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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.

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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