

HERBAL MEDICINE RESEARCH

HERBAL MEDICINE USE IN THE UK

Herbal medicine has been used for thousands of years to treat people's ills. There are currently about 2000 practitioners of traditional herbal medicine in the UK including Western, Chinese, Ayurvedic, Tibetan, and Kampo herbalists¹. It is estimated that 0.8% of the UK population has visited a herbal practitioner². Over the counter (OTC) natural remedies account for the majority of use, and according to an article in The Telegraph, 3 million people took herbal remedies in 2008³. An Ipsos MORI study commissioned by the Medicines and Healthcare Regulatory Agency (MHRA) found that 35% of respondents had used herbal medicine, and that 82% of these people had used OTC herbal medicines compared to just 13% who had visited a practitioner of herbal medicine. It is interesting that two thirds of the former group are people willing to take and trust the advice of family members, friends, and shop assistants on the subject of herbal medicines⁴. Herbal medicines and Nutraceuticals products are a booming industry. The total UK market value for herbal, homeopathic, and aromatherapy over the counter products has grown year on year and is estimated to be worth £290 million by 2012. This projected growth reflects increased availability of Complementary and Alternative Medicine (CAM) products, the continued aging of the UK population, and the increasing integration of CAM into orthodox healthcare⁵. Herbal medicine makes up a large part of this CAM products market - it is estimated that £126 million is spent on herbal medicines alone each year in the UK, and the world market is estimated at £41 billion⁶. Herbal Medicine is a therapy people are becoming increasingly aware of and seeking out - 10% of the UK population already visit complementary therapists²

HERBAL MEDICINE TRAINING

These various types of herbalists all practice in different ways, but most belong to a professional body and are trained to a very high standard. For example, Most Western herbalists have graduated from National Institute Medical Herbalists (NIMH) accredited degree courses with a BSc Hons in Herbal Medicine from UK universities such as: Edinburgh Napier, Middlesex, Westminster, Lincoln, East London and the Scottish School of Herbal Medicine (a college)⁷. A Herbal Medicine degree includes; studying anatomy & physiology, clinical medicine, rigorous training on the dangers of potent herbs, the potential interactions with conventional medicines, a thorough knowledge of diagnosis and when to refer potentially serious conditions, and 500 hours of clinical practice. All students undertake scientifically researched and referenced coursework and dissertations, which enables them to easily keep up to speed with the latest research once qualified. Clearly, qualified Western herbalists are in a good position to advise both the general public and other healthcare practitioners about herbal medicine and research.

¹ Thomas K, Coleman P. Use of complementary or alternative medicine in a general population in Great Britain. Results from the National Omnibus survey. J Public Health (Oxf) 2004; 26: 152–157

² Thomas K, Coleman P. Use of complementary or alternative medicine in a general population in Great Britain. Results from the National Omnibus survey. J Public Health (Oxf) 2004; 26: 152–157

³ Cohen, T (02 Nov 2009) Just how safe are herbal medicines? <http://www.telegraph.co.uk/health/alternativemedicine/6466718/Just-how-safe-are-herbal-medicines.html>

⁴ Ipsos MORI (Nov 2008) Public Perceptions of Herbal Medicines General Public Qualitative & Quantitative Research <http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicines/PlacingaherbalmedicineontheUKmarket/TraditionalHerbalMedicinesRegistrationScheme/index.htm>

⁵ Market and Business development Ltd, Manchester, www.mbdLtd.co.uk

⁶ National Institute of medical Herbalists. www.nihm.org.uk

⁷ www.nihm.org.uk

THE LAW & REGULATION OF HERBAL MEDICINE

In a study on paediatric patients' use of CAM, carried out by researchers at Aberdeen Royal Infirmary, 20% had used herbal preparations such as Echinacea, Cranberry and herbal vitamin supplements. 61% of the parents who responded on behalf of their children thought CAM was effective; however many had not informed their GP about giving herbal preparations or CAM treatment to their children⁸. Another study, on cancer patients' use of CAM, has found that the reason people do not disclose use of herbal medicines is because they fear clinician 'disapproval' about CAM products and therapies⁹. This 'disapproval' is repeatedly cited as being due to a lack of a base of scientific evidence. As can be seen from the market research figures above, a considerable number of people take CAM remedies and the perceived 'disapproval' of mainstream medicine could cause adverse drug-herb interactions through lack of communication between patients and healthcare practitioners.

The current Medicine Act 1996¹⁰ means that completely untrained people can practice herbal medicine and carry out consultations. This is underpinned by unfortunate cases like the recent trial of Susan Wu who worked at a 'Chinese Herbal Medical Centre' in Chelmsford and gave a patient *Aristolochia* for five years even though it is actually banned in the UK. This resulted in the patient having kidney failure and a heart attack¹¹. Western herbalists also use some very potent herbs such as Belladonna and Aconite which are only allowed to be given after a one to one consultation under Order 1977 (SI 1977/2130) - but if anyone can give that consultation, where is the safety?

The above problems have prompted the government to discuss these issues, and propose changes to the regulation of herbalists. The recent consultation on the statutory regulation of herbalists in the UK carried out by the Department of Health (DH) poses the question "*Would it be helpful to the public for these practitioners to be regulated in a way which differentiates them from the regulatory regime for mainstream professions publicly perceived as having an evidence base of clinical effectiveness?*"¹²

HERBAL MEDICINE RESEARCH IS BEING CONDUCTED

Empirical Evidence Base

The empirical evidence base for herbal medicine is strong. Western herbal medicine makes use of herbs which have been used continuously in Europe for the last 2000 years¹³. The evidence base for the clinical effectiveness of herbal medicine has been valid enough for the millions who seek out and use such therapies on an annual basis. Evidence in this case is often based on 'word of mouth' and positive experiences of patients finding herbal medicine 'clinically' effective. The fact that these patients are seeking out and using this therapy at their own cost is a powerful argument for effectiveness – people do not continue to pay for a service which fails to deliver benefit. While opponents of herbal medicine criticize the quality of the evidence base, the public continues to take herbal medicines regardless¹⁴. However, if herbal medicine is to be

⁸ Shakeel, M., Little, S, Bruce, J., (Sep 2009) , Use of complementary and alternative medicine in pediatric otolaryngology patients attending a tertiary hospital in the UK

International Journal of Pediatric Otorhinolaryngology, Volume 71, Issue 11, Pages 1725-1730

Department of Otolaryngology-Head and Neck Surgery, Aberdeen Royal Infirmary, University

9 Evans, M., Shaw, A. et al (Aug 2007) Decisions to use complementary and alternative medicine (CAM) by male cancer patients: information-seeking roles and types of evidence used, *BMC Complement Altern Med*, 4:7:25

¹⁰ OPSI (2002) *The Medicines Act 1968*, http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1968/cukpga_19680067_en_4#IDALFISD

¹¹ MHRA Source (18 Feb 2010) Traditional Chinese Practitioner Found Guilty Of Medicines Act Offences,

<http://www.medicalnewstoday.com/articles/179551.php>

¹² DH (Aug 2009) Joint consultation on the Report to Ministers from the DH Steering Group on the Statutory

Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems

Practised in the UK, http://www.dh.gov.uk/en/consultations/liveconsultations/dh_103567

¹³ Holland B (ed) 1996 *Prospecting for drugs in ancient and medieval European texts: a scientific approach*. Harwood Academic Publishers: Amsterdam

¹⁴ Daley A, et al 2006 Factors associated with the use of complementary medicine and non-pharmacological interventions in symptomatic menopausal women. *Climacteric* 9:336–346

accepted in wider conventional medical circles, communication and further research is vital. There is already a substantial body of research, and informing the wider community about what is already out there is also important for herbal medicine.

Scientific Research

Herbal medicine has seen a growth in scientifically referenced texts in the past twenty years¹⁵. There is now a substantial body of work on the analysis of the constituents of medicinal plants, and laboratory investigations of the pharmacological actions of whole plant extracts or constituents¹⁶. Examples include Sage (*Salvia officinalis*)¹⁷, Horse chestnut (*Aesculus hippocastanum*)¹⁸, and Nettle (*Urtica dioica*)¹⁹. There are many books now published with scientific evidence on the efficacy of herbal medicine - for example 'The Principles and Practice of Phytotherapy' by Mills and Bone (2000)²⁰ and Evidence-Based Herbal Medicine by Rotblatt (2002)²¹. There are over 50 scientific journals dedicated to different aspects of herbal medicine research such as studies on isolated constituents in plants, these include publications such as *Fitoterapia*, *Planta Medica*, *Herbalgram* and *Evidence-Based Complementary and Alternative Medicine*²². There are also well established databases on herbs and herbal research such as: The Natural Standard, *Herbmed*, and ESCOP. Below is an example from the www.herbmed.org database of the evidence gathered for St John's wort, the most popular herb sold in the EU and UK.

St. John's wort : Available data on www.herbmed.org	
Evidence for Efficacy (Human Data) Clinical Trials (214) Observational Studies/Case Reports (109) Traditional and Folk Use (82)	Safety Data Adverse Effects & Toxicity (76) Interactions (128) Contraindications (12)
Evidence of Activity Animal Studies (129) Pharmacodynamics (351) Analytical Chemistry (175) Pharmacokinetics (ADME) (55) Genetics & Molecular Biology (37)	Formulas/Blends Modern Methods of Preparation (39) Patents (25) Folk Blends (component) (0) Contemporary Mixtures (component) (0)
Other Information Pictures & Distribution Maps (6) Cultivation, Conservation & Ecology (44) Related Links (6)	Dynamic Updates Live PubMed Searches (15)

Forster D, et al 2006 Herbal medicine use during pregnancy in a group of Australian women. *BMC Pregnancy and Childbirth* 6:21 [online] last accessed 8 aug 2009 at URL <http://www.biomedcentral.com/1471-2393/6/21>

¹⁵ Mills, S, Bone K 2000 Principles and Practice of Phytotherapy. Churchill Livingstone: London, Trikey, R. 2003) Women Hormones and the Menstrual Cycle, Allen & Unwin, Crows Nest, Australia

¹⁶ Bradley P 2006 British Herbal Compendium Volume 2. British Herbal Medicine Association: Bournemouth

¹⁷ Lu Y, Foo L 2002 Polyphenolics of *Salvia*- a review. *Phytochemistry* 59:117-140

¹⁸ Sirtori C 2001 Aescin: pharmacology, pharmacokinetics and therapeutic profile. *Pharmacological Research* 44:183-193

¹⁹ Chrubasik J, et al 2007 A comprehensive review on nettle effect and efficacy profiles Part 1:

Herbae Urticae. *Phytomedicine* 14:423-435

²⁰ Mill, S. & Bone, K. (2000). Principles and Practice of Phytotherapy. Edinburgh: Churchill Livingstone.

Muarry, M. & Pizzorno, N.D. (2002). The Encyclopaedia of Natural Medicine. London: Time Warner Books.

²¹ Rotblatt M, Ziment I (2002) Evidence-Based Herbal Medicine. Philadelphia: Hanley & Belfus Inc

²² Examples of Journals: *Chemical and Pharmaceutical Bulletin*, *Japan / Economic Botany / Ethnobotany Research and Applications / Fitoterapia / HerbalGram / Journal of Ethnopharmacology / Medical Herbalism / The Journal of Natural Products / Herbal Pharmacotherapy / Natural Products Reports/ Natural Product Research/ Phytomedicine / Phytotherapy Research / Planta Medica / Journal of Ethnobiology and Ethnomedicine / Evidence-based Complementary and Alternative Medicine / Alternative Therapies (In Health and Medicine / American Herbalists Guild / Complimentary and Alternative Medicine Library information service.*

Herbal Medicine Market Research

Plant sourced ingredients account for about 80% of pharmaceutical drugs. The market leaders are the USA, Germany, France and the UK. The use of natural ingredients is expected to continue to rise because the market for self-medication was worth € 25.4 billion in 2007, 70% of the total non-prescription market. This growth is due to the increasing validation of safety and efficacy of herbal remedies, legislation improving the status of plant medicine, renewed interest in isolating new compounds and a search for new treatments for drug resistant diseases²³.

The European Union Herbal Monographs and Herbal Medicinal Product Research

The law is changing regarding over the counter CAM remedies as well as regulation of practitioners. Over the counter herbal medicine products now need a license. The European Medicines Agency (EMA) set up the committee on Herbal Medicinal Products (HMPC) to establish a collection of herbal community monographs to aid manufacturers with Traditional Herbal Registration of their products in accordance with the EU Directive 2004/24/EC on medicinal products for human use. About 150 herbs are being monographed, of these about 30 have had a final opinion adopted and the rest are either being studied or will be studied according to priority. A community monograph comprises of the Committee's scientific opinion on a given medicinal product, based on evaluation of scientific data as well as traditional use²⁴.

Collaborative CAM Research

The present state of UK CAM research encompasses 14 universities who have more than 2 part-time or full-time researchers engaged in CAM research in the United Kingdom. Research at Exeter, Leeds, Thames Valley, Westminster, and Northampton universities are all led by researchers with professorial appointments - an example of the academic respect which this area is slowly beginning to develop²⁵. Collaborative efforts between the NHS, The Princes of Wales's Foundation for Integrative Health, and the Research Council for Complementary medicine (RCCM)²⁶ have led to a growing collection of CAM research in the National Library for Health and the NHS Evidence-CAM website (which provides a specialist collection of CAM research for professionals, practitioners, researchers and patients)²⁷. There is also some movement in the direction of new methods of research. The Scottish School of Herbal Medicine is conducting Goethean research, a more experiential research method. Schumacher College in Devon teaches a MSc in Holistic Science which includes learning about research methodologies which may be more appropriate to fields of science such as herbal medicine. The authors of studies such as the aforementioned ones on CAM use amongst paediatric and cancer patients, conclude that further research into CAM therapies is necessary. In a survey of 430 surgical unit patients in Scotland 52% had used herbal preparations. 2/3 of this group had not informed their GP about their use of CAM²⁸ and a seven year study of the use of CAM in North East Scotland found that a greater percentage of the population were both aware of and using CAM therapies such as herbal medicine. Both these studies concluded that more research into the use of CAM therapies and conventional medicine in tandem was required to establish an working knowledge of herb/drug interactions²⁹.

²³ CBI Market Survey (Oct 2008) The Market for Natural Ingredients for Pharmaceuticals in the EU, <http://www.cbi.eu> (This report is not free)

²⁴ EMA (Oct 2009) Committee on Herbal Medicinal Products (HMPC) Overview of HMPC assessment work-status Sep 2009, <http://www.emea.europa.eu/pdfs/human/hmhc/27806706en.pdf>

²⁵ Lewith, G., Verhoef, M et al (Mar 2006) Developing CAM Research Capacity for the Complementary Medicine, eCAM 3 (2) pp. 283-289

²⁶ www.rccm.org.uk

²⁷ www.library.nhs.uk/CAM/

²⁸ Shakeel, M., Bruce, J. et al (Oct 2008) Use of Complementary and Alternative Medicine by Patients Admitted to a Surgical Unit in Scotland, Ann R Coll Surg Engl. 2008 October; 90(7): 571-576.

²⁹ Emslie, M.J., Campbell, M.K., & Walker, K.A. (Sep 2002) Changes in public awareness of, attitudes to, and use of complementary therapy in North East Scotland: surveys in 1993 and 1999, Complement Ther Med. 2002 Sep;10(3):148-53.

EVIDENCE-BASED MEDICINE – IS IT TIME TO MOVE ON?

The question posed about therapies perceived to have a lack of evidence base in the consultation on statutory regulation has sparked further debate amongst practitioners of CAM about the nature and value of different research methodologies, and about what is meant by 'evidence base'. Evidence based medicine (EBM), as we know it today, came to the fore in the early 90s in the US. It is based largely on ranking research models into a 'hierarchy of evidence' in which the Randomised Controlled Trial (RCT) is considered the gold standard. However this discriminates against other forms of research methods³⁰. The National Institute of Health and Clinical Excellence (NICE) has implemented evidence based medicine as standard research practice. Many conventional medical scientists and well known detractors of herbal medicine such as Professor Edvard Ernst advocate that a solid evidence base for CAM should be based on RCTs³¹. However, some herbalists and other CAM practitioners argue that the RCT is too narrow a methodology for herbal medicine research. The RCT may be effective when assessing a single medication for a single disease, but it is difficult to apply this methodology to herbal medicine practice in which prescriptions vary substantially from person to person depending on the individual's symptoms and constitution, not the disease. As well as this, each herb contains a multitude of therapeutically active chemicals, rather than just one or two as found in most orthodox medications³². EBM is not an absolute in orthodox medicine anyway it seems, for example the efficacy of the HPV (Human Papilloma Virus) vaccine will not be known for another 10 to 20 years and the only research carried out has been conducted by the manufacturers of the vaccine, yet teenage girls are already being immunised³³. In a 2005 Health Committee report titled '*The influence of the pharmaceutical industry*' they highlighted that the pharmaceutical industry has big influence on the gathering of clinical evidence used by NICE. Understandably they conduct the majority of drug research because this forms part of drug licence applications, however follow up on the long term effect and efficacy of drugs once on the market is lacking. They also found that clinicians would like to see research opened up to include patient experience and disease management³⁴.

Confusion between the objectives of science and those of the practice of medicine has perhaps led to misunderstanding and criticism levelled at EBM. Even more problematic, the term evidence is commonly used for many types of evidence of relevance to clinical practice, not just health care research evidence. For example, clinicians collect evidence of patients' circumstances and wishes. Thus, it is hardly surprising that the term evidence-based medicine is confusing to many, who do not appreciate that its evidence is narrowly defined as having to do with systematic observations from certain types of research. Applied qualitative research provides evidence to practitioners and patients that is often better suited for the specific problems they must deal with.³⁵

Research questions are all different in nature, they require different types of research evidence to best answer them. Thus, the idea of one evidence-based hierarchy to encompass them all has been questioned. RCTs as evidence base for clinical effectiveness is not absolute as a research methodology nor is any methodology suitable across the board for all research questions³⁶. Practitioners of CAM accept this, and many herbalists would like to be part of the evolving picture of research and medical practice which is in tune with public choices for diverse forms of healthcare.

³⁰ Haynes, R, B (March 2002) What kind of evidence is it that Evidence-Based Medicine advocates want health care providers and consumers to pay attention to?, BMC Health Serv Res 2:3

³¹ Ernst, E. (2002) 'What's the point of rigorous research on complementary/alternative medicine?' Royal Society of Medicine, Vol 95 (Issue 4) pp211-213

³² Institute of Medicine US (Mar 2005) Report on Complementary and Alternative Medicine in the United States, Seminars in Integrative Medicine, Vol 3, Issue 1 p4-8

³³ Editorial BMJ (2005) 'Cervical cancer, human papilloma virus, and vaccination' British Medical Journal Vol 331, pp915-916

³⁴ H of C- Health Committee (22 March 2005) The Influence of the Pharmaceutical Industry Fourth Report of Session 2004-05, volume 1, <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf>

³⁵ Haynes, R, B (March 2002) What kind of evidence is it that Evidence-Based Medicine advocates want health care providers and consumers to pay attention to?, BMC Health Serv Res 2:3

³⁶ Boon H, et al 2005 Evaluating Complex Healthcare Systems: A Critique of Four Approaches. Evidence Based Complementary and Alternative Medicine 4(3), pp 279-285

It is also important to remember that skeptics of herbal medicine and CAM therapies have a fairly loud voice, but do not necessarily carry out quality research. A good example is a 2006 article in the Daily Mail entitled 'Aromatherapy: Nice Smell, but no health benefit.' This was based on research carried out by Dr. Neil Martin, a psychologist at Middlesex University who conducted a study which consisted of 60 volunteers plunging their arms into very cold water for 15 minutes, whilst a third smelt lemon aroma to see if it eased their discomfort, unsurprisingly it did not. Lemon is not usually indicated as an analgesic essential oil and plunging your hands into cold water is not the same as pathological pain, however Dr. Martin concluded "Aromatherapy is more a marketing ploy than a scientific Statement." Research designs are very influential on results, and often the results are paraphrased in the media without awareness of quality of the methods³⁷.

Public healthcare research must develop in step with the healthcare choices the general public is making. It now seems inappropriate and paternalistic to dismiss herbal medicine and claim it lacks efficacy when millions of people in the UK are using it and other CAM therapies. What is more Herbal medicine does have an active research field and an 'evidence base'. Development of integrated research on herbal medicine and exploration of truly valid research methodologies for all medical practices is probably set to evolve. Herbal medicine as a practice and profession has through changing legislation been forced to advocate itself and this will continue to raise positive awareness about herbal medicine research in the future.

³⁷ Freeman, S (2006) 'Aromatherapy: Nice Smell, but no health benefit' Retrieved 12 Mar 2008 from <http://www.dailymail.co.uk/pages/live/articles/health/>