



July 21, 2019

Mr. Gopal Khanna
Director
Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857

Re: AHRQ RFI on *The Impact and Use of Evidence-Based Practice Center (EPC) Evidence Reviews*

Comments submitted electronically to epc@ahrq.hhs.gov

Dear Mr. Khanna:

The Alliance is a nonprofit multidisciplinary trade association of physician specialty societies, clinical and patient associations whose mission is to promote evidence-based quality care and access to products and services for people with chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of Alliance clinical specialty societies and organizations who not only possess expert knowledge in treating complex chronic wounds, but also in wound care research. A list of our members can be found on our website.

The Alliance appreciates being afforded the opportunity to provide our feedback regarding the Impact and use of AHRQ Evidence Based Practice Evidence Reviews issued by AHRQ. AHRQ has posed specific questions of interest for stakeholder feedback. The Alliance is only addressing 2 of the 7 questions. Our comments will be brief:

- *How the AHRQ EPC evidence review changed your decision, recommendation, or action.*

While the Alliance believes that the work conducted by AHRQ is important, we find that at least in the area of wound care, the assessments are typically myopic, key questions are too narrowly focused in order to impact coverage of wound care products, and there are more often than not significant errors in the methodology and therefore the conclusions reached by AHRQ. We also have significant issues with the fact that key investigators do not have expertise in chronic wound care.

As a result, we find that that the reports do not impact how our clinicians treat their patients and therefore are useless to our members in their daily practices. Our members do not make any decisions regarding whether to use a specific device based on these reports as a result. However, these reports are still impactful to our members because CMS is the one that is providing the guiding or key questions to AHRQ typically with the purpose of limiting coverage and therefore, the reports negatively impact our members by limiting coverage and or reimbursement despite the significant flaws in the reports being issued.

- *Based on your experiences, suggestions for how the EPC program can make its evidence reviews more useful and impactful.*

The Alliance would like to provide a few suggestions on how the evidence reviews can be more useful and impactful.

1. Key investigators should be required to actually practice in the area of the report. In wound care, too often AHRQ utilizes dermatologists or only those in academia when issuing chronic wound care related assessments. This is not acceptable. Furthermore, the key investigators should be published prior to the release of the final assessments.
2. There are often flaws/errors in the methodology AHRQ utilizes when conducting assessments and the questions posed usually are usually submitted by CMS with a specific goal of limiting coverage. The AHRQ assessments/reviews should be made independent of coverage or payment.
3. AHRQ can, and should, utilize Real World Data/Evidence and/or registry data when reviewing chronic wound care issues. This will give a much clearer and representative picture of the wounds being treated and the benefits of treatment.
4. In limiting evidence reviews to a certain time frame AHRQ is creating bias in their literature reviews. For example, AHRQ issued a technology assessment in 2012 for “skin substitutes”. A literature review was conducted, and a report issued, based on the key questions posed in that assessment. In 2019, AHRQ conducted another technology assessment for skin substitutes but did not review any of the evidence it reviewed in 2012 despite that fact that the key questions posed in the 2019 assessment were different than those provided in 2012. As a result, the conclusions reached in the 2019 report was faulty as not all the evidence was reviewed.

The Alliance has utilized and/or cited these assessments when we submit comments to other government agencies but otherwise these reports are not useful to our members.

We appreciate the opportunity to provide our feedback. Thank you in advance for your consideration. I can be reached at 301-530-7846 or marcia@woundcareholders.org.

Sincerely,



Marcia Nusgart, R.Ph.
Executive Director