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Acupuncture research: the story so far

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INTRODUCTION TO THE HISTORY OF ACUPUNCTURE

While acupuncture probably had its roots elsewhere, the first texts of acupuncture appeared in China a little over 2000 years ago, circa 200 BCE (Unschuld 1985). The theories and methods of acupuncture that were first described at this time already reflected considerable variety. This was to be expected since the early texts were themselves collections of many different people's ideas from different places and times (Birch & Felt 1999, Lu & Needham 1980, Unschuld 1985). Subsequent ideas and methods used in the practice of acupuncture continued changing as a consequence of China's evolution and also as acupuncture migrated to, and was adopted as, an effective treatment in different Asian and European countries and cultures. Consequently there are often many contradictory ideas about acupuncture that can be found in historical and modern literature (Birch & Felt 1999, Lu & Needham 1980).

Acupuncture is thus a broad and diverse field of medical practice. Much of what has been described about the clinical practice and use of acupuncture over the last 2000 years can appear confusing and even contradictory. This is reflected in the past and present diversity in the expression, models of theory and practice, and understanding of acupuncture. It has also added to the difficulty in interpreting acupuncture's clinical literature (Birch & Felt 1999). These historical facts are relevant to the discussions of acupuncture research in this and later chapters.

Acupuncture is a multi-faceted and multi-modal therapy. It may combine many different ideas and theories with the clinical application of those theories in diagnosis and treatment selected from amongst a range of very different 'acupuncture' techniques (Birch & Felt 1999, MacPherson & Kaptchuk 1997). Additionally, the therapist may use Chinese traditional medical theory to advise the patient, for example by explaining and justifying lifestyle, and dietary changes, as well as employing an evolving therapeutic

intervention involving needling, moxibustion, cupping, herbs and massage. It is wise not to approach acupuncture as though it were a single simple therapy around which there is expert consensus, but rather as a complex intervention (Medical Research Council 2000). One of the challenges that acupuncture research faces is the development of appropriate methods that are able to capture and investigate this complexity (Paterson & Dieppe 2005, Verhoef et al 2005). Another important challenge is the development of a more complete understanding of the nature of acupuncture, including the inherent diversity derived from its philosophical and cultural roots.

OVERVIEW OF IMPORTANT PHILOSOPHICAL AND CULTURAL CONTEXTS OF ACUPUNCTURE

Acupuncture arose in quite different cultural contexts from Western medicine and the scientific method encapsulated in the 'Enlightenment'. Therefore there are important cultural and philosophical differences between acupuncture and modern bio-medicine. Highlighting some of these differences illustrates some of the problems that researchers face when trying to investigate acupuncture using scientific methods.

One of these differences is the historical East Asian trend of seeing body, mind, emotions as one, rather than distinct (Birch & Felt 1999, Ikemi & Ikemi 1986, Roth 1999, Shen 1986). Since the time of Rene Descartes, Western science has been struggling with its tendency to see the body, mind and emotions as separate, especially in the fields of biology and medicine (Foss & Rothenberg 1987).

Another important difference lies in the virtual absence of the 'either-or' logical assumptive approach in ancient China and other Asian cultures. While this dominates modern Western scientific thinking, its virtual absence in ancient Asian philosophies is often overlooked. Unschuld argues that this is probably a by-product of science having developed in a monotheistic culture (Unschuld 1987). In the either-or assumptive model, one cannot accept the validity of competing ideas; if one idea is right a contradictory one must be wrong. The scientific method for establishing 'truth' is a clear example of the either-or approach. Scientific truth is developed using methods that assume this to be axiomatic. However, the traditional literature on acupuncture is full of contradictory ideas, even within the same texts. This was not a problem for early authors since they did not assume that if one approach was right the other had to be wrong. Rather ideas and assumptions of all kinds coexist at many different 'levels' of interpretation with no attempt or indeed any reason to derive an absolute truth (Unschuld 1985, 1987, 1992). This is reflected in acupuncture being more than a single uniform therapy; it is, and always has been, defined by diversity of ideas and methods (Birch & Felt 1999, Scheid 2002, 2006). This creates problems for scientists when they assume a 'Western' truth model as well as uniformity in acupuncture theories and try to formulate testable hypotheses on the basis of their (rather than acupunctures') assumptions.

Systemic differences

Much of the early evolution and development of acupuncture was based on practitioners collecting their own experiences during their clinical lifetime and learning from it, and passing that information on to their pupils as their wisdom. The perspective of objectivity that underlies the scientific approach did not develop in Asia until it was gradually imported from the West after the seventeenth century (Birch & Felt 1999). This is not to say that acupuncture did not follow a systematic approach in making observations and then further developing theories based on those observations, but it did so with empiricism and respect for the wisdom of the experienced individual physician, in much the same way as medicine evolved in Europe before the enlightenment. Today we speak of 'evidence-based medicine' as helping provide a standardised medical care based on research. In a parallel way we can speak of acupuncture as 'experience-based medicine', relying on systematic use of empirical and pragmatic observations. The latter can be said to rely strongly on three basic steps, while the former uses the same three steps but then adds two more steps in order to make the process more objective (see Table 2.1).

Of course practitioners of experience-based medicine also published and discussed their cases and observations, which, over time constituted a peer-review process. But in the evidence-based approach these last

Table 2.1 Iterative stages in the process of development of evidence-based medicine and experience-based medicine

Stages	Evidence based medicine	Experience based medicine
(i)	models of theory and practice	models of theory and practice
(ii)	process of inquiry	process of inquiry
(iii)	experience of the patients and practitioners as well as the case history literature	experience of the patients and practitioners as well as the case history literature AND then iterative feedback from Stage (iii) to Stages (i) and (ii) to develop and improve the models of theory and practice
(iv)	verifiable observations and planned experiments	
(v)	peer review of observational and experimental literature AND iterative feedback from Stages (iii), (iv) and (v) to Stages (i) and (ii) to develop and improve the models of theory and practice	

two stages are highly formalised, following strict guidelines. For example publication is preceded by peer review rather than vice versa. Verification of observations and experiments includes the use of validation processes and objective measurements, each of which is tested and verified before being acceptable. Thus Stages (iv) and (v) in an evidence-based approach are more rigorous and formalised than in the experience-based approach.

Cultural-philosophical differences

Acupuncture developed in China mostly under Confucian and Daoist philosophical influences (Unschuld 1985, Lo 2001). Asian historical cultural processes and their primary philosophical and cultural contexts were based on a very different world view than that which predominates today in Western scientific thinking (Birch & Felt 1999). Important features of these East Asian thought processes were to see the body and mind as necessarily interconnected and inseparable, and to see the connections and interactions of everything as equally if not more important than the individual elements of an illness or pathological process. In modern scientific thinking we frequently but not invariably consider the minutiae of specific organ-based pathologies as primary because of the dominance of Cartesian mind-body dualism and reductionist thinking (Birch 1995, Birch & Felt 1999, Foss & Rothenberg 1987, Unschuld 1987, 1992). These are useful generalisations as they highlight some of the challenges researchers face (Birch 1998, Birch & Felt 1999). Table 2.2 summarises the differences in philosophical and cultural tendencies between traditional and historical forms of acupuncture medicine and modern scientific medicine.

Table 2.2 Differences in philosophical and cultural tendencies between traditional East Asian medicine and Western scientific medicine

Western scientific medicine	Traditional East Asian medicine
General adoption of an 'either-or' assumptive approach	General adoption of a 'both-and' assumptive approach
Widespread effort at generating objective descriptions	Little to no effort at generating objective descriptions
Widespread adoption of mind-body dualistic thinking	Widespread adoption of mind-body integrative thinking
Widespread use of reductionist type thinking processes	General emphasis on holistic thinking processes

[For more discussion of these differences, see references Birch (1995), Birch & Felt (1999), Unschuld (1987, 1992).

The importance of these philosophical and cultural differences becomes clear if we contrast the tendency in the West of making the 'tenuous distinctions between energy and matter and between mind and body' (Roth 1999, p 41). The lack of these divisions in China and subsequently traditional East Asian medicine is apparent within acupuncture (Birch & Felt 1999). Instead the ancient Chinese theoretical model posited the existence of '*Qi*' which is both the source of all material objects and all psychic and spiritual phenomena. In cosmological theory it was proposed as early as 140 BCE that *Qi* is the origin of heaven and earth and everything in between (Roth 1999, p 41), and circa 90 CE that just as water freezes to become ice, so too *Qi* condenses to become matter (Birch & Felt 1999, p 92). Likewise *Qi* was described in the early literature as lying at the heart of all emotional, mental and spiritual phenomena (Birch & Felt 1999, Roth 1999). There has thus been a distinct absence of Western mind-body duality and the reductionist tendencies of modern Western thinking in traditional East Asian medicine healthcare models (Birch & Felt 1999, Unschuld 1992). The concept of *Qi* lies at the heart of the more unified and holistic models of traditional East Asian medicine. These fundamentally different assumptions about the nature of the human being and the world remain unaddressed issues in the scientific investigation of acupuncture.

Given these important philosophical and cultural differences between Western ways of approaching and understanding the body and the more historically based approaches from Asia we can expect to find important challenges confronting us when investigating acupuncture. Three examples highlight some of the important challenges researchers face investigating acupuncture.

How helpful or relevant is it to use the placebo-controlled randomised clinical trial (placebo RCT) for assessing acupuncture's clinical effects? This kind of clinical trial may assume that the components of the treatment that contribute to the overall treatment effects are separable and do not interact so they can be reduced to discrete components. However the validity of these assumptions has been questioned in the context of acupuncture research (Foss & Rothenberg 1987, Kaptchuk 1996, Paterson & Dieppe 2005). If the traditional model of practice that is being assessed is more holistic, meaning that it does not assume a mind-body duality and does not permit isolation of part of the whole process and is not based on an either-or logical assumptive approach, then the RCT must be designed around this assumption. It will then only be able to assess the 'whole system', rather than evaluate the effects of various components within that system. This may mean that we require more pragmatic studies (see Chapter 7), even though such studies will tell us nothing about the contribution from contextual factors, sometimes labelled the 'placebo' effects (see Chapter 8).

Likewise, how can the mechanisms of acupuncture's treatment effects be identified using laboratory research methods? If we ask, for example, how acupuncture is able to treat pain, this tends to lead into an examination

of known analgesic mechanisms in the body and how acupuncture may affect them (Birch & Felt 1999). How do we separate mechanisms from a whole system of interacting effects and meaningfully discuss those with reference to acupuncture? What theoretical model of acupuncture was used for the research question – one based on known Western analgesic mechanisms or one based on traditional acupuncture theories and methods? Sometimes it appears that the varied traditional theories of acupuncture are ignored in these studies in favour of current Western physiological understanding (Kim 2006). It is certainly possible to address these issues but it requires sensitivity and sophistication as well as an understanding of the historical evolution of acupuncture.

A third example of these difficulties lies in the influence of the 'eitheror' assumptive model. Today the most popular theoretical model underpinning acupuncture in the West has become that of 'TCM' (traditional Chinese medical) acupuncture, sometimes loosely called 'traditional' or 'classical' acupuncture. Since this has now become misnamed but synonymous with all traditional forms of acupuncture (Birch 1995, Birch & Felt 1999) it is then assumed that it not only covers all forms of traditional acupuncture but that other forms (if they exist) may be 'incorrect' (Birch 1995) as they are not real TCM. However TCM is not the monolithic system it has been portrayed to be in the West and is itself a mix of diverse traditions (Scheid 2002). Further, it is not representative of all the other traditional forms of acupuncture (Birch & Felt 1999, MacPherson & Kaptchuk 1997). But researchers have assumed that if they are testing what they consider to be 'TCM', 'traditional' or 'classical' acupuncture they have investigated all forms of 'traditionally based systems of acupuncture' (Birch 1997). There is a major problem with attempting to generalise about traditional forms of acupuncture under the misnamed and misunderstood rubric of 'TCM', 'traditional' or 'classical' acupuncture.

While we can expect that science and scientific methods will be used to investigate traditional medical practices, it is vital to understand and attempt to deal with these philosophical and cultural issues when we wish to conduct such research and interpret the results. Calls for further research into the more traditional methods and ideas of acupuncture (Acupuncture 1998) require that efforts be made to address these fundamental issues.

THE ACCULTURATION OF ACUPUNCTURE: A HISTORY OF CLINICAL RESEARCH ON ACUPUNCTURE

The situation for understanding acupuncture and modern iterations of traditionally based systems of acupuncture is further complicated by the fact that modern Western ideas have been penetrating and influencing Chinese, Japanese and Asian cultures over the last 300 years (Birch & Felt 1999, Lu & Needham 1980, Unschuld 1985). Equally, traditional Asian ideas have been penetrating into Western cultures for the

same period of time. Thus, for many forms of acupuncture we can no longer look only to the traditional ideas and methods of thinking, we find many new culturally based 'blends' that merge East and West, explicitly or implicitly combining the different approaches.

Sometimes traditional ideas are translated in modern texts in terms that seem familiar to us in the West, often as a result of modification of those terms in light of modern scientific concepts. This problem is encountered both when modern Asian authors have attempted to translate historical ideas into modern language and concepts (Sivin 1987) and even more so when Westerners attempt to translate the historical and modern Asian texts into Western European languages (Wiseman & Feng 1997). This complicates the process of developing accurate models of acupuncture that are to be tested (Stage (i) in Table 2.1). It is also difficult to establish congruence of terms between different traditions of practice (Stage (iii) in Table 2.1). A debate has been occurring about how to translate Asian medical texts into Western languages for the last 20 years and is still unresolved (Bensky et al 2006, Birch & Felt 1999, Reid 2006, Wiseman & Feng 1997). This raises difficult questions about how to interpret the acupuncture theories and ideas that are available to us in the West when we initiate research into the methods of practice on which they are based. The difficulties are considerable and are not simply limited to trying to find a one-to-one translation of seemingly similar terms such as '*gan*' to 'Liver' or '*xin*' to 'Heart'. Traditional acupuncture is full of terms and concepts that are completely foreign to Western scientific cultures, with no obviously equivalent terms or concepts available for translation. The most obvious being the term '*Qi*' variously translated as 'energy', 'vital energy', 'breath', 'vapours' and 'influences'. These problems challenge clinicians and research scientists (Birch & Felt 1999). Many invalid cultural assumptions are honestly but unwittingly made by practitioners and researchers when they translate acupuncture into terms and concepts familiar to them (Lu & Needham 1980, p 11–12, Unschuld 1987, 1992, p 55).

Sometimes the traditional ideas are reframed in the context of a modern scientific model of the body. This also complicates the processes of inquiry, observation, the interpretation of findings and designs intended to improve the model and process of inquiry (Stages (i)–(iii) in Table 2.1). Three examples are outlined below.

Currently the most popular form of acupuncture in the West is some form of the TCM approach following developments in China after the communists took over. Starting in the early 1950s under Mao's rule, traditional medicine was encouraged to continue in China provided it was adapted to fit within the socio-political systems of the day. Traditional forms of medicine were called '*zhong yi*', literally 'centre medicine' or 'Chinese medicine' to distinguish them from '*xi yi*' or 'Western medicine'. The process of adaptation involved blending acceptable forms of traditional theory and methods from the diverse traditions of acupuncture, herbal medicine and massage with a modern Western medical model (Birch & Felt 1999, Unschuld 1985, p 250–251, 1992, Scheid 2002,

Sivin 1987, p 17, Taylor 2004, Wang & Zhao 2007). With an eye to Western interests in China, the first publications to label it as 'traditional Chinese medicine' or TCM appeared in 1955 (Taylor 2004). This occurred alongside a desire to project China as contributing to the modern scientific world and with the beginnings of a research agenda that projected TCM to 'be a showpiece of the progress of science' (Taylor 2004). What is widely known as TCM acupuncture in China and the West reflects this combination of traditional Chinese and modern Western thinking, raising questions about its claims of historical validity (Ogawa 1996, Unschuld 1998) and concerns about the survival of traditional theories and methods (Freuhauf 1999, Kaptchuk 1985).

Acupuncture developed quite differently in Japan from the late 1800s. During the push to modernisation of the Meiji Restoration, modern biomedicine was adopted as the 'standard' of healthcare. Acupuncture was relegated to a technique that modern physicians (using Western medicine) or blind practitioners could practise. The practice by blind practitioners was eventually restricted by eliminating all traditional concepts from their training (Manaka et al 1995, p 14). This led to a backlash and the development of a growing traditional style of acupuncture known as '*keiraku chiryo*' — 'meridian therapy' (Fukumoto 2006, Shudo 1990). This new traditionally based model developed with the explicit goal of re-establishing traditional acupuncture methods, with unnecessary and impractical ideas stripped out to allow it to survive in the modern western Japanese environment (Birch & Felt 1999). After 1948 acupuncture had become standardised in the licensing curriculum but with increasing diversity of approaches in post-graduate education and clinical practice. Here purely 'traditional' schools, purely 'scientific' schools and all kinds of other combinations were allowed to develop (Birch & Felt 1999). Some schools of acupuncture combined biomedical with traditional ideas and methods, while some attempted only traditional or only scientific approaches. Just as we find a broad diversity of approaches to the practice of acupuncture today in China (Scheid 2002) we also find a broad diversity of approaches in Japan (Birch & Felt 1999, Lock 1980). This suggests that acupuncture is not a single entity.

A third example of the attempted integration of modern Western ideas into traditional approaches can be found in those models that have incorporated modern Western psychological theories and concepts into their systems of acupuncture practice (Hammer 1990). Just as psychoanalytic theory was new for Western medicine in the twentieth century, it was very new for East Asian cultures and their medicines. Western practitioners familiar with both systems have found unique ways of combining them (Hammer 1990, Seem 1987). These combinations muddy the waters further for the researcher attempting to investigate acupuncture as they tend to create more confusion about its nature and practice (Birch 1998).

Sometimes, the Western student is searching for an alternative to the dominant Western medical model and picks out only those 'holistic' sounding ideas and methods as representing 'traditional acupuncture'.

One consequence of this is the construction of very selective approaches to acupuncture in the West that possibly fit better to the assumptions and desires of the Western student and practitioner than the traditional model or practice (Unschuld 1987, 1992). This complicates the processes of development, inquiry, observation and patient experience (Stages (i)–(iii) in Table 2.1).

So far we have examined how acupuncture has been acculturated in the modern period. But, science and modern medicine have also been adopted in and acculturated into East Asian cultures. As we will see, this has consequences for how East Asian and Western scientific investigations of acupuncture have proceeded.

SCIENTIFIC INVESTIGATIONS OF ACUPUNCTURE

Early research

Early investigations of acupuncture were more speculative than scientific, focusing on trying to understand this traditional medicine. These occurred both in Asia as well as the West. Following Sugita Gempaku's publication of a Japanese translation of a Dutch anatomical text in 1774, Western-based anatomical and physiological concepts began influencing the understanding and practice of acupuncture in Japan (Lu & Needham 1980, Kuriyama 1992). Less than 25 years later in France in 1798, Rougement speculated that acupuncture was a kind of 'counter-irritation' therapy, thus invoking current physiological understanding. This model was reiterated by Japanese physician Tesai Okubo in 1894 (Lu & Needham 1980). Today there are well-developed models of 'counter-irritation therapy' such as that of 'diffuse noxious inhibitory control' with scientific evidence of the analgesic mechanisms involved and proposals that they may help us understand some of the effects of acupuncture (Le Bars et al 1988). These and other writings of the eighteenth and nineteenth centuries focused on the use of acupuncture for pain relief, often in rheumatic diseases (Lu & Needham 1980).

There were also some important innovations during this time that set the stage for later scientific investigations. For example in 1825 Sarlandiere in France started applying electrical stimulation to the inserted needles to see how this altered treatment effects (Lu & Needham 1980). But in general, acupuncture did not make sufficient inroads in Western countries to warrant much attention from scientists. However, following the Meiji Restoration in the latter part of the nineteenth century, Japan was modernizing rapidly. After Western-style medical practice was adopted as the standard of healthcare in Japan, a number of physicians and scientists turned to studying acupuncture and its related moxibustion therapy. This in turn led to the establishment of a research movement in 1905 led by Kinnosuke Miura (Manaka et al 1995, p 349). Then, beginning in 1912, studies exploring the biological and physiological basis of

moxibustion therapy were published. Historically moxibustion was rolled into small pieces and burnt on the skin, leaving small blisters on the acupoints. While this style of moxibustion has become less popular in modern China, it is still common in Japan where the method is called '*okyu*'. At the beginning of the twentieth century this style of moxibustion had developed the reputation for curing serious infectious diseases such as tuberculosis. Thus one of the early foci for the physiological investigations of *okyu* was into its immunological effects (Hara 1929, Tamura 1934). Between 1912 and 1941 more than 45 studies were completed showing the probable physiological and immunological basis of *okyu* moxibustion therapy (Manaka et al 1995, p 353–354). For example studies found that this kind of moxibustion stimulated red blood cell production (Hara 1927) while acupuncture needling generally did not — leading to a clinical differentiation still taught in many Japanese acupuncture schools (Manaka et al 1995, p 353). Other researcher suggested a physiological model of moxibustion as a kind of stimulation therapy similar to the counter-irritation therapy, focusing on the zones of the Head (Goto 1914).

Reductionist science and electrodermal measurement

In the 1950s in France, Niboyet and colleagues began the first studies of the acupuncture points and channel systems using electro-dermal measurement methods (Lu & Needham 1980, Zhu 1981). This work provided the first circumstantial evidence that the acupuncture points and channels may exist and were scientifically measurable. This innovative work was capitalised by others who developed commercial applications. In the 1950s Yoshio Nakatani started measuring the acupuncture channels and points using an electro-dermal measurement technology that he acknowledged measured the galvanic skin response. He assumed that this measured the state of the autonomic nervous system (Nakatani & Yamashita 1977). This was accompanied by the development of the Ryodoraku diagnosis and treatment system which claimed to focus on the autonomic nervous system (ANS), a system that many Japanese believe to be central to acupuncture (Oda 1989). Parallel developments occurred in Germany with the work of Voll who also investigated the electro-dermal properties of acupuncture points and channels developing the system known as 'Electro-acupuncture according to Voll' or EAV (Voll 1975). This, like Nakatani's system, involved commercial developments in the form of a diagnostic instrument with treatment protocols. However, differences in how the electro-dermal measurements were made and simultaneous interest in more Western medical therapies such as homeopathy led to completely different approaches to those used in Ryodoraku. There were different models and social pressures in Germany leading to more of an integrated approach, where acupuncture (the new therapy) was integrated with homeopathy (an already established and accepted Western therapy). The basic approach in Japan

was one of trying to validate traditional ideas and treatments in a modern social and scientific context.

The issue of how to measure electro-dermal properties of the skin, acupoints and channels re-emerged in the 1970s with questions about pressure, electrochemical artefacts, appropriate voltage and current parameters (McCarroll & Rowley 1979, Noordergraaf & Silage 1973, Omura 1975). American researchers Reichmanis and Becker made important contributions to this debate with their landmark studies in the mid 1970s (Becker & Selden 1985, Reichmanis et al 1975, 1976). While theoretically important it has been difficult to demonstrate the immediate clinical relevance of this work to the scientific community, which, naturally, is more interested in understanding acupuncture in biomedical terms, through the accepted physiological systems in the body. Tiller provides the most comprehensive discussion of electro-dermal research in acupuncture for those wishing to enter this debate more completely (Tiller 1989).

The physiology and biochemistry of pain

The physiological basis of acupuncture was investigated by research teams in China and Japan from the 1950s onwards. In the West, following James Reston's now famous 1971 article about receiving acupuncture for post-appendectomy abdominal pain, physiological studies of acupuncture developed momentum. Ji Sheng Han was conducting important research in Beijing (Han & Terenius 1982), but it was the developments in the West that seem to have dominated this research. In particular, the Western fascination with pain control played a major role in much of the physiological research. How does acupuncture act on the body to block pain during surgery? Researchers acknowledge that in order to do this research more rigorously it was necessary to standardise the research protocols by using electrical stimulation of the needles with fixed settings (frequency, amplitude) rather than manual handling and manipulation of the needles. In part acupuncture was a useful tool for researching pain mechanisms (Anon 1988). This focus led in the 1970s to the important discovery that acupuncture influences the body's natural opiate systems, for example endorphins. Bruce Pomeranz was one of the investigators involved in this important work (Pomeranz & Chiu 1976) and has summarised the findings of these lines of investigation (Pomeranz & Berman 2003). Since the early work in the 1970s significant progress has been made in mapping out the analgesic mechanisms of acupuncture and other physiological effects (Bowsher 1998) (see Chapter 10 for more details of physiological studies on acupuncture).

Controlled clinical trials

The first clinical trials of acupuncture began in Japan in the 1960s with the arrival of 'biostatistics' and the methodologies such as randomisation

that are fundamental to controlled clinical trials (Shichido 1996, Tsutani et al 1990). Prior to this the more common approach for examining clinical treatment effects was one of observation and case history reporting. Historically, within acupuncture and traditional East Asian medicine in general, case history reporting has been the most important tool for communicating information about the effectiveness of treatments (Chace 1992, Chen & Wang 1988). This can be done systematically and rigorously and is still used in modern medical research as a tool for communicating initial or exceptional clinical findings. Bio-medicine sees careful observation as an important early phase of clinical research, one that sets the stage for more detailed scientific clinical studies such as the RCT. All clinical investigations have their origin in a desire to define clinical effects and communicate these observations to the world of practice. This begins with a case description and in modern medicine results in a multi-disciplinary research team that delivers a large-scale RCT (Berman et al 2004, Scharf et al 2006). The concepts and methodologies involved in the various types of modern clinical trials, such as pragmatic and fastidious studies, are discussed elsewhere (Chapters 7 and 8).

In terms of using modern biomedical methods for investigating the clinical effects of acupuncture, not only were the first RCTs of acupuncture conducted in Japan in the 1960s by Kinoshita and Okabe (Shichido 1996), but the earliest attempts at 'inter-rater' reliability studies were also Japanese (Debata 1968, Matsumoto 1968, Ogawa 1978).

Tensions reflected in different research agendas

Acupuncture has been socially accepted in Japan for some time. Starting in 1948 practitioners have been licensed and obtain life-long licenses after completing their 3–4-year training. Acupuncture receives almost no social insurance reimbursement. Practitioners are thus under no pressure from the government, insurance or healthcare systems to prove themselves, so why develop a research agenda? Acupuncture and moxibustion therapies in Japan are quite diverse (Birch & Felt 1999). Over the last two centuries, since Gempaku's revelations, there has been an increasing trend towards accepting modern anatomical and scientific models of the body. This created pressure on traditional Japanese medical systems like acupuncture and herbal medicine (Kampo), both during the Meiji Restoration in the early 1900s and again post 1945, to align themselves with modern science (Birch & Felt 1999, p 40). The scientific establishment in Japan tried to ban or limit acupuncture, but failed. There has been a long-standing tension in the acupuncture community between the more scientifically oriented and the more traditionally oriented practitioner groups. Yoshio Manaka and Kodo Fukushima both spoke about this development in the 1960s (Y Manaka, personal communication, 1986, K Fukushima, personal communication, 1990). The scientific acupuncture community saw the possibility of

challenging the more traditional acupuncture community using new biostatistical methodologies. Some senior figures such as Manaka were concerned about whether those methodologies were appropriate for investigating the complex systems of practice that are used in acupuncture, especially traditional acupuncture. They therefore considered how they might develop different investigative approaches (Manaka et al 1995, Manaka & Itaya 1986). Others in the practitioner community were put off by the arguments from the scientific community about the supposed failures of traditionally oriented acupuncture in clinical research (K Fukushima, personal communication, 1990). This tension still exists in Japan today and mirrors the worldwide debate in acupuncture between researchers and practitioners.

Over the last five decades research has also been conducted in China but has been influenced by different pressures than in Japan and the West. Like Japan, acupuncture was already socially and politically accepted, but unlike Japan it was also government supported and sanctioned as part of the solution to a massive public health crisis. As a result of this public health role most research on acupuncture was not focused on trying to prove that it works, rather on how to understand it within the existing healthcare system and how to promote it as part of the whole field of TCM. Thus while research in China was conducted partly for internal political consumption, it was also intended to help show the West something of the development of China, both modern and traditional. Research was informed by perceived needs to achieve that goal, allowing for significant influences from the West both on the formulation of the medical systems of TCM (Taylor 2004) and how models of understanding and practice were constructed (Scheid 2006), thus some aspects of the research agenda influenced this newly developed approach to acupuncture. One of the major trends in the last five decades in mainland China has been the development of an integrated medical system, bringing together traditional and modern biomedical ideas into a single system (Scheid 2002, 2006, Sivin 1987, Taylor 2004, Unschuld 1985). One such example has been the effort to find correlations between traditional ideas and modern biomedical concepts, for example studies seeking correlations between traditional diagnostic signs and biomedical markers in the blood (Chen 1988, Fu 1988, Xie 1988), as well as investigating the correlations between traditional pathological conditions such as kidney yang vacuity and the biomedical condition of adrenal insufficiency (Scheid 2006). Clinical trials often focused more on demonstrating to an accepting audience that the treatments could be used within the public health system rather than in a real search for new information. There was little interest in demonstrating that acupuncture works, as this was and is accepted wisdom. Fulfilling this social and political need has often allowed methods of investigation to be used that would not be acceptable to scientists outside of China because they were asking different questions. Therefore much of this research is not cited in high quality scientific publications;

for example few mainland Chinese clinical trials are of the required quality to be included in systematic reviews of acupuncture.

Since the end of the cultural revolution in China (1976) scientific research in China has increased. In 1978 the first WHO Western group of conventional doctors to learn about acupuncture in China was taught the newly developed integrated approach to TCM (Lewith & Lewith 1981). Western diagnoses were used as the 'entry criteria' to understand the traditional approach and then an appropriate differentiation of syndromes occurred based on a *zang/fu* diagnosis with specific tradition functions ascribed to many of the important acupoints. This allowed the conventional physician learning acupuncture to 'know where to start' and to develop a simple approach in order to access the wisdom and centuries of experience of the traditional acupuncturist. The major research institutions in Shanghai and Beijing were fundamentally physiology and biochemistry laboratories using Western methods to investigate traditional approaches such as acupuncture and herbal medicine. In recent years collaborations have sprung up between many modern Chinese research institutions and Western research environments that have led to further developments. A recent example is the collaborative project that is working to develop a sham moxibustion research model (Zhao et al 2006).

The social and political needs for investigating acupuncture in the West have, on the whole, been quite different than in Japan and China. Acupuncture is relatively new in the West and uses terminology and models that sound exotic. It is often practised in countries where insurance reimbursement is available so research has a different focus to that in Asia. On the one hand it must prove itself to be effective following accepted models of research, such as the placebo-controlled randomized clinical trial; and on the other hand it must also demonstrate itself to be cost-effective to warrant insurance reimbursement or health service provision (Bovey 2005, Cherkin 2001, Sherman & Cherkin 2003, Wonderling 2006). It must demonstrate that its mechanisms are consistent with a Western scientific understanding of biology; if it is to be acceptable, it must be plausible. Thus the understanding of acupuncture in the scientific community has tended not to focus on traditional concepts or methods, rather it has often been forced to ignore them. These different social concerns have recently surfaced as acupuncture has been shown to be a more complex intervention (Paterson & Dieppe 2005) with different research needs (Medical Research Council 2000, Verhoef et al 2005), including the particular need to include its own traditional explanations, concepts, theories and clinical methods within the research paradigm (Acupuncture 1998).

Western clinical trials of acupuncture

Clinical trials of acupuncture in the West began soon after US President Richard Nixon's visit to China in 1972. The first trials started appearing

in 1973 (Scarognina et al 1973). They naturally focused on trying to test the effectiveness of the methods that had been observed in hospitals in China. During Nixon's visit the Chinese showcased their developments of acupuncture during surgery, which triggered much interest and excitement in the Western scientific community. The first trials were thus related to this use of acupuncture as an analgesic. This focus on the analgesic effects of acupuncture in clinical trials follows the pattern of the understanding of acupuncture from the eighteenth and nineteenth centuries in the West (Lu & Needham 1980). It also parallels the focus on understanding the analgesic mechanisms of acupuncture that have dominated physiological studies of acupuncture in the West (Pomeranz & Berman 2003). Hundreds of clinical trials have been conducted in Western countries since the early 1970s. Since the late 1980s meta-analyses and systematic reviews of these RCTs have been conducted with an evolving consensus about which medical conditions acupuncture appears to help (Birch et al 2004). (See also Chapter 11 for more on systematic reviews and meta-analyses.)

Because the philosophical and cultural issues involved in applying Western-based methods to traditional East Asian systems were virtually ignored (Birch & Felt 1999), there remain a number of important methodological challenges for the researcher investigating acupuncture.

CHALLENGES FOR RESEARCHERS INVESTIGATING ACUPUNCTURE

Researching acupuncture in a way that is fair to the medicine has proven to be a difficult task. While hundreds of RCTs and thousands of basic science studies of acupuncture have been conducted, results are often equivocal and many challenges remain. Among these challenges, two relate to the important scientific concepts of external validity and model validity (sometimes called 'model fit validity'). The first of these, external validity, tells us how well results from studies are representative of actual practice. This challenge is also addressed in Chapter 11. The second challenge, model (fit) validity, is articulated by Cassidy in the context of a question: 'Are the assumptions underlying the design well understood and factored into the design so that the resultant data accurately represent the people or practice or intervention being tested?' (Cassidy 2002). Verhoef et al define model validity: it 'encompasses the need for research to adequately address the unique healing theory and therapeutic context of the intervention' (Verhoef et al 2005). Model validity must be considered in relation to many of the issues discussed in this chapter, and in particular, what is the model of theory and practice that is to be tested? Table 2.3 summarises some of the main challenges that researchers face in light of issues discussed in this chapter, and highlights the relevance of specific items in relation to external validity (EV) and model validity (MV).

Table 2.3 Challenges for acupuncture researchers and relevance to external validity and model validity

1. Mapping and investigating the diversity of acupuncture practice
   i. Historical developments, role of culture, politics, social & economic pressures on development and manifestations of models of practice (MV)
   ii. Cultural translational issues (MV)
   iii. Linguistic translational issues (MV)
   iv. Recognising differences in the nature of different systems of practice and being explicit about the specific approach that is being investigated (MV + EV)
   v. Developing better research methods for investigating traditionally based systems of practice (MV + EV)
   vi. Making valid generalisations from research (EV)
2. Addressing the bias of cultural assumptions about acupuncture and science
   i. Applicability of either-or logical assumptions when investigating acupuncture (MV)
   ii. Applicability of Cartesian mind-body duality model when investigating acupuncture (MV)
   iii. Applicability of reductionist approaches when investigating acupuncture (MV)
   iv. Recognising the validity of different investigational approaches: evidence-based medicine versus experience-based medicine (MV)
3. Modelling and assessing acupuncture
   i. Development of models of theory and practice and their assessment as complex interventions (MV + EV)
   ii. Development of models of theory and practice and their assessment as whole systems with holistic models and approaches (MV + EV)

EV = external validity; MV = model validity.

If we look to the scientific method itself, we can restate these challenges for both clinical and basic science research in another, perhaps more fundamental way:

The fundamental feature of the scientific method is that it does not prove a theory to be true. Rather, it disproves competing, alternate or opposite hypotheses. Thus any scientific experiment can only disprove competing hypotheses (hence the common use of the 'null hypothesis') and is consequently entirely dependent on the initial theoretical framework or model. Most experiments on acupuncture have had significant difficulties formulating, or have ignored, a valid model of 'acupuncture' based on a clearly articulated theoretical framework. This necessarily means that 'acupuncture', as we have discussed, has been neither proved nor disproved in most if not all scientific experiments. Until such time as better models of acupuncture theory and practice are formulated and included in clinical trial design, the theories and practices central to acupuncture will remain untested. We will simply be evaluating

individual re-interpretations of acupuncture. This represents a significant challenge not only for the medical research community but also for acupuncture practitioners and researchers.

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