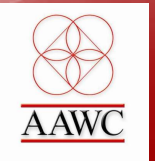


Medical Devices Advisory Committee General & Plastic Surgery Devices Panel

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Disclosures

- Podiatric Physician Board Member
 - Association for Advancement of Wound Care 2015-2017
- Scientific Advisor and Consultant
 - Hollister Wound Care, Libertyville, IL
- Consultant
 - Integra Life Sciences, Plainsboro, NJ





- ✓ The leading interprofessional wound care association in US
- ✓ 2500+ members
- ✓ Multidisciplinary clinicians, researchers and educators
- ✓ Over 240 patient/caregiver members
- ✓ Every US state & DC and PR represented
- ✓ Over 80 international members representing > 30 countries

- ❑ **Mission:** To advance the care of people with and at risk for wounds

- ❑ **Vision:** To set the standard and advocate for all wound care



Complexity of the Patient

- ❑ Incidence of non-healing wounds: 5-7M episodes per year
 - Resulting in \$20B in healthcare spending
- ❑ Average physician-in-training receives under 10 hours of formal didactic education related to wound care – e.g. comfort level of physicians to use silver when managing a wound
- ❑ Diabetic patients w/ non-healing wounds that results in amputation – may have a mortality rate of up to 50 percent in 5 years – a rate similar to several types of cancer
- ❑ Patient compliance to instruction effects outcomes & wound management choices
- ❑ Antiseptic & antimicrobial dressing/gels/solutions in the {FRO} category have been used for many years without significant reactions or documented potentials for antimicrobial resistance

Patient Complexity Changes With Wound Type

- ❑ Wound healing is a complex process that involves a coordinated integration of numerous clinical and biochemical pathways
- ❑ Surgical wound in a healthy individual typically takes 30 days on average to heal
- ❑ Arterial wound in a patient with severe atherosclerosis can take **over a year** to heal completely

Common Causes of Chronic Non-Healing Wounds

- ☐ Diabetes
- ☐ Vascular Disease (arterial and venous)
- ☐ Cardiovascular or Renal Disease
- ☐ Infection
- ☐ Immobilization
- ☐ Trauma
- ☐ Surgery
- ☐ Burns
- ☐ Radiation Therapy

Complex Patients / Complex Wounds



Compromising Factors in Complex Wound Patients

☐ Wound-healing can be compromised by many factors:

- ☐ Obesity
- ☐ Diabetes
- ☐ Smoking
- ☐ Vascular disease
- ☐ Infection
- ☐ Renal failure
- ☐ Autoimmune diseases
- ☐ Cancer
- ☐ Malnutrition

☐ A classic example of a non-healing wound is diabetic foot ulceration.

Clinical Decision Making

- ❑ Management of wound environment
 - ❑ Depends on wound type, depth, condition, tissue viability, bioburden, location
 - ❑ Removal of all devitalized tissue [debridement]
 - ❑ Cleansing/irrigation
 - ❑ Bioburden management [antiseptics/ antimicrobials]
 - ❑ Support local healing environment [dressings, gels, ointments]
 - ❑ Treat infection [antibiotics]
- ❑ Diabetic Foot Ulcers: commonly infected [IDSA Guideline]
 - ❑ Off-loading & reduction of bioburden/ infection risk – paramount treatment plan

Clinical Decision Making

- ❑ Venous Ulcer: often variable edema and exudate issues
 - ❑ Compression and exudate management - cornerstones of care
- ❑ Arterial Ulcers: usually require more hydration and moisture
 - ❑ Topical management based on patient presentation, long healing times, risks of infection & clinical judgment
- ❑ Surgical Wounds: most are closed by day 30
 - ❑ Complicated surgical or dehiscent wounds - left to discretion of surgeon due to increased risk of contamination/infection
- ❑ Pressure Ulcers: require off-loading and reduction in shearing forces to improve outcomes
 - ❑ Sacral ulcer at risk of contamination from urine/ feces

Topical Management/ Dressing Considerations

- ☐ Wound healing is a complex dynamic of issues that involve much of the following:
 - ☐ Metabolism
 - ☐ Nutrition
 - ☐ Bioburden
 - ☐ Biofilm
 - ☐ Exudate
 - ☐ Ambulatory status
 - ☐ Co-morbidities of patient

Guideline Issues for Panel

- Terminology:
 - These products are not termed “Antimicrobial” in their 510k Clearances –
 - The proper terminology is “ANTIBACTERIAL”
- The Executive Summary confuses these terms (slides 71-73) with respect to these products in the {FRO} category. This is misleading as these reference papers refer to ANTIBIOTICS (oral and parenteral), sometimes topical.

Guideline Issues for Panel & Clinicians

- ❑ *Guidelines do not all agree on topical use of antiseptic, antimicrobial & antibiotic dressings, gels, solutions*
- ❑ ABA 2001 (1972-1998 data) Burn wounds
 - ❑ For minor P-T **burns** (only) no difference on healing rates for antimicrobial vs. gauze w/ petrolatum dressings (1972 single study)
 - ❑ Infection in minor burns rare”
 - ❑ Limited P-T burns no difference in infection rates for dressing used w/ or w/o antimicrobials (1988 single study)
- ❑ WHS 2006 Chronic Wounds
 - ❑ $\geq 10^6$ CFU/g tissue – use topical antimicrobials, D/C once wound bioburden in balance

Guideline Issues

- ❑ WHS (2006) Chronic Wounds (VU, AU, DFU, PU)
 - ❑ “Systemic administration of antibiotics do not effect bacterial levels in granulating wounds, however topical application can be effective”
 - ❑ “Infected tissue must be treated by topical antimicrobials, systemic antibiotics or surgical debridement”

- ❑ AVF/ SVS (2014) Venous Ulcers
 - ❑ “Recommends against ‘routine use’ of topical antimicrobial containing dressings for non-infected VU”

Guideline Issues

- ❑ ASPS (2007) Chronic Wound of LE (AU, VU, DFU)
 - ❑ “a critical quantity of bacteria appears to predict wound infection in complex extremity wounds”
 - ❑ “majority of chronic wounds are colonized by a polymicrobial aerobic-anaerobic microflora. If the involved tissue is devitalized (e.g., ischemic, hypoxic, or necrotic) and the host immune response is compromised, conditions are optimal for microbial growth and invasion”
 - ❑ “rational antibiotic use in the Tx of chronic wounds of the LE distinguishes among contamination, inflammation, and infection”
- ❑ IDSA (2012) Diabetic Foot Ulcers
 - ❑ “Wounds w/o evidence of soft tissue or bone infection do not require antibiotic therapy”
 - ❑ Use topical therapy for selected mild superficial infections (strong, moderate)

Guideline Issues

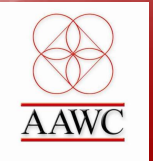
☐ IDSA (2012) Diabetic Foot Ulcers

- ☐ “clinicians should consider the possibility of infection occurring in any foot wound in a patient”
- ☐ “the controversial concept of excess wound bioburden has led to the increasing use of antimicrobials, particularly topical antiseptics (eg, cadexomer- iodine) and silver-based dressings, despite little evidence substantiating any benefit of these dressings over conventional therapy”

☐ AAWC (2010)* Pressure Ulcer & Venous Ulcer Guidelines

- ☐ “Use topical antimicrobial solutions, dressing, gels, ointments effective against Gram -/+ and anaerobes w/ sustained-released silver, iodine, other agents”
- ☐ “Initiate on clean ulcers w/ delayed healing despite 2-4 weeks optimal care”
- ☐ Re-evaluate every 2 weeks, D/C when wound progresses

* Not reviewed or included in FDA Report



Guidelines

❑ The VLU and Pressure Ulcer guidelines from the AAWC was not considered, which states:

- ❑ E. Adjunctive interventions to apply if conservative therapy does not work in 30 days
 - 1. Antimicrobial VU topical care if no healing is seen in 30 days: A (O'Meara et al., 2010) Consider systemic antibiotic use only on VU with clinical signs of infection: A (O'Meara et al., 2010)
 - ❑ 2. Cadexomer iodine dressings improves healing on clinically infected wounds: A (Hansson, et al., 1998; O'Meara et al., 2010)
 - ❑ 3. Silver-containing foam or collagen/oxidized regenerated cellulose dressings: A (Dimakakos et al., 2009; Jørgensen et al, 2005; Munter et al., 2006)

Guideline Issues

- ❑ WHS (2006) Chronic Wounds (VU, AU, DFU, PU)
 - ❑ “pts. w/ neuro-ischemic ulcers should be considered for a short course of systemic antibiotics even when clinical signs of infection are **not present**. These chronic wounds have a bacterial load that may impede healing before any evidence of clinical signs of infection.”
 - ❑ “chronic treatment w/ systemic antibiotics does not prevent infection and may worsen outcome if infection develops”
 - ❑ “routine use of antibiotics should be avoided, and antibiotics should be stopped if no response occurs”
 - ❑ “topical antimicrobial dressings may be beneficial in management of chronically/ heavily colonized wounds, decreasing their bacterial load and helping wound healing”

Guidelines are a Guide

- ❑ ASPS (2007) Chronic Wound of LE (AU, VU, DFU)
 - ❑ “This guideline should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients’ needs in different ways.
 - ❑ **The ultimate judgment regarding the care of a particular patient must be made by the physician** in light of all circumstances presented by the patient, the available diagnostic and treatment options, and other available resources.”

Guidelines

- Uckay/Lipsky: IWGDF
 - Diabetic foot infections **MUST** be done clinically
 - Identify at least 2 points of clinicals to ID infection
 - Rubor, Warmth, Pain/Tenderness, Purulence
 - May also have the following:
 - “**necrosis, friable or discolored granulation tissue, non-purulent secretions, fetid odor or the failure of a properly treated wound to heal**”
- **EXPERT OPINION:**
 - The **rationale** for prescribing topical, oral or parenteral antibiotics for patients with a diabetic foot wound is to **treat clinically evident infection**. Available published evidence suggests that there is no reason to prescribe antibiotic therapy for an uninfected foot wound as either prophylaxis against infection or in the hope that it will hasten healing of the wound.

Concluding Comments

- ❑ Devices (FRO category) w/ antiseptic & antimicrobial components are used for local management of complex & chronic wounds to control the wound bioburden
 - ❑ Not used to treat infection!
 - ❑ Important tool for clinicians to contain, control and help remove detrimental bacteria/debris that impedes healing
 - ❑ Used for high-risk and heavily contaminated wounds
 - ❑ Minimal risk for adverse events
 - ❑ Have not demonstrated in the literature any potential for resistance

- ❑ ***Products that are the subject of this review should remain as the Class II/ 510(k) process as agreed upon by the 2005 FDA review***