ALLIANCE OF

Wound
Care
Stakeholders

November 1, 2011

Scientific Resource Center, Oregon EPC
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Submitted Electronically

Re: Chronic Venous Ulcers: A Comparative Effectiveness Review of Treatment Modalities

To Whom This May Concern:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am submitting the following comments in response to the AHRQ Chronic Venous Ulcers: A Comparative Effectiveness Review of Treatment Modalities. I serve as the Executive Director of the Alliance, a 501 (c) (6) multidisciplinary trade association consisting of over 15 physician, clinical, provider, and patient organizations, whose mission is to promote quality care and patient access to wound care products and services. These comments were written with the advice of Alliance organizations that not only possess expert knowledge in complex acute and chronic wounds, but also in wound care research.

I had the opportunity to speak with AHRQ staff Dr. Christina Chang to help clarify the rationale for AHRQ asking these questions. She responded with the following answer to me:
Our interest at this point in the project is ensuring that we are asking the right questions. In asking these questions we would like ensure that we are including the right comparators, interventions, and patient population. We also would like to ensure that the questions address the decisional dilemmas that providers face when caring for patients with chronic venous ulcers. We believe that knowing which areas in which we have evidence and do not have evidence is helpful for stakeholders.

The Alliance convened a number of conference calls to discuss how our comments could help AHRQ in light of the information presented above. Many of our comments regarding the existing evidence will come from the American Association for the Advancement of Wound Care Updated Venous Ulcer Guideline and evidence file. Both were recently submitted to the National Guideline Clearinghouse. I have attached both as references. Therefore, our comments are divided into two sections—those relating to the questions and those addressing areas where we believe need further research.

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COMMENTS RELATED TO KEY QUESTIONS

Question 1- **For patients with chronic venous leg ulcers, what are the benefits and harms of advanced wound dressings (i.e., dressings with active chemical, enzymatic, or antibacterial component(s) compared with standard pressure dressings?**

We have a number of concerns related to this question and will offer recommendation to change the sentence to make it more meaningful. Our concerns include the following:

1. We question if AHRQ intended to use the terms "standard pressure dressings" in reference to those dressings providing compression. Compression therapy is the gold standard of treating venous stasis ulcers as indicated in the AAWC venous ulcer guidelines. (Page 3- C-4). Examples include the 2-4 layer compression systems, the Unna's Boot or Duke Boot. We would recommend that the words "standard pressure dressings" be replaced with "compression systems."
2. We also are concerned that the question, as worded, implies whether wound **dressings** are used *in lieu* of, rather than in conjunction with appropriate compression **therapy**. As stated above, appropriate compression **systems** are ALWAYS indicated for venous ulcer treatment (excepting patients with arterial disease). The wound dressings placed underneath the systems will vary depending upon the needs of the wound. Despite the manner in which clinical trials have been carried out (at the insistence of the FDA), in no case clinically would a single type of dressing be used throughout the course of wound healing. Dressings are changed as the needs of the wound change. Therefore, we would recommend that the sentence state:

   For patients with chronic venous leg ulcers, what are the benefits and harms of using advanced wound dressings in conjunction with compression systems as compared with using solely compression systems?

3. A standard **wound** dressings can be one of multiple categories of dressings; collagens, hydrocolloids, foams, absorptive specialty dressings, hydrogel sheet dressings, composite dressings, transparent films, gauze, gauze-based dressings, aqueous hydrogels, etc. Dressings with or without an active chemical, antimicrobial or enzyme are used based on the condition of the wound and often in combination with other dressings. As stated above, rarely is one type of dressing used consistently throughout the full time to healing a wound. Therefore, what would be the 'effectiveness parameters' measured per dressing type, per dressing use, and how would AHRQ intend to evaluate one from another when used together for a period of time in the wound healing cycle?
4. We also have concerns about information included in Table 1. We believe that the table should be broken into three parts:
   - ***Surgical dressings***—all of the dressings should be included in this section. While there is much information about definitions and descriptors of surgical dressings in the literature, we would recommend that AHRQ use definitions that are currently contained in the DMEMAC local coverage determination (LCD) for surgical dressings to be consistent. For correct

examples of each category, AHRQ can turn to the listings in the Medicare Pricing Data Analysis and Coding (PDAC) website (www.dmepdac.com). There should be noted that there is a difference within this category between traditional wound care dressings (i.e. gauze) and advanced wound care dressings (all the other categories). The example used in the question (i.e. dressings with active chemical, enzymatic, or antibacterial component(s)] may not really accurately encompass the variety of advanced wound dressing so we are deleting those words. We would also recommend the following:

  - Collagen dressings should be a category by itself—it should not say ECM (which should not include OASIS products)
  - Enzymatic products should be removed from the surgical dressing category since they are biologics (see next section)
  - Contact layers and hydrogels should also be included since they are indicated for the treatment of venous stasis ulcers.

- ***Acellular biomaterials-*** examples include but are not limited to: OASIS Wound Matrix, OASIS Ultra Tri-Layer Matrix (ones that are indicated for venous ulcers)
- ***Biologics-*** examples include but are not limited to: TheraSkin, SANTYL Collagenase ointment, AlloSkin, APLIGRAF (ones that are indicated for venous ulcers)

5. In addition to our recommendations on the reorganization of Table 1, we also have some concerns regarding its accuracy. Our concerns include the following:
   a. We question the need to have the first column addressing functional categories since it may not be relevant to the table (the other columns of types, characteristics, functions and examples seem to be the information that is most important) and the terminology is not accurate. Examples include:
      i. The functional category of Low Water Vapor Transmission Rate (WVTR) does not apply to all hydrocolloids. Additionally, manufacturers measure and indicate WVTR (or more appropriately Moisture Vapor Transmission Rate-MVTR) by various methods and the descriptor "Low" is a relative term and not well defined.
      ii. The term "antibacterial" does not really define the scope of the products that are included in this category. Instead, we would recommend that the term "antimicrobial" be used since this would encompass the categories of antibacterials, antifungals and antiseptics. This terminology could then be included in the category of "type of advanced wound category" instead of functional categories.
   b. In the foam category, we recommend that the words "semi-permeable polyurethane foam" be eliminated under "characteristics" since not all foams have that characteristic. In fact, many are made of products other than polyurethane.
   c. In the composite category, a waterproof cover should be included in the definition since that is included in the DME MAC surgical dressing LCD.

d. In the "characteristics' section of the antibacterial dressing category (which again should be termed "antimicrobial dressing category)," gentian violet, polyvinyl alcohol with methylene blue, cadexomer iodine and chlorhexidine and derivatives should be included. Also the correct spelling for the term PHMB is polyhexamethylene biguanide.

Recommendations: We would suggest that question 1 be broken into three questions and compare advanced surgical dressings, acellular biomaterials, and biologics with compression systems against solely a compression system. Thus, the questions would be:

1A For patients with chronic venous leg ulcers, what are the benefits and harms of using advanced wound dressings in conjunction with compression systems as compared with using solely compression systems?
1B For patients with chronic venous leg ulcers, what are the benefits and harms of using acelluar biomaterials in conjunction with compression systems as compared with using solely compression systems?
1C For patients with chronic venous leg ulcers, what are the benefits and harms of using biologics in conjunction with compression systems as compared with using solely compression systems?

<u>Question 2A-</u> For patient with chronic venous leg ulcers that do not have clinical signs of cellulitis that are being treated with conservative care, what are the benefits and harms of using systemic antibiotics?

The Alliance believed that this is an area where research may be of value.

<u>Question 2B</u>- For patients with chronic venous leg ulcers that do not have clinical signs of cellulitis that are being treated with advanced wound dressings, what are the benefits and harms of using systemic antibiotics?

The Alliance wanted clarification of the definition of "advanced wound dressings"—is it the definition noted in question #1?

<u>Question 3A</u>- For patient with chronic venous leg ulcers, what are the benefits and complications of surgical procedures aimed at the underlying venous abnormalities when compared with no surgical intervention?

The Alliance agrees that there needs to be further evidence on this issue. We also wonder if AHRQ intends to evaluate for each compartment—superficial, perforator or deep vein? The AHRQ might want to consider questioning if it aids healing or prevents recurrence or both?

<u>Question 3B</u>- What is the comparative effectiveness and safety of different surgical procedures for a given type of venous reflux and obstruction?

It is our understanding that there are several recent studies for surgical procedures but more research is needed on the effects of value reflux versus occlusion as a causative factor in venous ulcer disease.

COMMENTS RELATED TO TOPICS WHERE FUTURE RESEARCH IS NEEDED

The Alliance organizations recommended that further research should be done in the following areas and AHRQ might want to consider them for funding:

- What are the barriers regarding providers using evidence based practice to determine the best wound care practice for venous stasis ulcers but unable to provide it due to patient's insurance and their site of service?
- What is the best care for patients who have mixed venous and arterial ulcers?
- What is the place for skin grafts in venous stasis ulcers?
- What form of debridement improves time to complete venous stasis healing?
    - Compared to mechanical debridement with wet-to-dry dressings/
    - Compared to any other form of debridement?

CONCLUSION

The Alliance appreciates the opportunity to provide AHRQ with our comments. We recognize that this area is very complex and would be pleased to serve as a resource to you now or in the future. If you have any questions, or would like further additional information, please feel free to contact me.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director