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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Skin Substitutes for Treating Chronic Wounds

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Skin Substitutes for Treating Chronic Wounds,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

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5600 Fishers Lane

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FOR FURTHER INFORMATION CONTACT:

Jenae Benns, Telephone: 301-427-1496 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Skin Substitutes for Treating Chronic Wounds*. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Skin Substitutes for Treating Chronic Wounds*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: https://www.ahrq.gov/research/findings/ta/index.html

This is to notify the public that the EPC Program would find the following information on Skin Substitutes for Treating Chronic Wounds helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
    - *For completed studies that do not have results on ClinicalTrials.gov*, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. Materials submitted must be publicly available or able to be made public. Materials that are considered

confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/email-updates.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

1. *What skin substitutes currently used to treat chronic wounds are being regulated by the U.S. Food and Drug Administration (FDA) under the following pathways: Premarket Approval (PMA), Premarket Notification (510[k]), Section 361 of the Public Health Service Act (21 CFR 1270 and 1271)?*
2. *What classification systems have been developed to categorize skin substitutes?*
    a. What are important skin substitute parameters and active components currently being used when classifying skin substitutes?
3. *What are the study design characteristics (such as those listed below) in each included investigation for each chronic wound type?*
    a. Comparator to skin substitute

b. Inclusion/exclusion criteria of patients including at least age, gender, and general health requirements (e.g., status of HbA1c, diabetes, peripheral vascular disease, obesity, smoking, renal)
c. Inclusion/exclusion criteria of wounds including at least wound type, wound size/depth/duration/severity, vascular status, infection status, and prior treatment requirements (e.g., no treatment with growth factors or negative pressure wound therapy)
d. Patient characteristics of enrollees including at least age, gender, general health (e.g., status of HbA1c, diabetes, peripheral vascular disease, obesity, smoking, renal), and prior and concurrent wound treatments
e. Wound characteristics of enrollees including at least wound type, wound size/depth/duration/severity, vascular status, and infection status
f. Basic study design and conduct information including at least method of patient enrollment, care setting, and use of run-in period
g. Definition of wound characteristics: definition of “failure to heal”, and definition of a successfully healed wound
h. Method of applying skin substitutes including provider, frequency of application, definition of standard of care, and handling of infections
i. Measurement and assessment methods including method of assessment(s); frequency and time points for assessment(s); and blinding of assessors
j. Statistical methods including power calculations, intent-to-treat analysis for studies designed to test superiority, and handling of drop-outs

4. *What are the outcomes of treatment strategies including skin substitutes alone and/or in addition to other wound care modalities compared to other wound care modalities in patients with different types of chronic wounds, for patient oriented outcomes such as the following? Consider at least:*
    a. Number/percentage of completely closed/healed wounds (skin closure with complete re-epithelialization without drainage or dressing requirements versus failure to heal)
    b. Time to complete wound closure
    c. Wound reoccurrence (include time when initial wound healing was measured, and follow-up to assess durability of healed wounds)
    d. Wound infection
    e. Need for amputation
    f. Need for hospitalization (frequency and duration)
    g. Return to baseline activities of daily living and function
    h. Pain reduction
    i. Exudate and odor reduction
    j. Adverse effects (besides those above)
5. *What skin substitutes are currently being investigated in ongoing trials?*
6. *What best practices in study design could be used to produce high quality evidence on skin substitutes?*

Gopal Khanna,

Director.

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