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Ms Doris Chan
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Legislative Council of The Hong Kong SAR
Legislative Council Buliding
8 Jackson Road, Central, HONG KONG
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9 June 1999

Dear Ms Chan,

Bills Committee on Chinese Medicine Bill: Meeting on 10 June 1999

Referring to our telephone conversation and your letter (CB2/BC/18/98) of 8 June 1999, I forward you herewith a copy of our views on the research and development in traditional Chinese medicine in Hong Kong entitled 'Evidence-based medicine and the research priority in traditional Chinese medicine', which we wish to submit to the Bills Committee on Chinese Medicine Bill for the captioned meeting. This written submission has been read and endorsed by Professor Joseph Lee, the Dean of the Faculty of Medicine of the Chinese University of Hong Kong. It is a draft written for a Chinese medical journal for publication. An English version of it is now not available but can be prepared should it be further required.

Incidently, enclosed please also find a copy of the paper entitled 'The need to evaluate the clinical effectiveness of traditional Chinese medicine' which gives supports to some of the arguments developed in the main submission.

Yours sincerely,

J. L. Tang

Jin-Ling Tang, MD PhD
Associate professor of epidemiology and community medicine.

cc: Professor Joseph CK Lee, Dean of the Faculty
Professor SH Lee, Chairman of the Department
Ms Lolita OB Shek, Director of Public Relations of the Faculty

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實証醫學與中醫藥研究的重心（初稿・摘要）

香港中文大學醫學院社區及家庭醫學系　唐金陵
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一九九九年六月九日

醫學以防治疾病，促進健康為根本任務。預防或治療的臨床效果（以下簡稱臨床療效或療效）是衡量一切預防和治療措施（以下簡稱防治措施）價值的最高準則。實証醫學正是建立在這個最高準則之上的新的醫學實踐模式。它的核心就是任何有關疾病防治的整體策略和具體措施的制定都應基於現有最嚴謹的關於其臨床療效的科學証據之上。隨機對照臨床試驗是獲取這種証據的最嚴謹的科學方法。具有有效的防治作用是一個防治措施在醫學實踐中存在的根本價值所在。使用無效甚至有害的防治措施在醫學倫理上是不能接受的，更是對人類寶貴醫療資源的巨大浪費。

中醫藥研究和開發應從臨床療效的驗証開始。防治機理的研究和有效成份的探索是其次的，應以証實臨床有效為前提。因為一個防治措施若沒有防治作用，就沒有其作用機理可被發現，也沒有其有效成份可被探索。其次，中醫藥臨床療效評價，為從中醫藥中開發新藥提供一個經濟的、快捷的途徑。因為它節省了用於無臨床療效的藥物的臨床前研究所需要的大量人力、物力和財力資源。同時也大大縮短了一個新藥從開發到臨床使用的時間。第三，中醫藥臨床療效評價具有巨大的經濟效益。臨床上無效的防治措施將會被否定而淘汰，而有效的會被肯定和進一步推廣，從而一個醫療體系會因停止使用無效的防治措施而節省大量的資源。第四，對中醫藥臨床療效的評價也是對其理論體系在實踐上的檢驗。糾正和改進中醫藥理論的局部錯誤，必將促進中醫藥理論的進一步發展和完善。

由於安全和倫理上的原因，一個新藥的研制往往是不能從人體上開始的。但是，中醫藥已在人類使用了幾千年，從安全和倫理上講，直接在人體上進行療效的檢驗是可以接受的。這使得中醫藥開發走從臨床療效評價開始的捷徑成為可能。至少在中國是可行的。因此，對中醫藥的臨床療效評價和實施中醫藥實証醫學應是現階段中醫藥研究工作的重心。它不但是中醫藥現代化的必經之路，也是對中醫藥走向世界最好的“包裝”方式。這樣的研究也必然會帶來巨大的社會及經濟效益。第一，停止使用無效的治療方案，節省大量醫療資源；其次，加快從中醫藥中開發新藥及其它治療方法的速度；再次，促進用於中醫藥研究的有限資源更合理、更有效地分配和利用；第四，促進中醫藥研究的全面發展及其理論的提高和完善。

然而，實現中醫藥實証醫學是一個極為複雜和長期的工程。它涉及到思想模式的轉換，研究重心的轉移，資源的重新分配、有關專業人員的培訓和有關服務及研究機構的建立。更有許多面臨的理論問題亟待解決。因此需要社會及政府有關部門有計劃地組織人力、物力和財力進行系統地研究、思考和探索。這樣巨大而長期的工程在西方國家是不可能的。他們缺少中醫藥方面的專家，語言不通，而且中醫藥研究也不是他們的主要興趣。因此我呼籲社會及政府有關部門儘快地組織系統的、全面的中醫藥實証醫學、臨床療效評價及其有關問題的研究，以推動和加速中醫藥的現代化，中醫藥發展和開發，以及最終走向世界的進程。

目前中醫藥實証醫學及臨床療效評價方面的研究應集中在以下幾個方面：1）以 Coclurane Collaboration 的模式，系統地收集、整理和推廣現有有關中醫藥的隨機對照臨床試驗的証據及建立相應的資料庫。這是實施中醫藥實証醫學的重要一環。也為新藥開發和其它中醫藥領域的研究提供臨床基礎和生攻方向；2）（包括從收集的隨機對照試驗中）篩選有進一步研究和開發價值的藥物或其它防治方法；3）對初步認為有開發意義的藥物或防治方法做更嚴謹的全面評估；4）研究隨機對照試驗用於中醫藥療效評價的特殊性（如診斷的標準化和療效標準的制定）、存在的問題及解決方法，以提高未來中醫藥療效評價結果的準確性，可靠性和可推廣性；5）研究和建立中醫藥臨床療效証據的推廣，傳播和利用的機制；6）研究和建立中醫藥實証醫學在本地區特殊環境下實施的運作機制。7）培訓一批實証醫學、臨床試驗和証據綜合等方面的專業人員和建立有關研究中心、臨床試驗基地和相應輔助機構。

實証醫學與中醫藥研究的重心（初稿・全文）

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一九九九年六月九日

實証醫學與中醫藥臨床療效評價的必要性

醫學以防治疾病，增強健康為根本任務。因此，預防或治療的臨床效果（以下簡稱臨床療效或療效）是衡量一切預防或治療措施（以下簡稱防治措施）價值的最高準則。實証醫學(Evidence-Based Medicine)正是建立在這個最高準則之上的新的醫學實踐模式。David L. Sackett 領導的加拿大 MacMaster 大學實証醫學工作組於一九九二年在美國醫學會雜誌上正式提出實証醫學的概念(EBMWP 1992)。在短短七年時間，實証醫學已引發了醫學實踐模式的一場深刻變革。實証醫學旨在把過去以個人經驗為主要依據的臨床實踐提高到一個以嚴謹的科學研究証據為基礎的標準之上。它的核心就是任何有關疾病防治的整體策略和具體措施的制定都應基於現有最嚴謹的關於其臨床療效的科學証據之上。因為使用無效甚至有害的防治措施在醫學倫理上是不能接受的，更是對人類寶貴醫療資源極大的浪費。隨機對照臨床試驗(Randomised Controlled Clinical Trial)是獲取這種証據的最嚴謹的科學方法。隨機對照試驗在過去五十年的發展，成熟和廣泛應用，以及所累積的大量有關臨床療效的証據正是引發這場醫學實踐模式變革的原始動因(Spilker 1993)。實現實証醫學的第一步就是用隨機對照試驗的方法對現有的以及所有新的防治措施的療效進行全面、系統的評價。

因此，實施中醫藥實証醫學以及對中醫藥臨床療效進全面的、系統的、嚴謹的科學評估是醫學使命對中醫藥的根本要求，也是中醫藥更有效地為人類健康服務的第一步。中醫藥已有幾千年歷史並被廣泛地接受和利用。無疑，中醫藥做為一個整體有其極為成功的一面。但長期和廣泛利用並不等於其每一個防治措施都是有效的，因為無效的防治措施也可能被長期地廣泛利用(Sackett 1995)。例如，西醫中的放血療法曾被視為靈丹妙藥，用於治療百病長達幾百年之久。美國第一任總統喬治・華盛頓在他生命最後一刻還在接受這樣的治療(Warren 1993)。另外，臨床病例觀察和非隨機的對照研究也是不可靠的。它們往往會對臨床療效作出錯誤的結論。那些利用一兩個專家、名人或公司總裁親身試用的體驗作為某個藥物是否有效的標準的作法，在科學上幼稚的，更是對廣大醫學和科學工作者的無視。醫學實踐以防治疾病，增進健康為本，是個嚴肅的問題，也是一個科學的問題。它又涉及大量的人類資源。它是需要以極慎重的和科學的態度來對待的。關於中醫藥臨床療效需

要用嚴謹的科學方法進行評價的必要性的詳細論述，請參閱唐金陵等“試論中醫臨床療效評價的必要性”一文(Tang 1998)。在此我着重對為什麼要把中醫藥臨床療效評價作為現階段中醫藥科學研究工作的重心進行論証。

<u>臨床療效是中醫藥發展和研究之根本</u>

一個防治措施之所以被稱為和用作防治措施根本在於其具有防治作用。換句話說，具備防治作用是一個防治措施在醫學實踐中存在價值的根本所在，也是醫學研究興趣的根本所在。因此，中醫藥科學研究應以其臨床療效的論証開始。而其防治機理的研究和有效成份的探索是次要的，應該建立在証實具有臨床療效的前提之下。因為一個防治措施如果沒有防治作用，就沒有其作用機理可被發現，也沒有其有效成份可被尋找。因此，任何脫離了療效的理論研究，便成為無本之木。況且，機理是否闡明和有效成份是否明確並不從根本上影響一個具有防治作用的措施在臨床上的接受和廣泛應用。實際上在過去幾千年中，中醫藥也正是這樣產生和發展起來的。又如，天花疫苗的發現和應用，遠早於醫學對人類免疫系統的發現和認識。

<u>臨床療效評價具有巨大的經濟效益</u>

所有設計嚴謹的臨床試驗的研究結果都是具有應用價值的。用於臨床療效評價的資源因此不會被浪費。它或者否定一個藥物並停止其進一步的臨床使用，這樣將會節約大量的醫療資源。相反，若証明一個藥物有效，該藥的使用會被進一步肯定和推廣。一個醫療體系中所使用的有效防治措施的比例越高，其本益比就越高(Gray 1997)。因此，中醫藥臨床療效評價的結果勢必不斷增加中醫藥應用的整體經濟效益。

相比之下，機理的闡明和有效成份的探索屬於科學發現的範疇。而科學發現成功與否往往是偶然的和不可預測的(Kuhn 1970)。即使對証明有效的防治措施，成功與否多是由運氣決定。因此這樣的研究必是事倍功半。過去幾十年裏關於中醫藥機理的研究進展緩慢也証明了這一點。更何況分子、細胞及動物體上的實驗結果也未必能在作為一個整體的人體上得到應用。從臨床療效研究開始，就避免了對臨床上無效的防治措施的機理的研究和有效成份的探索。研究資源也因此得到更有效地利用。

<u>臨床療效評價是從中醫藥中開發新藥的經濟、快捷的途徑</u>

從臨床療效的証實開始，為從中醫藥中開發新藥提供了一個捷足先登的機會。這和目前流行的西藥開發的程序是相反的。西藥的開發，目前主要以從分子的設計和合成開始(Harvey 1998)。由於安全的原因和倫理上的考慮，藥效的論証必須從分子和細胞學開始，到動物測試，然後到在人體的藥理、

毒性和代謝的研究。最後方能在人體上進行隨機對照臨床試驗的驗証。

與此相反，由於中醫藥已在人類使用了幾千年。從安全和倫理道德上講，直接在人體上進行療效的檢驗是可以接受的。這使得中醫藥開發走從臨床療效評價開始的捷徑成為可能。至少在中國是可行的。這就給中醫藥的開發提供了一個捷足先登的機會。因為只有對臨床上証明有效的防治措施的臨床前研究才是有必要的，以臨床療效評估開始便可以節省用於不必要的臨床前研究所需要的大量人力、物力和財力資源。同時也大大縮短了一個新藥從開發到臨床使用的時間。

舉例說明，美國費瑞公司開發的新藥偉哥，歷經十年，花費上億元的研究經費。若不是意外地發現其治療男性陽萎的作用，所有有關研究便會前功盡棄，浪費是巨大的。而中醫對濕疹的治療，其臨床價值僅由幾個高質量的隨機對照試驗便得以肯定(Sheehan 1992, Latchman 1994)。目前我們並不知道其治療機理和有效成份，但它在臨床上的應用價值已在西方得到廣泛的承認。用於中醫治療濕疹的証實的費用和時間與偉哥的開發相比，真是九牛一毛。節約是巨大的。

臨床療效評價同時也是對中醫藥理論體系的檢驗

中醫藥理論是一個獨立的、完整的體系。但和西醫一樣，它的功用是指導防治疾病和促進健康的醫學實踐。其理論正確與否決定于其能否正確地指導醫學實踐活動。因此，對中醫藥療效的評價，同時也是對其理論體系的檢驗。臨床療效的証實便是對理論的正確性的有力的支持。相反，臨床療效的否定，便是對其正確性的質疑。(當然每一次這樣的肯定和否証只是對其相關的部份或局部的理論而言。)整體而言，肯定的比例越高或否証的比例越低，越証明中醫藥基礎理論的正確性。糾正和改進中醫藥理論中的局部錯誤，必將促進中醫藥理論的進一步發展和完善。

總合上述，對中醫藥進行嚴謹的療效評估和實施中醫藥實証醫學應是現階段中醫藥研究之重心。它是中醫藥走向現代化的根本舉措；是中醫走向世界、更廣泛地為人類健康服務的必經之路；是從中醫藥中開發新藥最經濟快捷的途徑；既是中醫藥研究中的"扶本"之舉，也是為中醫藥走向世界的最好'包裝'方式；最終必將促進中醫藥理論進一步發展和完善。它也必將帶來極大的社會及經濟效益：1) 停止使用無效的治療方案，節省社會資源；2) 加快從中醫藥中開發新藥及防治方法的速度；3) 促進用於中醫藥研究的有限資源更合理、更有效地分配和利用；4) 促進中醫藥研究的全面發展及其理論的發展和完善。

實施中醫藥臨床療效評價和中醫藥實証醫學所面臨的問題

然而，對整個中醫藥進行臨床療效評價及實施中醫藥實証醫學是一個極為複雜和長期的工程。它涉及到思想模式的轉換，研究重心的轉移，資源的重新分配、有關專業人員的培訓和有關服務及研究機構的建立。更有許多面臨的理論和實際問題亟待解決。譬如，哪些防治措施應最先予以評價？怎樣有效地篩選這些防治措施？如何制訂療效評判的指標和標準？怎樣解決隨機對照臨床試驗用於中醫藥評價中的特殊問題？對臨床試驗中收集的証據如何進行系統的分析和整理？這些整理過的証據如何系統地傳播和推廣？如何利用這些証據指導中醫藥其它方面的研究和新藥的開發？每一個醫生如何充分利用這些証據來指導其臨床實踐？解決這一系列複雜問題，需要社會及政府有關部門有計劃地組織人力、物力和財力進行系統地研究、思考和探索。

進行這樣巨大而長期的工程，在西方國家是不可能的。首先他們缺少中醫藥方面的專家。其次是語言不通的障礙。更何況發展中醫藥也不是他們的主要興趣。這個任務必然落到廣大的中國醫務工作者身上。比如，目前西醫的臨床試驗已達幾十萬個，而傳統醫學（包括中醫藥）的臨床試驗只有不足一萬個(Tang 1999, Ernst 1998)。正如所說，這一萬左右的臨床試驗絕大部份是在中國完成的。但是，這些臨床試驗大部分存在著方法學上的質量問題。系統地總結、推廣和利用這些臨床試驗的結果的重要性也沒有得到充分認識和重視。

鑒於中醫藥實証醫學和系統地評估中醫藥臨床療效的重要性、迫切性以及可能帶來的巨大的經濟效益，我呼籲社會及政府有關部門及早開始有計劃、有組織地對中醫藥臨床療效進行系統地、全面地評價，並研究和思考有關中醫藥實証醫學等有關方面的問題。中醫藥療效的系統評價和中醫藥實証醫學的研究必將推動和加速中醫藥走向現代化，中醫藥的發展和開發，以及最終走向世界的進程。

目前的主要研究任務

我認為現階段中醫藥實証醫學和臨床療效評價的研究應集中在以下幾個方面：1）以 Cochrane Collaboration 的模式，系統地收集、總結整理和推廣現有有關中醫藥的隨機對照臨床試驗的証據，並建立相關的資料庫(Chalmers 1993)。這是實施中醫藥實証醫學的重要一環。也為新藥開發和其它中醫藥領域的研究提供必要的臨床基礎和主攻方向；2）（包括從隨機對照試驗中）收集和篩選有進一步研究和開發價值的藥方或其他防治方法；3）對初步認為有開發意義的藥方或防治方法做更嚴格的、全面的評估，為新藥開發做最後的臨床論証，并為未來中醫藥隨機對照試驗研究提供一個好的模式；4）探討隨機對照試驗在中醫藥研究中的特殊性（如診斷的標準化和療效標準的制定）、存

在的問題及解決方法，以提高未來中醫藥療效評價結果的準確性、可靠性和可推廣性；5）研究和建立中醫藥臨床療效証據的推廣、傳播和利用的機制；6）研究和建立中醫藥實証醫學在本地區特殊環境下實施的運作機制；7）培訓一批實証醫學、臨床試驗和証據綜合等方面的專業人才及建立有關的研究中心，臨床試驗基地和相應輔助的機構。

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（全文完）

COMMENTARY

The need to evaluate the clinical effectiveness of traditional Chinese medicine

JL Tang, TW Wong

Traditional Chinese medicine is gaining increasing attention and popularity in Hong Kong. There is no doubt that traditional Chinese medicine as a system of medicine works; however, this does not imply that every therapy is efficacious. Prevention of the initiation and continuation of ineffective intervention is extremely important for the efficiency of any health care system. The evaluation of the clinical effectiveness of traditional Chinese medicine is thus a top priority. Efforts should be made to register all randomised trials in traditional Chinese medicine and to regularly review and disseminate the evidence from organised research. These actions are essential for the promotion and practice of evidence-based decision making in traditional Chinese medicine.

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Key words: Alternative medicine; Delivery of health care; Evidence-based medicine; Medicine, Chinese traditional; Randomized controlled trials

Traditional Chinese medicine (TCM) is gaining increasing attention and popularity in Hong Kong. The Government of the Hong Kong Special Administrative Region (SAR) has taken measures to promote, develop, and regulate the practice of TCM in the SAR.[1] Local universities are setting up educational programmes to train doctors in TCM. Approximately 50% to 60% of the population in Hong Kong have consulted TCM practitioners.[2] Our preliminary survey shows that Hong Kong residents spent about HK$3 billion on TCM in 1996 (unpublished data). Traditional Chinese medicine is undoubtedly becoming a more important component of the SAR's health care services.

There has been an increasing general interest in traditional medicine. In Europe, traditional medicine has been used by 20% to 25% of the population; this figure is growing rapidly.[3] Americans spent an equivalent of approximately HK$100 billion on alternative therapies in 1990, which was comparable to the amount spent on visits to primary care physicians.[4] The United States Government has set up an Office of Alternative Medicine, and centres for alternative medicine have begun to appear in respected medical schools such as those at the universities of Harvard and Columbia.[5]

Traditional Chinese medicine has a history of several thousand years and is one of a few forms of 'alternative' (as opposed to conventional) medicine that are endorsed by the World Health Organization. There is, however, an urgent need to evaluate the clinical effectiveness of TCM. In acknowledgement of this need, the World Health Organization has established an Office for the Evaluation of Traditional Medicines and has developed guidelines for the evaluation of traditional medicines.[6] The primary drive for the evaluation of TCM is concern about the efficiency of the health care system. The first step is to prevent the introduction of new but ineffective interventions to medical care and to stop those that are currently being used.[7]

There is no doubt that TCM works. It has developed its own coherent theories with regard to aetiology, diagnosis, and treatment of disease. It has also accrued a myriad of valuable clinical observations, some of which have provided the basis for some successful conventional medicines. Artemisinin (Qinghaosu), for example, is an extract that is prepared from the Qinghao plant (*Artemisia annua*) and has been used by TCM practitioners for 1500 years; it is now a very promising

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antimalarial drug.[8] Ephedrine, a widely used medicine, was originally extracted from a plant that is used in TCM. In addition, a TCM cure for eczema has proved so successful in recent trials that a pharmaceutical company has patented its own version.[9,10]

The fact that a system of medicine works as a whole, however, does not mean that its every intervention is efficacious. Many interventions that are widely used in conventional medicine have been shown by randomised controlled trials (RCTs) to be ineffective or even harmful.[11,12] Evidently, convention is not the best indicator of the effectiveness of a medicine; popularity, enthusiasm, or anecdotes should also not be taken as evidence for clinical efficacy. It is thus reasonable to believe that many TCM interventions may not be clinically effective.

The most scientifically rigorous method for evaluating the clinical effectiveness is the RCT.[13] This is particularly true for therapies that have a moderate (but worthwhile) effect.[14] Many medical treatments have only moderate, rather than large, effects if major end-points (such as mortality) are concerned. Powerful interventions whose effect is clearly evident, such as penicillin and smallpox vaccine, are few and far between; most other interventions have only moderate effect. Conventional medicine has responded positively to this challenge—we now accept that virtually no new drug can enter clinical practice without a demonstration of its efficacy in clinical trials. Currently used interventions are also being subjected to RCTs. Should TCM be an exception?

To demonstrate what works and what does not in TCM has other important implications. Firstly, it will provide a scientific basis for the further advancement of TCM theories. Secondly, treatments of proven effectiveness will identify fruitful directions for basic research in disciplines such as physiology, biochemistry, and pharmacology. Thirdly, a clinically effective recipe may lead to the development of new drugs which may be refined for better formulation and research. Fourthly, diseases or syndromes that are only recognised and curable in TCM may open up new opportunities for research in conventional medicine. Fifthly, it will provide necessary information for the regulation of the practice of TCM. Finally, it will help to dispel misconceptions about TCM, increase its acceptance, and promote better and wider utilisation.

Much research has been done in TCM; most, however, is at the laboratory or biochemical level. Today, traditional therapies are still viewed by many as quackery and stigmatised as mere superstition.[15] The lack of understanding of the mechanisms underlying TCM is undoubtedly a major reason for the widespread misconception and reluctant acceptance of this form of medicine. There is thus a need to study how TCM works. Research also often helps in clinical practice and basic research to 'do the right things better'. However, research progress may be restricted by the available methodology and technology.

Clinical effectiveness is what matters most in any medical treatment. Understanding the mechanisms of action is secondary, and lack of this knowledge should not prevent the use of effective therapies. For example, many of the most powerful medical interventions in medical history (eg penicillin, digitalis, sulphonamides, smallpox vaccination) were accepted and widely used, long before their mechanisms of action were understood. Therapies that lack a demonstration of clinical effectiveness, such as bloodletting and radical mastectomy, have been discarded, regardless of whether we understood the mechanisms. In contrast, the mechanism underlying acupuncture has been well studied and documented; nevertheless, acupuncture does not seem to work for many diseases for which it claims to be effective.[16] The misunderstanding and scepticism about TCM therapies will likely continue until their clinical effectiveness is demonstrated by RCTs. Demonstration of the clinical effectiveness of TCM is thus an immediate and urgent task for researchers of TCM.

Randomised controlled trials have already been conducted in TCM. There are, however, a few methodological issues that need to be resolved so that the quality of trials can be further improved. The first RCTs in TCM in China were conducted in the early 1980s; the number of trials has doubled every 2 to 3 years over the past 15 years. A preliminary systematic review of the evidence for the effectiveness of TCM has identified some 2800 RCTs that were published in medical journals in China. It is estimated that the total number of trials published in China alone is around 8000 (unpublished data).

Further work is needed to identify and to register all clinical trials ever published in the medical literature. The goal of the Cochrane Collaboration is to systematically review and summarise the evidence from clinical trials and to make the evidence available to practitioners and policy makers in an accessible and digestible manner.[17] These efforts are essential for the promotion and practice of evidence-based decision making in TCM. It is a waste of human resources to

continue the use of clinically ineffective treatments. It is therefore ethically an obligation—and scientifically a challenge—for health workers to terminate the use of clinically ineffective TCM therapies and to promote the use of effective ones. This can only be achieved through the systematic evaluation, review, and dissemination of the evidence among decision makers.

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Editorial note

The *British Medical Journal* has declared an 'amnesty' for unpublished trials. For details on submitting such research, please see the editorial on page 249 which has been reproduced, with permission, from the *British Medical Journal* 1997;315:622.