

Alliance of Wound Care Stakeholders’ Comments Regarding AHRQ Draft Technical Brief (TB) and Supplemental Evidence and Data for Systematic Reviews (SEADS) Report on “Skin Substitutes for Treating Chronic Wounds.”

The Alliance of Wound Care Stakeholders (“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:

<http://www.woundcarestakeholders.org/about/members>.

The Alliance appreciated the opportunity to meet with AHRQ on March 19, 2019 after the Draft Technical Brief (TB) on “Skin Substitutes for Treating Chronic Wounds” was issued. During our meeting, we raised several points regarding the protocol as well as concerns with the key questions. We were told in order for AHRQ to have considered our concerns, we should have provided them to AHRQ prior to ECRI’s review and ultimately the Draft Technical Brief being released. However, that information was never published in order for us to do so. As a result of our meeting, AHRQ recognized that notice of the protocols was never issued prior to ECRI’s review based on a glitch in the system and the government shut down.

In order to remedy the situation, on April 25, 2019, AHRQ provided an additional opportunity to submit scientific information to be considered for the technical review. The submission deadline was extended to May 13, 2019.

While the Alliance is pleased that AHRQ permitted additional evidence to be submitted as a result of our meeting, we still have significant concerns. In addition to those that we already raised in our submitted March 8, 2019 comments to AHRQ, the Alliance has important and critical issues with the process by which AHRQ is moving forward with the TB release and the AHRQ comments related to the SEADs including the rationale for exclusion of some of the evidence submitted.

Our concerns include the following:

1. Had the protocols been issued along with the key questions prior to ECRI’s review, the Alliance would have raised the significant concerns that we had on the protocols and the key questions prior to the review. Due to the AHRQ glitches, we lost that opportunity. Having this opportunity to have the conversation with AHRQ staff consequently could have changed the study questions, impacted the content of the review and ultimately the outcome of the results reached in the technical review.
2. AHRQ, in recognizing that there was an error, reopened the opportunity to submit additional evidence to be considered in the report including published and unpublished studies. However, it seems that AHRQ

and ECRI had no intention of accepting most of the evidence submitted – even though the request to submit evidence included the type of evidence submitted by stakeholders. This is evident in the acceptance of only 3 of the 83 studies being submitted.

3. By reopening the ability to submit additional evidence, AHRQ should be required to reissue the technical brief for comment. First, there were already significant errors in the draft report which were addressed in stakeholder comments and need to be corrected. Secondly, AHRQ did not follow the necessary procedures to ensure that the public was afforded the opportunities to provide feedback on the protocols and key questions prior to the assessment being released. Finally, stakeholders have the right to review the next version of the draft to ensure that the corrections were made, the evidence was utilized correctly and read whether any conclusions were altered as a result. Thus, the technical brief should be reissued for comment before being finalized.
4. In its June 27, 2019 “Research Review Disposition of Comments Report, AHRQ states “much of the evidence submitted by stakeholders was reviewed and included in an earlier TA issued in 2012; therefore, these studies will not be reviewed for this technical review.” In order to adequately and accurately review evidence in this area, AHRQ should be reviewing and including all clinical studies from all years because the key questions and outcomes from the earlier TA are different from this report; therefore all evidence – including evidence that was reviewed for the 2012 technical review, should be included for inclusion in this 2019 technical brief. **At its current state, this brief is not complete and contains bias on behalf of the Agency.** The Alliance strongly believes that AHRQ should not limit its review of the evidence especially given that the key questions, protocols and conclusions are different from one report to the other.

As a result of serious errors in the first draft to which the Alliance has provided our comments, the bias created by excluding 2012 data in this report (despite differences in key questions, protocols, and conclusions between the two reports), the exclusion of most of the evidence submitted from the expanded evidence search, and the fact that protocols were not followed prior to the technical review being conducted, we urge AHRQ to release the next draft of the technical review with an additional public comment period prior to final publication.

We appreciate the opportunity to provide you with our feedback and concerns. We are happy to continue our dialogue with the Agency. Should you have any questions or like further information please do not hesitate to contact me.

Sincerely,



Marcia Nusgart, R.Ph
Executive Director