ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

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Mark Wilson
CEO
The Cochrane Collaboration
18-24 Middle Way
Summertown Pavilion, Middle Way
Oxford
Oxfordshire
OX2 7LG
UK

Dear Mr. Wilson,

I am writing on behalf of the Board of the Alliance of Wound Care Stakeholders ("Alliance") to address our concerns with a recent Cochrane Review on "Honey as a Topical Treatment for Wounds." The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient organizations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of the Board representing wound care clinical specialty societies and organizations who not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at: www.woundcarestakeholders.org.

Since wound care research is an issue on our workplan, we continually monitor and review websites such as Cochrane that address wound care systematic reviews. We are concerned about the statement "health services may wish to consider avoiding routine use of honey" made in the 2013 Cochrane Review on "Honey as a Topical Treatment for Wounds" since it includes a recommendation which to our knowledge as shown below has not been part of previous wound care Cochrane Reviews.

In reviewing many of the Cochrane Reviews on wound care, we noted that those addressing wound care dressings have generally stated in their conclusions that there is "no research evidence" that the one wound care dressing being evaluated is more effective in healing than other types of dressings.

For example, one conclusion that is indicative of the many Cochrane Reviews on wound care dressings is from the "Foam Dressing for Healing Foot Ulcers" which states: "Currently there is no research evidence to suggest that foam wound dressings are more effective in healing foot ulcers in people with diabetes than other types of dressing however all trials in this field are very small. Decision makers may wish to consider aspects such as dressing cost and the wound management properties offered by each dressing type e.g. exudate management."

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814
T 301.530.7846 | **C** 301.802.1410 | **F** 301.530.7946
marcia@woundcarestakeholders.org

Similarly, the Cochrane Reviews on wound care therapies such as negative pressure wound therapy and topical or systemic hyperbaric oxygen also address their conclusions the following manner: "There is no valid or reliable evidence that topical negative pressure increases chronic wound healing" and "This review update of randomised trials found that HBOT seems to improve the chance of healing diabetes-related foot ulcers and may reduce the number of major amputations in people with diabetes who have chronic foot ulcers. In addition this therapy may reduce the size of wounds caused by disease to the veins of the leg, but the review found no evidence to confirm or refute any effect on other wounds caused by lack of blood supply through the arteries or pressure ulcers."

As noted in the conclusions stated above, the authors simply state there is a lack of evidence but does not give guidance to the prescribers or purchasers on whether to use or buy the wound care product or procedure as it does in the "Honey as a Topical Treatment for Wounds." We were surprised to see that originally the statement in the conclusion was "There is insufficient evidence to guide clinical practice in other types of wounds, and purchasers should refrain from providing honey dressings for routine use until sufficient evidence of effect is available." It was only when this issue was brought to the authors' attention that they stated:

> *"Thank you for your feedback. this statement has been present in the Authors' conclusions since the review was first published in 2008. However this is a valid point and does contravene Cochrane guidance from the Handbook which states "The primary purpose of the review should be to present information, rather than to offer advice". As a result we have modified this section to read: "There is insufficient evidence to guide clinical practice in other areas, health services may wish to consider avoiding routine use of honey dressings until sufficient evidence of effect is available"*

We still have concerns with leaving this statement in the conclusion for the following reasons:

1. If there is insufficient evidence, then why would the authors make any recommendations to the health services for the use of the product if there is not the data?
2. The revised statement would still be considered a recommendation. This deviates from the intent of the Cochrane Review to only inform clinicians of the sufficiency of data for the use of particular product or procedure.

We were curious to see if there were other examples of Cochrane authors using the words "avoid using" in their conclusion in other sectors outside of wound care. We found this example in the pharmaceutical sector:

> Chlorpromazine for psychosis induced aggression or agitation (Review) 2010
>
> *Authors' conclusions*
> Overall the quality of evidence is limited, poor and dated. Where drugs that have been better evaluated are available, **it may be best to avoid use of chlorpromazine**. Where chlorpromazine is used for acute aggression or where choices are limited, relevant trials are possible and urgently needed.

Both the wound care and pharmaceutical examples seem to be precedent setting for Cochrane and we question why there was a change in the approach when writing the conclusions. We are concerned that statements like the ones made in these conclusions will be repeated in Cochrane reviews in the future. The Cochrane Review is very well respected in the healthcare community, especially by clinicians looking to cut through the noise of

commercial posturing for some objective assessment of product categories or technologies. If these recommendations represents a clear departure from Cochrane's past focus on clinical evidence as the governing factor to allow the clinician make their own determination on recommendations, then the Alliance would like to remind Cochrane that their objectivity is the real value they have to offer. In addition, it is also inappropriate for a body with an international reach such as Cochrane to provide any form of procurement advice.

We would like to go on record that going forward the Cochrane Reviews should focus their conclusions on the evidence and data rather than give recommendations to the clinical community or purchasers whether to use the product or procedure since according to Cochrane's own guidance "it is contrary to the purpose of the review to present information than to offer advice."

Therefore, the type of conclusions that the authors should be making are exemplified by those we illustrated in the third and fourth paragraphs of this letter as well as the one below which come from the pharmaceutical sector:

> Oral anti-pseudomonal antibiotics for cystic fibrosis (Review) 2013
>
> *Authors' conclusions*
> We found no conclusive evidence that an oral anti-pseudomonal antibiotic regimen is more or less effective than an alternative treatment for either pulmonary exacerbations or long-term treatment of chronic infection with P. aeruginosa. **Until results of adequately-powered future trials are available, treatment needs to be selected on a pragmatic basis**, based upon any available non-RCT evidence, the clinical circumstances of the individual, the known effectiveness of drugs against local strains and upon individual preference.

Finally, we would like to point out that the Cochrane Review might want to take into consideration in its future conclusions the recommendations in the commentary "EBM's Six Dangerous Words" by R. Scott Braithwaite in the November 27, 2013 issue of JAMA (Volume 310, Number 20 pp 2149-50.) The author states that four other phrases could be used which would have clearer implications for decision making than the term "there is no evidence to suggest". The author writes the following:

> *The six most dangerous words in evidence-based medicine (EBM) do not directly cause deaths or adverse events. They do not directly cause medical errors or diminutions in quality of care. However, they may indirectly cause these adverse consequences by leading to false inferences for decision making*
>
> *Indeed, the fundamental problem with the phrase "there is no evidence to suggest" is that it is ambiguous while seeming precise. For example, it does not distinguish between the vastly different evidentiary bases of U.S. Preventive Services Task Force (USPSTF) grades I, D, or C, each of which may have distinct implications for decision making.*
>
> *"There is no evidence to suggest" may mean "this has been proven to have no benefit" (corresponding to USPSTF grade D), which has very different implications than alternative meanings for "there is no evidence to suggest" such as "scientific evidence is inconclusive or insufficient" (corresponding to USPSTF grade I) or "this is a close call, with risks exceeding benefits for some patients but not for others" (corresponding to USPSTF grade C). As a result, these six dangerous words may mask the uncertainty of experts. They even may be used to deny treatments with potential benefit, if they are interpreted as the equivalent of USPTF grade D ("this has been proven to have no benefit") but really mean the equivalent of USPSTF grade I ("scientific evidence is inconclusive or insufficient").*

Beyond its ambiguity, "there is no evidence to suggest" creates an artificial frame for the subsequent decision. It may signal to patients, physicians, and other stakeholders that they need to ignore intuition in favor of expertise, and to suppress their cumulative body of conscious experience and unconscious heuristics in favor of objective certainty. Suppressing intuition may be appropriate when the evidence yields robust inferences for decision making, but is inappropriate when the evidence does not yield robust inferences for decision making. Yet "there is no evidence to suggest" is compatible with either scenario. Because decisions are particularly sensitive to patient preferences when the favorability of an intervention is unclear (eg, USPSTF grade C), "there is no evidence to suggest" may inhibit shared decision making and may even be corrosive to patient-centered care.[8] Indeed, it is instructive to note that most people make patient-centered decisions every day without high-quality (eg, randomized controlled trial) evidence, and these decisions are not always wrong. Furthermore, foundational papers in the EBM field make it explicitly clear that EBM was never meant to exclude information derived from experience and intuition.[4] While some may argue that misuse of this phrase is only a symptom of not having received appropriate training in EBM, my experience with practitioners of EBM across the clinical, educational, research, and policy spectra suggests the contrary.

I suggest that academic physicians and EBM practitioners make a concerted effort to banish this phrase from their professional vocabularies. Instead, they could substitute one of the following 4 phrases, each of which has clearer implications for decision making: (1) "scientific evidence is inconclusive, and we don't know what is best (corresponding to USPSTF grade I with uninformative Bayesian prior) or (2) "scientific evidence is inconclusive, but my experience or other knowledge suggests "X" (corresponding to USPSTF grade I with informative Bayesian prior suggesting "X"), (3) "this has been proven to have no benefit (corresponding USPTF grade D) or (4) "this is a close call, with risks exceeding benefits for some patients but not for others" (corresponding to USPSTF grade C). Each of these four statements would lead to distinct inferences for decision making and could improve clarity of communication with patients.

EBM practitioners should abandon terms that may unintentionally mislead or inhibit patient-centered care. "There is no evidence to suggest" is a persistent culprit. Informed implementation of EBM requires clearly communicating the status of available evidence, rather than ducking behind the shield of six dangerous words.

We look forward to your response and would welcome speaking to you about this at your convenience.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director on Behalf of the Board of the Alliance of Wound Care Stakeholders

Dr. Caroline Fife, Co-chair
Dr. John Steinberg, Co-chair
Peggy Dotson, Board Member
Jule Crider, Board Member
Karen Ravitz, Board Member
Marcia Nusgart, Executive Director and Board Member

c.c. David Tovey, Editor in Chief