Revise Guidelines/Standards to Reflect Clinical Evidence and New Technology

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In recent years, professional medical societies and other organizations have developed clinical practice guidelines and standards to guide the work of wound care scientists, manufacturers, researchers, and clinicians. Wound care stakeholders tend to follow the guidelines and standards developed by organizations to which they belong. This article emphasizes the need to monitor all published wound care guidelines and standards and to revise them when new clinical evidence is published, and/or new technology is released. The article also emphasizes that payers use published clinical practice guidelines and standards to make coverage and payment decisions.

Keywords: cellular and/or tissue-based products for skin wounds (CTPs), skin substitutes, chronic wounds, clinical practice guidelines, technology standards

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INTRODUCTION

WOUND CARE CLINICAL practice guidelines and standards are developed by many medical professional societies and wound care organizations throughout the world. These guidelines and standards are used by wound care (1) scientists when developing new technology, (2) manufacturers when producing or launching new technology, (3) researchers when designing clinical trials, and (4) professionals to guide their clinical practice. Unintended users of the guidelines/standards are payers who often refer to them when making coverage and payment decisions for wound care products and procedures.¹

When societies and organizations develop and implement wound care guidelines/standards, their work has just begun: they must routinely review and revise the guidelines/standards to incorporate new technology and new clinical evidence. Outdated wound care guidelines/standards can

negatively affect care provided to patients with chronic wounds, as well as coverage and payment by the payers. Wound care stakeholders should make a conscious effort to gather pertinent wound care guidelines/standards released by all societies and organizations and should recommend revisions when new technology and new clinical evidence are available.

Wound care stakeholders often make the mistake of only focusing on the guidelines/standards released by the societies/organizations to which they belong. Meantime, to make coverage and payment decisions, the payers use published wound care guidelines and standards from all societies and organizations. This article provides an example of (1) how an outdated wound care standard created by an international organization, which was not on the radar screen of most wound care stakeholders, was used by payers to deny

coverage and payment for new wound care technology, and (2) how some astute wound care stakeholders volunteered to update the standard, so payers would cover and pay for new technology that was included in current wound care clinical practice guidelines.

WOUND CARE PROBLEM ADDRESSED

As the new millennium began, new cellular and acellular technology started to trickle into the wound care marketplace. As clinical evidence was published, clinical practice guidelines were updated to include these new products.

In addition, a standard was developed by the ASTM, an organization that was little known by wound care stakeholders. The standard, entitled *Standard Guide for Classification of Therapeutic Skin Substitutes F2311-08*,² was originally released in 2003 and was revised in 2006 and 2008. Although the standard was a useful reference at the time, it focused on products that could be called skin substitutes (a term that the Food and Drug Administration (FDA) does not allow most products in this space to use now). Many of the products that are used today to manage skin wounds do not resemble skin tissue and do not act to substitute for skin or to mimic skin. Instead, these products consist of cells and/or tissue-based constructs that are introduced into/onto skin wounds, where they support the synthesis of new skin tissue *in vivo*. As such, these products do not qualify as skin substitutes and should not be referred to as skin substitutes. Therefore, the standard was not inclusionary of all the new products on the market and in the manufacturers' pipelines. In addition, the standard focused on the surgical procedure for the application of one specific product.

The scope of the standard was specified for "products that can be substituted for tissue grafts." Many of the existing/in-development products were primarily used, or were targeted for use, to manage chronic wounds, which are not typically treated with grafts. Finally, the outdated standard did not distinguish the cellular and/or tissue-based products for skin wounds from surgical dressings.

Unfortunately, governmental and private payers used the limited scope of that standard (products that can be substituted for tissue grafts) and some outdated definitions in the standard as the basis for denying coverage and payment for the new technology for chronic wounds that are not typically managed with grafts. When an astute wound care reimbursement consultant identified that the outdated standard was the reference doc-

ument used by payers to deny coverage for the state-of-the-art new technologies, the Alliance of Wound Care Stakeholders³ created a workgroup composed of wound care scientists, researchers, clinicians, and manufacturers. All the workgroup members agreed their goal should be to revise the standard to be inclusive, rather than exclusive, of all the new technologies that were needed to manage chronic wounds that did not respond to standard of care.

DISCUSSION

When wound care stakeholders find a need to develop or revise clinical practice guidelines or standards through professional medical societies and/or organizations, they must learn the process for accomplishing that large task. Because none of the Alliance of Wound Care Stakeholders³ workgroup members knew anything about the ASTM, they had to learn about the organization and the process for creating and revising standards.

The workgroup was surprised to learn that ASTM International⁴ was developed in 1898 by a group of scientists and engineers to address the frequent rail breaks, which were affecting the fast-growing railroad industry. The engineers developed an ASTM standard for manufacturing the steel used in the rails. The organization was originally called the "American Society for Testing and Materials" because the scientists and engineers not only developed/published standards but also demonstrated how to test the product(s) and how to document if the products met the published standard.

Today, ASTM International⁴ has 12,500 global ASTM standards, 30,000 volunteer members who work to develop the standards, and 1,150 organizational members in 140 participating countries. ASTM International has always been a voluntary organization where clinicians, scientists, manufacturers, and civilians can join and participate. ASTM International supports more than 149 sections dealing with different aspects of materials and manufacturing. The ASTM section most pertinent to wound care is F04 (Medical and Surgical Materials and Devices). F04.41 is a subsection of F04 that specifically focuses on creating standards for devices/products used to manage chronic wounds, for example, F2311-08.²

ASTM standards originate when a member identifies a need to develop a new standard or revise an existing standard and submits a request to the appropriate subsection. The subsection members discuss the request and determine if a collaborative

workgroup should be formed. If a workgroup is established, a chairperson is selected: that person is often the member who identified the need and submitted the request for the new or revised standard. The chairperson solicits workgroup volunteers who are interested in the topic. The workgroup meets in person, by conference call, or by e-mail with the collaborative chairman and discusses the options and fine points of the proposed standard. Once the workgroup has developed the proposed standard, a vote is taken by the workgroup to accept the language of the proposed standard.

Then the proposed standard is balloted at three levels. The first ballot is at the subsection level, the second ballot is at the section level, and the third ballot is by the entire ASTM membership. At each level, the proposed standard must pass with 60% of the members either casting an affirmative vote or abstaining. The proposed standard cannot pass if any negative votes are cast. If one or more members vote negatively at any level, the workgroup reconvenes to discuss the concerns of the member(s) who voted negatively and to work with those member(s) to resolve their concerns. The proposed standard is then revised, and the balloting process is repeated. Once the proposed standard has successfully passed all three levels, it becomes an ASTM Standard.

Once the Alliance of Wound Care Stakeholders³ workgroup understood the process, they began working together via conference calls and e-mails to vet terminology that (1) better describes and includes the many diverse products in this space and (2) would be the best title for a revised standard. After considering nearly 100 different terms, the workgroup finally settled and agreed on *Cellular and/or Tissue-Based Products for Skin Wounds (CTPs)*. The workgroup also described classifications and nomenclature for the CTPs based on their composition.

The workgroup then presented a proposal to ASTM to (1) rename the existing standard F2311-08 from *Standard Guide for Classification of Skin Substitutes* to *Cellular and/or Tissue-Based Products for Skin Wounds (CTPs)*, (2) use the new terminology throughout the standard, and (3) use the classifications and nomenclature for the products based on their composition. The request was discussed at several semiannual F04.41 subsection meetings.

The workgroup was finally advised by ASTM to develop a new standard following the ASTM format rather than try to revise F2311-08. The workgroup

TAKE-HOME MESSAGES

- Wound care stakeholders should continually watch for and read new/ revised clinical practice guides and wound care standards that are released.
- Wound care stakeholders should be aware of terminology in guidelines and standards that is used by payers when making coverage and payment decisions.
- Wound care stakeholders should routinely review all pertinent clinical practice guidelines and wound care standards and volunteer to assist the societies/organizations when revisions should be made to align the guidelines/standards with new clinical evidence and new technology.

accomplished this task after another year of teamwork. The new proposed standard was submitted to and balloted by the F04.41 subsection membership. When the ballot included several negative votes, the workgroup reviewed each negative vote, contacted the members who cast the negative votes, and refined the proposed standard with language that all parties could accept. This revised proposed standard was balloted again, refined again, and accepted at the third ballot. At that point the proposed standard was balloted by the larger F04 membership. Again, there were negative comments which the workgroup reviewed, discussed with the negative voters, and used their ideas to refine the standard with language that was acceptable to the workgroup and the negative voters. The draft standard passed the F04 level at the second ballot and was sent to the entire ASTM membership for a ballot. The ASTM membership voted positively for the proposed standard in 2016 and it was accepted as F3163-16, *Standard Guide for Classification of Cellular and/or Tissue-Based Products for Skin Wounds (CTPs)*.²

Because ASTM standards are global, F3163-16 is now used to classify CTPs internationally by scientists, researchers, manufacturers, clinicians, and payers. Scientists reference it to categorize products by composition, obtain definitions pertinent to this wound care space, incorporate vetted terminology into their publications, and use in their dossiers prepared for agencies such as the FDA. Researchers reference it when creating the protocols for clinical trials. Manufacturers use the standard's terminology when communicating with agencies such as the FDA and with payers such as the Centers for Medicare & Medicaid Services. Clinicians use the standard's terminology in their daily vocabulary, their medical record documentation, their published articles, and their educational presentations. Most important, to the best of this author's knowledge, now that the F3163-16 is in-

clusive of all the categories of CTPs, no U.S. payer has used terminology in the new standard to deny coverage for any CTP. In fact, one of the major Medicare Administrative Contractors adopted the CTP term for the title of its Local Coverage Determination⁵ pertaining to these products.

All these positive outcomes validate the many hours of volunteer work that the Alliance of Wound Care Stakeholders workgroup spent to revise a standard, created by an organization little known to them, which was preventing patient access to new wound care technologies. The positive outcomes also validate why wound care stakeholders should pay attention to pertinent guidelines and standards that are created and implemented by all

organizations, not just the organizations to which they belong.

AUTHOR DISCLOSURE AND GHOSTWRITING

No competing financial interests exist. The content of this article was written by the author listed.

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Abbreviations and Acronyms

CTPs = cellular and/or tissue-based products for skin wounds

FDA = Food and Drug Administration