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SUBMISSION RE: CMBA PROPOSED GUIDELINES FOR NATIONAL REGISTRATION AS AN ACUPUNCTURIST AND/OR CHINESE HERBAL MEDICINE PRACTITIONER; RECOMMNEDATIONS ON THE CMBA GRANDPARENTING REGISTRATION STANDARD: TRANSITIONAL ARRANGEMENTS FOR QUALIFICATIONS.

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INTRODUCTION

I believe a significant challenge to the CMBA is the management via registration of the rapid uptake of CHM in Australia and the interactive effects when complemented with WM medications and nutritional medicines for a range of more serious WM conditions such as auto immune disease, heart disease, lung disease, dementia, liver pathology such as cirrhosis, kidney disease such as kidney failure and cancer. WM clinical skills, knowledge and research experience will be just as essential as CM qualifications and experience in order to provide safe and effective health care to patients with serious disease who would like to trial CHM and Acupuncture with their WM medication(s).

It is my understanding that if a CHM product is TGA approved then any WM practitioner is free to prescribe it without any knowledge of CM differentiation and individualization of treatment, presumably without CMBA registration. I would like to argue that it is an inequitable situation if I am not registered under the CMBA grandparenting guidelines given my qualifications and strong WM clinical training and experience through the Chiropractic degree, combined with CM and Acupuncture academic qualifications, clinical training and experience when WM practitioners will still be able to prescribe TCPHM and Acupuncture not necessarily according to differentation of syndromes and individualization of treatment. In China this is often the case and there are no restrictions on WM practitioners in using CHM and Acupuncture in WM Hospitals, yet they are usually not academically trained at the same standard as CM practitioners. I know this to be the case from two significant trips to China, one working in the Weifang WM hospital in 1994 leading a team of Chiropractors, teaching Chiropractic to WM Specialists. Finally, WM practitioners are keenly studying the literature on CHM for WM conditions and seem very interested in the benefits demonstrated.

For example, WM's Reid and Stuart at the University of Adelaide School of population health and clinical research have produced a systematic review of efficacy of TCM for female infertility and found it can improve pregnancy rate 2-fold within a 4 month period compared to WM fertility drugs or IVF (in Complem Therapies in Medicine, Oct 2011). WM's Yeh-Ching et al in Haematology departments in Singapore hospitals have studied CHM against chronic cytopaenic marrow disease. They have used oral TCM herbs according to TCM syndromes for 24 weeks while on current WM magement and demonstrated some degree of haematological improvement. This study provides evidence of CHM supporting WM management for serious haematological conditions.

In Australia if a drug is legal, WM practitioners are free to prescribe it. They commonly attend medical-drug seminars, often read the medical literature and other pharmacuetical reports to be easily influenced to prescribe. This will be true for CHM and the CMBA won't be able to influnce the Federal

government to exclude WM practitioners from using TCPHM or Acupuncture in the near future. The WM view of the current practice of Acupuncture is described in the book *Medical Acupuncture: A Western Scientific Approach*, Churchill Livingston, 1998 where it is stated “although respecting its Traditional Chinese Medical origins, the TCM explanations of Acupuncture are no longer the only available option, for many practitioners in the West and China, there is every reason to believe that mechanisms of Acupuncture will eventually be explained by science. Such that WM treatments are based on evidence from RCT's and this will need to be demonstrated in Acupuncture which is now well under way. The RCT is the gold standard for clinical effectiveness of a treatment. The conclusions reached on the relationship between pulse and internal organs can differ widely according to the system used, usually no two interpretations are alike and it has been recommneded that pulse diagnosis be relegated to the domain of medical history. There seems no useful application for pulse in scientific Acupuncture”. It is apparent as to what the WM stance will be on registration for Acupuncture and CHM. The CMBA will not be able to control the WM application of Acupuncture or TCPHM prescriptions to the patients of Australia.

A problem in Acupuncture and TCM research is multiplicity of hyposthesis and techniques of treatment. Many variables in most studies are difficult to manage and reproduce in further studies. In Acupuncture there are issues of TCM versus WM recipe point selection, needle stimulation factors, needle characteristics and what is the neurophysiology mechanism versus TCM diagnosis and syndrome differentiation and CM functions of say improve qi stagnation or qi deficiency. In CHM research there are issues of TCM examination especially pulse and tongue, syndrome differentation and actions of CHM versus WM clinical diagnosis of a condition and treatment effects of single CM or TCPHM with some address to pharmacology and pathopysiological mechanisms of action that can usually only be tested in animal models in a laboratory setting.

Based on the above issues I am submitting a report that challenges the current proposed basis for grandparenting registration in Chinese Herbal Medicine and Acupuncture based on my academic experience in the department of Chiropractic, Osteopathy and Complementary Medicine at RMIT (1992-96 full time and 1997-98 sessional part time). The Chinese Medicine (CM) course commencing in 1995/96 and Acupuncture (Ac) and Medical Acupuncture (WMAc) courses commencing in 1994 formed the Complementary unit, which eventually changed to reflect CM as a separate department and research group in its own right.

I will also report on the great wealth of research data on Traditional Chinese Patent Herbal Medicine (TCPHM) and single herbal Chinese Medicine (CM) evaluated in the medical research literature via many case studies and RCT's which is becoming the gold standard proof for support of CHM management for WM conditions. Of the hundreds of clinical trial research evaluated, TCPHM is commonly employed against a placebo CHM or WM and demonstrates TCPHM pills or powders as a legitimate clinical therapuetic protocol for Chinese herbal Medicine (CHM) practice. Individual CHM formulas for a RCT on a biomedical condition is difficult to manage and reproduce.

THE INTEGRATION OF WM AND TCM DIAGNOSIS

In the Australian context, all patients visit health providers from all discplines reporting their chief complaint as a WM condition. Therefore, it is important to evaluate the patient with WM as well as CM clinical history taking, assessment and examination methods leading to a WM diagnosis and/or differential diagnosis to be a safe practitioner. Then a CM diagnosis of differentiation of syndrome(s) needs to be concluded which is just as critical for the formulation of a TCPHM formula of powders or

pills or granules, as it is for an individualized CHM formula based on combining single herbs, or adding single CM herbs to a TCPHM formula.

In my thirty years of clinical experience in practice it has been my observation that serious WM conditions do present to the allied health practitioner and that the safe and effective management of serious WM conditions requires that the practitioner be able to juggle both the WM diagnostic skills with their knowledge of the paricular allied health modality they practice. I would like to briefly alude to a couple of case histories which demonstrate this issue. A female patient had been admitted to hospital with severe flu symptoms diagnosed as swine flu. The patient had a thirty year history of SLE the symptoms of which were exacerbated by the flu. After release from hospital she was refered to me by her GP complaining of severe headaches and low back pain. In a scenario such as this the safe and effective management using CM required awareness of her clinical condition, the ability to interpret the researh literature relevant to SLE, and then making a careful decision about the application of CHM in conjunction with WM medications taken by the patient. Another example is a female patient with severe chronic lung allergic reactivity to dust and pollens in both autumn and spring who often develops allergic symptoms with sudden onset of acute asthma. This patient is often given several courses of antibiotics and high doses of oral cortisone to try to bring the condition under control. As a CM practitioner I made the decision that the risk of adding CHM to the WM management of the patient was too great a risk to the patient. Because the interactive effects can vary from patient to patient when mixing CHM and WM drugs, how will the CM practitioner deal with this issue. Zhou et al in Current Drug Metabolism, 9(8) allude to much individual variation in drug response, inter-individual variations in drug clearance and responses in clinical practice.

The above debate raises the issue of safe practice because WM is already responsible for numerous side effects in patients across Australia. I have a reasonable number of such patients in my practice in Hobart. The medical literature and media reports the following; in Tasmania 2009-10, 1000 ambulance call outs were for side effects for prescribed or over the counter medications, in a year from 95 million GP visits from a population of 17.5 million people in Australia two million patients have suffered side effcts from medications pescribed by a GP, Pexige used for arthritis since approval by the TGA in 2004 was recalled in Tasmania in 2007 due to severe side effects including death, pain relievers for headache can make them more difficult to manage including rebound effects, WHO in 2011 has been critical of overuse of antibiotics leading to a build up of resistance to virile bacteria such as hospital based golden staff.

The challenge is for the CMBA to acknowledge that the validity of the CM syndrome diagnosis for any one patient can vary between CM practitioners. I witness this debate every day in practice with other health care practitioners including Chiropractors, Physiotherapists, Osteopaths, Naturopaths and WM practitioners in relation to a WM diagnosis for a patient's presenting signs and symptoms. Even CHM formula prescription will vary between CM practitioners especially in more insidous WM conditions such as CFS, headache, neck pain, metabolic syndrome, insomnia, low back pain, sciatica, bloating and irritable bowel syndrome, depression, lack of energy, occupational overuse syndrome, bloating and upper gastric symptoms with no evidence of pathology (i.e.endoscope), chronic mild eczema and dermatitis, post exercise fatigue and obesity. Numerous TCPHM's manufactured in China for herbal supply companies in Australia are sold according to WM illness and disease conditions. That is, IBS relief, acne relief, eczema relief, cough relief, prostate support, hayfever tablets, constipation, bronchitis, skin diseases, tonsilitis, tinnitus, insomnia, bloating and dry cough. For example, Cathay Herbal HC307 prostate support discusses TCM use according to regulation of qi and blood, clears

damp heat and used for WM diagnosed benign prostatic hypertrophy. HC005 TCM Acne Relief is discussed as useful for WM acne, carbuncles, UTI and according to TCM patterns of heat toxin, cools the blood and reduces swelling. Some TCPHM's are also made in Japan for immune booster, vitality activator, immune activity and liver detox enhancer. For example, Cathay Herbal CIT174 Immune Booster-ganoderma & spore discusses use for WM conditions of antioxidant, relieves symptoms of allergies and hayfever and is a tonic for liver.

Therefore I feel I have presented strong evidence to demonstrate how WM practitioners work in Australia and I wonder how will the CMBA deal with WM practitioners who currently practice more alternative medicine, including using Acupuncture and TCPHM pills and powders which will continue to be easy to purchase from herbal dispensaries. Besides this well documented development in Australia, I know that numerous WM practitioners incorporate Naturopathic and Alternative medicine as part of their WM practice, using herbal medicines and nutritional medicine which they commonly criticised their use just a few years ago. Many of the formulas they prescribe from companies like Blackmores or in Pharmacy settings incorporate many single CM herbs. Two classic herbs very commonly used are ren shen (radix ginseng or panax ginseng C.A. Meyer) and Ginkgo biloba (bai guo or yen Xing leaf). Naturopaths have incorporate these CM herbs and others in their formulas for the last decade or more. These two CM herbs have been proven to be very beneficial in numerous clinical trial research for cardiovascular conditions and Dementia. WM GP and Surgeon practitioners and Physiotherapists and lately Masseurs have been using Chiropractic and Osteopathic manual manipulation management and other techniques for many years, despite this being the historical domain of Chiropractic and Osteopathy which dates back to the 1870's.

RELEVANT QUALIFICATIONS AND CLINICAL EXPERIENCE

I hold a certificate of CM from RMIT based on five subjects from the undergraduate program in 1996, MAppSc (Acup) from RMIT and I have supervised numerous minor theses in the Acupuncture and Medical Acupuncture programs at RMIT from 1996-98. Further, I have an academic and research background in epidemiology, research methods and statistics, occupational health and ergonomics and thesis study on injury morbidity in the Perth (WA) population based on the MPH course at Curtin University (1987-91) and through development of Masters courses by coursework at RMIT and teaching clinical epidemiology in these programs, and finally through experience of supervision of masters and PhD students by research at RMIT from 1993-96. My WM clinical qualifications and training are gained from the Chiropractic degree program at PIT from 1978-82 (BAppSc, now RMIT program). In conjunction with the practice of Chiropractic for 30 years, I have clinical experience in the practice of WM examination and diagnosis, and TCM application of Acupuncture and CM practice over the last 15 years.

CURRENT CMBA PROPOSED GRANDPARENTING REGISTRATION GUIDELINES

As a further issue which springs from the above discussion, I would like to express serious concern about the proposed grandparenting registration standard that is to be based on " evidence of receipts for the purchase of raw herbs and/or single herbs in powdered or extract form" and " operation of a dispensary" and "design a herbal formula specific to the persons condition" and " an individualised Chinese Herbal Medicine prescription" tied to "Chinese Herbal Medicine Formulae construction as applied to the individual patient". That is, the clear message is that if the grandparenting registrants have mainly used TCPM powders or pills, this will demonstrate inadequate evidence of the practice of CM.

THE REALITY OF CM CLINICAL PRACTICE IN AUSTRALIA

Like many CM Practitioners across Australia I have developed and followed the application of prescribing mostly patent Traditional Chinese Patent Medicine (TCPHM) for several sound practical reasons. I am confident to suggest that herbal stores and CM dispensaries across Australia supply patent CM to CM practitioners, of which numerous practitioners mainly use because they find it convenient and simple and very safe to prescribe. To satisfy the public, that is the patients who attend for CM management will require confidence from the WM culture that there is scientific evidence to validate CHM for a clinical condition such as influenza, arthritis, dysmenorrhea. Their WM practitioners will certainly demand this otherwise their advice will be not take the CHM. I have witnessed this many times in practice in Hobart. A good example is witnessed with the WM management of cancer.

For TCM to play a critical role in improving public health in Australia will require developments in a number of areas. That is, the need for a large CM profession with strong WM and CM knowledge and skills who are able to function in the Australian Western Medical system. The public opinion is formulated by the WM culture driven by a scientific model of proof that the WM practitioner can formulate an accurate diagnosis and the drug or surgical solution is valid and reliable. WM practitioners have been able to convince the public that they practice scientifically where as every one else is alternative or complementary who have limited evidence to support their methods of treatment.

Patent CHM powders and pills are safe and easy to use in practice. It is much more difficult to mix up a formula that is already the same as or similar to a patent formula but has to combine 8-10-15 single CM powders, which need to be weighed out and labelled. The patent powders or pills have already passed stringent manufacturing processes (GMP) and packaging and in Australia are typically licensed by the TGA. All the individual herbs are listed by name with quantities (wt, %) with indications to any side effects possible recorded on the container (e.g..An Shen Ding Zhi Wan pills).

Patent CM has a long and rich history of clinical application in China and over the last thirty years in Australia and overseas. Maclean and Taylor (2000) state that “the Chinese have been making patent medicines for centuries and the number of patent medicines produced are vast. They offer many advantages. They are cheap and easy to take and patient compliance tends to be high. Many have been used for centuries on countless patients and have proved themselves to be both effective and safe new patent medicines are being produced on the basis of modern research findings, leading to an amalgamation of the best of science and tradition.” Geng Junying et al, 1997 has written a very traditional CM text book that outlines a rich list of TCHPM formulas for CM syndromes and WM conditions. Patent CM pills are very easy to use in practice. Their potency is weak which guarantees very safe small doses are feasible. They are easy to take for patients, especially children and even adults who often gag on the taste of powders and decocted CHM.

The majority of formulas and modifications starts with a TCPHM formula which are well described in the text literature and journal literature. The majority of the TCPHM formulas listed in Geng Junying et al (1997) and Maclean and Taylor's book (2000, piii-viii) are listed and well described in the comprehensive CM text of Bensky Dan and Gamble Andrew 1986, Chinese Herbal Medicine Materia Medica (Revised Edition), Eastland Press, Seattle, Washington. They are also well described in very traditional CM books published out of China such as in two text books written by Geng Junying et al, 1997, whose Herbal formulas book has 253 pages devoted to TCPHM formulas. For example, under the CM clinical conditions of release the exterior with reference to simple classic formulas of sang ju yin, yin qiao san, and mediation formulas such as xiao chai hu tang, xiao yao san and clearing heat

formulas such as huang lian jie du tang, wu wei xiao du yin which are very commonly used in clinical practice. These TCPHM formula are commonly applied very effectively in my practice in Hobart. I have treated numerous patients with wind heat and wind cold (i.e.URTI and allergic rhinitis) conditions over the last 10 years.

It is accepted that TCPHM (patent CHM of single powdered and granule herbs and pills) are manufactured mostly in China and in Taiwan, Hong Kong, Japan and recently in some limited development in Australia. From outside Australia, single herbal CM and patent CM are subsequently exported to Australia under GMP and registered with the TGA. This is now a large pharmacuetical like enterprise for CM dispensaries and CM practitioners across Australia. Decocted dry herbs are also imported usually outside TGA scrutiny and GMP guidelines for obvious reasons.

EVIDENCE OF TCPM PRACTICE WORLDWIDE AND IN AUSTRALIA
In the medical research literature, it is apparent that a TCPHM formula and/or a CHM formula is specially patented for all of the trial subjects studied in the research period. In nearly all research, subjects receive the patent CHM throuhout the trial period, even when differentation of syndrome(s) are formulated.

I will argue that the current proposed registration guidelines defies the reality of CM clinical trial research data base, which provides compelling evidence that single herbal CM and TCPHM is commonly used as a TCM herbal treatment in China, other overseas countries such as Taiwan, Japan, America, Europe, Middle East and of course in Australia. There are numerous well documented literature reviews on TCPHM and/or patented CHM for the trial(s) for a large range of WM conditions.

CNS Disease
For example, Wu et al in a Meta-analysis of TCPM for Ischemic Stroke published in Stroke, 2007, Jun 38(6):1973-9, Epub 2007 Apr 26) evaluated 190 trials (120RCT, 71 controlled) with 19,338 patients that used 22TCPM herbs. Some adverse reactions were reported in some of the trials. Of the 22 TCPM used, 8 herbs had relatively more studies and patient numbers. They were milk vetch, mailiuoning, ginko biloba, ligustrazine, danshen agents, xuesetong, puerarin and acanthopanax which appear potentially beneficial and nontoxic. Wu at al (in Cochrane Data Syst Rev 2007 Apr 18(2):CD004295) has also reviewed *Dan Shen* agents for acute ischemic stroke, assessing 6 trials and 494 patients found that Dan Shen agents were associated with a significant improvement with neurological deficit at the end of treatment. Li and Wu et al (in Cochrane Data Syst Rev 2009 Jul 8 (3):CD007032) have reviewed 13 trials and 962 patients for Acanthopanax for acute ischemic stroke and found a significant increase in the number of patients whose neurological impairment improved. Zeng et al (in Cochrane Data Syst Rev 2005, Oct 19(4):CD003691) have reviewed 10 research trials with 792 patients for acute ischemic stroke using Ginkgo biloba (bai guo or yen Xing leaf) and report that patient improvement occurred but high quality and large scale randomized controlled trials are needed to test its efficacy for the future. Ginkgo Biloba is also reported to be helpful in Dementia (includes Alzheimer's disease and vascular dimentia) in Ernst and Pittler (Perfusion, 2005, 18:388-392). Numerous other trials using a range of TCPM have also been used for Dementia. Some of these well described prepared formulas described in Bensky and Barolet (1990; *p265, **p147,*** p405)include; *Ba Wei Di Huang Wan-pills (Iwasaki et al, 2004 J AmGeriatr Soc, 52:1518-21), **Yi Gan San-powder (Iwasaki et al, 2005 J Clin Psychiatry, 66:1612-1613 & 248-52), *** Gou Teng San-granule (Suzuki et al, 2005 J Am Geriatr Soc, 53:2238-40). May et al in (Phyto Med Res, 2009, 23:447-459) has demonstrated that many CHM trials provided overall positive evidence for the effectiveness and safety of several TCPHM and single herbal CM in

the management of Dementia. This area of clinical research is essential given the serious clinical ramifications of Dimentia. That is, Massoud and Gauthier in (Curr Neuropharmacol, 2010, 8(1):69-80) provide an elaborate discussion on the pathopysiology and pharmacological management of Alzheimer's disease, suggesting a prevalence of 24 million cases worldwide growing to 80 million by 2040.

Cardiovascular

Guo et al (in Eur Respir J, 2006, 28(2):330-8) discusses the use of *Panax ginseng* (Ginseng used in many conditions including cardiovascular, see Huang, 1993, pages 21-45) and *Salvia miltiorrhiza* (Tan Seng) used in a range of cardiovascular conditions including angina, see Huang, 1993, page 81). Guo et al discusses that their effectiveness was not necessarily established by 2007. Lu et al (Chin J Integr Med, 2011, 17(6):473-7) reports progress in 10 years of research on CHM *Radix Astragali* (Huang Qi is used due to its cardiovascular effect and is regarded as very safe even in high doses, see Bensky and Gamble p318-20) in treating chronic heart failure. Fu et al (Plos One, 2011, may 6, 695):e19604) reviews the literature on the patent CHM of *Huang Qi* injection for chronic heart failure, and despite promise as a treatment, after review of 1,205 articles and 62 RCT's conducted in China, no adequate conclusion could be drawn. Chen et al (Cochrane Data Sys Rev 2007, Oct 17(4):CD005052) has reviewed 19 trials in the literature on use of patent CHM of *Shengmai* and usual treatment for management of heart failure and concluded that significant improvement in New York Heart Association of classification of clinical status. Sheng Mai San is well described patent CHM formula usually made up of dang shen or ren shen, mai dong and wu wei zi (Maclean and Taylor, p144; and Maclean and Littleton, p96 and p762 discuss use in cardiac disorders, chronic lung conditions and for convalescence). Xue et al have reviewed the literature and are preparing a study protocol for evaluating Panax ginseng C.A.Meyer root extract for moderate Chronic Obstructive Pulmonary Disease (COPD) (Trials, 2011, Jun 30;12 164 and Respir Med, 2011, 10592):165-76).

Lung disease

Guo et al (in Eur Respir J, 2006, 28(2):330-8) in a systematic literature review describe trials assessing herbal medicine for COPD. Promising results existed for panax ginseng (ren shen) and salvia miltiorrhiza (tan seng), but more rigorous studies are required. An et al (in Respir Med, 2011, 105(2):165-76) in a systematic literature review on CHM for COPD found that panax ginseng (ren shen) showed promise for stable COPD patients, improving lung function and quality of life, including benefits when combined with pharmacotherapy. Xue et al (in Trials, 2011, 30912):164) describe a RCT study protocol using a capsule (100 mg) of panax ginseng C.A.Meyer root extract (ren shen) for moderate COPD to be conducted in Melbourne in 2011. Sisi Chen, Flower et al (in Lung Cancer, 2010, 68(2):137-45) report in a systematic review of 15 trials and 862 patients that CHM in conjunction with chemotherapy for non-small cell lung cancer is beneficial for quality of life and associated neutropenia, but needs further more rigorous trials and a study on long term survival rates.

Influenza

For example, Chen et al reviewed 11 trials and 2088 patients and the role of Chinese Medicinal Herbs for Influenza in (Cochrane Data Sys Rev, 2005, 25(1):CD004559) from PubMed data base found that CHM is beneficial but the low quality of most studies made the evidence far from conclusive for clinical decision making, although CHM as a whole seem to be effective compared to different WM chemical drugs such as anti-virals. Wu et al (Cochrane Data Syst Rev, 2007, Jan 24(1):CD004782) reviewed 14 studies involving 2440 patients for the common cold found that 5 CHM preparations were found to be more effective at enhancing recovery than the control treatment, but the studies were

regarded as lacking a high quality so the authors could not currently recommend any kind of CHM preparation. Ji et al in (Regul Toxicol Pharmacol, 2009, 5592):134-8) reports on anaphalaxix outcomes fron CHM injection for common colds and URTI.

Allergic Rhinitis

A recent clinical trial studying 108 patients by Yang SH, Yu CL et al 2010, published in *Int Immunopharmacol* 10(8), p951-8, Epub 2010 May, found that the patent CM formula of *Xin Yi San* compared to a placebo was very effective at reducing perennial allergic rhinitis nasal symptoms and congestion by immunomodulatory effects such as suppression of serum IgE levels. Bensky and Barolet also discuss Xin Yi San on page 51 as an appropriate patent CM formula to disperse wind-cold and unblock nasal passages. Shen et al in (Phyto Med Res, 2008, 15(10):808-14; and (Curr Med Chem, 2008, 15(16):1616-27) has demonstrated that the key single herb Xin Yi Hua (Flos Magnoliae) used in Xin Yi San is able to inhibit mast cell derived histamine release in rat peritoneal mast cells.Yang and Yu 2008 published in *(J Ethanopharmacol*, 115(1), p104-9, Epub) have also demonstrated that the patent CM formula of *Bu-zhong-yi-qi-tang* has had an anti inflammatory effect on dust mite allergen induced perennial allergic rhinitis patients (36) compared to a placebo patient (24) CM formula of Ping-wei-san, both taken for 3 months. Bensky and Barolet on page 241-243 have an elaborate discussion on this very significant patent CM formula for severe qi deficiency, but not usually used to manage acute allergic rhinitis. A key benefit in relation to allergic rhinitis (wind cold attack) is to provide support for yang qi to circulate and support protective qi. Thus it is possible to use this CM formula in chronic rhinitis, verified by trial research. Many other trials and review of trials have assessed CM and acupuncture for allergic rhinitis. Brinkhaus B et al 2004, in Allergy, 59(9), 953-60 discusses using the same Chinese Herbal Formula as a decoction three times daily for 6 weeks on the active treatment group versus a control group who received nonspecific CHM as above and acupuncture to non-specific points. In the USA there is growing interest from mainstream health care providers and scientific investigators in CHM for asthma and food allergies especially in children (Li XM, 2007, J Allergy Clin Immunol, 120(1);25-31 and Li XM, 2011, Mt Sinai J Med, 78(5):697-716) Li reports that two patent formulaes are now well studied and under further investigation. That is, anti asthma *herbal medicine* and *herbal intervention food allergy herbal formula-2.)* Xiu-Min Li in (Jn of Allergy and Clinical Immunology) discusses the trend in USA government agencies to apply scientific investigation to TCM and alternative medicines, including the most promising CHM remedies for asthma ansd food allergy. Lenon et al in two reports in 2007 (Evid Based Compl Alternat Med June 4(2):209-17) and 2009 (Phyto Ther Res 23:1270-75) has demonstrated that two similar patent formulas (RCM-101 and RCM-102) can inhibit the formation of several allergic inflammatory mediators that can be involved in allergic rhinitis. Yu Zhao et al in (Annals of Allergy, Asthma and Immunology, 2006, 844-50) has studied Shu bi lin a modified version of Jia wei cang er zi san in a guinea pig animal model of AR and demonstrated that suppressed production of IgG1 in the passive anaphylaxix test, with reduced eosinophil infiltration in nasal tissue.

Gynecology

Zhou and Qu (Afr J Tradit Complement Altern Med 2009, Jul 3, 6(4):494-517) reviewed the literature for CHM in treating a wide range of gynecological disorders and found that 32 commonly used CHM formulas have been used. Jing et al (Cochrane Data Syst Rev, 2009, Jan 21 (1):CD006414) reviewed CHM for PMS. Two RCT considering 548 women were included. The two CHM formula employed were *Jing qian ping* and *Xiao Yao Wan.* Again, despite the effectiveness it is stated that well controlled trials are needed before any final conclusions can be drawn.

Dysmenorrhea and Endometriosis
Presently, results are limited by the poor methodological quality of the included trials in reviews. This is the case for CHM for Primary Dysmenorrhea in a review by Zhu et al 2007, 9in Cochrane Data Syst Rev, 17(4):CD005288) where 39 RCT's involving 3475 women included in the review, which found that there was promising evidence supporting CHM for primary dysmenorrhea, but the results are currently limited. Flower et al (in Cochrane Database Syst Rev, 2009, 8(3);CD006568) describe two RCT's of 158 patients using CHM (Nei Yi pills and Nei Yi enema) was potentially more beneficial than the WM treatment of danazol for shrinkage of adnexal masses but no change for low back pain, rectal and vaginal discomfort. Flower et al (in J Altern Complem Med, 2011, 17(8);691-9) report that CHM has been employed according to individualized decoctions versus a placebo for 28 women with endometriosis diagnosed laparoscpically. This trial has set the scene for a larger and more rigorous study.

Depression
Zhao et al in (Am J Chin med, 2009, 37(2):207-13) has reviewed 18 trials with 1260 patients and demonstrated that there was no evidence to support CHM for management of depression using a Hamilton depression scale or a self-rating depression scale.

Musculoskeletal
He at al (J Clin Rheumatol, 2007, Dec 1396):317-21) report that in a comparison trial of 197 patients receiving WM treatment of diclofenac, methotrexate versus CHM patients to receive GlucosidorumTripterygil Totorum tablets and Yi shen Juan bi tablets demonstrated that both were beneficial in managing the symptoms of rheumatoid arthritis, but CHM merited further study to evaluate if it could guide specific therapy. Cui et al (in Cochrane Database Syts Rev, 2010, 20(1):CD006556) report in neck pain due to discal degenerative disease that in one trial CHM of Qishe tablets relieved pain better than placebo or Jingfukang, and another trial of CHM oral formula of (huang qi, dangshen,sangqi,chuanxiong, lujiao, Zhimu, relieved pain better tha mobicox.

Chronic Fatigue Syndrome
In a study by Sheng et al (in Evid Based Compl Alternat Med, , PMID: 200008077) a laboratory experiment using mice tested the use of a single CHM of a Polysaccharide of Radix Pseudostellariae (tai zi shen) was used at different concentrations to improve anti-fatigue effects from forced swimming time effects and chemical induced fatigue symptoms from injection of a poly I:C into the intraperitoneal space. Immune function also improved with decreased serum cortisone levels, increased T-lymphocytes in thymus and spleen.

Prostate
Chen and Hu in (J Altern Complem Med, 2006, 12(8):763-9) reviewing 19 trials of CHM against WM treatment demonstrated that there may be beneficial effects from CHM for chronic prostatitis (CPT) in China, but CHM was not superior to WM.

Inflammatory Diseases
Jung et al in (J Ethnopharmacol, 2007, 114(3):439-45) reports that Wen pi tang hab wu ling san extract CHM (from modified wen pi tang) has demonstrated that the CHM formula exhibits anti-inflammatory effects through modulation of MAPK and the NF-kappaB-dependent pathway involved in inflammation.

Cancer Immunotherapy

Zee-Cheng (in Methods Find Exp Clin Pharmacol, 1992, 14(9):725-36) discuuses the use of a classic TCPHM, SQT-Shi quan da bu tang (ten significant tonic decoction made up of shu di, dang gui, dang shen, bai shao, bai zhu, fu ling, huang qi, chuan xiong, gan cao, rou gui) to help potentiate and detoxify anti-cancer drugs. It is reported that animal models and clinical studies demonstrate that SQT has low toxicity, can stimulate hemopoietic factors and interleukins production in association with KN cells and potentiates activity in chemotherapy and radiotherapy and prolongs survival time. Kim et al (in Am J Chin Med, 2002, 30(1):127-37) describe the use of TCPHM formula-Bu zhong yi qi tang as beneficial as a radiotherapy protector in mice irradiated with high and low dose gamma-rays. Protection was provided to the jeunal crypts, reduced radiation induced apoptosis and increase formation of endogenous spleen colony.

RELEVANCE OF CLINICAL TRIAL RESEARCH FOR CHM

The numerous studies listed above represent just a few of whats available in the medical literature. They all clearly demonstrate many single herbal CM and TCPHM herbs have been tested in clinical trial research which further validates the clinical practice reality proposition that individualization CHM formulaes are not employed in most research published in CM and WM journals at this point in time. Therefore, there is clinical evidence that it is not always necessary to treat a clinical condition with an individualized CHM formula even though this is a traditionally and currently valid way to practice CM.

Yang et al and numerous other researchers on CHM have also commented on CHM trial research, that assessing case studies on CHM is a problem due to quality and validity issues (J Altern Complement Med 2009, 15(5):513-22). However, Yang et al have stated that evidence from quality RCT's and systematic reviews still holds the credibility of TCM in the scientific community, which helps develop evidenced based TCM developments including dealing with individualization and holism which complicate effective execution of RCT's in TCM therapies (Xue at al, J Altern Complement Med 2010, 16(3):301-12).

THE RESEARCH IMPLICATIONS AND FUTURE ROLE OF TCPHM IN WM PRACTICE IN AUSTRALIA

In China CM hospitals and WM hospitals exist side by side and CM and WM practitioners are registered by the same health departments in the different provinces. I know that from working for 1 month at the Weifang Western Medical Hospital (and being a patient for 2 days with an acute gastric infection) in the Shandong province that TCPHM and CHM are used differently than in CM hospitals. That is, individualisation is not commonly employed as most WM Doctors are not comprehensively trained in CM, although some are dual trained. Single CMH and TCPHM are still used as is Acupuncture and equally, CM practitioners prescribe WM drugs concurrently with CHM and TCPHM in CM hospitals

Just like what happens in China can be predicted to occur in Australia in the near future. That is, it is only a matter of time that with further clinical trial evidence of efficacy of TCPM supported by the large production lines by the Chinese CHM pharmaceutic companies that more CHM will be marketed to be used by more and more of the patient populations world wide, including Australia. WM

practitioners and within the WM hospitals CHPM will in due course start to be used and the CMBA will not be able to control this development. Historically it is the case that many WM drug prescriptions once the exclusive domain of registered WM GPs are now available across the pharmacy counter without prescription. TCPHM will be made available to the WM fraternity in Australia in due course. This equally applies to the use of Acupuncture by many WM practitioners in Australia. It is so well accepted that they can claim a medicare fee. They certainly dont necessarily follow the individualization of a formula for an acupoint prescription according to differentiation of a syndrome.

THE INFILTRATION OF CM HERBS INTO NUTRITIONAL PRODUCTS

In recent years, a new development in Australia has occurred where many natural (Naturopathic) based products now include TCPM herbs in their formulaes. They are added to vitamin and mineral mixtures. They have got to this point based on research evidence of several single CM herbs efficacy against clinical conditions. Good examples are, Interclinical laboratories in NSW has developed nutritional lines of medicines that include CM herbs. Trace nutrients: Para-Pack contains Zinger officinale, allium Sativum, Phytolocca decandra and Aden Complex contains Panax ginseng, Glycyrrhiza globra and Zinger officinale. Metagenics produces numerous practitioner only range of medication lines that contain CM herbs in combination with naturopathic herbs and nutrient chemicals. Blackmores has now produced a large range of products that contain CM herbs in combination with naturopathic herbs or nutrient chemicals. A well known WM pharmacy in Hobart specialises in dispensing Naturopathic Medicines and adds CM herbs to some of their mixtures. Finally, the product catalogue of nutri medicine and phyto medicine in QLD (ph-1800639122) produce a wide range of products with several well known CM herbs in them. All these products have become patented natural nutritional medicines available for alternative and WM prescription. Many WM Doctors prescribe metagenics and other companies products in conjunction with WM pharmaceutical drugs.

SUMMARY ARGUMENT PERTAINING TO CHM INDIVIDUALIZATION FORMULA TION AS A KEY CRITERIA FOR ASSESSING SUITABILITY FOR GRANDPARENTING REGISTRATION IN CM AT THE NATIONAL LEVEL

I have tried to demonstrate that is likely to be unreasonable to expect many CM practitioners including myself applying for grandparenting registration to meet the standard of CM individualization of a CM herbal formula using only single CM herbs based on syndrome differentiation.

Based on my diverse clinical experience across three states of Australia and teaching at RMIT, it is my observation that different practitioners despite similar training end up practicing differently with the knowledge and skills acquired. They can attract different types of patients, start to almost specialise in certain WM conditions and focus on certain Acupuncture and CHM formulas based on experience. They need to achieve a reasonably high degree of patient satisfaction to financially survive in practice. Patients aren't easily fooled and if they don't feel better within a short time line from their WM condition or symptoms they present with, they will soon stop coming in for treatment. Over time practitioners have to or endeavour to improve their clinical knowledge and skills by attending seminars put on by the profession, keep reading their discipline books and maybe journal literature and finally try harder to be better in getting patients “better' from their reporting symptoms or known WM condition which they have often been diagnosed by their WM GP. How can this all be assessed to prove competency. Therefore I would like to suggest that CM practice of Acupuncture and CHM and/or TCPHM will be in fact made up of many elements of knowledge and skills and not just prescribing an original individualized CHM and/or Acupuncture formula.

This raises the key debate in relation to competency of alternative or complementary clinicians across all disciplines. Competency needs to be judged across many elements of practice. Just imagine if all Chiropractors and Osteopaths were judged to be competent based on capacity to use manual manipulation as the key treatment in clinical practice. Many practitioners from each profession no longer perform manual manipulation methods which historically is the basis of treatment for both professions and certainly the Australian educational institutions teach this as the main model of treatment and management of spinal and extremity musculoskeletal and viscera-somatic conditions.

If evidence based CM practice is to be established, this will be driven by research that proves in numerous RCTs that CHM can effectively treat WM conditions. The WM system will push hard for this process to occur once national registration is put in place. Inevitably CM practitioners will be competing with WM practitioners for the same patients. The WM profession won't be as friendly when registration is in place. If CM practitioners, educational institutions and research centres want acceptance and access to large clinics and hospitals they will need to undertake a lot of research across many locations in and outside China. In the Australian context, a strong contribution will be necessary, which has already started at RMIT under Professor Changli Xue's efforts and guidance.

A large data base of CHM research has been undertaken especially in China. Countless numbers of literature reviews demonstrate that single CM herbs or TCPHM are the key herbs tested against WM conditions and not the registration standard of individualization CHM formulas across experimental subgroups based on differentiation of syndromes, as this is very difficult to undertake, although not impossible.. The proposed registration standard of CM practice remains an ideal in relation to RCTs for assessment of TCM. Therefore it is obvious that CM Research is driven by WM models of evaluation.

If the extensive clinical trial research data demonstrates that good evidence exists for use of TCPHM and/or single CM herbs, why can't this be applied to clinical practice?. If the registration standard is to be applied, then CM practitioners applying for grandparenting registration should be given opportunity and time to work towards this standard. This should not be by having to enroll in extensive Bachelor and Masters by coursework degrees. Rather, it can be achieved by continuing professional clinical training in CM diagnosis and differentiation of syndromes and individual CM formula construction for both Acupuncture and CHM.

There is adequate demographic and trial research evidence in the medical literature that should make allowance for many of the current CM practitioners across Australia to be able to use TCPHM as a way of practicing in their clinics. Under the grandparenting provisions it is stated that provisions are broad with intentions to not unjustly disadvantage practitioners who are legitimately practicing the profession. This doesn't satisfy my interpretation of the set out required competence level on page 42-46 of the section 7. Grandparenting registration standard: Transitional Arrangements for Qualifications. Given that TCM texts describe and discuss traditional TCPHM formula and these are readily purchased by CM practitioners from CM herbal suppliers across different Australian states, then why can't this be an acceptable way of practicing CM. It is obviously the case that a CM practitioner can consult these texts (such as described in Geng Junying et al books written from China) and make up the formula from single CM herbs, even with some level of modifications, which will be time consuming and add to the costs of running a busy clinic. But it could be done. However, if a CM practitioner hasn't practiced this way over the last 5-10 or 15 or so years, they will be disadvantaged in the extreme given the currently proposed guidelines under grandparenting registration.

I would therefore like to make the following recommendations for consideration by the CMBA:

RECOMMENDATIONS FOR ASSESSMENT CRITERIA FOR GRANDPARENTING REGISTRATION IN ACUPUNCTURE AND CHINESE HERBAL MEDICINE

1. A more flexible assessment instrument could be achieved to judge CM applicants for grandparenting registration. I believe that the current requirements are too rigid due to a strict requirement of individualization of treatment. The current competence and practice evidence required could be expanded to include a list of other elements of competence so as to provide other ways of judging that a CM practitioner is competent and safe to practice on patients. Their application for registration could be supported by demonstrating they can achieve some of the following skills of taking an extensive case history according to a WM and CM model, be informed regarding more severe WM conditions, evaluate the chief complaint, perform a physical examination of the patient with WM and CM procedures, inspect the different structures of the body such as nails, head hair, eyes, face, skin and muscle tone and joints, inspect the tongue and feel the pulse, review WM laboratory tests and Xray reports, write reports to WM practitioners about findings and special concerns on behalf of the patient and consider interactive effects with WM drug therapy and formulate relevant individual prescriptions for either Acupuncture and/or CHM and/or TCPHM.
2. The grandparented registered CM practitioner be granted a reasonable time period to achieve continuous professional education (CPE) so as to enhance their knowledge and skills in CM diagnosis, syndrome differentiation and individualization of treatment for Acupuncture and/or CHM and/or TCPHM.
3. CPE hours to be mandatory for each year of registration, but Grandparented CM practitioners could be requested to undertake more mandatory hours than other registered CM practitioners to acquire further critical CM knowledge and skills that the CMBA would ideally like to see exist. The CPE process is instead of studying in a more formal Degree or Masters course.
4. Hopefully the CMBA will adhere to the stated special rule that allows registration of competent practitioners in the first three years. Competence being assessed with a more flexible instrument for practice evidence and clinical skills and knowledge evidence, with flexibility regarding individualized treatment especially for CHM

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