

The Current Status and Acceptance of Traditional Medicine of East Asia in the UK

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Abstract

Objectives : Traditional medicine(TM) of East Asia has been taking its status as part of complementary and alternative medicine(CAM) in the UK. However, the efficacy and safety issues make it hard to be accepted in the healthcare system. The aim of the research is to find out the current status of TM of East Asia in the UK and to discuss some issues around its acceptance as formal healthcare method.

Methods : Articles, books and regulations related to the acceptance of TM of East Asia were analysed and the internet websites were visited such as Westlaw UK for legal materials, government websites for formal documents, and some UK-based associations. Keyword searches were followed and the essential parts from the articles and documents were generalised for the analysis and discussion.

Results : Issues over TM of East Asia include identity as medicine, efficacy and safety, and the statutory regulation can be a measure for the acceptance. Osteopathy and chiropractic therapies came under statutory regulation among the CAM in the UK.

Conclusions : TM of East Asia could be under the statutory regulation in the near future. Efficacy and safety issues are the challenging barrier. However, the approach from the viewpoint of TM of East Asia is necessary for development and good practice. The simplified registration procedure for traditional herbal medicinal product in EU can be the model. Education, evaluation, assessment and managing quality of practice are essential for the standard care and formal regulation.

Key words : law, regulation, formalisation, TM, CAM, TCM, acceptance, medicine, UK

I. Introduction

Traditional Medicine (TM) is the regional medicine which has been used widely before the advent of modern orthodox western medicine and now taken as a kind of complementary and

alternative medicine. Therefore traditional medicine can be found everywhere in the world such as countries in Europe, Africa and Asia. In Asia India and China are well known for their traditional medicine.

In Europe they also have a wide range of TM and complementary and alternative medicine(CAM). Most common therapies are homeopathy, phy-

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totherapy (herbal medicine), naturopathy, anthroposophic medicine, traditional Chinese medicine, acupuncture, osteopathy and chiropractic¹⁾. Those who use unconventional medicine in European countries including the UK are increasing year by year²⁾, and accordingly the acceptance of CAM is now one subject in the health system in the UK³⁾.

There is a survey research on acupuncture use in the UK performed in 2002⁴⁾. Patients came to the practitioner mainly by self-referral (39.6%) and by recommendation of family member, friend, or colleague (34.1%) while only 5.4% visited by GP's referral. Almost three fourths of the subject patients were female (74%), and among the main problems musculoskeletal symptoms took the first by 38.1% and next was psychological (9.1%) which was way behind the first, then came general purpose (9.1%). 4.7% of the acupuncture treatments was paid by NHS.

According to a paper using Health Survey for England 2005 data²⁾ CAM therapies marking high prevalence were massage, aromatherapy, acupuncture/acupressure, relaxation, osteopathy, herbal medicine, reflexology, homeopathy, chiropractic and meditational/visualisation therapy by ranking. Lifetime prevalence was 44.0% and 12-month prevalence was 26.3%. And it showed a significant meaning that women, university graduates, anxiety or depression patients, those who have poorer mental health, lower levels of perceive social support, and those who taking five or more portions of fruit and vegetables per day are using CAM service more.

Treatments of TM and Complementary medicine are getting quite popular, however, insufficient evidence on the safety and efficacy has been pointed out. For example, Chinese herbal medicines has been increasing in the industrial market worldwide, however with regard to examination of toxicity and safety still lots of herbal medicines have been arousing apprehension compared with

the modern pharmaceutical products⁵⁾.

The toxic effects of medicinal herbs and products are reported widely in the world. Even in China, Korea and Japan lots of adverse effect are the issues for the safety of the patient, and in the past a lot of western medical doctors blamed TM for those problems especially on the liver and kidney. Recently unqualified herbal medicine for diet has been the new and still going issues and since some consumers died due to intake of those supplements produced with banned medicinal herbs. But at least in Korea it has been revealed that herbal products prescribed by qualified TM doctors are safe and effective while there still remains the interaction between herbal medicine and drugs upon which there is not enough data. Fortunately WHO are trying to develop TM in each country and not long ago it published a Global Atlas of TM and CAM and it provides a wide range of knowledge on the traditional and complementary medicine worldwide¹⁾.

Our concerns are over the traditional medicine of East Asia and its acceptance in the UK. Here the traditional medicine of East Asia will be looked over shortly, and some issues around the treatments of the TM and CAM will be discussed through the relevant published articles. And finally the need for regulation over the CAM will be covered.

II. Methods

This research focused on the present situation of TM of East Asia in the UK and the process of its acceptance or formalisation as part of public healthcare system. Therefore articles, books and regulations related to the acceptance of TM of East Asia were analysed and the internet websites were visited for in-depth researches such as Westlaw UK for legal materials, government websites for formal documents, and some UK-

based associations. Keyword searches were conducted mostly on the google scholar UK, with some direct searches on journal websites, if necessary. Keywords includes 'formalisation', 'acceptance', 'TCM', 'CAM', 'acupuncture', 'herb', 'herbal medicine', 'traditional medicine', 'Chinese medicine', 'Korean medicine', 'integrated medicine', etc.

Once collected and classified, the essential parts from the articles and documents were generalised for the analysis and discussion. This study takes the form of mixture of literature study and review article on this account.

III. Traditional Medicine of East Asia

As far as TM is concerned in East Asia, the root dates back to nearly two thousand years ago when the Han(漢) dynasty of ancient China was interacting with ancient countries of Korea. And it was handed down to the ancient Japan. The TM in each country had been developed in its own way and faced a big challenge in 19th century along the introduction of western civilization to Far East. The three countries made their own ways then, therefore they showed different aspects of TM in later periods. The names of traditional Chinese medicine(中醫學), Korean medicine(韓醫學) and Kampo medicine(漢方醫學) now represent their own TM respectively.

TM is often taken as alternative or complementary to modern bio-medicine since modern bio-medicine, which has been developed by the Western leading countries, is the contemporary mainstream medicine in our society. In this context, TM has also been contributing to the countries where the access to the orthodox medical service is highly restricted. From the view of modern Western medicine, the term CAM might

be appropriate for describing the TM because every healthcare service other than orthodox medicine is peripheral and supportive. However, so many kinds of health care service exist in the area of CAM it is rather hard to define it in the easy-to-understand form⁶⁾. In addition there are variations for TM and CAM such as Traditional, Complementary and Alternative medicine (TCAM)¹⁾ and Traditional East Asian medicine (TEAM)⁷⁾. It would be more confusing to use similar expression in a slightly different way so it seems better to use TM and CAM as the basic acronyms.

National Center for Complementary and Alternative Medicine (NCCAM) modified the CAM definition proposed at a NIH research methodology conference in 1995, and that version has been widely used as a working definition as follows:

“Complementary and alternative medicine (CAM) is a broad domain of resources that encompasses health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the dominant health system of a particular society or culture in a given historical period. CAM includes such resources perceived by their users as associated with positive health outcomes. Boundaries within CAM and between the CAM domain and the domain of the dominant system are not always sharp or fixed.”⁸⁾

In short, CAM is the term for “medical treatments that are not part of mainstream medicine”⁹⁾. Historically TM in East Asia has long been the major part of healthcare systems to the early twentieth century. Now it acts as alternative on some occasions and usually complement to the modern medicine, which in part makes integrated or integrative medicine.

IV. Issues over Traditional Medicine in the UK

1. Identity as Medicine

Since TM of East Asia comes into CAM category the status as medicine is up to the academic and clinical research evidence. In East Asia TM is treated as important heritage and endless attempts have been made to modernise and even integrate it into current health system inclusive of health insurance. TM of East Asia in the UK has been developed through Chinese community and clinics, and now we can find some research papers began to propose that the NHS should do something on the coverage of acupuncture¹⁰⁾. Since the UK has been the centre for the development of biomedicine and public health it seems to be stricter in accepting TM for health care use. Yet the practice of TM of East Asia is not regulated by the government. Hence at some points TM seems to play a role as medicine, but at others TM has quite a few weak points to be qualified for. It's closely related to the scientific evidence of efficacy and safety that can be used to back up the statutory regulation. So in this context, all the issues are interrelated together.

Modernisation has long been an agenda for TM to be adapted to modern science and technology. IT technology can also contribute to the development of TM, for example, management of knowledge information database such as information from the huge collection of classic text books. Information on the chemical constituents, formulae and safety with respect to each herbs and medicines with trace of trade can make better quality of herbal products¹¹⁾.

As for the medical education it is necessary to build up for training and evaluation system firmly, then some kind of integration into NHS can be expected¹²⁾. To be more specific, TM should take

the critical examination of its overall clinical practice and herbal medicines as well as in the process of treatment the clear diagnosis and treatment. Then theoretical and clinical researches should follow and support the practice and training system.

Lately lots of research articles on safety and efficacy have come out with systematic review papers on the clinical trials mainly from US, Europe and China. We have to admit that there are certain areas we cannot solve out clearly at this point such as territories of qi, meridian and full scan of constituents in medicinal herbs. However with the help of the multidisciplinary study we are gaining more knowledge on the efficacy and safety issues year by year, maybe being enough to apply for statutory regulation in the near future, which could provide legal framework for TM to be integrated into current health system.

The property of herbal products between food and drug is also one of the issues¹³⁾. The origin of the traditionally used medicinal herbs is fruit, seed, stem, root, etc. and many of them have also been used as food. So it is hard to tell the herbal medicine from the food. Countries like china, Korea, Taiwan have restricted use of herbal medicine as food by regulations, but the situation in US is rather different where most of the medicinal herbs fall into the dietary supplements. Considering the US potential to have the influence on the worldwide application and trade in CAM, the classification should be discussed over a period of time.

2. Efficacy and Safety

Now efficacy and safety is taken as a matter of course for all the treatments to be provided for human beings. From the viewpoint of modern medicine and health system this should be applied to all TM treatments. For integration of traditional Chinese acupuncture treatment into NHS

in Scotland, a survey was performed in 2006 being intended for physiotherapists, GPs and other doctors¹⁰. Most subjects agreed that the acupuncture treatment was clinically useful. (Physiotherapists: 93%, GPs: 93%, Other doctors: 72%). However, to the question 'Should Traditional Chinese Acupuncture be an integral part of NHS Scotland?' major responses were 'neutral' and 'don't know', and 'agree' was from a third of the physiotherapists, around 15% of the GPs, and slightly over 20% of other doctors. It suggested that for acupuncture to become a part of NHS, more attention should be paid to the evidence of effectiveness.

The attitude to the CAM among the common consumers has been favourable³ but still there is the controversy over the clinical effectiveness of CAM treatments. This situation is well expressed at the following phrase. "There is a disparity between highly prevalent use of CAM in Europe and solid knowledge about it"¹⁴

Among the medical research methodologies to prove efficacy or to find out causation in the process of TM treatments by far the most credible experimental study is randomised controlled clinical trial (RCT). However, RCT is optimised for the modern pharmaceuticals not for the traditional herbal medicines. And also blinded test is hardly possible for the acupuncture treatment except in a very restricted condition. For that reason even to make methodology becomes the research theme in TM and CAM. So to evaluate the efficacy and safety of TM and CAM treatment some special consideration should be given for the time being.

In the EU herbal medicine and product were regulated under the directive relating to medicinal products for human use (2001/83/EC) which was amended 10 2004 for traditional herbal medicinal product and some additional explanations (2004/24/EC, 2004/27/EC). Traditional herbal medicinal product, herbal medicinal product, herbal subs-

tances, herbal preparations were added In Article 1¹⁵. A simplified registration procedure was established for traditional herbal medicinal product, which included the minimum period of medicinal use: '... corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community...'. This is clearly stated at the Headings: "The long tradition of the medicinal product makes it possible to reduce the need for clinical trials, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience."

Therefore growing use of traditional herbal medicines and products of both European and non-European origin require more attention and support by law and regulations for health maintenance and promotion in EU¹⁶.

National Center for Complementary and Alternative Medicine (NCCAM) in US described acupuncture as generally safe when a skilled and qualified practitioner performed the therapy in a sanitised environment lest infection should occur. With respect to Chinese herbal medicine, it has been reported that some herbal products were missing ingredients or contaminated with foreign matters like heavy metals, toxins or drugs. And since the herbal medicine contains chemical components there is always a risk of side effects and interference with other drugs. But the NCCAM stated that there is not yet clear evidence enough for TCM treatments to be recognised as effective to a certain situation¹⁷.

There are some common reasons or beliefs in using CAM therapy among people. People can be dissatisfied with modern medicine because they did not get the effective care with safety, and CAM has been supposed to be safer than conventional medicine which sometimes is related to personal experience, belief and philosophical ground¹⁸.

The quality of herbal medicines and products have not been managed to an extent that conventional medicines are controlled. Because herbal medicine is based upon the medicinal herbs of plants, though it includes some materials of animal and mineral origin, the percentage of the effective components can vary according to the region, climate, the way of cultivating them, etc. Besides that, contamination of the herbal medicine by mould, toxin, or heavy metal during the manufacturing, distributing and keeping processes can occur rather easily if it is not controlled under the strict regulation¹⁸⁾. These kinds of barriers make it difficult to standardise the quality and efficacy of the herbal medicine. Thus the researches are being made to find out more about the marker compounds which can be single or multiple, however, there are still a lot more of active ingredients to be unveiled.

V. Statutory Regulation in the UK

It is taken for granted that medical profession should be regulated by the law, for the health is very important issue in a civilised country. And in the UK the health care service is managed by NHS system with other councils and committees. For example, General Medical Council (GMC) does the independent job for managing register, practice, and education of medicine to protect and promote the health standard¹⁹⁾. Accordingly the practice of conventional or orthodox medicine is under the regulation by the related laws and this makes sure that the practitioners have reasonable qualifications and meet the minimum standards as clinician.

However, when it comes to unconventional medicine, the situation is different. Most of the professions in the unconventional medicine are not controlled by the statutory regulation, therefore confirming the quality, specialty, and sui-

tability of a certain kind of complementary medicine practice is only up to the patients. Fortunately the practitioners themselves have been trying to correct these issues by making their association, by managing qualification through education for up-to-date knowledge and techniques and by attempting to be formally recognised.

At present, only osteopathy and chiropractic are under the normal regulation of the government as is the same way as conventional medicine. Practitioners are registered by the General Osteopathic Council and the General Chiropractic Council respectively according to their specialties. This 'statutory professional regulation' ensures that the practitioners registered to the General Osteopathic Council and the General Chiropractic Council are properly qualified and their practice, ethical codes and standards are well managed by the regulators²⁰⁾.

Herbal medicine has a long history in the UK but it still belongs to the traditional and complementary medicine. The European Herbal Practitioners Association (EHPA) (now the European Herbal and Traditional Practitioners Association (EHTPA)) was organised in 1993 and worked with the Medicines Control Agency (MCA) (now the Medicines and Health Care products Regulatory Agency (MHRA)) on the legal support for herbalists' prescription of herbs²¹⁾ and has been collaborating with other organisations for the purpose of setting standards for practicing properly in herbal medicine²²⁾.

In case of acupuncture, main regulatory body is the British Acupuncture Council (BAcC)²³⁾ which has around 3,000 members. It tries to keep standards of acupuncture practice, to provide training for good practice, and to promote researches by funding as well as represents the interests of the members. As a well prepared professional association they are equipped with the professional codes such as 'the Code of pro-

professional Conduct', 'the Code of Safe Practice' and 'the Code of Disciplinary Procedures'. For the education and accreditation purpose the British Acupuncture Accreditation Board²⁴⁾ was formed in cooperation with the acupuncture associations and colleges. It aims for setting the educational standards with respect to the acupuncture profession and for establishment of formal processes to assess and approve. Most of the members of the BAAC were reportedly to be in favour of finding a way to attain the acupuncture statutory regulation in the UK²²⁾.

The herbal medicine and acupuncture seems to have been around the goal of statutory regulation for a long time. The House of Lords Select Committee reported in 2,000 that the herbal medicine and acupuncture met the criteria: "We consider that *acupuncture and herbal medicine comply with these criteria and we support their moves towards statutory regulation.*"²⁵⁾ And this trend was reconfirmed by the note of 'Executive summary and recommendations' on 'Regulation of Medical Herbalists, Acupuncturists and Traditional Chinese Medicine Practitioners' by Health Professions Council (HPC) in 2008²⁶⁾. It states: "medical herbalists, acupuncturists and traditional Chinese medicine practitioners should be statutorily regulated in the public interest and for public safety reasons" and "The Health Professions Council is appropriate as the regulator for these Professions."

Another document by HPC in 2009 explains about the statutory regulation of CAM practitioners of acupuncture, herbal medicine, TCM. The HPC assessed the application for seeking regulation by process criteria in terms of a potential for harm, evidence of efficacy and a discrete body of knowledge, then recommended the practitioners of acupuncture, herbal medicine, TCM should be regulated²⁷⁾. And finally the Department of Health released in 2011 an 'Analysis report on the 2009 consultation on the statutory

regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK²⁸⁾. The report dealt with some pros and cons of the statutory regulation of herbal medicine, acupuncture and TCM stating that 85% of the respondents in consultation supported the statutory regulation. It was assumed that the major benefits would be in the qualified practitioners, and quality and safety of practice.

Department of Health estimated that there are 13,000 Acupuncturists, 1,500 Herbal Medicine Practitioners and 2,800 Traditional Chinese Medicine Practitioners in the UK²⁹⁾. And the number of practitioners of TCM registered to the private associations^{30),31)} are not small. There had been the need to establish governmental system to regulate the TCM practitioners, and the department of health proposed to introduce regulation to provide the reasonable quality.²⁹⁾

VI. Conclusion

Traditional medicine is commonly treated as a kind of complementary and alternative medicine. Traditional medicine of East Asia started at least two thousand years ago, and the root of the TM of each country (China, Korean and Japan) is the same. Complementary and alternative medicine is used in contrast to conventional medicine or orthodox medicine.

The issues over TM and CAM include identity, safety and efficacy. Because TM consists of some factors that cannot be proved at this time, it is necessary to take into account this background to make standard for TM. If the authorities provide some tolerance considering the characteristic of TM of East Asia it would be better to contribute to the health system. Simplified procedures for herbal medicine in EU could be a challenging model.

CAM has not been yet recognised as regular medicine but a lot of people use CAM as treatment in addition to modern medicine. Among TM and CAM, osteopathy and chiropractic therapies have been recognised and under formal regulation in the UK. Acupuncture and traditional Chinese medicine, herbal medicines have been trying to be under statutory regulation and they seem to achieve the formal position in the near future.

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