

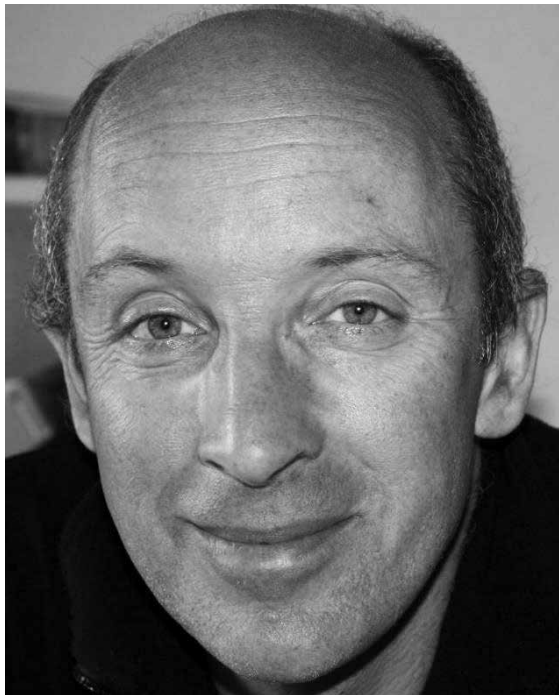
The Trials and Tribulations of Clinical Research and Chinese Herbal Medicine Education: A Conversation between Andrew Flower and Peter Deadman

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Abstract

Andrew Flower is a long-standing practitioner of Chinese medicine, a pioneering researcher into Chinese herbal medicine (CHM), and is in the process of creating new educational opportunities for a thorough grounding in the study and practice of CHM. This conversation was recorded in early 2018 and transcribed for publication.



PD: Andrew, how did you first get into Chinese medicine (CM)?

AF: It started with an enthusiasm for Chinese yoga, Buddhism, and martial arts. Then one day, when I was studying English literature at university, I went for a walk with a (Western) herbalist and had one of those 'lightbulb moments'. He was pointing at what looked like ordinary weeds by the side of the footpath and saying things like, 'that's good for cystitis, that's good for headache' and I really liked that. So when I left university in 1984 I tried to find a way to study Chinese herbs in the UK. I found a Chinese teacher,

Dr Lee, who had a clinic in London's Baker Street (right next to a brothel), and did a two and a half year part-time acupuncture and herb course with him. The thing I remember when I first went there was this wonderful smell of moxa and some herb he was frying up (pao zhi) ... I think it was Xiang Fu in vinegar. He was a great practitioner – probably the best acupuncturist I've seen in the UK - but a really poor teacher in the Chinese textbook style. I realised I'd have to start again from the beginning if I was going to practice safely and effectively. I did a brilliant first year at the ICOM school in Sussex, and when that fragmented I went to the London School of Acupuncture for my last two years. At the same time, I signed up to Nguyen Tinh Thong's herb course at the London Academy of Oriental Medicine.

PD: So when you graduated you practised both acupuncture and herbs. Did you feel confident about both those practices?

AF: I felt more confident about acupuncture than herbs. I was working in the East-West herb shop in Covent Garden and we were treating up to 30 people a day. We had people coming in for Chinese herbal medicine, complaining about problems like scabies or hay fever, and I was rushing round the back of the shop and looking up the treatment. I realised my training was inadequate so I sat in on a course with Mazin Al-Khafaji and Michael McIntyre, and did as much post-graduate training as I could, including two trips to China. I spent three months in Guiyang, living with a Chinese family. All I did was work in the clinic, study at home and eat great food. But I still feel my training left gaps that I have had to spend the rest of my life filling.

PD: Do you want to say something about how you feel about acupuncture compared to CHM.

AF: I think I'm naturally a herbalist more than an acupuncturist. I love making a pattern with herbs that matches the pathological pattern of the patient. I like its rigour. It makes a lot of sense to me physiologically and pharmacologically. I've never been interested in the intellectual side of acupuncture. If I was going to focus more on acupuncture I would do more qigong. But the thing I love about acupuncture is that there's something magical and mysterious about it. The fact that you can hold the needle sometimes and get the needle sensation going one way and then the other, without telling the patient in advance. Just through what feels like intention. There's no explanation of that in Western physiology and I find that fascinating. I love acupuncture's dynamism and vitality, and that it can be effective instantly. I've just treated a woman with severe endometriosis pain and the pain completely disappeared immediately after the treatment. You can't do that with herbs.

PD: So moving on to herbs, how do you deliver them?

AF: I've changed my approach in the last few years. When I first started, I used decoctions in quite large doses. It was how I first learned from Dr. Lee, who gave substantial Chinese-style doses and it always seemed to me the best way to prescribe – the most effective clinically. Then about 20 years ago I experimented with herb powders because they were more convenient and cheaper. I did a little comparison study. I treated 10 to 15 people with powders, then switched to decoctions, and vice-versa over the course of a year or so. I found the powders to be considerably less effective and stopped using them. Then many years later I had to use granules for some research I was doing and this time they seemed to work really well. Apparently the quality of the granules has massively improved and this is apparent in their chromatographic signature. They're much more similar to the actual herb, with the same peaks and troughs indicating they've got the same active compounds. So nowadays I almost exclusively use granules which are much cheaper and more convenient than cooking up the raw herbs. When I worked in a clinic that cooked up decoctions and packed them in bags, it wasn't unusual for them to cost £100 (\$140) a week. That's elitist and not available to most of the population, especially considering you might have to take herbs for several months. I now get equally good results using the granules so for me the choice is obvious.

PD: Talking about long-term treatment, you have a special interest in supporting patients with cancer.

AF: I think CM has a huge amount to offer in treating

at different stages of cancer – at every point along a person's journey, whether it's before or after diagnosis, during or after treatment – and particularly when they finish Western medicine (WM). Acupuncture is brilliant for managing the stress of a diagnosis of cancer and the subsequent treatment. It gives the person the feeling that they're doing something healing for themselves, rather than just being brutalised by the WM treatment. And the herbs are very useful in terms of supportive treatment during chemotherapy, radiotherapy and recovery from surgery. The thing that really interests me at the moment is treating people who've either been told there is nothing more to be done for them, or treating people who've been told 'you're clear now – just go away and live your life as though nothing happened'. So the ones on palliative care and the ones who've been discharged – both can, and need to, make major changes in their lives, and acupuncture, herbs and lifestyle changes can nudge them in the right direction.

PD: You're saying that the people who are not responding to WM treatment can be helped?

AF: Yes. I find that more and more. I've got patients on my books (and I know other herbalists who have too) who are not responding well to, or have come to the end of the line with conventional treatment, and whilst I don't think the herbs are curing them, they are keeping them alive and keeping them alive better than if they'd been left to decline. For example, one patient with stage 4 colon cancer that spread to his liver had to have surgery every nine to twelve months to clear the liver of tumours and was feeling wretched and miserable ... he's been taking herbs for three years now and hasn't needed any more surgery. I don't think he's cured but he's maintained. Chinese medicine can definitely support some patients in living longer and better.

PD: What about those who've been discharged?

AF: I think CM has a huge amount it can offer to prevent recurrence. I have a number of patients who are beating the odds. I think CM is only part of what patients need to do though. It's one piece in the puzzle – it's not magic ... they also need to change their diet and lifestyle, look at their emotional patterns, do the things that make them feel alive, joyful and creative. CM is just one part of a whole programme.

PD: So, moving on, I know that in recent years you've been involved in research in Chinese herbal medicine. What led you into it?

AF: Foolishness! Actually I was clear about two things. The first was personal – I felt I'd hit a glass ceiling in my

study of CM. I felt there were a limited number of books in English and I wanted to deepen my knowledge. So I used the PhD as a structured way of doing this. For example it forced me to improve my reading of Chinese so I could read Chinese medical papers. The second was political. I understood that if CHM was to really take root and flourish in the West we needed to provide solid evidence of effectiveness.

PD: Your first study was into endometriosis?¹

AF: Yes, that was my PhD. I did a Cochrane review ... I reviewed 140 clinical trials of which we could only include two as all the rest were too poor quality.² But I learned from them – for example dosages, which herbs were the most commonly used etc. Then we did a clinical trial – we think it was the first ever double blinded randomised controlled trial (RCT) using herbal decoctions.

PD: You made a fake decoction?

AF: Yes out of all kinds of disgusting dried vegetables. And the double blinding worked. People didn't know what they were on – herbs or placebo - and neither did I. Unfortunately the trial was compromised by my own lack of rigour in collecting data. For any practitioner thinking of doing research, there's a real potential conflict. As a researcher you have to be fairly distanced, even ruthless, about collecting data, whereas as a practitioner, you're there for the patient in a different way. I found I was good with the patients but when it came to collecting their outcome data I was useless.

PD: But do you think it was valuable purely from a research point of view?

AF: Well one of the problems with it – and the next research we did – was very poor support from conventional doctors who were supposed to be referring endometriosis patients. I contacted 30 GPs and visited two consultants who said they would support me, and out of that we got precisely zero referrals. So we had to recruit via a self-help group. But what I discovered was that the self-help group was made up of really hard-core, seriously recalcitrant cases. For example, one woman was on 180ml of morphine a day and still scoring nine out of ten on a pain score. Even so, some did get benefit from CHM. But it was a taster of what I think is one of the big problems with CM (and other) research: that you often attract an atypical patient population. In pharmaceutical trials this is often loaded in favour of the drug being tested - so participants with co-morbidities, who may be on other medications, older or of child bearing age for example, may be excluded. In our study it was loaded against CHM treatment. There are outcomes studies of surgical treatment for endometriosis

using self-help groups where only around eight per cent reported positive outcomes from the surgery they previously had, with 44 per cent saying they got worse. But in a different cohort, recruited from hospital records, nearly 90 per cent reported positive outcomes from surgery. This shows the importance of where you recruit from.

But there were some positive outcomes. One was that it's possible to do a double-blind RCT study into CHM using decoctions, though it would be hard to get funding for this kind of approach, because most grant making bodies are looking for a simplified standardised remedy that can be wheeled out into the National Health Service. Also it was salutary to discover how powerful the placebo response was ... I got some superb responses with my vegetable soup! It was probably the most professionally disturbing day of my life when we broke the code. Some of the patients I was totally convinced were taking herbs were actually taking the placebo. And these were women who had been in a lot of pain. One woman, for example, hadn't been able to have sex with her husband for two years – it was too painful. Three weeks after starting the trial she had no pain and was able to resume sexual activity, but when I broke the code we found she was on the vegetable mix. So it was all pretty interesting but a nightmare too – getting ethical and regulatory approval to do a clinical trial in CM took huge amounts of time, effort and, above all, persistence.

PD: After all that delving into endometriosis do you have any clinical nuggets to share?

AF: Yes. First, I used fairly robust dosages – for example up to 20 or 30 grams of San Leng and E Zhu if necessary. I think the animal products made a big difference – things like Shui Zhi and Tu Bie Ching which unfortunately we can't use at the moment in the UK. I learnt about the importance of herbs which both move blood and clear fire poison - things like Bai Jiang Cao and Da Xue Teng. This dual action improves the anti-inflammatory effect of the blood-moving herbs, clearing some of that burning, inflamed feeling women have. I also learned about the importance of the mind in these conditions. I think with a lot of people with pelvic pain there's an element of qi stagnation – the compression of difficult emotions into an area. I think that's true for endometriosis, chronic pelvic pain and even urinary tract infections. And the other thing is that endometriosis is not an easy condition to treat. It's tough and it comes back. CM can improve symptoms and fertility but there's no denying it's a tough disease to treat.

PD: So despite the challenge – even the occasional nightmare of your research into endometriosis, you decided to undertake another piece of research – into urinary tract infection (UTI)³?

AF: Yes, a glutton for punishment! Actually, my very first idea, even before the endometriosis study, was to study the use of CHM alongside breast cancer chemotherapy, but my Professor - the late George Lewith - said there was no chance of getting a grant for that as the authorities would never support the use of herbs during cancer chemotherapy. So I had to bite the bullet and accept that if I wanted to continue my research career I'd have to find something that was fundable. I applied for a National Institute for Health Care Research post-doctoral fellowship grant into UTI and to everyone's surprise, I got it. I think one reason I did so was because of the growing fear about antimicrobial resistance. UTIs often don't respond to antibiotics in the way they used to so they're looking to herbs as an alternative. They gave us five years funding to review the evidence and conduct a feasibility study.

PD: *So how did that work?*

AF: Well, my approach to research has always been to try and piggyback my own interest on top of what the funders want. I wasn't interested in just picking a couple of herbs and testing them, so I set up a process to define best practice in CM beyond just my own knowledge and practice. So we developed a five phase model. We looked at reflective practice (fire); what modern textbooks said (earth); research and clinical trials, which led to another Cochrane review (metal);⁴ peer review - asking other practitioners how they treated UTIs (wood); and what the classical texts said (water). I worked with Vivienne Lo, looking at the traditional disease categorisations such as lin zheng and long bi and how they were treated, which was extraordinarily relevant. And we tried to pool all this information together to determine how UTIs should best be treated. Using this five phase model was a slightly artificial division but as a process it worked and is one I would recommend to anyone doing CM research because it broadens your understanding. We've written papers on this approach.^{5,6} And before I started the randomised controlled trial I did an observational study.⁷ This is really important for anyone who wants to do research into CM - don't just jump into doing a big randomised controlled trial. It should be a phased process, first teasing out what works. That's actually why I decided to research UTI - because I was getting good results in my own practice. So I treated 15 women with UTIs and monitored the outcomes. They did really well and we wrote that up as a paper, then moved on to the feasibility study. So it needs to be a 'phased intervention into a complex intervention' - not just trying to cherry pick a couple of ingredients and putting them into an RCT, which I think is a recipe for disaster.

PD: *So what was the outcome of the UTI study?*

AF: As it was a feasibility study, I can't give you any definitive proof that CHM works. In terms of feasibility, it was tough. There were two arms to the trial. One was a standardised prescription, delivered by GP practices through the UK National Health Service (NHS). The other was individualised treatment administered by me, though patients were supposedly recruited by the NHS as well. But we found that recruitment by the NHS was really poor and slow, the dropout rate from the GP practices was 50 per cent, which is extraordinarily high, and the outcomes they collected were rubbish. So it wasn't really taken seriously by GPs, and the data we got was compromised. And in the individualised arm, we got barely any recruitment via the NHS. So we had to recruit via self-help groups again and found the same thing as the previous research - women with really severe infection and continuous UTIs - burning on urination, abdominal pain, cloudy smelly urine, frequency, urgency, nocturia etc. Over 50 per cent of the individualised group had continuous infection compared to none out of 30 in the GP arm. We treated the individualised patients for 16 weeks, and although the patient diary we used to determine outcome didn't really work because it wasn't designed for continuous infection, actually we got really good results - an average 44 per cent improvement in symptoms and a significant reduction in antibiotic use. In the follow-up, 80 per cent had reduced antibiotic use and over 50 per cent had completely stopped using them (remember some of them had been using antibiotics for months, even years). And interestingly, well over 50 per cent didn't have another infection within six to 12 months after the trial, whereas in conventional medicine with antibiotic prophylaxis, around 50 to 60 per cent relapse within three months of stopping antibiotics. However, it was a tiny sample - 30 in the standardised arm of which only 15 completed, and 31 in the individualised arm with 77 per cent completion. And it was supposed to be a placebo-controlled arm but the company we used screwed up and mixed placebo with active herbs so it invalidated the placebo arm. But overall, despite all the deficiencies I'm happy to end my research career with that kind of data.

PD: *Before we move on to your next venture, are there any clinical nuggets that came out of the trial?*

AF: Yes. It emphasised even more for me the importance of understanding the CM pathology as a dynamic pattern. In UTIs there's a very common pre-existing pattern of Spleen deficiency with dampness sinking down to the lower jiao, and Liver qi stagnation from emotional causes generating heat that combines with the dampness. There may also be an underlying Kidney deficiency in those who have over-worked or are older. The damp-heat smoulders

over time and creates the conditions where bacteria can enter opportunistically to generate fire poison in the bladder. The intense heat consumes the qi, blood and yin and obstructs the flow of qi and blood. So you get a complex, self-reinforcing pathological pattern. I think it's really important to understand that process. Treatment at the acute stage focuses on clearing the infection, so I use a lot of clearing fire-poison herbs in very substantial doses and I find that really effective. For example Bai Hua She She Cao, Ban Zhi Lian, Bai Jiang Cao. And then herbs like Huang Qin, Ku Shen and Shi Wei to clear heat, with draining dampness and clearing heat herbs on top of that, plus herbs to regulate circulation of qi and blood like Hu Zhang and Wu Yao. Then after the acute phase you have to regulate the root causes of the condition so promoting the circulation of qi, strengthening the Spleen and clearing dampness etc. This approach is how I deal with virtually every disease I treat now – not looking at patterns as a static list which is the way we are often taught, but as a process, a dynamic interplay.

PD: So you've drawn a line beneath your research career now.

AF: Yes, but I should stress that research is really important – both for learning more about CM and politically. For example the positive eczema studies that were done around 20 years ago made a big difference to CHM, as the fertility studies have to acupuncture. Research can have a profound effect on people's practice. But my feeling is that the research that can be done in today's climate is a simplified intervention on an atypical population, with blunt outcomes and unreliable statistics at the end of it. It's down to the research model that the main funders want us to use. They're not interested in individualised treatment because they need CM herbalists for that. The people with the research money want to take something from CM that they can generalise and standardise and which doctors can use. But for me, every step in that direction diminishes the medicine – you're reducing it by standardisation and by limiting the number of herbs you can use. For example, in our standardised arm we were only allowed to use three herbs. That's all you're likely to get a product licence for, and the stability testing required in research makes it very expensive to do anything more than that. And as I said, recruitment often results in atypical patients and the final outcomes are really crude. For me they didn't reflect the more subtle, holistic changes CM offers. We know that one of the best things about CM is that the things you weren't even treating can get better. The outcome measures don't capture that. Don't get me wrong. I still think research can be really valuable. I'm currently supervising someone who's doing a PhD in the use of Chuan Xin Lian for respiratory tract infections. I think we might get a decent result with that – it's a simple herb that's used on its own in China. It's antiviral, antibacterial, immune-enhancing,

anti-inflammatory, and it might work. So if you can get a remedy like that out there and reduce antibiotic use it's great, but for myself doing that kind of research no longer interests me. What I most enjoy now is teaching CHM. Despite a focus on research and regulation, in my opinion CHM has gone downhill - in the UK at least. The number of people prescribing and using CHM has declined and several schools have closed their CHM courses.

PD: Why do you think that is?

AF: Partly because of lack of demand, and partly because universities have stopped teaching CHM for political reasons. There are fears about regulation of CHM and that the available materia medica is being diminished by regulation, though that still leaves loads of herbs we can use. Also I think acupuncture training is better than it was and maybe acupuncturists have become overconfident about what they can treat, for example skin diseases, which actually respond better to herbs. Also acupuncturists are tired and poor because the courses are so expensive now. The idea of spending another three years studying herbs – plus many more thousands of pounds – is putting people off. We need to reverse this.

PD: Which is why you've started up the White Crane Academy of Herbal Medicine - a new school to teach CHM.

AF: Yes. I've taught for various colleges that I have a lot of respect for, but I've never felt that the students I taught were graduating at the level they should have been – partly due to lack of time, partly due to the level at which the courses were being pitched. For example, it's often being taught as an MSc when it should be an undergraduate course because people really need to learn the basics, not go off on self-directed learning on the internet. They absolutely have to learn the herbs properly. It's like teaching people to learn a language and expecting them to write poems before mastering the basic vocabulary. I want to teach the basics of CHM really well, especially what's clinically meaningful – what works in practice. We both know about the often huge discrepancy in CM between theory and practice. I learned a lot of theory that didn't work in practice. For example early on I treated a patient with migraine with Tian Ma Gou Teng Yin [Gastrodia and Uncaria Drink] – the classic Liver yang rising prescription and it just didn't work. And when I consulted another senior practitioner he said yes, we know that doesn't work, you have to move blood as a priority. But that wasn't what I was taught. So I'm very keen that people are not taught theory that doesn't work because it makes them feel underconfident and more likely to give up practice.

PD: *That ties in with my own experience of first learning herbs, then prescriptions, then diseases and appropriate prescriptions for them, then going into the clinic and finding those prescriptions weren't used. Do you think it's a particular Chinese way of educating?*

AF: Exactly. There's a reverence for tradition – however constructed that tradition is. For example I have read when they formalised TCM in the 20th century it wasn't necessarily done by the best practitioners and teachers, but often by keen younger doctors who were also in favour with the party at the time. We also know that some of the great historical figures in CM didn't actually treat patients. I mean the theory and philosophy of CM is a beautiful thing but the key thing is what works in practice, for example the street prescriptions that Paul Unschuld has located, rather than the academic texts. This was how people made a living and the prescriptions had to work - if not they had to change them.

PD: *So are you suggesting that people may spend a lot of time and money studying CHM, and then find when they apply what they've been taught that it's not that effective in practice.*

AF: I think that's true. That was my experience when I supervised graduates from different colleges. I'm not sure it was only that the prescriptions they were taught sometimes didn't work, but other issues like dosage and differential diagnosis which aren't always taught very well. And I think practitioners often lack confidence because they can be a bit scared of herbs. You can pretty much get away with anything in acupuncture and it will work. And herbs will usually work to some degree just because of placebo. But to go beyond that you need to have a clear diagnosis, write a targeted prescription with the right dosages, and have the confidence to take the patient through what might be a difficult process. They might be challenged by the taste of the herbs, get diarrhoea, get headaches – you've got to stay with them and support them through that process, and you need confidence and good clinical training to manage that.

PD: *So you're setting quite a high bar for your herb course.*

AF: Yes maybe. It's a three year course but I've been telling the students that this just gives them the foundations. We both know that CM takes years. I've been practising for 25 years and I'd call myself an intermediate level practitioner. But however high you aim you have to have a solid foundation, otherwise you can't build your house. That's what I want to give our students – a solid foundation.

Endnotes

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