ALLIANCE OF

Wound Care Stakeholders

May 21, 2009

Dr. Sean Tunis
Director
Center for Medical Technology Policy
Inner Harbor Center
400 East Pratt Street, Suite 808
Baltimore, MD 21202

Dear Dr. Tunis;

As executive director of The Alliance of Wound Care Stakeholders ("Alliance"), I appreciate the opportunity to serve on the Center for Medical Technology Policy (CMTP) advisory group and thus receiving a copy of a draft Effectiveness Guidance Document (EGD) on Mechanical Interventions for Chronic Wound Healing for review and comment. I am submitting these comments on behalf of the Alliance, a multidisciplinary consortium of over 15 physician, clinical, provider, manufacturer 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 the following Alliance organizations who possess expert knowledge in complex acute and chronic wounds: Association for the Advancement in Wound Care, American Professional Wound Care Association, American Association of Wound Care Management, Undersea and Hyperbaric Medical Society, National Association for the Support of Long Term Care, and the Coalition of Wound Care Manufacturers. There were other organizations who took part in our conference call and were in agreement with our comments, but due to the time constraints could not obtain sign on approval by their boards.

In order to provide comments to you by today, the Alliance convened a conference call yesterday. We determined that while this EGD could be very valuable, due to our significant concerns with the document, we are requesting CMTP not to distribute it further until a conference call and meeting could be held with the Advisory Group to address and solve the problematic issues. This document could be very valuable in helping with wound care research, but we believe that it needs to be done right and the process needs to be slowed down in order for this document to be reflective of current clinical research.

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Our concerns include the following:

1. We question the reason for the short time frame for the Advisory Group to comment on the EGD. There was a tremendous amount of information to read and think through and having only a week or so to review the material and submit appropriate comments is inadequate. The CMTP has assembled a stellar array of wound care experts to sit on this board, and the Alliance would request that you engage them more in an advisory capacity. As mentioned above, we ask that CMTP convene a conference call with the Advisory Board to discuss their concerns and comments. In addition, as I stated in a previous email to you, a meeting of wound care researchers, many who are represented in the Alliance, should be convened to discuss these issues more thoroughly.

2. Our general concerns are as follows:

a. We would like to have further discussion on the definition of the composite outcome being the time to wound closure or time to wound healing depending on the population and the nature of the wounds being studied. With respect to the endpoints, the EGD does not provide any consideration for any other beneficial effects of technology and ignores adjunctive rather than primary benefits for most technologies. We would also like to further discuss using the wound care trajectories as secondary endpoints.
b. It appears that CMTP is applying the pharmaceutical research model to wound care – we believe that it is inappropriate and does not translate to wound care.

3. We would like to discuss further our specific concerns since we are only addressing below a small sampling of them due to the fact that we have not had a chance to review the EGD as thoroughly as we would like. Our specific concerns include the following:

a. The EGD contains multiple and contradictory definitions for "chronic" wounds on page 5. One definition describes a chronic wound as fails to respond to standard therapy within 3 months or 90 days. We have concerns with this definition for the following reasons:
    i. We question where this definition comes from since there is nothing in the literature – or in clinical practice - to support this.
    ii. The typical standard for RCT's is: Subjects must have had the wound open for at least 4-6 weeks from day one on screening visit. Ulcers which decrease in area by >30% during the screening 1 or 2 week run-in period are usually disqualified.
    iii. We have concerns that if this definition is 90 days, it will be included in payers' coverage policies. The current definition for chronic wound in Medicare coverage policies for 'advanced technologies' included in the guidance document are based on wounds that failed to show progress to healing in one month. At the 2005 MCAC Meeting on Chronic Wounds, CMS staff were challenged even on where the timeframe for 30 days was issued.

b. We believe that the document incorrectly link systemic hyperbaric oxygen therapy with local oxygen and then proceeds to incorrectly classify both as

mechanical devices. The FDA does not consider local oxygen to wounds as hyperbaric oxygen therapy. In addition, mechanical devices are an inappropriate overall descriptor.

c. In regards to blinding, the document excludes NPWT. We would call to your attention that HBO should also be excluded since blinding by sham treatment for HBO wound trials has been demonstrated to be unnecessary.
d. The exclusion criteria guidelines are too excessive. This can jeopardize the generalization of the RCT results to real world populations.
e. The EGD requires one or more board certified physician with demonstrated expertise in wound healing to have medical responsibility for the study. We do not agree that only a physician is required for this type of study. By stating this, we submit that this requirement will limit study options.
f. Trial comparison control groups are described as standard care (accepted) and 'usual care' (not-acceptable) without clarification of what the difference is in these two methods of care.
g. The document suggests inclusion of patient with co-morbidities that may slow healing (systemic steroids, immunosuppressives) and also lists this as exclusion criteria.
h. The guidance suggests the follow-up post trial to determine recurrence should be a minimum of 16 weeks however, this will be directly impacted by patient compliance to post healing instruction and not truly reflective of the effectiveness of the therapy. We disagree with this length of time as a measure for recurrence.
i. There are many additional specific concerns or errors, (e.g., Instead of pressure next to Unna Boot, it should be patients with venous insufficiency), but due to time constraints, we cannot list all of them here.

The Alliance has fundamental concerns with the document as written and has only had time to provide you with a few of our concerns. The EGD could be very valuable if it is done well but could stifle wound care research if it is not. We strongly recommend that CMTP not distribute this document to any additional parties until a conference call has been convened with the Advisory Group. While we appreciate the opportunity to comment on the EGD, some of our concerns might have been alleviated if CMTP allowed the Advisory Group the opportunity to assist you during the drafting process so some of these issues could have been resolved prior to the release of the draft document.

If you have any questions on any of the information provided in our comments, please feel free to contact me. The Alliance supports the concept of a EGD, but wants to ensure that it does reflect the current wound care clinical research and the thinking of wound care clinicians and researchers. We are delighted to work with you in developing the next version of the document and in participating in your future conference.

Sincerely,

Marcia Nusgart R.PA.

Marcia Nusgart
Executive Director