



Figure: China—kidney and liver transplants for past decade
Data from Chinese Ministry of Health.

transplantations. At present, 87 institutions have full approval from the Ministry of Health; 77 others have provisional approval and 18 months to comply with all the regulations. This number is a reduction from the more than 600 institutions that did transplants 1 year ago. Regulations have been set up to ban transplant tourism. The penalty for participating in a transplant that involves payment for organs is substantial. Reforms have decreased the number of cadaveric organ transplants by more than two or three fold and increased the number of living-related organ transplants by more than 100% in China in 2007. The drop in transplantation over the past 3 years is a result of these changes acting in tandem. Currently, post-transplant registries are being developed.

An organisational structure for transplantation must be established to oversee, implement, audit, and set up a balance of authority between the central and provincial governments. A registry of recipients that uses robust methods of data-collection should be started. Donation, use of organs, and selection of patients are currently hospital based, without centralised standards, and a

transparent system for organ procurement, equitable organ allocation, and selection of patients is needed.

China is planning regulations for the new phase of transplantation, which will largely conform to international standards. There are nuances within the system to accommodate cultural differences. For example, the laws for brain death will incorporate language that will respect the family's wishes, especially when they are based on religious belief that requires the whole body be buried. Despite a sharp decrease, capital punishment still exists in China. The long-term goal for social development is to abolish the death penalty but, until then, regulations need to protect prisoners' rights and desires and separate transplant programmes from the prison system.

*Jiefu Huang, Yilei Mao, J Michael Millis

Vice-Minister of Health, Beijing, China (JH); Peking Union Medical College Hospital, Beijing, China 100730 (JH, YM); and Section of Transplantation, University of Chicago, Chicago, IL, USA (JMM) liuyong@moh.gov.cn

We are supported by a grant (06-837) from the China Medical Board, New York, NY, USA. We declare that we have no conflict of interest.

- 1 Department of Health and Human Services: Centers for Medicare and Medicaid Services. Medicare program; hospital conditions of participation: requirements for approval and re-approval of transplant centers to perform organ transplants. *Fed Regist* 2007; **72**: 15198–280.
- 2 United Network for Organ Sharing. Designated transplant program criteria. 2007. http://www.unos.org/policiesandBylaws2/bylaws/UNOSByLaws/pdfs/bylaw_122.pdf (accessed Sept 8, 2008).
- 3 Cronin DC 2nd, Millis JM, Siegler M. Transplantation of liver grafts from living donors into adults—too much, too soon. *N Engl J Med* 2001; **344**: 1633–37.
- 4 Huang JF. Ethical and legislative perspectives on liver transplantation in mainland China. *Chinese J Surgery* 2007; **45**: 292–96.
- 5 Health CMO. Regulation on human organ transplantation. June 23, 2008. http://www.gov.cn/zwqk/2007-04/06/content_574120.htm (accessed on Sept 8, 2008).
- 6 Tibell A. The Transplantation Society's policy on interactions with China. *Transplantation* 2007; **84**: 292–94.
- 7 Steering Committee of the Istanbul Summit. Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul. *Lancet* 2008; **372**: 5–6.
- 8 Huang J. Ethical and legislative perspectives on liver transplantation in the People's Republic of China. *Liver Transpl* 2007; **13**: 193–96.
- 9 Wenjun C. Organ action as liver transplants go on a roll. June 18, 2008. http://www.shanghaidaily.com/sp/article/2008/200806/20080616/article_363391.htm (Sept 8, 2008).

Traditional Chinese medicine

Published Online
October 20, 2008
DOI:10.1016/S0140-6736(08)61354-9

Systematic reviews show that Chinese herbs and acupuncture can be effective for atopic eczema and chemotherapy-induced nausea, respectively.^{1,2} Traditional Chinese medicine (TCM) is one of the oldest healing systems. TCM includes herbal medicine, acupuncture, moxibustion, massage, food therapy, and

physical exercise, such as shadow boxing. TCM is a fully institutionalised part of Chinese health care and widely used with western medicine. In 2006, the TCM sector provided care for over 200 million outpatients and some 7 million inpatients, accounting for 10%–20% of health care in China.³

Most of the principles of TCM were derived from the philosophical basis that contributed to the development of Taoism, and Confucianism.^{4,5} Ancient Chinese scholars noted that all natural phenomena could be categorised into Yin and Yang (two opposite, complementary, interdependent, and exchangeable aspects of nature), everything in the universe consisted of five basic elements (wood, fire, earth, metal, and water), and the universe was constantly changing towards dynamic balance or harmony. Such knowledge was applied to understand, prevent, and cure disease.

In TCM, Yin refers largely to the material aspects of the organism and Yang to functions. There is a circulation of Qi (energy) and blood. The organs work together by regulating and preserving Qi and blood through the so-called channels and collaterals. Disease occurs after a disturbance in Yin–Yang or flow of Qi or blood, or disharmony in the organs caused by pathogenic (eg, sadness, joy, lifestyle) and climatic factors (dampness, heat, cold). Treatment aims to expel or suppress the cause and restore balance.

Imbalance is assessed by four traditional examination methods: looking, listening and smelling, asking, and touching. Observations of the pulse, face, tongue, urine, and stool provide essential information. The diagnosis is derived with theories such as the eight diagnostic principles to differentiate between Yin–Yang, exterior–interior, deficiency–excess, and cold–heat, the five elements theory to assess the relations between organs and functions, and the visceral manifestation theory to establish the disease location.

The diagnosis that guides treatment is called Zheng, a temporary state at one time and which is like a syndrome defined by symptoms and signs. The same disease in western medicine can manifest in different Zhengs and vice versa. Thus, treatment in the same patient varies over time and the same disease can be treated differently. For example, kidney Yin deficiency as a Zheng has three components: kidney, Yin, and deficiency. Other examples include preponderant liver Yang, flaring up of heart fire, and spleen–stomach dampness–heat. For each or a combination of the components, there are specific herbs or treatments. For example, bitter herbs are cool in nature and can be used to treat heat-ridden diseases. TCM can make diagnoses and treat patients without needing a scientific understanding of cause and pathogenesis.

	Adverse reaction(s)	Reasons for adverse reaction	Reference
Mercury, lead, cadmium	Various	Contamination, such as in Fu Fang Lu Hui Jiao Nang	15
<i>Ginkgo biloba</i> , garlic, Chinese angelica, <i>Salvia miltiorrhiza</i>	Severe bleeding	Interaction with western drugs, such as warfarin	16
<i>Radix aconiti lateralis</i> <i>Preparata</i> spp, <i>Aconite</i> spp	Cardiotoxicity, such as severe arrhythmia	Used raw and unprocessed, inappropriately prepared form, or overdosing	17
<i>Caulis aristolochiae</i> <i>Manshuriensis</i> spp	Nephrotoxicity and carcinogenicity	The herb contains aristolic acid and is wrongly used as <i>Caulis clenmatidis armandii</i> (eg, in some weight-loss products and Long Dan Xie Gan Wan)	18

Table: Adverse reactions and toxic effects caused by TCM

Acupuncture was introduced in developed countries in the 1600s.^{6,7} Variolation was developed in the 16th century in China as a method to immunise people against smallpox. Dried smallpox scabs were blown into the nose of an individual who then developed a mild form of the disease and lifelong resistance. The method was introduced to Europe in the early 1700s. Artemisinin and ephedrine are also derived from Chinese herbs.⁸

TCM was challenged by western medicine in China in the late 19th century.^{6,7} Western medicine had its most notable effects in surgery and public health, areas that had not been well developed in China until then. The increasing emphasis on western medicine slackened the development of TCM in the early 20th century. Since 1949, TCM has been scientifically studied and integrated with western medicine. Biomedical sciences have made considerable changes to TCM.^{4,9} For example, standardised formulae of herbal therapies are now commonly used as tablets, capsules, and even ampoules as well as the traditional decoctions of individualised prescriptions.

The integration of TCM and western medicine has been widely promoted and studied in China.⁴ Integration aims to eventually combine the two systems. Currently, integration is mainly at the level of physicians who have received training and can treat patients in both. For example, over a third of the training in TCM schools is in western medicine, and western-medicine schools also offer some training in TCM.

Despite decades of research and integration, the fundamentals of TCM remain largely unchanged and its theories inexplicable to science.^{4,5,9} The absence of scientific understanding has caused scepticism and criticism about TCM. However, randomised trials have shown efficacy for some TCM therapies.^{1,2,8} The efficacy of most assessed therapies, however, remains

uncertain, often because of the low methodological quality of trials.^{10,11} Furthermore, most of these trials are published in Chinese, inaccessible to western doctors, and not included in systematic reviews. Selective publication of positive trials is another problem.^{10,12}

The quality of TCM trials could be improved by adopting the bias-reduction points in the CONSORT guidelines. Meanwhile, the patient, intervention, comparator, and outcome should also be carefully documented. For example, it is important to compare TCM with a placebo or an intervention of proven efficacy rather than interventions with unknown effects. Furthermore, patients' inclusion and exclusion criteria, and indications and contraindications of the tested therapy, must be specified clearly in a language comprehensible to users who have never learnt TCM. Tested herbal products also need to be standardised to ensure manufacturing consistency. Standardisation is similarly important for diagnosis and procedural treatments, such as acupuncture.

Because TCM and western medicine differ, debates arise about which outcomes to use. Patients' views might provide an answer: outcomes that patients think relevant and important, such as pain and survival, are where TCM and western medicine can find a common footing. A real challenge is how to interpret and generalise the findings from trials of TCM delivered in the traditional way, in which the same patients are treated differently over time.

International collaborations and dialogues between practitioners of TCM or western medicine are important to further improve the scientific quality and clinical significance of TCM trials. Because TCM has long been in use, research could move to an efficacy-driven approach, in which TCM therapies are tested in trials on human beings first and studies on mechanisms of action and active substances should start only when efficacy is firmly shown.¹³

TCM does have adverse effects (table).¹⁴⁻¹⁸ The main reason for adverse effects is contamination and inappropriate use rather than inherent risks with herbs themselves. Most adverse reactions can thus be avoided by quality control and guided applications. In a sceptical environment, it would be a mistake to dismiss effective therapies on the basis of adverse effects rather than benefit-harm ratios.

Particularly in developing countries, over 80% of the populations depend on herbal medicine for basic health care.¹⁹ An absence of evidence of efficacy for these

treatments is likely to aggravate the entrenched inequity in access to effective care for poor people.

**Jin-Ling Tang, Bao-Yan Liu, Kan-Wen Ma*

Hong Kong Cochrane Centre, School of Public Health, Faculty of Medicine, Chinese University of Hong Kong, Hong Kong, China (J-LT); China Academy of Chinese Medical Sciences, Beijing, China (B-YL); and Wellcome Trust Centre for the History of Medicine, University College London, London, UK (K-WM)
jltang@cuhk.edu.hk

We thank Thomas Chan, Chinese University of Hong Kong, Jung-Nien Lai, National Yang-Ming University, for suggestions and references on adverse effects, and Ying Qin, Chinese University of Hong Kong, for information on the use of TCM in China. We declare that we have no conflict of interest.

- Zhang W, Leonard T, Bath-Hextall F, et al. Chinese herbal medicine for atopic eczema. *Cochrane Database Syst Rev* 2005; **2**: CD002291.
- Ezzo JM, Richardson MA, Vickers A, et al. Acupuncture-point stimulation for chemotherapy-induced nausea or vomiting. *Cochrane Database Syst Rev* 2006; **2**: CD002285.
- General Office of the State Administration of Traditional Chinese Medicine and School of Management of Beijing University of Chinese Medicine. China statistical yearbook of Chinese medicine. 2006. <http://www.satcm.gov.cn/96/9/C8%AB%B9%FA%D6%D0%D2%BD%D2%A9%CD%B3%BC%C6%D5%AA%B1%E0/main.htm> (accessed July 7, 2008) [in Chinese].
- Chen KJ, Xu H. The integration of traditional Chinese medicine and Western medicine. *European Rev* 2003; **11**: 225-35.
- Kaptchuk TJ. The web that has no weaver: understanding Chinese medicine. Illinois, MI: Contemporary Books, 2000.
- Ma KW. East-West medical exchanges and their mutual influence. In: Hayhoe R, ed. Knowledge across cultures—universities east and west. Toronto: OISE Press, 1993: 154-181.
- Strathern P. A brief history of medicine. London: Robinson, 2005: 179.
- Pittler MH, Ernst E. Artemether for severe malaria: a meta-analysis of randomized clinical trials. *Clin Infect Dis* 1999; **28**: 597-601.
- Liang MX. The predicaments and future of the search for the nature of disease in traditional Chinese medicine. Beijing: The People's Medical Publisher, 1998: 1-48 [in Chinese].
- Tang JL, Zhan SY, Ernst E. Review of randomised controlled trials of traditional Chinese medicine. *BMJ* 1999; **319**: 160-61.
- Wang G, Mao B, Xiong ZY, et al. The quality of reporting of randomized controlled trials of traditional Chinese medicine: a survey of 13 randomly selected journals from mainland China. *Clin Ther* 2007; **29**: 1456-67.
- Vickers A, Goyal N, Harland R, Rees R. Do certain countries produce only positive results? A systematic review of controlled trials. *Control Clin Trials* 1998; **19**: 159-66.
- Tang JL. Research priorities in traditional Chinese medicine. *BMJ* 2006; **333**: 391-94.
- Tomlinson B, Chan TYK, Chan JCN, Critchley JAHJ, But PPH. Toxicity of complementary therapies: an Eastern perspective. *J Clin Pharmacol* 2000; **40**: 451-56.
- Medicine and Healthcare Products Regulatory Agency. Tough action by UK medicines regulator against a traditional Chinese medicine containing high levels of mercury. May 16, 2006. <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON2023749> (accessed July 19, 2008).
- Fugh-Berman A. Herb-drug interactions. *Lancet* 2000; **355**: 134-38.
- Brown AC. Potentially life-threatening herbs: reported cases in MEDLINE of liver toxicity, renal toxicity, cardiotoxicity, cancer, and death. 2002. <http://www2.hawaii.edu/~amybrown/PotentiallyHarmfulHerbList%20-%20Table.pdf> (accessed July 9, 2008).
- European Medicines Agency. Public statement on the risk associated with the use of herbal products containing *Aristolochia* species. Nov 23, 2005. <http://www.emea.europa.eu/pdfs/human/hmpc/13838105en.pdf> (accessed July 10, 2008).
- Vines G. Herbal harvests with a future: towards sustainable sources for medicinal plants. 2004. <http://www.plantlife.org.uk/uk/assets/saving-species/saving-species-publications/Herbal-Harvests-with-a-Future.pdf> (accessed July 9, 2008).