General

Guideline Title


Bibliographic Source(s)


Guideline Status

This is the current release of the guideline.


This guideline meets NGC’s 2013 (revised) inclusion criteria.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- **August 31, 2016 – Opioid pain and cough medicines combined with benzodiazepines**: A U.S. Food and Drug Administration (FDA) review has found that the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. FDA is adding Boxed Warnings to the drug labeling of prescription opioid pain and prescription opioid cough medicines and benzodiazepines.

- **March 22, 2016 – Opioid pain medicines**: The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.
Recommendations

Major Recommendations

A strength of evidence rating (A-C) and strength of recommendation grade (Strong positive recommendation, Weak positive recommendation, No specific recommendation, Weak negative recommendation, Strong negative recommendation) have been assigned to each recommendation and are defined at the end of the “Major Recommendations” field.

Note from the National Pressure Ulcer Advisory Panel (NPUAP), the European Pressure Ulcer Advisory Panel (EPUAP), Pan Pacific Pressure Injury Alliance (PPPIA) and the National Guideline Clearinghouse (NGC): The pressure ulcer clinical practice guideline has been divided into individual summaries covering prevention, interventions for prevention and treatment, treatment, and special populations. This summary should not be read in isolation but in conjunction with the other summaries. In addition to the current summary, the following are available:

- Prevention of pressure ulcers
- Interventions for prevention and treatment of pressure ulcers
- Special populations

Classification of Pressure Ulcers

Differential Diagnosis

1. Differentiate pressure ulcers from other types of wounds. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

Pressure Ulcer Classification Systems

1. Use the International NPUAP/EPUAP Pressure Ulcer Classification System to classify and document the level of tissue loss. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2. Rely on assessment of skin temperature, change in tissue consistency and pain rather than identification of nonblanchable erythema when classifying Category/Stage I pressure ulcers and suspected deep tissue injury in individuals with darkly pigmented skin. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

3. Assess skin heat, tenderness, change in tissue consistency and pain to assist in identifying the severity of Category/Stage II to IV and unstageable pressure ulcers in individuals with darkly pigmented skin. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

4. Use the International NPUAP/EPUAP Pressure Ulcer Classification System to classify and document the level of tissue loss in medical device related pressure ulcers. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

5. Do not use the International NPUAP/EPUAP pressure ulcer classification system for wounds other than pressure ulcers. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

6. Do not categorize/stage pressure ulcers on mucous membranes. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

7. Verify that there is clinical agreement in pressure ulcer classification amongst the health professionals responsible for classifying pressure ulcers. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

Assessment of Pressure Ulcers and Monitoring of Healing

Assessment of the Individual with a Pressure Ulcer

1. Complete a comprehensive initial assessment of the individual with a pressure ulcer. An initial assessment includes:
   - Values and goals of care of the individual and/or the individual’s significant others
   - A complete health/medical and social history
   - A focused physical examination that includes:
     - Factors that may affect healing (e.g., impaired perfusion, impaired sensation, systemic infection)
     - Vascular assessment in the case of extremity ulcers (e.g., physical examination, history of claudication, and ankle-brachial index or toe pressure)
     - Laboratory tests and x-rays as needed
   - Nutrition
   - Pain related to pressure ulcers
• Risk for developing additional pressure ulcers
• Psychological health, behavior, and cognition
• Social and financial support systems
• Functional capacity, particularly in regard to positioning, posture and the need for assistive equipment and personnel
• The employment of pressure-relieving and redistributing maneuvers
• Resources available to the individual (e.g., pressure redistribution support surfaces)
• Knowledge and belief about prevention and treatment of pressure ulcers
• Ability to adhere to a prevention and management plan (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2. Reassess the individual, the pressure ulcer and the plan of care if the ulcer does not show signs of healing as expected despite appropriate local wound care, pressure redistribution, and nutrition. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2.1 Expect some signs of pressure ulcer healing in most individuals within 2 weeks. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

2.2 Adjust expectations for healing in the presence of multiple factors that impair wound healing. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

3. Teach the individual and his or her significant others about:
  • The normal healing process
  • How to identify signs of healing or deterioration
  • Signs and symptoms that should be brought to the health professional's attention (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

Pressure Ulcer Assessment

1. Assess the pressure ulcer initially and re-assess it at least weekly. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

1.1. Document the results of all wound assessments. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2. With each dressing change, observe the pressure ulcer for signs that indicate a change in treatment is required (e.g., wound improvement, wound deterioration, more or less exudate, signs of infection, or other complications). (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2.1 Address signs of deterioration immediately. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

3. Assess and document physical characteristics, including:
  • Location
  • Category/Stage
  • Size
  • Tissue type(s)
  • Color
  • Periwound condition
  • Wound edges
  • Sinus tracts
  • Undermining
  • Tunneling
  • Exudate
  • Odor (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

4. For Category/Stage II to IV and unstageable pressure ulcers in individuals with darkly pigmented skin, prioritize assessment of the following characteristics:
  • Skin heat
  • Skin tenderness
  • Change in tissue consistency
  • Pain (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
5. Position the individual in a consistent neutral position for wound measurement. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

6. Select a uniform, consistent method for measuring wound length and width or wound area to facilitate meaningful comparisons of wound measurements across time. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

7. Select a consistent, uniform method for measuring depth. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

   Caution: Care should be taken to avoid causing injury when probing the depth of a wound bed or determining the extent of undermining or tunneling.

8. Consider further diagnostic investigations of wound bed tissue when healing does not progress. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

9. Use the findings of a pressure ulcer assessment to plan and document interventions that will best promote healing. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

9.1. Reevaluate the pressure ulcer assessment plan if the pressure ulcer does not show signs of healing within two weeks. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

Methods for Monitoring Healing

1. Assess progress toward healing using a valid and reliable pressure ulcer assessment scale. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

2. Use clinical judgment to assess signs of healing such as decreasing amount of exudate, decreasing wound size, and improvement in wound bed tissue. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

3. Consider using baseline and serial photographs to monitor pressure ulcer healing over time. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Pain Assessment and Treatment

Assess for Pressure Ulcer Pain

1. Assess all individuals for pain related to a pressure ulcer or its treatment and document findings. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2. Assess for pressure-ulcer-related pain in adults using a scale that is valid and reliable. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

   2.1. Incorporate the individual’s cognitive ability into the selection of a pain assessment tool. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

3. Assess for pain in neonates and children using a validated scale. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

   3.1 Use the FLACC (Face, Leg, Activity, Cry, and Consolability) tool for children 2 months to 7 years of age. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

   3.2 Use the CRIES (Crying; Requires O₂ for Saturation >95%; Increasing vital signs; Expression; Sleepless) Scale for neonates up to 6 months. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

4. Pain assessment tools may not provide sufficient information to guide interventions. Investigate other aspects of the pain in order to provide more effective, individualized interventions. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

   4.1. Incorporate the individual’s body language and nonverbal cues into the assessment of pain. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

   4.2. Incorporate the words used by the individual to express pressure ulcer pain character into the assessment of pain. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

   4.3. Evaluate factors that increase pain frequency and/or intensity when conducting an assessment of pain. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

   4.4. Evaluate the duration of the pressure ulcer and associated pain when conducting an assessment of pain. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

5. Assess for deterioration of the ulcer or possible infection when the individual reports increasing intensity of pain over time. (Strength of
6. Assess the impact of pressure ulcer pain on the individual's quality of life. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Prevent Pressure Ulcer Pain

1. Use a lift or transfer sheet to minimize friction and/or shear when repositioning an individual, keeping bed linens smooth and unwrinkled. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

2. Position the individual off of the pressure ulcer whenever possible (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

3. Avoid postures that increase pressure, such as Fowler’s position greater than 30° or 90° side-lying position, or the semi-recumbent position. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Manage Pressure Ulcer Pain

1. Organize care delivery to ensure that it is coordinated with pain medication administration and that minimal interruptions follow. Set priorities for treatment. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2. Encourage individuals to request a “time out” during any procedure that causes pain. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

3. Reduce pressure ulcer pain by keeping the wound bed covered and moist, and using a non-adherent dressing. (Note: Stable dry eschar is usually not moistened.) (Strength of Evidence = B; Strength of Recommendation = Strong positive recommendation)

4. Select a wound dressing that requires less frequent changing and is less likely to cause pain. (See the “Wound Dressings for Treatment of Pressure Ulcers” below for further recommendations on wound dressing selection). (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

4.1. Where available, consider ibuprofen impregnated wound dressings as a topical analgesic treatment for pressure ulcer pain. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation) n.b. Ibuprofen-impregnated dressings are not available in the U.S.

5. Consider the use of non-pharmacological pain management strategies to reduce pain associated with pressure ulcers. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

6. Administer pain medication regularly, in the appropriate dose, to control chronic pain following the World Health Organization Pain Dosing Ladder. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

7. Encourage repositioning as a means to reduce pain, if consistent with the individual's wishes. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

Reduce Procedural Pain

1. Use adequate pain-control measures, including additional dosing, prior to commencing wound care procedures. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2. Consider using topical opioids (diamorphine or benzylamine 3%) to reduce or eliminate pressure ulcer pain. (Strength of Evidence = B; Strength of Recommendation = No specific recommendation)

   Caution: Topically applied opioids may be associated with increased systemic side effects in individuals taking systemic opioids. Local itching and irritation has been reported, but not more frequently than when a placebo gel is applied.

3. Consider using topical anesthetics to reduce or eliminate pressure ulcer pain. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

Manage Chronic Pain

1. Refer the individual with chronic pain related to pressure ulceration to the appropriate pain and/or wound clinic resources. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2. Work with the multi-disciplinary health care team to develop a holistic plan to manage chronic pressure ulcer pain. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

Educate Individuals, Family and Health Care Providers

1. Educate the individuals, caregivers, and health care providers about causes, assessment and management of pressure ulcer pain. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
Wound Care: Cleansing

1. Cleanse the pressure ulcer at the time of each dressing change. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
   1.1 Cleanse most pressure ulcers with potable water (i.e., water suitable for drinking) or normal saline. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
   1.2 Consider using an aseptic technique when the individual, the wound or the wound healing environment is compromised. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
   1.3 Consider using cleansing solutions with surfactants and/or antimicrobials to clean pressure ulcers with debris, confirmed infection, suspected infection, or suspected high levels of bacterial colonization. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation) (See the "Assessment and Treatment of Infection and Biofilms" section in the original guideline document for information on appropriate selection of topical antiseptics and cytotoxic profiles of different topical preparations.)
   1.4. Cleanse pressure ulcers with sinus tracts/tunneling/undermining with caution. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendatio

2. Apply cleansing solution with sufficient pressure to cleanse the wound without damaging tissue or driving bacteria into the wound. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
   2.1 Contain and properly dispose of used irrigation solution to reduce cross-contamination. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

3. Cleanse surrounding skin. (Strength of Evidence = B; Strength of Recommendation = Strong positive recommendation)

Wound Care: Debridement

1. Debride devitalized tissue within the wound bed or edge of pressure ulcers when appropriate to the individual's condition and consistent with overall goals of care. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
   Caution: Debridement should only be performed when there is adequate perfusion to the wound (refer to Recommendation 11 below).

2. Debride the wound bed when the presence of biofilm is suspected or confirmed. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

3. Select the debridement method(s) most appropriate to the individual, the wound bed, and the clinical setting. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

4. Use mechanical, autolytic, enzymatic, and/or biosurgical methods of debridement when there is no urgent clinical need for drainage or removal of necrotic tissue. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

5. Surgical/sharp debridement is recommended in the presence of extensive necrosis, advancing cellulitis, crepitus, fluctuance, and/or sepsis secondary to ulcer-related infection. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

6. Conservative sharp debridement and surgical/sharp must be performed by specially trained, competent, qualified, and licensed healthcare professionals consistent with local legal and regulatory statutes. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

7. Use sterile instruments for conservative sharp and surgical/sharp debridement. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

8. Use conservative sharp debridement with caution in the presence of:
   - Immune incompetence
   - Compromised vascular supply
   - Lack of antibacterial coverage in systemic sepsis (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
   Caution: Relative contraindications include anticoagulant therapy and bleeding disorders.

9. Refer individuals with Category/Stage III or IV pressure ulcers with undermining, tunneling, sinus tracts, and/or extensive necrotic tissue that cannot be easily removed by other debridement methods for surgical evaluation as is appropriate to the individual's condition and goals of care. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

10. Manage pain associated with debridement. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

11. Perform a thorough vascular assessment prior to debridement of lower extremity pressure ulcers to determine whether arterial status/supply is sufficient to support healing of the debrided wound. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
12. Do not debride stable, hard, dry eschar in ischemic limbs. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

12.1 Assess stable, hard, dry eschar at each wound dressing change and as clinically indicated. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

12.2 Consult a medical practitioner/vascular surgeon urgently in the presence of symptoms. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

12.3 Debride the pressure ulcer urgently in the presence of the above symptoms (i.e., erythema, tenderness, edema, purulence, fluctuance, crepitus, and/or malodor). (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

13. Perform maintenance debridement on a pressure ulcer until the wound bed is free of devitalized tissue and covered with granulation tissue. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Assessment and Treatment of Infection and Biofilms

System Consideration

Follow local infection-control policies to prevent self-contamination and cross-contamination in individuals with pressure ulcers. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Assessment of High Risk Individuals and Pressure Ulcers

1. Have a high index of suspicion of local infection in a pressure ulcer in the presence of:
   - Lack of signs of healing for two weeks
   - Friable granulation tissue
   - Malodor
   - Increased pain in the ulcer
   - Increased heat in the tissue around the ulcer
   - Increased drainage from the wound
   - An ominous change in the nature of the wound drainage (e.g., new onset of bloody drainage, purulent drainage)
   - Increased necrotic tissue in the wound bed
   - Pocketing or bridging in the wound bed (Strength of Evidence = B; Strength of Recommendation = Strong positive recommendation)

2. Have a high index of suspicion for the likelihood of infection in pressure ulcer patients that:
   - Have necrotic tissue or a foreign body present
   - Have been present for a long period of time
   - Are large in size or deep
   - Are likely to be repetitively contaminated (e.g., near the anus). (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

3. Have a high index of suspicion for local wound infection in individuals with:
   - Diabetes mellitus
   - Protein-calorie malnutrition
   - Hypoxia or poor tissue perfusion
   - Autoimmune disease
   - Immunosuppression (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

4. Have a high index of suspicion of biofilm in a pressure ulcer that:
   - Has been present for more than 4 weeks
   - Lacks signs of any healing in the previous 2 weeks
   - Displays clinical signs and symptoms of inflammation
   - Does not respond to antimicrobial therapy. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Diagnosis of Infection

1. Consider a diagnosis of spreading acute infection if the pressure ulcer has local and/or systemic signs of acute infection, such as:
   - Erythema extending from the ulcer edge
   - Induration
- New or increasing pain or warmth
- Purulent drainage
- Increase in size
- Crepitus, fluctuance, or discoloration in the surrounding skin
- Fever, malaise, and lymph node enlargement
- Confusion/delirium and anorexia (particularly in older adults) (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2. Determine the bacterial bioburden of the pressure ulcer by tissue biopsy or quantitative swab technique. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

2.1. Consider using tissue biopsy and microscopy to determine the presence of biofilm. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

3. Consider a diagnosis of pressure ulcer infection if the culture results indicate bacterial bioburden of \( \geq 10^5 \) colony-forming-units (CFU)/g of tissue and/or the presence of beta hemolytic streptococci. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

Treatment

1. Optimize the host response by:
   - Evaluating nutritional status and addressing deficits
   - Stabilizing glycemic control
   - Improving arterial blood flow
   - Reducing immunosuppressant therapy if possible (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2. Prevent contamination of the pressure ulcer. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

3. Reduce the bacterial load and biofilm in the pressure ulcer as outlined in the "Wound Care: Cleansing" and "Wound Care: Debridement" sections above. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

4. Consider the use of tissue appropriate strength, non-toxic topical antiseptics for a limited time period to control bacterial bioburden. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

   **Warning:** Hydrogen peroxide is highly toxic to tissues even at low concentrations and should not be used as a preferred topical antiseptic. Its use should be totally avoided in cavity wounds due to the risk of surgical emphysema and gas embolus.

   **Caution:** Iodine products should be avoided in patients with impaired renal failure, history of thyroid disorders or known iodine sensitivity. Sodium hypochlorite (Dakin's solution) is cytotoxic at all concentrations and should be used with caution, at concentrations no greater than 0.025%, for short periods only when no other appropriate option is available. There is a risk of acidosis when acetic acid is used for extended periods over large wound surface areas.

5. Consider the use of topical antiseptics in conjunction with maintenance debridement to control and eradicate suspected biofilm in wounds with delayed healing. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

6. Consider the use of topical antiseptics for pressure ulcers that are not expected to heal and are critically colonized topically infected. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

7. Consider use of silver sulfadiazine in heavily contaminated or infected pressure ulcers until definitive debridement is accomplished. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

   **Caution:** Silver may have toxic properties, especially to keratinocytes and fibroblasts; the extent of the toxicities is not fully described. Topical silver products should not be used on individuals with silver sensitivities, and silver sulfadiazine products are not recommended for people with sulfur sensitivities.

8. Consider the use of medical-grade honey in heavily contaminated or infected pressure ulcers until definitive debridement is accomplished. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

   **Caution:** Before applying a honey dressing, ensure the individual is not allergic to honey. Individuals who have bee or bee stings allergies are usually able to use properly irradiated honey products.

9. Limit the use of topical antibiotics on infected pressure ulcers, except in special situations where the benefit to the patient outweighs the risk of antibiotic side effects and resistance. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

10. Use systemic antibiotics for individuals with clinical evidence of systemic infection, such as positive blood cultures, cellulitis, fascitis, osteomyelitis, systemic inflammatory response syndrome (SIRS), or sepsis. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
11. Drain local abscesses. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
12. Evaluate the individual for osteomyelitis if exposed bone is present, the bone feels rough or soft, or the ulcer has failed to heal with prior therapy. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Wound Dressings for Treatment of Pressure Ulcers

General Recommendations

1. Select a wound dressing based on the:
   - Ability to keep the wound bed moist
   - Need to address bacterial bioburden
   - Nature and volume of wound exudate
   - Condition of the tissue in the ulcer bed
   - Condition of periwound skin
   - Ulcer size, depth and location
   - Presence of tunneling and/or undermining
   - Goals of the individual with the ulcer (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2. Protect periwound skin. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
3. Assess pressure ulcers at every wound dressing change and confirm the appropriateness of the current dressing regimen. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
4. Follow manufacturer recommendations, especially related to frequency of dressing change. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
5. Change the wound dressing if feces seep beneath the dressing. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
6. The plan of care should guide usual dressing wear times and contain provisional plans for dressing changes as needed (for family, the individual, and staff) due to soilage, loosening, etc. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
7. Ensure all wound dressing products are completely removed with each dressing change. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

See the sections "Wound Care: Cleansing" and "Wound Care: Debridement" above for guidance on preparing the wound bed for dressing application.

Hydrocolloid Dressings

1. Use hydrocolloid dressings for clean Category/Stage II pressure ulcers in body areas where they will not roll or melt. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)
2. Consider using hydrocolloid dressing on noninfected, shallow Stage III pressure ulcers. (Strength of Evidence = B; Strength of Recommendation = No specific recommendation)
3. Consider using filler dressings beneath hydrocolloid dressings in deep ulcers to fill in dead space. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)
4. Carefully remove hydrocolloid dressings on fragile skin to reduce skin trauma. (Strength of Evidence = B; Strength of Recommendation = Strong positive recommendation)

Transparent Film Dressings

1. Consider using film dressings for autolytic debridement when the individual is not immunocompromised. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)
2. Consider using film dressings as a secondary dressing for pressure ulcers treated with alginates or other wound filler that will likely remain in the ulcer bed for an extended period of time (e.g., 3 to 5 days). (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)
3. Carefully remove film dressings on fragile skin to reduce skin trauma. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
4. Do not use film dressings as the tissue interface layer over moderately to heavily exuding ulcers. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
5. Do not use film dressings as the cover dressing over enzymatic debriding agents, gels, or ointments. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)
Hydrogel Dressings

1. Consider using hydrogel dressings on shallow, minimally exuding pressure ulcers. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)
2. Consider using amorphous hydrogel for pressure ulcers that are not clinically infected and are granulating. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)
3. Consider using hydrogel dressings for treatment of dry ulcer beds. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
4. Consider using hydrogel dressings for painful pressure ulcers. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
5. Consider using hydrogel sheet dressings for pressure ulcers without depth and contours and/or on body areas that are at risk for wound dressing migration. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
6. Consider using amorphous hydrogel for pressure ulcers with depth and contours and/or on body areas that are at risk for dressing migration. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Alginate Dressings

1. Consider using alginate dressings for the treatment of moderately and heavily exuding pressure ulcers. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)
2. Consider using alginate dressings in clinically infected pressure ulcers when there is appropriate concurrent treatment of infection. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
3. Gently remove the alginate dressing, irrigating it first to ease removal if necessary. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
4. Consider lengthening the interval between wound dressing changes or changing the type of wound dressing if the alginate dressing is still dry at the scheduled time for dressing change. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Foam Dressings

1. Consider using foam dressings on exuding Category/Stage II and shallow Category/Stage III pressure ulcers. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)
2. Avoid using single small pieces of foam in exuding cavity ulcers. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)
3. Consider using gelling foam dressing in highly exuding pressure ulcers. (Strength of Evidence C; Strength of Recommendation = Weak positive recommendation)

Silver-Impregnated Dressings

1. Consider using silver-impregnated dressings for pressure ulcers that are clinically infected or heavily colonized. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)
2. Consider using silver-impregnated dressings for ulcers at high risk of infection. (Strength of Evidence = B; Strength of Recommendation = No specific recommendation)
3. Avoid prolonged use of silver-impregnated dressings. Discontinue silver dressings when wound infection is controlled. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
   Caution: Topical silver products should not be used on patients with silver sensitivities. Silver may have toxic properties, especially to keratinocytes and fibroblasts; the extent of the toxicities has not been fully described.

Honey-Impregnated Dressings

1. Consider using dressings impregnated with medical-grade honey for the treatment of Category/Stage II and III pressure ulcers. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)
   Caution: Before applying a honey dressing, ensure the individual is not allergic to honey. Individuals who have bee or bee stings allergies are usually able to use properly irradiated honey products.

Cadexomer Iodine Dressings

1. Consider using cadexomer iodine dressings in moderately to highly exuding pressure ulcers. (Strength of Evidence = C; Strength of
Recommendation = Weak positive recommendation

Caution: Iodine products should be avoided in individuals with impaired renal failure, history of thyroid disorders or known iodine sensitivity. It is not recommended for individuals taking lithium, or for pregnant or breast-feeding women. Iodine toxicity has been reported in a few case studies, especially in those individuals with large wounds, in whom dressings were changed often. The risk of systemic absorption increases when iodine products are used on larger, deeper wound or for prolonged periods.

Gauze Dressings

1. Avoid using gauze dressings for open pressure ulcers that have been cleansed and debrided because they are labor-intensive, cause pain when removed if dry, and lead to desiccation of viable tissue if they dry. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

   Caution: Avoid use of wet-to-dry gauze dressings.

2. When other forms of moisture-retentive dressing are not available, continually moist gauze is preferable to dry gauze. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

3. Use gauze dressings as the cover dressing to reduce evaporation when the tissue interface layer is moist. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

4. Use loosely woven gauze for highly exuding ulcers; use tightly woven gauze for minimally exuding ulcers. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

5. Loosely fill (rather than tightly pack) ulcers with large tissue defects and dead space with saline-moistened gauze when other forms of moisture-retentive dressing are not available, to avoid creating pressure on the wound bed. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

6. Change gauze packing often enough to manage exudate. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

7. Use a single gauze strip/roll to fill deep ulcers; do not use multiple gauze dressings, because retained gauze in the ulcer bed can serve as a source of infection. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

8. Consider using impregnated forms of gauze to prevent evaporation of moisture from continuously moist gauze dressings. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Silicone Dressings

1. Consider using silicone dressings as a wound contact layer to promote atraumatic dressing changes. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

2. Consider using silicone dressings to prevent periwound tissue injury when periwound tissue is fragile or friable. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

Collagen Matrix Dressings

1. Consider using collagen matrix dressings for nonhealing Category/Stage III and IV pressure ulcers. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

Composite Dressings

Many of the dressing types listed here are manufactured in combinations. Please refer to the statements about the individual components when considering the use of composites.

Biological Dressings for the Treatment of Pressure Ulcer

1. Due to insufficient evidence to support or refute the use of biological dressings in the treatment of pressure ulcers, biological dressings are not recommended for routine use at this time. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Growth Factors for the Treatment of Pressure Ulcer

Recombinant Platelet-Derived Growth Factor

1. Consider using platelet-derived growth factors for treatment of Category/Stage III and IV pressure ulcers that have delayed healing. (Strength of Evidence = B; Strength of Recommendation = No specific recommendation)

Other Growth Factors
1. Due to insufficient evidence to support or refute the use of growth factors (other than recombinant platelet-derived growth factor) in the treatment of pressure ulcers they are not recommended for routine use at this time. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

Biophysical Agents in Pressure Ulcer Treatment

Electrical Stimulation

1. Consider the use of direct contact (capacitive) electrical stimulation to facilitate wound healing in recalcitrant Category/Stage II pressure ulcers as well as any Category/Stage III and IV pressure ulcers. (Strength of Evidence = A; Strength of Recommendation = Weak positive recommendation)

Electromagnetic Agents

1. Consider the use of pulsed electromagnetic field (PEMF) treatment for recalcitrant Category/Stage II pressure ulcers as well as any Category/Stage III and IV pressure ulcers. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

Caution: No major adverse effects of electromagnetic therapy were reported in the research included in this review. Manufacturers of devices used to administer electromagnetic therapy do not recommend their use in individuals with pacemakers or other electrical implants, pregnancy or organ transplant. Caution is recommended for individuals with fever, active bleeding, seizures or dehydration.

Pulsed Radio Frequency Energy

1. Consider the use of pulsed radio frequency energy (PRFE) in the treatment of recalcitrant Category/Stage II pressure ulcers as well as any Category/Stage III and IV pressure ulcers. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

Caution: No major adverse effects of electrotherapy were reported in the research included in this review. Electrotherapy is contraindicated in individuals with electrical implants (e.g., pacemakers) or who are pregnant. Electrotherapy is contraindicated in local anatomical areas of the eye, testes and any malignancy. Electrotherapy should be used with caution in individuals with impaired circulation or devitalized tissue.

Phototherapy: Laser, Infrared and Ultraviolet

Infrared Therapy

1. Due to current insufficiency of evidence to support or refute the use of infrared therapy in the treatment of pressure ulcers, infrared therapy is not recommended for routine use at this time. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

Laser

1. Due to current insufficiency of evidence to support or refute the use of laser therapy in the treatment of pressure ulcers, laser therapy is not recommended for routine use at this time. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

Ultraviolet Light Therapy

1. Consider a short term application of ultraviolet C light (UVC) if traditional therapies fail. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

2. Consider a course of ultraviolet light as an adjunctive therapy to reduce bacterial burden in critically colonized Category/Stage III and IV pressure ulcers that have been debrided and cleansed. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

Acoustic Energy (Ultrasound)

1. Due to current insufficiency of evidence to support or refute the use of noncontact low frequency (40 kHz) ultrasound spray (NC-LFUS) in the treatment of pressure ulcers, NC-LFUS is not recommended for routine use at this time. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

Caution: Noncontact low frequency ultrasound spray should not be used near prostheses, near electronic implanted devices (e.g., cardiac pacemakers), over the lower back or uterus in pregnant women; or over areas of malignancy; or on the face/head.

2. Consider use of low frequency (22.5, 25 or 35 kHz) ultrasound for debridement of necrotic soft tissue (not eschar). (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)
3. Consider use of high frequency (MHz) ultrasound as an adjunct for the treatment of infected pressure ulcers. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

*Caution: No major adverse effects of ultrasound were reported in the research included in this review. Its use is not recommended over anatomical areas with implanted materials or devices.*

**Negative Pressure Wound Therapy**

1. Consider negative pressure wound therapy (NPWT) as an early adjunct for the treatment of deep, Category/Stage III and IV pressure ulcers. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

*Caution: NPWT is not recommended in inadequately debrided, necrotic or malignant wounds; where vital organs are exposed; in wounds with no exudate; or in individuals with untreated coagulopathy, osteomyelitis or local or systemic clinical infection. Cautious use by an experienced health professional is recommended for individuals on anticoagulant therapy; in actively bleeding wounds; or where the wound is in close proximity to major blood vessels.*

2. Debride the pressure ulcer of necrotic tissue prior to the use of NPWT. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

3. Follow a safe regimen in applying and removing the NPWT system. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

4. Evaluate the pressure ulcer with each dressing change. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

5. If pain is anticipated or reported consider:
   * Placing a nonadherent interface dressing on the wound bed, underneath the foam
   * Lowering the level of pressure, and/or changing type of pressure (continuous or intermittent)
   * Using a moist gauze filler instead of foam (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

6. Educate the individual and his/her significant others about negative pressure wound therapy when used in the community setting. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

**Hydrotherapy: Whirlpool and Pulsatile Lavage with and without Suction**

**Whirlpool**

1. Whirlpool should not be considered for routine use in treating pressure ulcers due to the potential for contamination and the emergence of newer hydrotherapies. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

*Caution: Individuals with dependent lower extremity edema or peripheral vascular disease, immunocompromised individuals, those who are mechanically ventilated and lethargic, and incontinent individuals should never be immersed.*

**Pulsed Lavage with/without Suction**

1. Consider a course of pulsed lavage with suction for wound cleansing and debridement. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

**Vibration Therapy**

1. Due to current insufficiency of evidence to support or refute the use of vibration therapy in the treatment of pressure ulcers, vibration therapy is not recommended for routine use at this time. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

**Oxygen for the Treatment of Chronic Wounds**

**Hyperbaric Oxygen Therapy (HBOT)**

1. Due to current insufficiency of evidence to support or refute the use of HBOT in the treatment of pressure ulcers, HBOT is not recommended for routine use at this time. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

**Topical Oxygen Therapy**

1. Due to insufficient evidence to support or refute the use of topical oxygen in the treatment of pressure ulcers, topical oxygen is not recommended for routine use at this time. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation)

**Surgery for Pressure Ulcers**
Preoperative Recommendations

1. Obtain a surgical consultation for possible urgent drainage and/or debridement if the pressure ulcer has advancing cellulitis or is a suspected source of sepsis. (See the "Wound Care: Debridement" section above for further discussion). (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

2. Obtain a surgical consultation for possible surgical sharp debridement for individuals with undermining, tunneling/sinus tracts, and/or extensive necrotic tissue that cannot be easily removed by other debridement methods as appropriate to the individual's condition and goals of care. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

3. Obtain a surgical consultation for possible operative repair in individuals with Category/Stage III or IV pressure ulcers that are not closing with conservative treatment as appropriate to the individual's condition and goals of care, or for individuals who desire more rapid closure of the ulcer. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

   3.1. Evaluate the risk of surgery for the individual. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

4. Confirm the individual's end-of-life preferences if anticipating surgery. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

5. Evaluate and optimize factors that may influence surgical healing and long term recurrence prior to surgery. (Strength of evidence = C; Strength of Recommendation = Strong positive recommendation)

   5.1 Evaluate and promote the individual's ability to adhere to a postoperative management plan. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

   5.2. Evaluate and optimize physical factors that may impair surgical wound healing. (Strength of Evidence = B; Strength of Recommendation = Strong positive recommendation)

   5.3. Procure and maintain equipment for the prevention and treatment of pressure ulcers. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

   5.4. Evaluate and optimize psychosocial factors that often impair surgical wound healing. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

6. Evaluate the individual for osteomyelitis if exposed bone is present, the bone feels rough or soft, or the ulcer has failed to heal with contemporary therapy. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

   6.1. Resect infected bone prior to or during surgical closure unless bone involvement is too extensive. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

Intraoperative Recommendations

1. Excise the ulcer, including abnormal skin, granulation and necrotic tissue, sinus tracts, bursa and involved bone to the extent possible at surgical closure. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

2. Design flaps with composite tissues to improve durability. When possible, choose a flap that will not violate adjacent flap territories to preserve all future options for flap coverage. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

3. Use a flap that is as large as possible, placing the suture line away from an area of direct pressure. Minimize tension on the incisions at the time of closure. Consider possible functional loss and rehabilitation needs, especially in ambulatory individuals. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

4. Transfer the individual from the operating table with adequate assistance to avoid disruption of the flap. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

Postoperative Recommendations

1. Select a high specification support surface that provides enhanced pressure redistribution, shear reduction, and microclimate control for individuals who have undergone pressure ulcer surgery. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

   1.1. Avoid transferring the post-surgical individual onto a non-high specification support surface unless clinically indicated. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

2. Avoid pressure, shear and friction in order to protect the blood supply to the flap. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)
2.1. Assess the associated benefits and risks before elevating the head of the bed. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2.2. Reposition the individual using proper manual handling technique and equipment. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

2.3. Dress the individual in appropriate clothing to prevent injury to the flap when using slide boards. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation)

3. Regularly monitor wound drainage systems. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

4. Report signs of flap failure to the surgeon immediately, including:
   - Pallor
   - Mottling
   - Incision separation
   - Increased drainage from the incision
   - Edema
   - Bluish-purple tissue (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

5. Prevent hazards of immobility. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

6. Initiate a program of progressive sitting according to the surgeon’s orders. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

   6.1. Position the individual on a pressure redistributing support surface when sitting out of bed. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

7. Confirm the presence of healthy lifestyle choices and a supportive social network prior to discharging the individual from a facility. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation)

8. Provide or facilitate access to pressure ulcer prevention education for the individual and his or her caregivers prior to discharge from the facility. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)

Definitions:

**Strength of Evidence Rating**

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>The recommendation is supported by direct scientific evidence from properly designed and implemented controlled trials on pressure ulcers in humans (or humans at-risk for pressure ulcers), providing statistical results that consistently support the guideline statement (Level 1 studies required).</td>
</tr>
<tr>
<td>B</td>
<td>The recommendation is supported by direct scientific evidence from properly designed and implemented clinical series on pressure ulcers in humans (or humans at-risk for pressure ulcers), providing statistical results that consistently support the recommendation (Level 2, 3, 4, 5 studies).</td>
</tr>
<tr>
<td>C</td>
<td>The recommendation is supported by indirect evidence (e.g., studies in normal human subjects, humans with other types of chronic wounds, animal models) and/or expert opinion.</td>
</tr>
</tbody>
</table>

**Strength of Recommendation Grade**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Description</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do it (Strong recommendation for using an intervention)</td>
<td>Indicates a judgment that most well informed people would make.</td>
<td>For patient consumers—Most people would want the recommended course of action and only a small proportion would not. For health professionals—Most people should receive the intervention. If health professionals choose not to follow the recommendation, they should document their rationale. For quality monitors—Adherence to this recommendation could be used as a quality criterion or performance indicator.</td>
</tr>
<tr>
<td>Don't do it (Strong recommendation against using an intervention)</td>
<td>Indicates a judgment that a majority of well informed people would make, but a substantial minority would not.</td>
<td>For patient consumers—Most people would want the suggested course of action, but many would not. For health professionals—Examine, and be prepared to discuss, the evidence with patients, as well as their values and preferences. For quality monitors—Clinicians’ discussion and consideration of pros and cons of the intervention, and documentation of discussion,</td>
</tr>
<tr>
<td>Probably do it (Weak recommendation for using an intervention)</td>
<td>Indicates a judgment that a majority of well informed people would make, but a substantial minority would not.</td>
<td>For patient consumers—Most people would want the suggested course of action, but many would not. For health professionals—Examine, and be prepared to discuss, the evidence with patients, as well as their values and preferences. For quality monitors—Clinicians’ discussion and consideration of pros and cons of the intervention, and documentation of discussion,</td>
</tr>
</tbody>
</table>
Clinical Algorithm(s)
None provided

Scope

Disease/Condition(s)
Pressure ulcers

Guideline Category
Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Treatment

Clinical Specialty
Critical Care
Dermatology
Family Practice
Geriatrics
Internal Medicine
Nursing
Pediatrics
Plastic Surgery
Preventive Medicine
Surgery

Intended Users
Advanced Practice Nurses

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Description</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>No specific recommendation</td>
<td>Trade-offs between risk and benefit unclear or lack of agreement between voting participants.</td>
<td>The advantages and disadvantages are equivalent; and/or the target population has not been identified; and/or there is insufficient evidence on which to formulate a strength of recommendation.</td>
</tr>
</tbody>
</table>
Guideline Objective(s)

- To provide evidence-based recommendations for the prevention and treatment of pressure ulcers that could be used by health care professionals throughout the world
- To provide evidence-based guidance on the most effective strategies to promote pressure ulcer healing

Target Population

Individuals with pressure ulcers

Interventions and Practices Considered

1. Classification of pressure ulcers (use of International National Pressure Ulcer Advisory Panel/European Pressure Ulcer Advisory Panel [NPUAP/EPUAP] Pressure Ulcer Classification System)
2. Assessment and monitoring of healing
   - Assessment of the individual
   - Pressure ulcer assessment
   - Methods for monitoring healing
3. Pain assessment and management
   - Assessing for pressure ulcer pain using appropriate assessment tools
   - Preventing pressure ulcer pain
   - Managing pressure ulcer pain through pharmacological and non-pharmacological methods
   - Reducing procedural pain
   - Managing chronic pain
   - Education of individuals, family, and health care providers in pain management
4. Wound cleansing
5. Wound debridement
6. Assessment and treatment of infection
   - Following local infection-control policies to prevent self-contamination and cross-contamination
   - Assessment of high-risk individuals
   - Diagnosis of infection
   - Treatment: reducing bacterial load and biofilm, topical antiseptics, systemic antibiotics, draining abscesses
   - Evaluating for osteomyelitis
7. Dressings: hydrocolloid, transparent film, hydrogel, alginate, foam, silver-impregnated, honey-impregnated, cadexomer iodine, gauze, silicone, collagen matrix, composite dressings
8. Recombinant platelet-derived growth factors
9. Biophysical agents in pressure ulcer management
10. Surgery for pressure ulcers (preoperative, intraoperative, and postoperative interventions)

Note: The pressure ulcer clinical practice guideline was divided into four individual summaries. Additional interventions are discussed in the following summaries:

Prevention of pressure ulcers
Major Outcomes Considered

- Interrater reliability of pressure ulcer classifications
- Development of new Stage I or greater pressure ulcer
- The percentage reduction in wound area
- Ulcer healing rates
- Length of treatment time
- Presence of infection
- Quality of life
- Complications of surgery
- Pressure ulcer recurrence

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Identifying the Evidence

Databases

The Guideline Development Group (GDG) identified clinical questions to guide literature searches. To identify the scientific literature on pressure ulcer prevention and treatment, several electronic databases were consulted, including: PubMed, CINAHL, MEDLINE, EMBASE, Scopus, Biomedical Reference Collection, Health Business Elite, The Cochrane Database of Systematic Reviews, The Cochrane Central Register of Controlled Trials, Health Technology Assessment, and AMED databases. As the guideline builds on a previously published body of evidence, the search dates for this update were 1st January 2008 through 1st July 2013. Some Small Working Groups (SWGs), particularly those that were addressing evidence in topics newly introduced in this version of the guideline, used different inclusion dates, as per the inclusion and exclusion criteria detailed below.

Search Strategy

A sensitive search strategy was developed and made available on the guideline website. The SWGs were permitted to conduct additional focused searches to ensure the full depth and breadth of their topic area has been covered.

Inclusion and Exclusion Criteria

All references retrieved by the electronic literature search were screened by the methodologist (during the interim period between guideline development periods from 2009 to 2012) based on the following inclusion criteria:

General Eligibility Criteria

Inclusion criteria:

- The articles must be primarily focused on pressure ulcer prevention, risk assessment, or pressure ulcer treatment in human subjects.
- The articles must have been published in a peer reviewed journal.
- An abstract must be available.
- The studies should have used one of the following designs: randomized controlled trials (RCTs), controlled clinical trials (CCTs), quasi-experimental studies, cohort studies, cross-sectional studies, survey studies, prevalence or incidence studies, case-control studies, and case
• At least ten subjects must have been included in any case series.
• Systematic reviews or meta-analyses were included if they used the Cochrane methodology or met at least 9 out of 11 quality criteria of the critical appraisal tool Assessment of Multiple Systematic Reviews (AMSTAR).
• SWG members reviewed, analyzed and used the original articles cited in systematic reviews and meta-analyses as the basis for guideline recommendations and systematic reviews were cited as additional supporting evidence. In order to rate the level of evidence, the quality of the systematic review was assessed, using the AMSTAR checklist. Meta-analyses should not be equated with systematic reviews.
• Studies using established qualitative methodologies were considered as appropriate to the research question.
• There was no restriction on the basis of the language of a study. However, studies published in languages other than English were required to indicate a high level of quality and unique data in the abstract report to warrant translation.

Exclusion criteria:

• Non-systematic literature reviews, narrative papers, opinion, commentary and descriptive papers. Papers falling into this category were used only to support expert opinion as required.
• Case series with less than 10 participants.
• Conference abstracts or other short papers with insufficient detail to enable an appraisal of the study methodology.
• Duplicate reports of research.
• Computational modeling and other research conducted in non-human subjects.
• Systematic reviews and meta-analyses that do not meet at least 9 of 11 criteria on the AMSTAR checklist.
• Papers without a substantial focus on pressure ulcer prevention or treatment or risk assessment.
• Foreign language studies for which the abstract does not indicate a high level study (i.e., at least Level 2) with unique data.

Eligibility Criteria for Research Reporting on Quality Improvement and Education

In addition to the criteria outlined above, additional inclusion criteria were:

• Articles with a time series design with at least three outcome measurement time points.
• Project should be institution-wide (i.e., not individual units). Projects in individual units could be covered in special population sections as appropriate (e.g., pediatrics, critical care).
• Outcomes should be incidence or facility-acquired pressure ulcer rates.
• Quality improvement projects should be described in sufficient detail to enable replication (i.e., specific methods used, barriers and facilitators).

Exclusion criteria:

• Publications before January 2008 and after December 2012 were not appraised for this guideline section.

Eligibility Criteria for Research Reporting on Risk Factors for Pressure Ulcers

The systematic review by Coleman et al., 2013 (see the "Availability of Companion Documents" field) was used as a basis for literature selection to identify patient characteristics that increase the probability of pressure ulcer development. This was supplemented by a search for literature published from 31st March 2010 to July 1st 2013.

Refer to Appendix 1: Methodology of the original guideline document for inclusion and exclusion criteria used by Coleman et al. (see also the Methodology addendum [see the "Availability of Companion Documents" field]).

Eligibility Criteria for Research Reporting on Risk Assessment Tools

Additional inclusion criteria for papers addressing the reliability of risk assessment tools were:

• Risk assessment tools are completed by qualified health professionals.
• The research involved comparing pressure ulcer risk assessment tool scores of different raters using the same scale (intrarater) or comparing pressure ulcer risk assessment tool scores of the same raters using the same scale at different times (intrarater).

The systematic review by Chou et al., 2013 (see the "Availability of Companion Documents" field) was used as a basis for literature selection related to identifying the validity of risk assessment tools. This was supplemented by literature published after the end of the review period (i.e., from 31st July 2012 to 1st July 2013).
Additional inclusion criteria for papers addressing the validity of risk assessment tools were:

- Prospective study design (i.e., RCTs, CCT, prospective cohort study).
- Reporting the evaluation of one or more risk assessment tool in the prevention of pressure ulcers (analytical methods).
- Follow-up data included on at least 75% of participants.
- Participants were aged over 18 years.
- Individuals were assessed systematically for the development of new pressure ulcers (e.g., all participants have baseline skin assessment and at follow-up intervals suitable to identify new pressure ulcers in the study population). Assessment only at baseline and discharge is not a suitable follow-up to detect all new pressure ulcers.
- Risk assessment tools are completed at baseline.
- Outcome clearly defined as development of a Category/Stage I or greater pressure ulcer.
- Analysis methods: sensitivity, specificity, positive likelihood ratio (PLR), negative likelihood ratio (NLR), relative risk and area under the receiver operating characteristic (AUROC) curve.

Exclusion criteria:

- Data used to generate the risk assessment tool are the same data used for the calculation of validity measures.

Number of Source Documents

A total of 356 papers were newly included in the guideline after the appraisal of papers in the updated literature search (search dates: 1st January 2008 through 1st July 2013).

As the 2014 guideline builds on the 2009 guideline, this number does not include papers that were already identified and included in the 2009 guideline.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Evidence for Intervention Studies

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Randomized trial(s) with clear-cut results and low risk of error OR systematic literature review or meta-analysis according to the Cochrane methodology or meeting at least 9 out of 11 quality criteria according to Assessment of Multiple Systematic Reviews (AMSTAR) appraisal tool</td>
</tr>
<tr>
<td>Level 2</td>
<td>Randomized trial(s) with uncertain results and moderate to high risk of error</td>
</tr>
<tr>
<td>Level 3</td>
<td>Non randomized trial(s) with concurrent or contemporaneous controls</td>
</tr>
<tr>
<td>Level 4</td>
<td>Non randomized trial(s) with historical controls</td>
</tr>
<tr>
<td>Level 5</td>
<td>Case series with no controls. Specify number of subjects</td>
</tr>
</tbody>
</table>

Levels of Evidence for Diagnostic Studies

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Systematic review of high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding</td>
</tr>
<tr>
<td>Level 2</td>
<td>Individual high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons</td>
</tr>
</tbody>
</table>
Levels of Evidence for Prognostic Studies

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Systematic review of high quality (longitudinal) prospective cohort studies according to the quality assessment tools</td>
</tr>
<tr>
<td>2</td>
<td>A prospective cohort study</td>
</tr>
<tr>
<td>3</td>
<td>Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial</td>
</tr>
<tr>
<td>4</td>
<td>Case-series or case-control studies, or poor quality prognostic cohort study, retrospective cohort study</td>
</tr>
<tr>
<td>5</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Direct vs. Indirect Evidence

Studies of pressure ulcers in humans and individuals at risk of, or with existing pressure ulcers were considered 'direct evidence' and were required to support an A or B 'strength of evidence' rating (see the "Rating Scheme for the Strength of the Recommendations" field). When studies of pressure ulcers in humans at risk of, or with existing pressure ulcers were not available, studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models were used as indirect evidence to support recommendations with a C 'strength of evidence' rating.

Evaluating the Evidence

Appraisal of Methodological Quality

The methodological quality of each study was evaluated by two members of the Small Working Groups (SWGs). Where large discrepancy of opinion was noted (such that the paper’s overall quality was rated differently by the two reviewers), a third reviewer evaluated the paper. The methodologist completed a quality check on a random sample of 80% of the critical appraisals for papers selected for potential appraisal, including those papers that the SWG assessed as not meeting inclusion criteria.

The methodological quality of each study was assessed by two reviewers using methodology checklists that were based on tools developed by the Scottish Intercollegiate Guidelines Network. Evaluation of study quality focused on the internal and external validity of the studies. The following quality criteria were considered: internal validity of the study; clear and appropriate research question(s); selection of subjects; allocation; baseline comparability; outcomes; blinding; confounding factors; statistical analysis; overall assessment of the study; and bias. A range of critical appraisal tools were used based on different types of study design: cross-sectional/survey/prevalence studies, case-control studies, cohort studies, randomized controlled trials (RCTs), quasi-experimental studies, diagnostic studies, SQUIRE guideline checklist for quality improvement papers, Critical Appraisal Skills Program (CASP) Qualitative Research Checklist, AMSTAR criteria for systematic reviews.

Each criterion on the critical appraisal forms was assessed as being fully met (++) or partially met (+), not met/not reported/unclear (—), or not met in the study.
Studies were generally described as high, moderate, or low quality using the following criteria:

- High quality studies: fully met at least 80% of applicable criteria
- Moderate quality studies: partially or fully met at least 70% of applicable criteria
- Low quality studies: did not partially or fully met at least 70% of applicable criteria

**Appraisal of Methodological Quality for Risk Factor Papers**

In the absence of guidelines for the quality assessment of risk factor studies, Coleman et al., 2013 (see the "Availability of Companion Documents" field) used an assessment framework based upon guidelines for assessing quality and risk of bias in prognostic studies and methodological considerations in the analysis, meta-analysis and publication of observational studies. Each study was appraised using the method described by Coleman et al. and the following factors were considered:

- Baseline characteristics are adequately described
- Study attrition: clear definition of risk factors
- Continuous variables used or appropriate cut-points for continuous data
- Risk factor measurement valid and reliable
- Method/sampling of measurement used for all individual patients
- Appropriate imputation methods
- Appropriate classification for outcome
- Potential confounders accounted for in study design
- Potential confounders accounted for in analysis
- No selective reporting

See Appendix 1 in the original guideline document and the Methodology addendum (see the "Availability of Companion Documents" field) for more information on appraisal of methodological quality for risk factor papers.

**Level of Evidence**

The level of evidence for individual intervention studies was noted for each study containing direct evidence, using a classification system adapted from Sackett, 1989 (see the "Rating Scheme for the Strength of the Evidence" field).

Levels of evidence are typically applied to intervention studies (e.g., RCTs, controlled clinical trials [CCTs], or case series studies) because these types of studies are regarded as most important knowledge sources for clinical decision making. However, there are many more study designs (e.g., epidemiological or descriptive studies) that provide valuable evidence to guide practice, yet cannot be classified with an intervention-based level of evidence system.

Studies on diagnostic and prognostic validity of pressure ulcer risk and pressure ulcer classification form an important body of knowledge in pressure ulcer management that should be appraised independently from intervention studies. Diagnostic accuracy studies are studies in which results of index tests are compared with results from reference standards at the same point in time. Therefore, cross-sectional designs are needed to establish the concurrent existence of both index test and reference standard results. Most studies in pressure ulcer risk research are not diagnostic accuracy studies according to this widely agreed upon definition, because the measured pressure ulcer risk is often compared with subsequent pressure ulcer occurrence. These designs resemble those of prognostic studies or diagnostic accuracy studies with imperfect reference standards.

Comparable to different phases of intervention research phases of diagnostic and prognostic research can also be distinguished. In diagnostic research, Phase I and II studies focus on differentiation between individuals with the target from those without. Phase III studies are typical diagnostic accuracy studies whereas phase IV research investigates the clinical impact of diagnostic procedures. Prognostic studies are comparable with diagnostic accuracy studies with the difference that based on factors or diagnostic cues future events are predicted. These types of studies are typically used to develop prognostic models. Prognostic models (e.g., pressure ulcer risk assessment tool scores), are used to predict the probability of future events in individuals or groups.

Test accuracy and validity estimates are only surrogate measures for clinical effectiveness. The clinical effectiveness of diagnostic test procedures can only be adequately investigated by diagnostic RCTs. In case of diagnostic or prognostic RCTs the described level of evidence hierarchy of intervention studies is used.

Corresponding "level of evidence" hierarchies for diagnostic and prognostic accuracy and many other studies have been proposed and have been adopted by the Guideline Development Group (GDG) in the guideline update (see the "Rating Scheme for the Strength of the Evidence" field).
The technical documents summarizing critical appraisals of included studies are made available at the guideline website (see the "Availability of Companion Documents" field).

**Data Extraction**

The full papers of selected references were obtained and made available to the relevant SWGs on a web-based (GoogleDocs) platform.

A data extraction template was used to extract relevant data from individual papers, including study design, description of participants, study groups and interventions, outcome measures, length of follow up, study results, and comments and limitations. Preliminary data extraction tables were prepared in the interim development period (i.e., period between the publication of the 2009 guideline and the commencement of the 2014 guideline development period).

The members of the SWGs were provided with the preliminary data extraction tables for checking, expanding on details and adding studies that had not yet undergone data extraction. The methodologist completed a quality check of a random sample of 80% of the completed evidence tables and the GDG completed a quality check of a random sample of 10% of the completed evidence tables.

The technical documents summarizing data extraction of included studies are made available at the guideline website (see the "Availability of Companion Documents" field).

**Methods Used to Formulate the Recommendations**

**Expert Consensus**

**Description of Methods Used to Formulate the Recommendations**

**Participants**

All members of the development team were screened for experience, expertise and potential conflicts of interest. In the interest of transparency, all guideline developers were asked to complete a form identifying potential conflicts of interest that covered the guideline review period.

**Guideline Development Group**

This second edition of the guideline was conducted by European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Ulcer Advisory Panel (NPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA). The Pan Pacific Alliance consists of the Australian Wound Management Association Incorporated (AWMA), the New Zealand Wound Care Society (NZWCS), the Hong Kong Enterostomal Therapist Society and the Wound Healing Society of Singapore.

The Guideline Development Group (GDG) determined and monitored each step of the guideline development process, as well as managing guideline dissemination strategy. Each of the three partner organizations nominated four representatives each to form the 12 member GDG. From its nominated representatives, each partner organization appointed a Chair. The three partner organizations each had four votes during joint deliberations, with the majority deciding. Examination of the evidence and consensus building preceded all voting. Minority opinions were represented in meeting minutes. A full description of the GDG role is available on the guideline website.

A nonvoting observer from the Japanese Society of Pressure Ulcers (JSPU) attended GDG meetings during the 2014 revision process, with the option to join the GDG for the next revision.

**Small Working Groups**

The guideline content was divided into working topic areas, and Small Working Groups (SWGs) were formed to review the evidence available for each topic. The SWG members were selected by each participating organization based on an experience and expertise. Representatives of industry were excluded from SWGs. The SWGs were formed based on the principle of equal contribution from all participating organizations. A full description of the SWG role is available on the guideline website. A total of 104 SWG members contributed to the guideline development process, with many members contributing to more than one SWG.

Guideline development was an iterative process, with GDG and SWG members maintaining communication via the methodologist. Evidence summaries and draft recommendations developed by the SWGs were reviewed by the GDG for:

- Comprehensiveness and accuracy of literature reviews
Methodological rigor in evidence analysis and application to clinical practice
Clarity and appropriateness of recommendations for an international audience

Methodologist

The guideline process was overseen by an experienced guideline methodologist. The methodologist assisted the SWG members in implementing the documented methodology, appraising and summarizing the new literature, revising the 2009 guideline recommendations and developing new recommendations, and presenting the evidence. The methodologist also managed the confidential consensus voting process (Grading of Recommendations Assessment, Development and Evaluation [GRADE]). The methodologist provided a link between the GDG and the SWG, managing communication and maintaining progress. The methodologist attended GDG and SWG meetings, but did not participate in GDG voting.

Stakeholders

The entire process of developing the guideline was made available to stakeholders on the guideline website. Anyone was invited to register as a stakeholder, either as an individual or as a representative for a society/organization. All members of the EPUAP, NPUAP and PPPIA were invited to register as stakeholders and participate in this process. When new sections of the guideline were made available on the guideline website, registered stakeholders were notified by electronic mail. The GDG reviewed all stakeholder comments and any additional evidence recommended by stakeholders before approving final recommendations.

Drafting/Revising Recommendations

Based on the identified, appraised and summarized empirical evidence recommendations were formed. Each SWG formulated conclusions about the body of available evidence based on the evidence tables and critical appraisals and levels of evidence. Evidence tables from previous guidelines were also made available to SWGs to ensure the full body of scientific literature was reviewed. A first draft of recommendations was developed by the respective SWGs using the 2009 guideline recommendations as a guide. The GDG reviewed the draft recommendations, making revisions as necessary.

To ensure uniformity and internal consistency in the final guideline, the GDG provided the following guidance.

- Each recommendation should start with an action verb and be a simple, short, direct, declarative statement, free of jargon.
- Multiple complex recommendations were broken down into a series of smaller, discrete recommendations.
- The SWGs were advised to start with broad, directive statements, followed by subsequent statements with more detail (how, when, how often).
- Recommendations should be specific and unambiguous.
- When available, information on health benefits, side effects and risks should be provided.
- Spelling will be based on the conventions of American English.

The GDG reviewed all recommendations to ensure the wording of the recommendations accurately translated available research into best practice while being sensitive to the many different individual cultures and professional standards represented among the international audience for these guidelines.

The term "individual" was selected to describe the patient, client, resident, or person with a pressure ulcer or at risk for a pressure ulcer. The terms "health professional" and "interprofessional team" were used when referring to health professional providing professional health care services to the individual. The disciplines of professionals performing a given service may vary from country to country based on the laws and regulations governing health care providers. Products available in one country may not be available in another. Generic names were used when referring to drugs and other products.

Assigning Strength of Evidence Ratings

'Strength of evidence' ratings were assigned to recommendations (see the "Rating Scheme for the Strength of the Recommendations" field). This rating identifies the strength of cumulative body of evidence supporting each recommendation.

A 'strength of evidence' rating of A requires Level 1 studies conducted in individuals with pressure ulcers or at risk for pressure ulcers. This rating is consistent with recommendations derived using the Cochrane methodology. 'Strength of evidence' ratings of B required Level 2, 3, 4, and/or 5 studies in these populations. Recommendations supported by A and B 'strength of evidence' ratings were developed first. This strategy provided recommendations with very direct evidentiary support. Where the guideline was considered to lack the breadth and depth of guidance necessary to provide care, additional recommendations based on expert opinion and/or indirect evidence and given a 'strength of evidence' rating of C were developed to fill the evidence gap.
The 'strength of evidence' supporting the recommendation is not the same as the 'strength of the recommendation'. For example, there are no randomized controlled trials in individuals with pressure ulcers that evaluate debridement compared to no debridement. Therefore, this recommendation would have a relatively low 'strength of evidence' supporting the recommendation, yet the recommendation is strongly recommended in many clinical situations based on evidence from studies of other types of chronic wounds, proof of principle from basic science research, and/or expert opinion.

In this guideline, evidence gaps have been explicitly identified. Systematic literature reviews were conducted to identify indirect evidence from studies of normal subjects, studies with intermediate or surrogate outcomes, studies of humans with other types of chronic wounds, and animal studies. For many recommendations, indirect evidence may be identified to support C 'strength of evidence' ratings. In the absence of indirect evidence, consensus from previous guidelines or expert opinion may support C 'strength of evidence' ratings, providing a broader base of expert opinion than that available in the SWGs and GDG. The SWG members were encouraged to evaluate previous guidelines for quality using the AGREE II Tool. All recommendations, including those supported solely by expert opinion were reviewed by stakeholders.

**Summarizing Supporting Evidence**

The SWGs summarized the evidence supporting each recommendation. An explicit link between the recommendation and supporting evidence was expected. The strengths and limitations of this body of evidence were clearly described. All recommendations with a 'strength of evidence' rating of A or B required an explicit summary of one or more studies conducted with human subjects with pressure ulcers or at risk for pressure ulcer development. The 'level of evidence' for each study is also identified in the summary.

The summary statements for recommendations with a 'strength of evidence' of C clarify whether the recommendation was supported by:

- Indirect evidence from studies of normal subjects
- Studies with intermediate or surrogate outcomes
- Studies of humans with other types of chronic wounds, and animal studies or other basic bench research
- Expert opinion supported by previous evidence-based guidelines
- The expert opinion of the SWG and GDG members as reviewed by international stakeholders.

Evidence gaps identified in these summary statements serve as an agenda for future research efforts.

**Assigning Strength of Recommendation Grades**

The recommendations are rated based on their importance and their potential to improve individual patient outcomes. The 'strength of recommendation' is the extent to which a health professional can be confident that adherence to the recommendation will do more good than harm. The grading of importance is not necessarily related to the strength of internal or external evidence. The overall aim is to help health professionals to prioritize interventions. See the original guideline document for points to be considered in grading the strength of recommendations.

The 'strength of recommendation' grades were achieved via a formal consensus process using the GRADE grid (see Table 5 in Appendix 1 in the original guideline document and in the Methodology addendum [see the "Availability of Companion Documents" field]). In this consensus process all SWG and the GDG members were invited to take part, each voting on every recommendation in the guideline. The consensus voting process (GRADE) was conducted on the website. Each guideline development team member was provided with a unique identification. Before commencing in the GRADE process, the methodology was outlined, including the considerations to be made in casting a vote. The participant was required to nominate their understanding of the procedure before commencing, or to request further information.

See the "Rating Scheme for the Strength of the Recommendations" field and the original guideline document for additional information on assigning strength of recommendation grades.

**Rating Scheme for the Strength of the Recommendations**

**Strength of Evidence Rating**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>The recommendation is supported by direct scientific evidence from properly designed and implemented controlled trials on pressure ulcers in humans (or humans at-risk for pressure ulcers), providing statistical results that consistently support the guideline statement (Level 1 studies required).</td>
</tr>
<tr>
<td>B</td>
<td>The recommendation is supported by direct scientific evidence from properly designed and implemented clinical series on pressure ulcers in humans (or humans at-risk for pressure ulcers), providing statistical results that consistently support the recommendation (Level 2, 3, 4, 5 studies).</td>
</tr>
</tbody>
</table>
The recommendation is supported by indirect evidence (e.g., studies in normal human subjects, humans with other types of chronic wounds, animal models) and/or expert opinion.

### Strength of Recommendation Grade

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Description</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do it (Strong recommendation for using an intervention)</td>
<td>Indicates a judgment that most well informed people would make.</td>
<td>For patient consumers—Most people would want the recommended course of action and only a small proportion would not. For health professionals—Most people should receive the intervention. If health professionals choose not to follow the recommendation, they should document their rationale. For quality monitors—Adherence to this recommendation could be used as a quality criterion or performance indicator.</td>
</tr>
<tr>
<td>Don't do it (Strong recommendation against using an intervention)</td>
<td>Indicates a judgment that a majority of well informed people would make, but a substantial minority would not.</td>
<td>For patient consumers—Most people would want the suggested course of action, but many would not. For health professionals—Examine, and be prepared to discuss, the evidence with patients, as well as their values and preferences. For quality monitors—Clinicians’ discussion and consideration of pros and cons of the intervention, and documentation of discussion, could be used as a quality indicator.</td>
</tr>
<tr>
<td>Probably do it (Weak recommendation for using an intervention)</td>
<td>Trade-offs between risk and benefit unclear or lack of agreement between voting participants.</td>
<td>The advantages and disadvantages are equivalent; and/or the target population has not been identified; and/or there is insufficient evidence on which to formulate a strength of recommendation.</td>
</tr>
<tr>
<td>Probably don't do it (Weak recommendation against using an intervention)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No specific recommendation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Cost Analysis

The guideline developers reviewed published cost analyses.

### Method of Guideline Validation

**External Peer Review**

**Internal Peer Review**

### Description of Method of Guideline Validation

**Stakeholders**

The entire process of developing the guideline was made available to stakeholders on the guideline website. A stakeholder is someone who has interest in pressure ulcers and wishes to contribute to the guideline by reading the methodology, search strategies, references under consideration, and draft recommendations, ensuring that all relevant evidence had been included and commenting on the draft guideline within the timeframes allowed. All members of the European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Ulcer Advisory Panel (NPUAP), and the Pan Pacific Pressure Injury Alliance (PPPIA) were invited to register as stakeholders and participate in this process.

In 2009, a total of 903 individuals and 146 societies/organizations registered as stakeholders. These stakeholders were all invited to register as stakeholders for the 2014 guideline. Additionally, patient representative organizations were also invited to participate in the stakeholder review process to provide a consumer perspective. A total of 988 individuals were formally invited to register as stakeholders, and many more received information about the process through colleagues and organizations. A total of 698 individuals registered as stakeholders to provide feedback as an individual or in representation of a society/organization.

When new sections of the guideline were made available on the guideline website, registered stakeholders were notified by electronic mail. The Guideline Development Group (GDG) reviewed all stakeholder comments and any additional evidence recommended by stakeholders before approving final recommendations.

### Final Review and Recommendations
Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate treatment of individuals with pressure ulcers

Potential Harms

- Use conservative sharp debridement with caution in the presence of immune incompetence, compromised vascular supply, or lack of antibacterial coverage in systemic sepsis.
- Care should be taken to avoid causing injury when probing the depth of a wound bed or determining the extent of undermining or tunneling.
- Topically applied opioids may be associated with increased systemic side effects in individuals taking systemic opioids. Local itching and irritation has been reported, but not more frequently than when a placebo gel is applied.
- Caution must be exercised using conservative sharp debridement in immunocompromised individuals to avoid large open cavities that may serve as portals for opportunistic infection. Additionally, caution must be exerted in those individuals with bleeding disorders and those taking anticoagulants.
- Topical antiseptics
  - Cytotoxicity is the main concern when applying a topical agent on an open wound. Antiseptics have been found, primarily using in vitro models, to be cytotoxic to cells essential to the wound healing process, including fibroblasts, keratinocytes, and leukocytes. However, this cytotoxicity appears to be concentration-dependent.
  - Sodium hypochlorite (Dakin's solution) is cytotoxic at all concentrations and should be used with caution, at concentrations no greater than 0.025%, for short periods only when no other appropriate option is available.
  - There is a risk of acidosis when acetic acid is used for extended periods over large wound surface areas.
  - Topical antiseptics should be discontinued when infection is managed, or the wound starts to heal, or if the patient experiences any adverse reaction to the agent.
  - Silver may have toxic properties, especially to keratinocytes and fibroblasts; the extent of the toxicities is not fully described.
- Before applying a honey dressing, ensure the individual is not allergic to honey.
- Iodine toxicity has been reported in a few case studies, especially in those individuals with large wounds, in whom dressings were changed often. The risk of systemic absorption increases when iodine products are used on larger, deeper wounds or for prolonged periods. It is not recommended for individuals taking lithium, or for pregnant or breast-feeding women.
- Caution is recommended for electromagnetic therapy in individuals with fever, active bleeding, seizures or dehydration.
- Electrotherapy should be used with caution in individuals with impaired circulation or devitalized tissue.
- Cautious use by an experienced health professional is recommended for individuals on anticoagulant therapy; in actively bleeding wounds; or where the wound is in close proximity to major blood vessels.

Contraindications

Contraindications
• Debridement
  • Autolytic debridement is contraindicated in the presence of untreated infection or extensive necrotic tissue, in large ulcers with
  undermining and sinus tracts, and in individuals with compromised immunity.
  • Biological debridement (larval therapy) should not be used where there are exposed blood vessels; acute infections that are limb-
  or life-threatening; ulcers requiring frequent inspections; necrotic bone or tendon tissues; or circulatory impairment significant enough to
  impair ability to heal.
  • Relative contraindications to conservative sharp debridement include anticoagulant therapy and bleeding disorders.
• Topical antiseptics
  • Iodine products should be avoided in patients with impaired renal failure, history of thyroid disorders or known iodine sensitivity.
  • Hydrogen peroxide is highly toxic to tissues even at low concentrations and should not be used as a preferred topical antiseptic. Its
    use should be totally avoided in cavity wounds due to the risk of surgical emphysema and gas embolus.
  • Topical silver products should not be used on individuals with silver sensitivities, and silver sulfadiazine products are not
    recommended for people with sulfur sensitivities.
• Avoid using gauze dressings for open pressure ulcers that have been cleansed and debrided because they are labor-intensive, cause pain
  when removed if dry, and lead to desiccation of viable tissue if they dry.
• Manufacturers of devices used to administer electromagnetic therapy do not recommend their use in individuals with pacemakers or other
  electrical implants, pregnancy or organ transplant.
• Electrotherapy is contraindicated in individuals with electrical implants (e.g., pacemakers), or who are pregnant. Electrotherapy is also
  contraindicated in local anatomical areas of the eye, testes and any malignancy.
• Noncontact low frequency ultrasound spray should not be used near prostheses, near electronic implanted devices (e.g., cardiac
  pacemakers), over the lower back or uterus in pregnant women; or over areas of malignancy; or on the face/head.
• Individuals with dependent lower extremity edema or peripheral vascular disease, immuno-compromised individuals, those who are
  mechanically ventilated and lethargic, and incontinent individuals should never be immersed.
• Use of ultrasound is not recommended over anatomical areas with implanted materials or devices.
• Negative pressure wound therapy is not recommended in inadequately debrided, necrotic or malignant wounds; where vital organs are
  exposed; in wounds with no exudate; or in individuals with untreated coagulopathy, osteomyelitis or local or systemic clinical infection.

Qualifying Statements

Qualifying Statements
The recommendations in this guideline are a general guide to appropriate clinical practice, to be implemented by qualified health professionals
subject to their clinical judgment of each individual case and in consideration of the patient consumer's personal preferences and available
resources. The guideline should be implemented in a culturally aware and respectful manner in accordance with the principles of protection,
participation and partnership.

Limitations and Appropriate Use of This Guideline

• Guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific
  clinical conditions. The recommendations may not be appropriate for use in all circumstances.
• The decision to adopt any particular recommendation must be made by the health care professional in light of available resources and
  circumstances of the individual patient. Nothing contained in this guideline is to be considered medical advice for specific cases.
• Because of the rigorous methodology used to develop this guideline, the Guideline Development Group members believe that the research
  supporting these recommendations is reliable and accurate. Every effort has been made to critically appraise the research contained within
  this document. However, they do not guarantee the reliability and accuracy of individual studies referenced in this document.
• This guideline is intended for educational and informational purposes only.
• This guideline contains information that was accurate at the time of publication. Research and technology change rapidly and the
  recommendations contained in this guideline may be inconsistent with future advances. The health care professional is responsible for
  maintaining a working knowledge of the research and technological advances that may affect his or her clinical decision making.
• Generic names of products have been provided. Nothing in this guideline is intended as an endorsement of a specific product.
• Nothing in this guideline is intended as advice regarding coding standards or reimbursement regulations.
• The guideline does not seek to provide full safety and usage information for products and devices; however commonly available safety and
  usage tips have been included. Adverse events reported in the included research have been reported in the evidence summaries and caution
Implementation of the Guideline

Description of Implementation Strategy

The newly introduced implementation section of the guideline addresses systems and strategy at an organization and professional level that are required for effective implementation of the clinical recommendations in this guideline. This includes sections addressing implementation strategy, health professional education, recommendations specifically for patient consumers and their caregivers, and quality indicators for monitoring guideline implementation.

Facilitators, Barriers and Implementation Strategy

This section of the guideline provides a review of quality improvement research published from 1st January, 2008 to 31st December, 2012. Quality of evidence in this field is extremely varied, and the Small Working Group (SWG) narrowed the research by seeking evidence of sustained effectiveness of reproducible interventions. Assessment of potential barriers and facilitators to guideline implementation, including education level of staff and appropriate equipment is essential prior to the introduction of a pressure ulcer prevention protocol. The evidence supporting practical strategies including nurse-led quality improvement, introduction of wound care specialists and awareness campaigns is presented.

Health Professional Education

Negative attitudes and lack of knowledge are common barriers to using guidelines in clinical practice. This section of the guideline provides a review of research on the effectiveness of strategies related to health professional education published from 1st January, 2008 to 31st December, 2012. Recommendations on the format, content and evaluation of education programs are made.

Patient Consumers and Their Caregivers

The patient consumer and his or her informal caregivers play an important role in pressure ulcer prevention. Knowledge of pressure ulcers and their prevention is important, and requires a special emphasis in those at high risk. This section of the guideline discusses responsibilities of the patient consumer to attain information and work with health professionals in order to prevent and treat pressure ulcers. The section also provides guidance on the selection and maintenance of equipment.

Quality Indicators for This Guideline

Monitoring of practice is an important component of continuous quality improvement. The quality indicators identified in this section of the guideline are intended for auditing the implementation of this clinical guideline in practice. The identified quality indicators are those that are considered important indicators of successful implementation of the guideline and delivery of quality pressure ulcer prevention and treatment. The indicators could be used by organizations who introduce the evidence-based practices recommended within this guideline, and may be measured in conjunction with other quality indicators (e.g., those associated with facility accreditation) to determine progress in provision of quality care and identify areas for improvement.

See the "Implementing the Guideline" section in the original guideline document for specific implementation recommendations.

Implementation Tools

Audit Criteria/Indicators

Quick Reference Guides/Physician Guides

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories
Identifying Information and Availability

Bibliographic Source(s)


Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2009 (revised 2014)

Guideline Developer(s)

European Pressure Ulcer Advisory Panel - Independent Expert Panel
National Pressure Ulcer Advisory Panel - Independent Expert Panel
Pan Pacific Pressure Injury Alliance - Professional Association

Source(s) of Funding

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• Sage Products LLC

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Guideline Development Group (GDG)
Small Working Group (SWG)

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Financial Disclosures/Conflicts of Interest

All guideline developers were required to complete a Conflict of Interest Disclosure form in order to be involved in the guideline development process and to receive acknowledgement as a member of the guideline development team within the guideline. The Guideline Development Group (GDG) and Small Working Group (SWG) members were required to be free of major competing (or conflicting) interests and were requested to disclose the nature of any minor competing interest and recuse themselves from related decisions. Additionally, the SWG members were instructed that appraisal of a study in which he or she was an author or significantly involved in the study undergoing appraisal presents a potential conflict of interest, and other SWG members undertook the appraisal.

See the "Methodology Addendum" companion document for more information on conflict of interest and all disclosures (see the "Availability of Companion Documents" field).

Guideline Status

This is the current release of the guideline.


This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Not available at this time.

Print copies: Available for purchase through the International Pressure Ulcer Guideline Web site.

Availability of Companion Documents

The following are available:


In addition, quality indicators are available in the original guideline document.

**Patient Resources**

None available

**NGC Status**

This NGC summary was completed by ECRI Institute on April 21, 2011. The information was verified by the guideline developer on May 4, 2011. This summary was updated by ECRI Institute on March 6, 2014 following the U.S. Food and Drug Administration advisory on Over-the-Counter Topical Antiseptic Products. This summary was updated by ECRI Institute on February 5, 2015. The updated information was verified by the guideline developer on March 1, 2015. This summary was updated by ECRI Institute on September 21, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on opioid pain medicines. This summary was updated by ECRI Institute on October 21, 2016 following the U.S. Food and Drug Administration advisory on opioid pain and cough medicines combined with benzodiazepines.

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