangerously high levels of undeclared pharmaceuticals have been discovered in a supposed ‘herbal Viagra’ being sold in many TCM stores in the UK. The product ‘*Jia Yi Jian*’ was seized by the MHRA in 2009 and claimed to contain only herbal ingredients. However, laboratory analysis revealed the unlicensed product contained 68.1 mg sibutramine and 50.06 mg tadalafil, four times the level found in prescribed medicinal products licensed for the treatment of erectile dysfunction and obesity respectively.

**Inclusion of adulterants**

Major problems resulting from the presence of adulterants in CHM have been experienced. It is therefore extremely important that TCM products...
are monitored closely. The European Agency for the Evaluation of Medicinal Products in London has a working party on herbal medicinal products, with the remit to include pharmacovigilance and the introduction of safety measures throughout member states. The MHRA performs a similar task in the UK. Currently, Chinese herbal suppliers are engaged in agreeing guidelines to ensure that their medicines are of the highest quality and free from adulterants.

The RCHM introduced a system of approving suppliers in 2002, where companies are required to submit themselves to an independent audit by a trained pharmaceutical auditor.

The audit examines the quality system of the UK supplier and focuses on the five Ps of GMP: premises, personnel, products, procedures and processes. The company is then inspected at yearly intervals.

Although still in its infancy, this approved suppliers’ scheme has provided a framework for future initiatives to increase confidence in the quality of Chinese herbs and herbal products.

**The aristolochia story – a complex problem**

Severe concerns about the safety of the herb *Aristolochia* arose in early 1992, when two women presented with extensive interstitial renal fibrosis to doctors in a Belgian clinic that specialised in weight-loss regimens. The condition rapidly progressed to terminal renal failure. The total number of patients exposed to the herb is not known exactly, but around 100 people with renal disease were eventually recorded, representing about 5% of those who took the slimming preparation.

The diet regimen used by the clinic for many years without problems comprised a mixture of acetazolamide, fenfluramine, and various animal and vegetable extracts. In the mid-1990s the formula was supplemented by the addition of powdered extracts of Chinese herbs. A possible relationship between the renal disease and the herbs was suspected. Subsequently, it was established from an epidemiological survey that *Stephania tetrandra* was the only herb associated with all the cases of renal disease. Most unexpectedly, the alkaloid normally derived from *Stephania* – tetrandrine – could not be found in the capsules taken by the affected patients. Instead, analysis revealed the presence of a series of substituted nitrophenanthrene carboxylic acids, known as aristolochic acids. These were considered to be the cause of the adverse reactions. The acids form the main active principle of various species of another Chinese herb, namely *Aristolochia*.

It was finally concluded that the *Stephania tetrandra* (*han fang ji*) must have been inadvertently replaced by *Aristolochia fangchi* (*guang fang ji*) in the powdered extracts delivered to Belgian suppliers. Herbal ingredients are usually traded using their common Chinese names and this can lead to confusion during translation. About 185 kg of the substituted *han fang ji*
was distributed to practitioners throughout Belgium but it was only one particular clinic that reported problems. The intrinsic nephrotoxic effects of the *Aristolochia* may have been potentiated in this case by the combination of orthodox drugs administered concurrently. The *British National Formulary*\(^{186}\) states that the use of diuretics for weight loss is inappropriate; this would seem to question the wisdom of including acetazolamide in the product. The Belgian medical authorities have also warned doctors not to prescribe slimming products composed of appetite inhibitors and diuretics.

The women may have been more vulnerable to adverse reactions due to a weakening of general health caused by the calorie-controlled diet that they were following.\(^{187}\) In addition, the herbs were prescribed by untrained doctors and not in accordance with Chinese medical theories.

Since 1994 a total of seven cases of Chinese herb nephropathy have been reported in France. In 1998 a case of reversible acute hepatitis in a patient using a Chinese herbal tea was reported in the Netherlands.\(^{188}\) *A. debilis* was identified in the tea mixture. Also around this time a case was reported in Spain of a patient with renal failure resulting from chronic intake of an infusion made with a mixture of herbs containing *A. pistolochia*. This species of the herb is native to Catalonia.\(^{189}\)

The first two cases of a specific nephropathy caused by ingestion of an unlicensed Chinese herbal remedy in the UK were reported in 1999.\(^{190}\) The first case was a 49-year-old woman who initially presented to her GP with headache and hypertension. Her only existing medication was a herbal preparation that she had been taking for about 2 years to treat her eczema. Renal function tests and a biopsy revealed substantial tubular atrophy and interstitial fibrosis in the cortex. The patient rapidly progressed to renal failure and dialysis was begun. Three years later she received a renal transplant.

The second patient was a 57-year-old woman who was admitted with renal failure and a 6-month history of anorexia, lethargy, nausea and weight loss. She had been taking Chinese herbal tea for eczema for 6 years. A renal biopsy showed evidence of deterioration, as in the case above. The patient was started on dialysis.

Subsequently, it was found that both patients had been exposed to aristolochic acids as a result of ingesting *A. manshuriensis* used as a substitute for *mu tong* in the herbal tea, in place of *Clematis* or *Akebia* spp.

An emergency ban was imposed on the import, sale and supply of *Aristolochia* by the UK Medicines Control Agency (MCA) in 1999. The ban was made permanent 2 years later.

Following the two cases in the UK the Australian Office of Complementary Medicine initiated a survey of products containing *Clematis* to determine whether inadvertent substitution with *Aristolochia* had occurred.\(^{191}\) Their concern was prompted by a realisation that the Chinese name *mu tong* could be used to describe three different herbs: *Clematis*
spp. (chuan mu tong), Akebia spp. (bai mu tong) and Aristolochia manshuriensis (guan mu tong). Of the 14 samples tested, a raw herbal material and a manufactured clematis product were found to contain Aristolochia. In TCM Aristolochia spp. are considered to be interchangeable with other commonly used herbal ingredients and substitution of one plant for another species is an established practice, when in fact this may not be the case (Table 6.4).

Pharmacokinetic data for aristolochic acids 1 and 11 have been studied in rats, mice, guinea-pigs, dogs and humans after oral treatment. The doses studied were in the range 0.6–85 mg/kg body weight. Most of the results relate to rats. After oral administration, aristolochic acid 1 was readily absorbed from the gastrointestinal tract. After oral administration of aristolochic acid 1 to rats, about 91% of the dose was recovered from the excreta, equally divided in the urine and faeces.

In vivo and in vitro studies have shown that aristolochic acids are both nephrotoxic and carcinogenic. Hence most European Union states have taken regulatory action to protect the public from unlicensed medicines that contain Aristolochia. In many member states (including the UK) Stephania tetrandra, Akebia and Clematis spp. are also being controlled because of the risk of substitution. Following the interim measures taken in July 1999, the UK MHRA introduced a permanent ban on the import, sale or supply of preparations containing plants of the genus Aristolochia and of Akebia and Clematis spp. used as mu tong. It is unfortunate that such action is necessary and some would say that this represents another example of the government restricting consumers’ choice.

There is undoubtedly a substantial potential risk to health from Aristolochia. Effective control is vital to ensure that the herb is used under appropriate supervision and is of the highest quality. Aristolochia has been a POM since 1997 but exempt from control when used in herbal or homoeopathic medicine. Homoeopathic medicines were unaffected by the legislation, although it is possible that at a later date the potencies (strengths) available could be restricted to those above 9c, when the dilution is of such magnitude that no molecules of drug are considered to be present.

<table>
<thead>
<tr>
<th>Table 6.4 Species of Aristolochia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
</tr>
<tr>
<td>A. fangchi</td>
</tr>
<tr>
<td>A. contorta, A. debilis</td>
</tr>
<tr>
<td>A. contorta, A. debilis</td>
</tr>
<tr>
<td>A. debilis</td>
</tr>
</tbody>
</table>
Slimming aids

Despite the permanent ban on *Aristolochia*, the UK MHRA has continued to find evidence of the supply of TCMs containing the herb in the UK. The Agency has advised dieters to be cautious when using any TCM slimming aid to help weight loss, following the discovery of a number of potentially dangerous and illegal products (including *Xiao Pang Meion* and *Qian Er/Ma zin dol/Chaso/Onshido*) in the UK and international markets in addition to *Aristolochia*. The Agency has posted information on its website (http://tinyurl.com/yoly5t).

Heavy metals

Another reported concern with regard to CHMs is the presence of heavy metals. Much confusion has arisen regarding the presence of heavy metals probably due in part to the way news is reported in the press. There have been reports of herbal products contaminated with extremely high levels of heavy metals when in fact the heavy metals were an intended constituent of the formula. An example of this would be the formula *tian wang bu xin dan* or ‘Emperor of Heavens Special Pill to Tonify the Heart‘.

This formula contains *zhu sha* (cinnabaris or red mercuric sulphide) and is prescribed in China in small doses and for short periods of time to treat mental and emotional conditions. It is prescribed in small doses and used for short periods of time and is still used in China today. There are only a few Chinese herbal formulae that contain heavy metals and, when a case does occur citing heavy metal contamination with thousands of times the permitted level, it is almost certainly due to the use of one of these formulae, probably smuggled in from China.

The problem with heavy metals for mainstream CHM is a very different one. Here we see a situation where heavy metals may be found in low levels in formulae that do not traditionally contain any compounds that could be responsible. It is a contamination problem. At the moment China is undergoing its own industrial revolution, manufacturing industries are everywhere and the result of this frenetic manufacture is increased pollution into the rivers, many of which go on to irrigate farmland, including those that grow herbs. Testing programmes are in place to monitor heavy metal levels but a longer-term solution is needed.

Not all herbs are susceptible to heavy metal contamination and many herbs are grown in areas free from contamination. Many herbs are now cultivated rather than picked from the wild, not only protecting the environment, but also making it possible to control growing conditions. Good agricultural practice (GAP) has been introduced to herb farms across China and steadily a situation is developing where it is possible to trace herbs back to the field where they were grown. This is a far cry from the previous situation,
where most herbs would be purchased from central markets dotted around the country.

Accidental contaminants may also include allergens, pollen, insect parts, moulds and mould spores. Mycotoxins are contaminants in a wide variety of natural products.193

**Future measures to improve safety**

The problems of TCM are not unlike those of orthodox medicine. There are both intrinsic adverse reactions resulting from the toxicity of the product and extrinsic adverse reactions arising from ancillary procedures, e.g. inappropriate diagnosis and prescribing. Both groups of problems need to be addressed. To minimise the chance of adverse reactions leading to a recurrence of the circumstances surrounding the use of *Aristolochia* with other herbs, the following measures should be instigated:

- Quality assurance and quality control should be put in place to ensure that unadulterated herbs are supplied to manufacturers and practitioners.
- Herbal practitioners should undergo a course of training to ensure that they provide a safe and effective service.
- Herbs with known potential to cause adverse reactions should not be mixed with orthodox drugs unless careful monitoring is carried out.
- Accurate records should be kept by all practitioners to monitor the incidence of adverse reactions. Regular audits should also be carried out. This is in any case a minimum requirement for the collection of the evidence of successful outcomes required by purchasing authorities. Effective use of the Yellow Card system by all disciplines of complementary medicine is long overdue. Non-medically qualified practitioners (‘professional practitioners’) should also be encouraged to take part. This would make sense because there are many more NMQPs than health professionals involved in TCM.

**Yellow Card ADR reporting schemes**

*RCHM*

The RCHM’s Yellow Card scheme was established in order to gather safety data on CHMs, through identifying suspected adverse drug reactions (ADRs) to herbs. Although Chinese herbs have a long established history of use there is still relatively little present-day information on herbal safety. An example of the card used to record the reactions is provided in Figure 6.12.
Figure 6.12 Example of Yellow Card used by the Register of Chinese Herbal Medicine (RCHM) to record adverse reactions.
### RCHM YELLOW CARD continued

#### 4) About the suspected adverse reaction

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you consider the reaction to be serious? Yes/No</td>
<td></td>
</tr>
<tr>
<td>Please describe the suspected adverse reaction in your own words including any treatment received for the reaction</td>
<td></td>
</tr>
<tr>
<td>How bad was the suspected adverse reaction? – please tick:</td>
<td></td>
</tr>
<tr>
<td>- Mild or slightly uncomfortable</td>
<td></td>
</tr>
<tr>
<td>- Uncomfortable, a nuisance or irritation, but able to carry on with everyday activities</td>
<td></td>
</tr>
<tr>
<td>- Bad enough to affect day to day activities, i.e. persistent or significant disability or incapacity</td>
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<td>- Bad enough to be admitted to hospital</td>
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<tr>
<td>- Life-threatening</td>
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<tr>
<td>- Caused death</td>
<td></td>
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<tr>
<td>- Caused congenital abnormality</td>
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<tr>
<td>Date adverse reaction started</td>
<td></td>
</tr>
<tr>
<td>Has the adverse reaction stopped? Yes/No If yes, what date did it stop?</td>
<td></td>
</tr>
<tr>
<td>How is the patient now? – please tick</td>
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</tr>
<tr>
<td>- Recovered completely</td>
<td></td>
</tr>
<tr>
<td>- Getting better</td>
<td></td>
</tr>
<tr>
<td>- Still has reaction</td>
<td></td>
</tr>
<tr>
<td>- Recovered but with some lasting effects (please describe these below)</td>
<td></td>
</tr>
<tr>
<td>Date adverse reaction started</td>
<td></td>
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<tr>
<td>Was the patient rechallenged? Yes/No If yes, at what dose</td>
<td></td>
</tr>
<tr>
<td>Did the adverse reaction re-occur? Yes/No</td>
<td></td>
</tr>
</tbody>
</table>

#### 5) More information about the person who had the adverse reaction

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other medical conditions including known sensitivities</td>
<td></td>
</tr>
</tbody>
</table>

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Figure 6.12  Continued
6) Other medicines

Please list any other medicines (including your own previous prescriptions, prescribed medicines and other herbal remedies) used three months prior to the suspected adverse reaction including the name of the medicine, the dosage, what it was used for, when started, and when stopped.

<table>
<thead>
<tr>
<th>Name of medicine including brand name if known and type of medicine e.g. pill, powder, cream</th>
<th>Type of medicine e.g. external cream, raw herbs, powder</th>
<th>Source</th>
<th>Used for?</th>
<th>Dosage</th>
<th>Date started</th>
<th>Date stopped</th>
</tr>
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<tbody>
<tr>
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</tr>
</tbody>
</table>

7) Additional information and comments

Was a doctor, pharmacist or other health professional told about the suspected adverse reaction? Yes/No/Don’t know (please delete as appropriate)

If yes, did the health professional complete a Yellow Card report? Yes/No/Don’t know (please delete as appropriate)

Please give any other information that you think might be relevant including test results, oriental medical diagnosis e.g. patient yang xu treating for wind heat attack, dietary information, your conclusions and suggestions. For congenital abnormalities please state all other drugs taken during pregnancy and the last menstrual period. Please continue on a separate sheet if necessary.

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Are you happy for the MHRA to contact you in the future to discuss the suspected adverse reaction or ask for more information? Yes/No

8) Would you like your Yellow Card submission to be analysed by an expert?

The RCHM provides a service whereby the Yellow Card information that you have submitted, along with a full case history, can be analysed by an expert practitioner. This process is completely anonymous and confidential. If you wish for your Yellow Card report to be sent for analysis then please enclose a copy of your full case history notes and tick this box

9) Finally, please sign and date this Yellow Card submission, thank you.

Signed (practitioner signature) ................................................................. Date ..................

Please return this form to: Yellow Card Report, Register of Chinese Herbal Medicine, Office 5, Ferndale Business Centre, 1 Exeter Street, Norwich, NR2 4OB.

Figure 6.12  Continued
The Yellow Card scheme for drug monitoring of orthodox drugs asks only for serious suspected reactions to established drugs and all suspected reactions to newer drugs. However, the RCHM’s Yellow Card scheme asks for any suspected reaction, however minor. This does not include minor known side effects such as loose stools with the use of greasy yin tonics, or any other symptom that you might warn your patient about as a mild transient side effect.

Sometimes it is hard to tell whether a possible adverse reaction is due to herbs prescribed or something else. However, even if a practitioner is unsure as to whether a herbal medicine or a combination of herbal medicines and other medicines has caused a side effect, but has a suspicion, completion of a card would be appropriate. Actively using the Yellow Cards will further every practitioner’s knowledge. Contact herbmed@rchm.co.uk.

**MHRA**

The Yellow Card scheme operated by the UK MHRA has been widened to encourage reporting of suspected ADRs in association with herbal medicines, including unlicensed products. Patients are now able to report suspected ADRs direct.

**Endangered species**

The conservation of rare medicinal plants is a worldwide problem affecting many cultures. The issue of the usage of various endangered species, including bears and tigers, which are ingredients in the formulation of Chinese herbal patent formulae, was brought to the public eye in the USA by a World Wildlife Fund-supported report entitled *Prescription for Extinction: Endangered species and patented oriental medicines in trade*. This report was released in 1994 and resulted in widespread media attention and subsequent public concern. Researchers at Bastyr University are studying the issue of endangered species usage in depth, along with the issues of excessive toxins, drugs, adulterants, and illegal and inaccurate labelling practices, which are prevalent in these formulae. Bastyr University is near Seattle, and integrates the pursuit of scientific knowledge with the wisdom of ancient healing methods and traditional cultures from around the world. Researchers plan to work with the manufacturers of Chinese herbal patent formulae toward establishing guidelines that may be implemented in the west and in Asia.

**Modern developments in CHM**

Over the last 20 years there have been initiatives in China to find new dosage forms that are more convenient than the traditional practice of
boiling up loose herbs at home. This has resulted in the now widespread use of concentrated powder and granule extracts. These products are proving popular with both western patients and in Chinese cities where the pace of life has recently increased significantly. Although there is no doubt that these products make the process of taking herbal medicine much easier and therefore patient compliance has certainly improved, traditionalists argue that the effectiveness of these products is less than when using raw herbs. Until more comparable research is undertaken it will remain a matter of practitioner preference.

One of the major advantages of these products is in the microbiological quality. Traditionally made powders are produced from grinding the raw herb and can have very high microbial loads. As a result of the heating steps involved in the manufacture of concentrated extracts, the microbiological loading will be close to zero. These products can be stored for several years without microbial spoilage.

**Western CHM**

The use of CHM has been continued in the traditional manner by physicians and pharmacists serving Chinese communities around the world.

In many western cities the Chinatown districts support herb shops and practices with remedies imported directly from Asia, and practitioners trained by the old system of long apprenticeship. Increasingly, local western practitioners are training in their home countries to satisfy the growing interest for CHM. In particular, acupuncturists seem to be extending their practice. Many are taking a 2-year postgraduate course accredited by the European Herbal and Traditional Medicine Practitioners Association (EHTPA) and offered by many colleges and universities around the UK, which covers around 200 herbs and 100 classic formulae.

**Examples of Chinese herbs used in the UK**

Examples of herbs used in TCM formulae in the UK are listed in Table 6.5.

With the introduction of these new dosage forms modern manufacturing and testing facilities have developed. Since March 2005 factories in China must be GMP certified and companies who failed to reach the standard have been closed down.

As relations are further developed between Europe and China it is likely that UK inspectors will also travel to China in order to assess suitability for the European market. This will be a challenging and exciting development.
The Bristol Chinese Herb Garden

The Bristol Chinese Herb Garden (Figure 6.13) was started in 2000 as a partnership between the University of Bristol Botanic Garden and the RCHM. With the move of the University Botanic Garden in 2006, an opportunity was taken to greatly enlarge the size and scope of the Chinese Herb Garden.

The Chinese Herb Garden aims to provide a comprehensive living collection of plants used in Chinese medicine that can be used in the teaching of students of herbal medicine and for research by the University and the herbal profession into the cultivation and chemistry of the plants.

The garden is affiliated to several University and botanic gardens in China and is divided into several distinct areas, including a herbal teaching display where plants are divided into ‘use class’ categories in line with Chinese medicine theory; a conservation bed highlighting some of the plants that are currently under threat from overuse or habitat loss; a research bed; a peony bed; and an area for ferns.

Table 6.5 Examples of common Chinese herbs

<table>
<thead>
<tr>
<th>Source material</th>
<th>Chinese name</th>
<th>Parts used</th>
<th>Main constituents</th>
<th>Clinical use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agastache rugosa</td>
<td>Hua xiang</td>
<td>Herb</td>
<td>Essential oil</td>
<td>Digestive stimulant, antiemetic</td>
</tr>
<tr>
<td>Cinnamomum spp.</td>
<td>Rou gui</td>
<td>Bark</td>
<td>Essential oil, resin</td>
<td>Warms, circulatory stimulant</td>
</tr>
<tr>
<td>Clematis chinensis</td>
<td>Wei ling xian</td>
<td>Root</td>
<td>Anemonin, saponins, sterols, phenols</td>
<td>Antirheumatic, stimulant, expels wind and damp</td>
</tr>
<tr>
<td>Glycyrrhiza uralensis</td>
<td>Gan cao</td>
<td>Root</td>
<td>Saponins, flavonoids</td>
<td>Expectorant, tonic, detoxifier</td>
</tr>
<tr>
<td>Lonicera japonica</td>
<td>Jin yin hua</td>
<td>Flowers</td>
<td>Luteolin, tannin</td>
<td>Cooling and disinfecting, antipyretic, detoxifier</td>
</tr>
<tr>
<td>Magnolia spp.</td>
<td>Xin yi hua</td>
<td>Bark</td>
<td>Essential oil, alkaloids</td>
<td>Digestive stimulant, expectorant</td>
</tr>
<tr>
<td>Panax ginseng</td>
<td>Ren shen</td>
<td>Root</td>
<td>Saponins, glycosides</td>
<td>Sedative, tonic</td>
</tr>
<tr>
<td>Phellodendron amurensei</td>
<td>Pa-mu</td>
<td>Bark</td>
<td>Alkaloids, triterpenoids, sterols</td>
<td>Bitter digestive, diuretic, antipyretic</td>
</tr>
<tr>
<td>Taraxacum mongolicum</td>
<td>Pu gong ying</td>
<td>Whole plant</td>
<td>Bitters, sterol</td>
<td>Anti-infective, antipyretic</td>
</tr>
</tbody>
</table>
Over the next few years it is planned to further develop the facilities into an advanced teaching and research centre using the combined expertise of the University of Bristol and the herbal profession.

Other elements of TCM

Chinese massage (tui na)

Massage has been an important element of TCM for at least 2000 years, featuring in the Yellow Emperor’s famous text. The therapy uses hand manipulation, pushing, rolling and kneading, on specific points and parts of the body. It may be used to balance yin and yang and to regulate the function of qi, blood and the zang fu organs as well as to loosen joints and relax muscles and tendons.

Dietary therapy

Chinese dietary therapy is an important part of life in the country as well as being included in many practitioners’ prescriptions. Knowledgeable Chinese housewives often prepare special meals for common family ailments. Thus a patient suffering from insomnia due to a disharmony of heart and kidney might be advised to make a soup of lotus plumule (lian zi xin) to nourish the heart and include morus fruit (sang shen zi) to enhance kidney essence. These measures would be in addition to other TCM treatments, e.g. CHM and/or acupuncture.
Nutritional interventions may be of three types:\(^\text{197}\)

- **Supplementation**: as well as various vitamins and minerals, the range may contain animal and plant products (e.g. algae or kelp).
- **Dietary modification**: this involves changes in dietary habits to exclude elements not considered nutritious or to establish better eating patterns.
- **Therapeutic systems**: the inclusion (or exclusion) of foods considered to have a contributory role to the patient’s health.

Examples of diets with properties beneficial to health include:\(^\text{199}\)

- **White rice porridge**: this regulates the bowels (constipation and diarrhoea), for nausea and loss of appetite.
- **Sweet and sour sauce**: considered to be an important constituent of diet because of its antiseptic properties.
- **Sweet and sour crispy noodles**: noodles are a good source of nutrients for athletes and growing children. The vinegar in the sauce has antiseptic properties.

Examples of dietary remedies for common illnesses include:

- **Acne**: infusion of the flowers of peach (*Prunus persica*) or almond (*P. amygdalus*) in water daily
- **Arthritis**: cinnamon tea (*Cinnamomum cassia*); for cold arthritis, sage steeped in rice wine sipped daily and for warm arthritis infusion of purslane (*Portulaca oleracea*) in water
- **Constipation**: fig wine, stewed pears and bananas eaten cold with honey
- **Flatulence**: seeds of mandarin orange chewed
- **Haemorrhoids**: simmer a mixture of almonds, peach kernels, pine nuts and sesame seeds in water and drink as a soup
- **Halitosis**: a few leaves of peppermint or the peel of a mandarin orange chewed.

**Martial art therapy**

This approach uses movements and exercises adapted from martial arts, such as *tai ji quan* and *kung fu*.\(^\text{200}\) A case study report has indicated that a patient suffering from severe cervical stenosis improved after martial art therapy.\(^\text{201}\)

**Qigong**

This is a meditative therapy with a history similar to that of Chinese massage. It is often combined with body movement and breathing exercises
to achieve a balance of energy in the TCM meridian system. Xin et al. performed a systematic literature review of qigong intervention studies published in English or Chinese since 1980 and found that 11 studies were identified that met their criteria for an association between qigong and the management of type 2 diabetes.202 They concluded that the exercise appeared to have beneficial effects on some of the metabolic risk factors but that methodological limitations made it difficult to draw firm conclusions about the benefits recorded.

Tai ji quan (tai c’hi)

Tai c’hi was created in the fourteenth century as a martial art and is practised widely in China. The term ‘tai ji’ refers to the balance of yin and yang. It consists of a series of slow flowing exercises inspired by the movement of animals, as reflected in the names given to the movements, e.g. ‘white stork spreading wings’.

Though exercise reduces the risk of falls, the challenge is finding a programme that interests participants. Research shows that tai c’hi, with its oriental overtones, may be such a candidate.

Wolf et al., working in Atlanta, found that older people taking part in a 15-week tai c’hi programme reduced their risk of falling by 47.5%.203 Wolf’s group compared several factors before and after the interventions, and found improvements in certain key areas. The most notable change involved the reduction in the rate of falling for the tai c’hi group. The groups receiving computerised balance platform training did not have significantly lower rates of falling. The tai c’hi participants also took more deliberate steps and decreased their walking speed slightly compared with the other groups. Fear of falling was also reduced for the tai c’hi group. After the intervention, only 8% of the tai c’hi group said that they feared falling, compared with 23% before they had the training. In other work led by Wolf it was concluded that there was no statistically significant reduction in falls compared with wellness education.204 The trial involved 287 people and lasted 48 weeks. It was suggested that tai c’hi does not begin to show a significant reduction in the risk of falling until after a number of months of regular participation. Fewer falls were observed in a subset of patients doing tai c’hi who had no history of fall fracture. Wolfson and colleagues found that several interventions to improve balance and strength among older people were effective.205 These improvements, particularly in strength, were preserved over a 6-month period while participants did tai c’hi exercises.

The possible reduction in falls following participation in a tai c’hi programme was evaluated in a group of active individuals between the ages of 70 and 92 years.206 Participants received three sessions of the exercise per week over 6 months when they were compared with a control group. They proved to have a lower incidence of falls and improved measures of balance.
There are other areas in which tai c’hi may be of interest to older patients. There is some evidence that tai c’hi improves the range of motion of the ankle, hip and knee in people with rheumatoid arthritis. A study showed that tai c’hi did not improve people’s ability to carry out household chores, joint tenderness, grip strength or their number of swollen joints nor did it increase their symptoms of rheumatoid arthritis, but people felt that they improved when doing the exercises and enjoyed it. 207 It is still not known if it improves pain in rheumatoid arthritis or that person’s quality of life. It is also not clear how much, how intense and for how long tai c’hi should be done to see benefits.

Wayne et al. evaluated the evidence for tai c’hi as an intervention to reduce rate of bone loss in postmenopausal women. 208 RCTs, prospective cohort studies and cross-sectional studies that included tai c’hi as an intervention, and had at least one outcome related to measurement of bone mineral density (BMD), were included. Conclusions on the impact of tai c’hi on BMD are limited by the quantity and quality of research to date. This limited evidence suggests that tai c’hi may be an effective, safe and practical intervention for maintaining BMD in postmenopausal women. In combination with research that indicates that tai c’hi can positively impact other risk factors associated with low BMD (e.g. reduced fall frequency, increased musculoskeletal strength), further methodologically sound research is warranted to better evaluate the impact of tai c’hi practice on BMD and fracture risk in postmenopausal women. However, less encouraging results emerged from an RCT carried out in Hong Kong. 209 The effects of tai c’hi (TC) and resistance exercise (RTE) were investigated on BMD, muscle strength, balance and flexibility in community living older people; 180 individuals (90 men, 90 women) aged 65–74 were involved. No effect was observed in men. No difference in balance, flexibility or the number of falls was observed between intervention and controls after 12 months.

Other traditional medicine related to TCM

Traditional Tibetan medicine

Tibetan medicine is reputed to be the most comprehensive form of Eurasian healthcare and the world’s first integrative medicine. 210 Incorporating rigorous systems of meditative self-healing and ascetic self-care from India, it includes a world-class paradigm of mind/body and preventive medicine. Adapting the therapeutic philosophy and contemplative science of Indian Buddhism to the quality of secular life and death, traditional Tibetan medicine (TTM) features the world’s most effective systems of positive and palliative healthcare. Based on qualitative theories and intersubjective methods, it involves predictions and therapies shown to be more accurate and effective than those of modern...
Tibetan medicine originated with the local folk tradition (known as Bon) that dates back to about 300 BC and was formally recorded by Xiepu Chixi, the physician to the Tibetan King Niechi Zanpu, in 126 BC. Aspects of both the traditional Chinese and Indian (ayurvedic) medical systems were added later; ayurveda (see Chapter 7) has had the most profound influence on Tibetan medicine. The medicine of India was introduced to Tibet as early as AD 254, with the visit of two Indian physicians. During the following century several physicians from India reinforced the teachings. Other influences came from Persian (Unani), Greek and Chinese medical systems, and it continues to be practised in Tibet, India, Nepal, Bhutan, Ladakh, Siberia, China and Mongolia, as well as more recently in parts of Europe and North America. It embraces the traditional Buddhist belief that all illness ultimately results from the ‘three poisons’ of the mind: ignorance, attachment and aversion. Tibetan medical theory states that it is necessary to maintain balance in the body’s three principles of function.

- **rLüng** (wind) the source of the body’s ability to circulate physical substances (e.g. blood), energy (e.g. nervous system impulses) and the non-physical (e.g. thoughts).
- **mKhris-pa** (bile) is characterised by the quantitative and qualitative characteristics of heat, and is the source of many functions such as thermoregulation, metabolism, liver function and discriminating intellect.
- **Bad-kan** (phlegm) is characterised by the quantitative and qualitative characteristics of cold, and is the source of many functions such as aspects of digestion, the maintenance of our physical structure, joint health and mental stability.

The imbalances in an individual are revealed by a combination of reported symptoms, pulse diagnosis, tongue diagnosis, and urine analysis. The overall physical appearance of the person and information about their daily habits, and consideration of seasonal influences also contribute to the analysis. The Tibetan pulse diagnosis appears to be derived from the Chinese system, and is taken at the same artery of each wrist, but the method of feeling the pulse and the interpretations differ. Tongue diagnosis is simplified compared with the Chinese system (long disorders are characterised by red and dry tongue, chiba disorders by a yellowish tongue coating, and peigen disorders by a greyish and sticky coating with a smooth and moist texture). Urine analysis is unique to the Tibetan system and may have been introduced from Persia. Physicians inspect the colour, amount of
vapour, sediment, smell and characteristics of the foam generated upon stirring, relying on the first urine excreted in the morning.

The modern materia medica of Tibet is derived from the book Jingzhu Bencao (*The Pearl Herbs*), published in 1835 by Dumar Danzhen-pengcuo. Its format includes two sections, one being in the style of the Buddhist sutra with praise of the medicines, and the other being a detailed classification of each substance, giving the material's origin, environmental conditions where it is found, quality, parts used and properties. The text included 2294 materials, of which 1006 are of plant origin, 448 of animal origin and 840 minerals. The heavier reliance on minerals and animals than on plants, compared with other traditional medical traditions, can readily be understood for a country at such high altitude which is very rocky and supports only small areas of plant growth over much of the terrain. About one-third of the medicinal materials used in Tibetan formulae are unique to the Tibetan region (including the Himalayan area in bordering countries), whereas the other two-thirds of the materials are obtained from India and China.

Although Tibetan herbal medicine includes the use of decoctions and powders, for the most part Tibetan doctors utilise pills that are usually made from a large number of herbs (typically 8–25 ingredients). Pills have the advantage of being easy to use and they can be prepared in advance at a medical facility where all the ingredients are gathered together. Due to the vast distances, rough terrain and limited development of Tibet, it was not possible to have the broad range of ingredients available to individual
doctors who might compound formulae for decoction, as was often done in
China. Instead, a relatively small variety of pills, prepared at central facili-
ties, would be carried by the doctors to their patients. For many doctors, a
collection of about two dozen principal formulae would have to suffice. In
Lhasa, where there is a large manufacturing facility rivalling pharmaceutical
manufacturing facilities in the west (Figure 6.14) doctors have access to
about 200 types of pills.

In general, Tibetan remedies emphasise the use of spicy (acrid), aromatic
and warming herbs. The climate has a substantial influence on these choices:
the high altitude of Tibet means that cold and windy conditions prevail.
The herbs help to compensate for this condition. Ayurvedic medicine relies
heavily on spicy herbs for stimulating the digestive system functions, which
is understood to be the key to health. Thus, among the commonly used
Tibetan herbs are those derived mainly from the ayurvedic system, such as the
peppers, cumin, cardamom, clove, ginger and other hot spices, comple-
mented by local aromatics such as saussurea and musk. Also, the Tibetan
system emphasises astringent herbs, possibly representing an attempt to
conserve body fluids and alleviate any inflammation of the mucous
membranes.

The ‘king’ herb of Tibetan medicine is the *chebulic myrobalan* (*Termi-
nalia chebula*), an astringent herb that is said to possess all the tastes
different parts of the fruit have different tastes), properties and effects.
Despite this emphasis on herbs with properties that are generally needed for
the Tibetan climate, cooling and bitter herbs are often required to treat the
disease manifestation, as inflammatory processes finally result if the patho-
genic influences are not conquered or expelled.

Popular herbs used alone and in combination with other herbs are
Tibetan *rhodiola* (*Rhodiola rosea*), known as stonecrop in the west, indicated
for the treatment of dysentery, back pain, lung inflammation, painful and
irregular menstruation, leukorrhoea and traumatic injuries, and *Hippophae
rhamnoides* (sea buckthorn), claimed to be effective in treating ischaemic
heart disease, eliminating phlegm, improving digestion and stopping coughs.

**Traditional Mongolian medicine**

Traditional Mongolian medicine (TMM) has developed over many years
with some Mongolian doctors (*emchis*) becoming so adept in its practice
that they became well known in Tibet and China. Mongolia is one of the
few countries that officially supports its traditional system of medicine.
However, Inner Mongolia, ruled by China, does not support TMM, and has
even imprisoned people for practising it. Although herbs are the mainstay of
Mongolian medicine minerals, usually in the form of powdered metals or
stones, are also used. Mongolian medicine uses water as a medicine. Water
is collected from any source, including the sea, and stored for many years until ready for use. Acidity and other stomach upsets were said to be amenable to water treatments.

**Traditional Bhutanese medicine**

The Himalayan kingdom of Bhutan is an independent state situated between China and India. It emerged as a unified polity in the early seventeenth century under the rule of an exiled Tibetan religious leader and much of its elite culture, including its medical traditions, were brought from Tibet during this period. The Bhutanese traditional medical system subsequently evolved distinct characteristics that enable it to be viewed as a separate part of the Himalayan tradition of *Sowa Rigpa* (‘the science of healing’), which includes what is now known as Tibetan medicine. Bhutan has evolved a state medical system in which their traditional medicine is an integral part and patients have the choice of treatment under traditional or biomedical practitioners.

As with Chinese and Tibetan medicine, the main methods of diagnosis in Bhutanese traditional medicine are feeling the pulse, checking urine, and examining the eyes and tongue, as well as interviewing the patient. The Bhutanese rely on herbal combinations, limited acupuncture (including use of the golden needle), applications of heat (usually with metal rods) and minor surgical interventions, all done in the context of Buddhist ritual. A European Union project to support traditional medicine in Bhutan was initiated in the year 2000. According to data collected as part of this project, there are about 600 medicinal plants used in Bhutanese traditional medicines, out of Bhutan’s 5600 identified species. About 300 of these herbs are used routinely and are at risk for ecological loss due to clearance of trees and over-collection of herbs. The EU has invested in having these herbs raised as cash crops to create jobs, provide a new medicine factory with raw materials and protect the environment.

**Further reading**


**More information**

British Acupuncture Council: http://tinyurl.com/2hb9zo
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