

What evidence is good enough?

Nicola Robinson^{1,✉}, Jian-ping Liu²

¹ Royal Botanic Gardens, Kew, London, TW9 3AE, United Kingdom

² Center for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine, Beijing, 100029, China

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International experts in research methodology and traditional Chinese medicine (TCM) gathered in Beijing on 24th October for the 6th Evidence-Based Medicine (EBM) Forum, hosted by the Center for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine. Participants from Canada, USA, Australia, South Korea, Norway, United Kingdom (UK), and Hong Kong (China) presented a range of specialist reports focussing on types of research evidence.

The opening speech by the vice president Prof. Chunzhi Liu, Beijing University of Chinese Medicine, emphasised the importance of international collaboration to widen the reach of TCM so that expertise and knowledge could be shared and support new cohorts of young researchers. Evidence is critical for guiding and refining safe and effective clinical practice. New technology should be assessed and strengths and weaknesses appropriately identified and rigorously assessed.

The birth and evolution of EBM was eloquently described at the Beijing EBM Forum by Prof. Mitchell Levine from McMaster University, Canada. He made reference to Dr. James Lind, who, in 1747 conducted the first controlled clinical trial on sailors with scurvy to evaluate whether a diet containing lemons and oranges could provide a potential cure compared to five other treatments some of which included cider, vinegar, and salt water. The concept of the placebo effect using a dummy treatment compared with an active treatment, emerged as the result of a clinical trial in 1863 conducted by Austin Flint, and exploring random variation and the probability of events occurring by chance was proposed 1925 by RA Fisher.¹ These research methods subsequently led to the birth of clinical epidemiology, critical appraisal and the need for doctors to be able to evaluate good and bad science for clinical decision making.

The hierarchy of evidence and aggregating evidence to provide an overall picture is critical but the availability of evidence does not in itself necessarily make the decision. The development of GRADE (Grading of Recommendations Assessment, Development, and Evaluation) has provided a systematic approach to assess the quality of a body of evidence generated from systematic reviews.² It has provided a method to determine certainty and strength underpinning a recommendation generating a transparent and rigorous process to evaluate evidence. Since 2011, China has progressed in introducing and promoting the GRADE approach,³ and marked by the establishment of Beijing GRADE Center at Beijing University of Chinese Medicine. The challenges experienced when using GRADE for the development of recommendations in traditional medicine have been previously reported.⁴ Issues highlight-

ed have not only included the lack of high-quality evidence but also the large variations between the practice of interventions, their individualized tailored treatment and the lack of stakeholder involvement.

Additionally, it has been reported that the methodological and reporting quality of systematic reviews and meta-analyses published by China's researchers in English-language is higher than those published in Chinese-language and this has relevance and potential implications for the evidence underpinning TCM and its use in clinical guidelines.⁵

Meanwhile the evaluation of the quality of clinical guidelines have been strengthened by using the AGREE (Appraisal of Guidelines for Research and Evaluation) II instrument.⁶ Despite this advancement, methodological quality and reporting of clinical practice guidelines in China are still below the international average.⁷

How much evidence is needed to be sure there is an effect? The British epidemiologist, Dr Archie Cochrane, also known as one of the fathers of clinical medicine was an advocate of the randomized controlled trial but other kinds of evidence are important. In addition we need to remember that the "Absence of evidence is not evidence of no effect".

Evidence may come from clinical observations and experience but may not be based on facts. Expert opinion is defined as scientific views/comments by designated experts which may include a review of the scientific evidence but in the absence of evidence expert opinion and clinical experience may be the only evidence available. It is widely understood that EBM should integrate the experience of the clinician, the values of the patient and the best available scientific information to make decision.

Research needs to be packaged appropriately for ready access for clinicians and to develop clinical guidelines. Clinical guidelines are to help clinicians to make the decisions on delivering the best care for patients.⁸

Clinical guideline development is not without its problems as guideline development groups may choose to ignore evidence, or only consider placebo-controlled trials as evidence and may exert personal bias about specific interventions and their understanding of traditional practice.⁹ This has been a problem where research on acupuncture as an effective treatment for low back pain in the UK was rejected, despite the need to move to non-drug treatment options.¹⁰ In 2015, Kmietowicz, had highlighted that there was too much of a focus on drugs over other treatments, change is still too slow.¹¹

There is however, a real need for "living guidelines" to ensure that the evidence included is regularly updated and used.

Combining evidence to include patient values has been emphasized as patients may perceive their outcomes differently to their clinician. Not all information is equal and the rapid development of the artificial intelligence (AI) environment is challenging us in deciding what is good and what is bad evidence and certainly does not adopt patient values. "Nothing about us, without us", the importance of patient involvement and the "lived experience"

✉ Corresponding author.

E-mail address: prof.nicky.robinson@outlook.com (N. Robinson)

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in developing research evidence was highlighted by a speaker at the EBM forum.

Case reports are important sources of evidence particularly for rare conditions, monitoring adverse events and new emerging diseases and these should be systematically reviewed and included as evidence, despite potential risk of bias.¹² The value of reviews of case reports and how they can also add to the patient perspective underpins the ethos of and evidence for TCM and cannot be underestimated.

There is controversy about evidence, how it is generated and its interpretation and this will be further confounded by the increasing use of AI. EBM is of critical importance for best patient care.¹³ China has made progress in promoting research quality and transparency, especially registering and reporting research but improvements are needed in sharing information on research implementation and good publication practice in TCM.¹⁴ What continues to be essential is ensuring good study design with a clear clinically relevant question which will help to develop the high-quality research needed for clinical decision making.

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Declaration of Competing Interest

Prof. Jian-ping Liu and Prof. Nicola Robinson are the Editors-in-Chief of Evidence-Based Chinese Medicine and Technology Assessment.

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