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Opinion paper

Challenges for clinical practice guidelines in traditional medicines: The example of acupuncture

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ABSTRACT

Clinical practice guidelines (CPGs) are an important tool for clinicians and health authorities to help select appropriate therapies for different patients and problems. While systematic reviews and meta-analyses look at best-available trial evidence, CPGs are less limited since they compare that best evidence to the same evidence for other therapies for the same condition, while at the same time including comparison of safety and cost-effectiveness of those therapies. Thus CPGs inform more about the clinical utility of a therapy within a broader health care context, still CPGs can be subject to bias in their inclusion and evidence-selection process. CPGs are influenced by many factors, including local political and socio-economic, in order to try to improve relevance for their target audience. Acupuncture, a traditional medical intervention that lies outside mainstream medicine, has been extensively investigated with emerging evidence for its effectiveness in many areas. The extent to which acupuncture is included in CPG development processes and recommended by CPGs is subject to many factors and is not well known within the acupuncture community. Many more recommendations for the use of acupuncture exist than previously thought, making it critical for the acupuncture community to become more informed about these recommendations and to try to improve implementation of the CPG recommendations in mainstream health care.

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1. Introduction

In modern medicine, especially since the advent of 'Evidence Based Medicine (EBM)', there has been an increasing reliance on published research to develop better treatment approaches for different health problems [1]. The results and the levels of evidence from clinical trials are summarized in systematic reviews (SRs) and meta-analyses (MAs), these have become standard tools for presenting evidence of a therapy for a particular condition. While SRs and MAs present the evidence so that health care policy makers and health care providers can be informed about the latest data from clinical research, they are not the most effective tool for informing clinical practice [2]. For this clinical practice guidelines (CPGs) have been developed. A CPG comprises "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" [3,4]. Thus the CPG not only examines the latest evidence from SRs and MAs of a particular therapy for a specific health problem, it examines the same evidence for *all* potential therapies for the specific condition including safety data and cost-effectiveness data for each therapy [2,4]. Then, in side by side comparisons, the CPG grades the evidence for and prioritizes the different therapies, including some, excluding some. The CPG usually discusses at what stage of treatment each therapy is best used, how to incorporate each therapy into the treatment approach, which *should* be used, which *may* be used and so on. These descriptions present strategies and decision making priorities for clinicians in primary and secondary health care. CPGs were further developed with the development of evidence grading standards (GRADE) [5,6] or others [4,7,8] and development of standards and criteria for CPG development (AGREE) [9–11]. CPG development groups usually consist of individuals with expertise in the specific health problem, statistics, health policy, CPG development and sometimes representation from the varied stakeholders involved (patients, practitioners of different interventions). CPGs also need updating on a

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regular basis so that they take into account new evidence, updated findings and experiences. Thus CPGs often have a defined 'shelf-life' with recommendations for when to perform the next CPG rewrite [4].

In modern medicine, CPGs have been developed for many medical problems. Different groups within a country and between countries often come to different conclusions so that there is a certain amount of variability in the recommendations for a particular health problem [12–15]. These variations can be due to many factors such as i) cultural and political differences between different countries where CPGs are developed, ii) availability of resources within different countries, iii) the foci and biases of the authors of a particular CPG. Examples of these influences follow.

2. Influencing factors

i) An example of cultural and political influence on CPG development can be found in South Korea, where modern medicine and Korean medicine (KM) are both government licensed and regulated. CPGs have been developed within mainstream medicine, but have not included analysis of evidence for KM. In order to correct this imbalance the South Korean government (Ministry of Science, ICT, and Future Planing) commissioned the KM community to develop CPGs regarding KM for a number of different conditions [16–19]. This split between health care practitioner community CPGs is not typical in other health care settings, where a CPG group would usually try to include *all* therapies in its analyses and recommendations, regardless of origin. The approach used in South Korea also ensures that the mainstream medical community will *not or is highly unlikely* to refer patients for those traditional therapies. Another example of cultural influence can be found in China. While the mainstream medical community has been developing CPGs for health care guidance, the TCM community has developed a number of CPGs for TCM practice. These CPGs do not follow usual guidelines for CPG development by evaluating evidence for the use of therapies they instead assume the TCM therapy works and give guidance on how to apply it [20,21]. These guidelines will likely not influence how patients are referred within China. Both the Korean and Chinese examples will have little impact outside their own countries.

ii) In poorer, resource low countries, where many medications and technologically advanced techniques may be in limited supply or unavailable, it makes sense to recommend interventions that are more low-tech and less costly, even if the evidence for those therapies is not as strong as for other interventions. The International Association for the Study of Pain (IASP) wrote a book on pain therapy for low resource countries making a range of recommendations for the use of acupuncture that take into account its developed levels of evidence and the fact that it is low tech, less costly and therefore readily adaptable to these health care settings [22]. Tailoring recommendations to the country in which the guidelines are developed is important for them to be effective and useful [23,24].

iii) CPG development groups sometimes exclude or evaluate complementary and alternative medicine (CAM) interventions in questionable ways. For example some guidelines appear to have simply ignored the evidence for acupuncture, not including any discussion of it. In a recent international CPG on osteoarthritis [25] the authors make no assessment or even mention of acupuncture despite the currently available evidence from SRs, MAs and cost-effectiveness studies showing that acupuncture is effective for osteoarthritis [26–29]. Similarly a CPG on nausea and vomiting [30] makes no assessment or mention of acupuncture despite the available evidence from SRs and MAs showing that acupuncture is effective for nausea and vomiting [31–34]. Reasons for not considering acupuncture when evidence clearly exists are not known but not mentioning CAM therapies in general has already been documented [35], suggesting a bias. Cho and colleagues examined CPGs for low back pain and compared the results and recommendations for traditional medicines such as acupuncture from SRs and MAs [36]. In their analysis they found that 'the current CPGs did not fully reflect the evidence for' traditional medicines such as acupuncture [36]. The National Institute of Clinical Excellence (NICE) is one of the premier British CPG development groups. Their recent CPG recommendations regarding acupuncture for osteoarthritis exhibit clear bias against acupuncture [37]. By focusing on sham comparison trial results they cherry picked the data they included to evaluate acupuncture (selection bias) and interpreted it without examining other relevant data such as safety and without comparing the levels of evidence to other recommended interventions (selection and interpretive biases). Their argument that acupuncture would increase cost of therapy compared to less expensive medications is not plausible when we note that they did not include costs associated with adverse effects of acupuncture and those medications, which profoundly affects any comparison of costs. The year before NICE rejected acupuncture for osteoarthritis, the Scottish Intercollegiate Network Group (SIGN), which is the other major British CPG development group, specifically recommended acupuncture for low back pain and osteoarthritis, recognizing that the small effect sizes are an artifact of an active sham treatment [38]. Other possible examples of this bias can be seen when reviewers only include selected (and often out-of-date) reviews or studies to support their conclusion that the therapy does not work. This can be seen in a recent review of treatments for headaches in pregnancy, where only out-of-date negative reviews were included to support the statement that acupuncture does not work [39]. These examples illustrate that a CAM intervention such as acupuncture may be excluded from evaluation or evaluated in inappropriate ways, exposing evidence of a possible bias against the intervention.

3. Grappling with acupuncture

Acupuncture, as a traditional therapy, originated long before the advent of modern medicine, many people trained in its use employ concepts and models that did not develop out of modern scientific investigations and discoveries and it has been in clinical use before clinical trials methods began to be employed to test it [40,41]. Naturally there is a degree of uncertainty about it, which can affect how evidence is evaluated and recommendations made for its use. Thus it is likely that there is a kind of bias against acupuncture that makes it more difficult to have it included in CPGs – we see that in South Korea, where mainstream medicine has excluded KM from its guidelines, and in the examples of osteoarthritis and nausea where the evidence for acupuncture was not considered. This bias can make it more difficult for fair evaluation by CPG groups – seen in the example of how NICE evaluated acupuncture for osteoarthritis. But the CPG represents an important mechanism by which therapies are included in health care, thus it is essential for traditional medicines like acupuncture to pursue inclusion in CPG development more actively. At present little data exists about knowledge of CPGs within the acupuncture community [42] and even less for active referral to acupuncture. It is also likely that when acupuncture is

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Table 1
International Symposium of Evidence Based Clinical Practice Guideline in Traditional Medicine (ISEBCPG-TM).

	Speaker	Affiliation	Title
1st ISEBCPG-TM (International trend of developing CPGs in TM), KIOM, Daejeon, 2012			
1	Hyung-Sik Ahn	Korea University, Korea	Introduction to methodology for developing CPGs in TM
2	Nicola Robinson	London South Bank University, UK	Good practice in TCM – results of an EU/China collaboration
3	Jianping Liu	Beijing University of Chinese Medicine, China	Current status and challenges of CPGs for CM in China
4	Tsutani Kiichiro	Tokyo University, Japan	Are international CPG possible in traditional medicine: How evidence can transcend national borders?
5	Sun-Yeong Jeong	Kyung Hee University, Korea	The development of CPG for Hwa-byung
6	Myeong Soo Lee	KIOM, Korea	Perception of developing CPGs in KM
2nd ISEBCPG-TM (Challenges in implementation of CPGs in TM), KIOM, Daejeon, 2013			
1	Hyeong-Sik Ahn	Korea University Korea	Implementation of PG in Korea
2	Li Zhou	Dongzhimen Hospital, China	Thoughts on establishing and implementing of evidence-based CPGs on TCM
3	Takeo Nakayama	Kyoto University	Evidence-based health care and CPGs: current movement in Japan
4	Nicola Robinson	London South Bank University, UK	Clinical guidelines in the UK: do they mention CAM: Are CAM professional bodies aware?
5	Jianping Liu	Beijing University of Chinese Medicine, China	A literature survey of recommendations for TCM in CPGs of Western Medicine
6	Dongwoo Nam	Kyung Hee University, Korea	Development of acupuncture guideline for muscular skeletal disease
7	Jongwoo Kim	Kyung Hee University, Korea	Development of CPGs for Hwa-byung: Concept of disease in TM
3rd ISEBCPG-TM (Translating evidence to recommendations in CPGs in TM), KIOM, Daejeon, 2014			
1	Myeong Soo Lee	KIOM, Korea	History and future of CPGs in TM
2	Jon Adams	ARCCIM, Australia	Overview qualitative and other inclusive health research design/methods in the task of successfully translating CPGs
3	Jianping Liu	Beijing University of Chinese Medicine, China	From systematic review findings to recommendations in CPGs
4	Terje Alraek	NAFKAM, UiT The Artic University of Norway	Is there inconsistency in the NICE 2014 guidelines for osteoarthritis?
5	Stephen J Birch	Kristiania University College, Norway	Positive recommendations for the use of acupuncture in national and international treatment guidelines
6	Nicola Robinson,	London South Bank University, UK	UK CAM practitioners' awareness of NHS CPGs mentioning CAM
7	Jongwoo Kim	Kyung Hee University, Korea	Application of CPG at the clinical field in KM – Present and future
8	Masayo Kojima	Nagoya city University, Japan	Integrating patient values and preferences in CPG: Development of CPG for rheumatoid arthritis management in Japan
9	Juah Lee	KIOM, Korea	The quality of CPGs for TM in Korea: appraisal using the AGREE instrument
10	Zhou Li	Dongzhimen Hospital, China	The key criteria for monitoring or auditing the guideline
4th ISEBCPG-TM (Challenges and solutions of evidence based CPGs development in TM), KIOM, Daejeon, 2015			
1	Robbert van Haselen	International Institute for Integrated Medicine, UK	Gap between research and practice
2	Jianping Liu	Beijing University of Chinese Medicine, China	Evidence base for recommendations in TCM and Western medicine guidelines for 18 diseases
3	Terje Alraek	NAFKAM, UiT The Arctic University of Norway	Exploration of the risk of bias against acupuncture implicit in sham acupuncture trials: impact on systematic reviews and CPG development groups and CPG recommendations about acupuncture
4	Stephen J Birch	Kristiania University College, Norway	Update of positive recommendations for the use of acupuncture treatment
5	Nicola Robinson	London South Bank University, UK	Is research evidence important for clinical guidelines?
6	Masayo Kojima	Nagoya city University, Japan	Findings from a comprehensive survey of living conditions in Japan: Use observational study in CPG development for TM
7	Zhou Li	Dongzhimen Hospital, China	A survey of the knowledge of prevention and treatment of TCM against NCDs in Beijing North Dongcheng district community residents
8	Juah Lee	KIOM, Korea	Preferred reporting Items for development of CPGs in KM
9	Byung-Cheul Shin	Pusan National University, Korea	Development of evidence based KM CPG for L-HIVD and shoulder pain
10	Myeong Soo Lee	KIOM, Korea	Overview of a project on the development of evidence based CPGs KM (2012–2015)

AGREE: Appraisal of Guidelines, Research and Evaluation in Europe; ARCCIM: Australian Research Centre in Complementary and Integrative Medicine; CAM: Complementary and Alternative Medicine; CM: Chinese medicine; CPG: clinical practice guideline; L-HIVD: lumbar herniated intervertebral disc; KIOM: Korea Institute of Oriental Medicine; KM: Korean medicine; NAFKAM: National Research Center in Complementary and Alternative Medicine; NCD: Non-communicable disease; NHS: National Health Service; TCM: traditional Chinese medicine; TM: traditional medicine; UiT: University in Tromso.

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recommended many within mainstream medicine are also not cognizant of these recommendations. This is probably worsened by government or health authority treatment guidelines that can dictate how medical practitioners such as general practitioners should act, taking into account factors like limited funding. In addition there are common problems in the implementation of CPGs within mainstream medicine, as many health care professionals do not follow the recommendations from CPGs [43,44]. Given these various problems it is important for the traditional medical communities, such as the acupuncture community, to develop more awareness and activity around CPGs. Greater efforts need to be made to ensure that acupuncture, as one of the stakeholders, is given more presence within relevant CPG development groups and that its evidence is examined without or at least with less bias.

4. CPG knowledge, awareness and development

When we look at scientific symposia or workshops on acupuncture, we do not usually find presentations about CPGs [45] this needs to change. In this regard the 'International Symposium of Evidence-Based Clinical Practice Guideline in Traditional Medicine' hosted by the Korean Institute of Oriental Medicine (KIOM) is, to our knowledge the only such international scientific event focused on CPGs. The KIOM initiated Symposia focusing on CPGs to help develop evidence based CPGs for KM for 7 diseases including ankle sprain, depression, obesity, idiopathic facial palsy, atopic dermatitis, lumbar herniated intervertebral disc, and shoulder pain [46–52]. There have been four CPG Symposia starting in 2012. Following the second symposium in 2013, a series of papers were published in the European Journal of Integrative Medicine. The symposia covered a wide range of topics, Table 1 lists the presentations from the four Symposia. Participants for these Symposia come from Korea, China, Japan, UK, Norway, Holland and Australia. These Symposia have been important for leading the way into a key area for acupuncture research and implementation, including the development of reporting guidelines for traditional medicine CPGs called PRIDE-CPG-TM (Preferred Reporting Items for the Development of Evidence-based Clinical Practice Guidelines in Traditional Medicine) and the CPG Network for Traditional Medicine [53], both implemented by KIOM researchers.

Despite the problems illustrated above, there are many CPG and other expert groups writing treatment guidelines around the world that have recommended acupuncture for different health problems. In an ongoing search, by November 2015 we had found over 870 recommendations for over 100 conditions from multiple international groups and over 30 countries [54]. The following are examples of the extent of these recommendations. The National German Gynaecologic Oncology Association (Arbeitsgemeinschaft Gynakologische Onkologie) recently recommended acupuncture for twelve problems in breast cancer [55]. The Ministry of Health of Rwanda recommended acupuncture for 8 problems [56,57]. The US Department of Veterans Affairs and Department of Defense have recommended acupuncture for 9 different problems [58–63]. Developing greater awareness of the potential uses to which acupuncture should be put in light of the extent to which it is recommended is important for the acupuncture community. But obviously a bigger problem lies with implementation of published CPGs. Research is needed to uncover problems with implementation of guidelines and strategies developed to improve implementation. This is a challenge that will increasingly take center stage in future symposia and workshops on the theme of CPGs in acupuncture and more broadly traditional Traditional East Asian Medicine.

We feel that the examples of the challenges that acupuncture faces in being included in CPG development and the need to develop strategies to address this will hold also for other CAM/TM interventions.

Conflict of interest statement

The authors declare that they have no potential conflict of interest.

Authors' contributions

All authors have contributed to this article. SB and TA conceived the project, performed the initial literature searches and began drafting the paper. MSL critiqued and edited the early draft of the paper, contributing further arguments and literature sources. All three authors then prepared, read and approved the final manuscript.

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