Understanding Pressure Ulcer Research and Education Needs: A Comparison of the Association for the Advancement of Wound Care Pressure Ulcer Guideline Evidence Levels and Content Validity Scores

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Abstract
Although difficult to quantify due to methodological variations, the worldwide burden of pressure ulcers (PUs) is substantial. Recognizing the importance of providing evidence-based care to help reduce this burden, the North American Wound Care Council societies collaborated to identify PU research and education opportunities using the PU “Guideline of Guidelines” developed and tested by Association for the Advancement of Wound Care Guideline Department (AAWC GD). Volunteer AAWC GD members compiled recommendations from PU guidelines available in 2008, searched the literature for additional research as needed, and developed evidence levels for all recommendations using an established level-of-evidence rating scheme. At the same time, AAWC members and Ostomy Wound Management readers were invited via email to participate in a content validation study of the 368 recommendations, rating items on a scale of 1 (not relevant) to 4 (very relevant and succinct). Items with a content validity index (CVI) >0.75 were considered valid. Recommendations with support from two or more randomized controlled PU trials or two or more cohort studies for diagnostic or predictive validity (A-level evidence) and a CVI >75 were grouped as ready for implementation. Recommendations with content validity but without A-level evidence were determined to be opportunities for research; recommendations that lacked content validity but that had A-level evidence were viewed as opportunities for education. Thirty-two (32) multidisciplinary healthcare professionals participated in the content validation study. Most (93.2%) recommendations were rated as valid. Of the 97 (26%) recommendations with A-level evidence, 90 (24.5% of total) met both strong content validity and strong evidence criteria and were rated as ready for implementation as standard of care. Most recommendations (253, 68.8%) were rated as valid but had B- or C-level evidence, representing opportunities for research. Only seven (1.9%) recommendations had a low CVI but A-level evidence, suggesting a need for education. The results show that most of the guideline recommendations are valid, that the number of PU intervention recommendations with A-level evidence is increasing, but that, in general, the need for research to replace opinion with evidence remains high across the entire spectrum of PU prevention and treatment. Understanding what is known (recommendation: ready to implement), what is not known (research needed), and what clinicians need to know (education needed) is an important step toward reducing the burden of pressure ulcers.

Keywords: pressure ulcer, guideline of care, evidence levels, content validity, education, research


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Economic, Social, and Clinical Burden of Pressure Ulcers

Pressure ulcer (PU) prevalence, incidence, and cost reporting methods vary across different healthcare systems, so the true magnitude of the global burden of PU is difficult to estimate. The costs of treating PUs in the US grew from an estimated $1.3 billion in 1992 to $17.2 billion in 2003, with an average charge of $21,675 per PU treated.1 Actuarial analysis of the 6,319,486 medical errors reported in the US in 2008 described the occurrence of 374,964 PUs as the most frequent and expensive medical error, costing more than $3.8 million.2 In UK general practice, the annual PU prevalence among patients at least 65 years of age was 0.31% to 0.70%, with PU incidence rising with increasing age to 3.3 per 100 person years for those older than 95 years of age.3

Due to the associated pain, related restrictions on social activities, and rehabilitation activities required, PUs also represent a personal burden. PU development can extend hospital length of stay from four4 to 30 days.5 In a prospective cohort study of 286 patients with a PU identified within 3 days of admission to a tertiary care urban teaching hospital, Allman et al6 reported that when compared to individuals without PUs, persons who developed PUs also were more likely to develop nosocomial infections (P = 0.001) and other hospital complications (P <0.001). Septicemia was the underlying or contributing cause of death recorded from death certificates in 40% of the 114,380 PU-associated deaths in 1990–2001 (0.4% of the total) and is the probable causal link between PUs and death.6,7

The burden of living with PUs extends beyond costs to the healthcare system and loss-of-life. Gorecki et al’s8 systematic review of 31 studies found PUs significantly limit many aspects of an individual’s well-being, including general health and physical, social, financial, and psychological quality of life. The patients in these studies needed knowledge of how the PU developed and how they or others would care for it. They reported improved quality of life when the ulcer healed and that competent care providers were of benefit.

Evidence-based Practice for Consistent Quality Care

Evidence-based practice can improve the efficiency and effectiveness of clinical interventions.9-11 In the last two decades, much of the PU prevention and treatment evidence has been propagated through evidence-based guidelines. Professionals around the world have generated evidence-based PU prevention and treatment guidelines.12,13 Many are accessible at the Agency for Healthcare Research and Quality (AHRQ) National Guideline Clearinghouse (NGC) website (www.guidelines.gov) or from PU organizations such as the National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP), and the Wound Healing Society (WHS).

In 2009, the NPUAP and EPUAP released their jointly developed Pressure Ulcer Prevention and Management Guidelines and published summaries on the websites of both organizations. In a parallel initiative to improve the consistency and quality of PU management,14 the Association for the Advancement of Wound Care Guideline Department (AAWC GD) compiled PU recommendations from guidelines posted by NGC in 2008,15-25 as well as those of the WHS26 and draft27-29 NPUAP-EPUAP International Guidelines (see Table 1) into one document.

Once the AAWC GD compiled best available evidence and established the content validity of clinical relevance for each recommendation, disparities between strength of evidence and strength of opinion (content validity) became clear. These disparities highlighted recommendations that needed either more research or more education to improve the consistency and quality of PU care. During the 2009 North American Wound Care Council meeting in Queretaro, Mexico, attending societies (see Table 2) pledged to collaborate in publishing these PU management recommendations requiring research or education as a way to guide related initiatives throughout all organizations, thus improving guideline implementation and PU outcomes.

Purpose

The purpose of this report is to: 1) describe the development and testing of the AAWC “Guideline of Pressure Ulcer Guidelines”, 2) tabulate the strength of evidence and content validity of individual recommendations, and 3) review consistencies and inconsistencies between available evidence and relevance ratings (content validity) in order to 4) identify PU prevention and management education and research needs.

Background, Methods, and Procedures

A review of existing PU guidelines14 revealed inconsistencies in PU definitions and management. The AAWC authorized its multidisciplinary voluntary guideline department
AAWC FEATURE

Table 1. Guideline sources included in the Association for the Advancement of Wound Care Guideline Department (AAWC GD) Pressure Ulcer Management Recommendations

<table>
<thead>
<tr>
<th>Guideline Sources</th>
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<tbody>
<tr>
<td>Agency for Health Care Policy and Research (AHCPR):</td>
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<tr>
<td>Treatment of Pressure Ulcers. Clinical Practice</td>
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<tr>
<td>Guideline, No. 15</td>
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<tr>
<td>AHCPR: Pressure ulcers in adults: Prediction and</td>
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<tr>
<td>prevention. Clinical Practice Guideline, No. 3.</td>
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<tr>
<td>American Society of Plastic Surgeons: Evidence based</td>
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<tr>
<td>clinical practice guideline: chronic wounds of the</td>
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<td>lower extremity</td>
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<tr>
<td>Consortium for Spinal Cord Medicine Clinical Practice</td>
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<tr>
<td>Guidelines: Pressure ulcer prevention and treatment</td>
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<tr>
<td>following spinal cord injury: a clinical practice</td>
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<tr>
<td>guideline for health-care professionals</td>
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<td>National Pressure Ulcer Advisory Panel (NPUAP) and</td>
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<td>European Pressure Ulcer Advisory Panel (EPUAP):</td>
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<td>International guidelines for pressur ulcer prevention</td>
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<td>and treatment</td>
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<td>The John A. Hartford Foundation (JHF) Institute for</td>
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<tr>
<td>Geriatric Nursing; Pressure Ulcer Prevention, 2003</td>
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<tr>
<td>National Collaborating Centre for Nursing and Support-</td>
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<td>ive Care and National Institute for Clinical Excellence</td>
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<tr>
<td>(NCCNNS/NICE): The use of pressure-relieving devices</td>
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<td>(beds, mattresses, and overlays) for the prevention</td>
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<td>of pressure ulcers in primary and secondary care</td>
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<tr>
<td>Paralyzed Veterans of America (PVA): Pressure ulcer</td>
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<td>prevention and treatment following spinal cord injury:</td>
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<td>a clinical practice guideline for health care</td>
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<td>professionals</td>
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<td>Registered Nurses Association of Ontario (RNAO):</td>
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<td>Guidelines for risk assessment and prevention of</td>
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<td>pressure ulcers</td>
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<tr>
<td>Registered Nurses Association of Ontario (RNAO):</td>
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<td>Assessment and Management of Stage I to IV pressure</td>
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<td>ulcers</td>
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<tr>
<td>Wound Healing Society: Guidelines for the treatment of</td>
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<td>pressure ulcers</td>
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<tr>
<td>Wound, Ostomy, and Continence Nurses Society (WOCN):</td>
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<tr>
<td>Guideline for prevention and management of pressure</td>
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<td>ulcers</td>
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(AAWC GD) to develop a comprehensive evidence-based, content-validated PU “Guideline of Pressure Ulcer Guidelines”. This project was called the AAWC Pressure Ulcer Care Initiative (PUCI). The AAWC GD compiled PU management recommendations from available guidelines (see Table 1). Recommendations were grouped into sections addressing PU risk and wound assessment, prevention, and treatment. Standards of PU care from all the guideline reviews were collated into 368 unique recommendations. AAWC members (N = 1,708) and readers of Ostomy Wound Management (N = approximately 23,000) were invited to participate in a content-validation survey accessible online at the AAWC website from December 12, 2008 through February 28, 2009. Thirty-two (32) multidisciplinary clinicians responded and completed the survey (see Participating surveyors/respondents).

Participants were asked to rate the relevance of each of the 368 recommendations to best-practice PU care using the following 4-point rating scale: 1 = not clinically relevant; 2 = wording or content confusing and unable to assess relevance without further information; 3 = relevant but needs minor improvement to make relevant and succinct (list recommendation in comment box); and 4 = very relevant and succinct.

The content validity index (CVI) was calculated as percent rated relevant (3) or very relevant (4) and considered acceptable if the CVI was at least 0.75.

Strength of literature-based evidence criteria (see Table 3) were adapted from original AHCPR Pressure Ulcer Guidelines\(^\text{15,16}\) to include criteria for diagnostic and screening evidence.\(^\text{31}\) The AAWC GD team searched MEDLINE, CINAHL, and Cochrane literature databases for all 368 recommendations to establish standardized strength of best available evidence; A-level evidence for treatment or prevention recommendations was defined as two or more randomized controlled trials (RCTs) on individuals with a PU. For PU diagnosis or risk assessment recommendations, A-level evidence was two or more PU RCTs or PU cohort studies reporting diagnostic or predictive validity for scales designed to diagnose or screen PU risk (see Table 3).

Using the above criteria for content validity and strength of best available evidence (see Table 4), the authors reviewed the 368 PUCI recommendations to identify PU research and education opportunities. Recommendations with a high CVI (>0.75) and A-level evidence were identified as “ready to implement” as best practice PU standards of care. Recommendations with content validity but lacking A-Level evidence...
were identified as “opportunities for research” to further validate them as standards of practice. Recommendations lacking content validity but supported by A-level evidence were identified as “opportunities for education” to increase awareness among bedside practitioners. Recommendations lacking both content validity and supporting evidence were identified as “not ready for implementation or inclusion” in an evidence-based content-validated guideline.

Results
The average CVI was 0.75 or higher for most (93.2%) of the 368 recommendations (see Figure 1). Of the 6.8% with a CVI <0.75, seven (1.9%) had A-level evidence, indicating an opportunity for education, and 18 (4.9%) had C-level evidence, suggesting a need for research and/or education.

Most recommendations (63.0%) were supported by C-level evidence (see Figure 2). Among the 97 (26.4%) recommendations with A-level evidence, 90 (24.5%) had a CVI >0.75. The remaining seven recommendations with a CVI <0.75 (1.9%) represent opportunities for education (see Column 3, Table 5). The 39 (10.6%) recommendations supported by B-level evidence all had a CVI >0.75 and represent areas believed to be effective with at least one RCT (or cohort study reporting screening or diagnostic validity for PU risk or PU assessment measures) supporting efficacy. These recommendations are nearly ready for implementation, requiring only one more qualifying study before meeting the standardized criterion for evidence-based practice. Overall, most research is needed in the areas of PU treatment and prevention (see Figure 3), key areas affecting both PU outcomes and costs of care.

Opportunities for education. Seven pressure ulcer management recommendations were supported by A-level evidence but were not rated as relevant, suggesting needs for education (see Table 4 and Table 5).

Table 3. Definitions and levels of strength of evidence ratings (adapted15,16,33)

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
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<tbody>
<tr>
<td>A</td>
<td>Results of a meta-analysis or two or more pressure ulcer (PU)-related randomized controlled trials (RCT) on humans provide support (or for diagnostics or risk assessment: prospective cohort [CO] studies and/or controlled studies reporting recognized diagnostic or predictive validity measures)</td>
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<tr>
<td>B</td>
<td>Results of one PU-related RCT in humans plus two or more similar historically controlled trials (HCT) or convenience controlled trials (CCT), or one HCT and one CCT provide support or when appropriate, results of two or more RCTs in an animal model validated as clinically relevant to PU provide indirect support. For diagnostics or risk assessment, one PU-related prospective CO study and/or a controlled study reporting recognized diagnostic or predictive validity measures</td>
</tr>
<tr>
<td>C</td>
<td>This rating requires one or more of the following: C1: Results of one controlled trial on PU prevention or treatment — eg, RCT, CCT, or HCT (or for diagnostics or risk prediction one prospective CO study may be substituted for a controlled trial); C2: Results of at least two case series (CS) or descriptive studies or a cohort study in humans; C3: Expert opinion (EO)</td>
</tr>
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Table 4. Criteria for opportunities for research or education

<table>
<thead>
<tr>
<th>Level of evidence and content validity</th>
<th>Research or education opportunity status</th>
</tr>
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<tbody>
<tr>
<td>A-level evidence and CVI value &gt;0.75</td>
<td>Strong evidence and validity: ready for implementation</td>
</tr>
<tr>
<td>&lt;A-level evidence and CVI value &gt;0.75</td>
<td>Strong evidence only: opportunity for research</td>
</tr>
<tr>
<td>A-level evidence and CVI value &lt;0.75</td>
<td>Strong evidence only: opportunity for education</td>
</tr>
<tr>
<td>&lt;A-level evidence and CVI value ≤0.75</td>
<td>Weak evidence and content validity: opportunity for research and education</td>
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</table>
1. Using a valid, reliable anthropometric measurement or body mass index (BMI) assessed by properly trained staff while conducting the nutritional assessment was identified as a PU risk factor in one RCT and four cohort studies, but the recommendation had a CVI of 0.71.

2. Culture or ethnicity can affect family and self-care attitudes and practices related to risk of developing a PU. Bergstrom and Braden noted a higher incidence of new PU among African Americans than for other racial/ethnic groups. The low content validity score for this recommendation may reflect a practice that represents best evidence for healing and cost effective PU outcomes.

3. Measuring technique for PU length and width as part of PU assessment, prevention, and treatment recommendations. One area where low content validity (CVI = 0.52) described clinical reality more accurately than best available evidence was in use of topical growth factors, which are not indicated for PU management. Gauze dressings were used to deliver growth factors and placebo (considered standard practice) in two PU RCTs conducted on more than 200 Stage I to Stage III PUs, and one controlled study on a PU model in mice.

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4. Research opportunities. The 253 recommendations supported by strong opinion (CVI >0.75) and less than A-level evidence are opportunities for research summarized below for each aspect of PU management. The number of content-validated recommendations needing more research to qualify for an A-level evidence base is listed in parentheses after each major category of PU management. Most recommendations needing research were in the areas of PU treatment and prevention.

Patient assessment (54 recommendations or 14.6% of 368). Research is needed to validate the need for all patient and PU assessments to be performed consistently on approved institutional forms or tools accessible to all members of the interdisciplinary PU or wound management team. Required frequency of PU risk assessment needs research in all settings, as does screening or diagnostic efficacy of having a previous or current PU as a risk factor for PU development.

Nutritional PU risk factor assessments needing validation research include factors affecting swallowing or nutrient intake, absorption or retention status, and laboratory reports of total protein, hematocrit, or transferrin.
Medical/surgical history factors requiring validating research to confirm value in PU management include documenting a comprehensive systems assessment. This entails recording sensory deficits; bowel and bladder habits; lower extremity perfusion deficits; edema; spastic or flaccid extremities; range of motion; malignancy; renal, pulmonary, or other severe chronic or terminal disease or condition; a history of extended pressure from hard surfaces related to Emergency Department wait, or ambulance ride; and procedures related to dialysis, catheters, or radiology.

Psychological and quality of life assessment parameters needing research to validate their value in PU management include sufficient cognition and motivation by patient, family, and care provider to use and follow-through on protocols of care, plus access to skilled, knowledgeable healthcare professionals and social, financial, and reimbursement resources to empower proper action.

Environmental assessment factors requiring research to verify value in PU care include documentation of posture irregularities, access to and proper fitting or use of devices, and prescribed offloading or pressure-redistribution modalities avoiding pressure, friction, and shear during all client/patient activities or interactions with staff, such as repositioning or transfers.

Physical exam including PU assessment (21 recommendations or 5.7% of 368). Research is needed to validate performing head-to-toe assessment of bony prominences and deviations, as well as areas of skin in contact with removable tubes or other devices. Ulcer staging requires stronger validation research, as does documenting PU evolution, duration, complications, and related treatment. Required frequency of PU assessment also needs research.

Diagnostic tests requiring more research to support their value in managing PU include vascular laboratory tests of tissue perfusion, blood analysis to assist in diagnosing infection or comorbid conditions affecting healing, testing PU biopsies after 12 weeks of nonhealing for suspected malignancy, and patient-appropriate bone imaging for suspected osteomyelitis.

PU prevention of occurrence or recurrence (75 recommendations or 20.4% of 368). Recommendations for all aspects of skin inspection and maintenance required further research to support efficacy in improving PU outcomes. These include inspecting skin beneath clothing or devices; managing excess moisture by use of absorbent products or incontinence interventions; use of effective no-rinse, pH-balanced skin cleansers with tepid bathing standards; hydrating dry skin with moisturizing agents; avoiding vigorous massage; using skin protectants, film, or hydrocolloid dressings over bony prominences to reduce friction and shear; and using support surfaces that wick away moisture and prevent skin overheating.

Hydration and nutrition recommendations for PU prevention needing a stronger evidence base include frequency and methods of providing hydrating fluids or nourishment and orienting that frequency to patient and family needs and wishes.

Rehabilitative and restorative programs to address immobility and/or inactivity in bed- or chair-bound patients as soon as their condition allows and to manage muscle spasms appropriately require research to support implementing progressive mobility or exercise.

Many recommendations for positioning standards of care to manage pressure/shear/friction remain untested in rigorous RCTs, although quasi-experimental before-and-after
studies suggest at least transient value in PU prevention. Recommendations needing research include keeping the head of the bed at or below 30° or at the lowest degree of elevation consistent with its occupant’s medical condition; avoiding trochanter pressure when sidelying by using a 30° laterally inclined position; using small positioning changes to redistribute pressure every 2 to 3 hours; using lift sheets or devices (and removing them when done) to reduce dragging, folding, stretching of skin, and friction during turns and transfers; using trapeze or side rails to facilitate patient independence in offloading; preventing contact between bony prominences with cushions or devices; and placing heating or cooling blankets above the individual, rather than beneath weight-bearing zones. Research also is needed to prove efficacy of self-conducted, pressure-relief exercises every 15 minutes by capable chair-bound individuals and avoiding sitting for more than 4 hours.

Offloading equipment recommendations in need of RCT research for preventing PU included those that advise avoiding doughnut-shaped devices and using medical grade sheepskins except with added heel and elbow protection; assessing function and effectiveness of support surfaces as patient status changes; ensuring access to and use of appropriate positioning and continence devices for all patients in at-risk environments and that regular positioning guidelines are followed, including an effective seating system, 3- to 4-inch thick high-density foam, or therapeutic cushioning systems, regular positioning, measured pressure redistribution, and evaluation of supportive aids by trained assessors for chair-bound patients.

Research is needed to assess the value of all aspects of caregiver and family health-care provider education as well as use of an interdisciplinary team to develop and implement an individualized plan of care based on an evidence-based position statement, such as the AAWC Statement on Benefits of Team Care available at aawconline.com. With the exception of healthcare professionals trained in offloading or nutrition, qualifications for participation on interdisciplinary teams needs research.

Pressure ulcer treatment strategies (103 recommendations or 28.0% of 368). Recommendations in need of research for implementing and continuing measures to prevent PU and optimize healing include setting treatment goals consistent with the patient’s goals, values, and lifestyle and continuing and/or evaluating response to previous and current prevention or treatment interventions.

Research is needed supporting several aspects of removing or alleviating the PU cause: effective pressure-redistribution products for all but individual Stage I or Stage II PUs; avoiding direct placement on the PU; use of cushions, repositioning, positioning schedules, protocols, and aids and their frequency of use; and use of static support surfaces that prevent “bottoming out” — ie, allow the bony prominence to be felt beneath the support surface.

Soft tissue and bone debridement interventions needing research to strengthen efficacy and/or safety evidence include all bone debridement methods; surgical, high-flow irrigation; laser and maggot debridement; and recommendations that debridement is contraindicated for stable heel ulcers in critically unstable or gravely ill persons. Wet-to-dry gauze debridement is substandard practice based on pain and healing outcomes, but still requires RCTs supporting its inadequacy for PU debridement.

All cleansing interventions need PU research, including cleansing the ulcer and surrounding skin with nonantiseptic, nontoxic clean or sterile water, normal saline, or Ringers solution applied at 4 to 15 lb per square inch of PU or skin surface with enough cleanser to remove debris while avoiding manual scrubbing.

Recommendations to manage bacterial colonization and infection needing research include use of universal precautions or standards for clean or sterile wound care technique, hand washing, and use of protective equipment in all settings; evaluating the PU at each dressing change for signs and symptoms of clinical infection, including unexplained lack of healing progress during 2 to 4 weeks of optimal care;
using a validated quantitative swab culture of 1 cm² viable wound surface to determine type and level of wound micro-organisms if signs of infection are noted; and treating at-risk patients’ distant infections, such as urinary tract infections. Topical antimicrobial agent use/protocols as PU cleansers or dressings needs more research to determine safety, efficacy, and duration of use.

PU dressing interventions requiring more research include managing excess ulcer drainage with a Hydrofiber® dressing, filling ulcer cavities, providing thermal insulation, and managing exuberant granulation tissue. Research also is needed to confirm schedules for monitoring or changing PU dressings, observing the wound status, and revising wound dressings according to PU outcomes and patient goals.

Managing ulcer-related pain also needs research on referral strategies, psychosocial interventions, or massage to manage muscle cramping or lymphatic conditions; avoiding massage over reddened bony prominences; systemic pain medication use; and using postural changes and support surfaces that minimize pain.

Nutritional interventions with insufficient evidence of efficacy include regular body weight evaluations, use of vitamin A or E supplements, and a hydration program including daily 30 to 35 cc of fluid per kg of body weight or as medically indicated depending on individual needs. Use of anabolic agents or appetite stimulants also requires research to address weight loss in underweight individuals or persons losing weight at unhealthy rates.

Advanced adjunctive interventions in need of RCTs on PUs unresponsive to 30 days of best available evidence-based therapy include hyperbaric oxygen therapy, negative pressure wound therapy (vacuum), allografts, contact or noncontact therapeutic ultrasound, and ultraviolet (UV) light/multi-wavelength phototherapy.

More research is needed to support all aspects of surgical interventions for PU, including direct closure, flaps, and skin grafts. Preoperative measures with insufficient evidence include smoking cessation, bowel regulation, medical stability with adequate nutrition and hydration, and reducing the tissue bacterial burden to <10⁵ colony forming units/g of wound tissue before surgical closure. Postoperative measures in need of research include pressure redistribution interventions; adequate nutrition and hydration; gradually increased mobility and sitting; patient and caregiver education about re-injury and recurrence; and daily skin and wound examinations to check for surgical complications such as wound dehiscence, infection, abscess, hematoma, seroma, or procedure-related pain.

All recommendations addressing documentation of response to treatment required more research, including use of photographs, validated tools such as the Bates-Jensen Wound Assessment Test,62 DESIGN Tool,37 and PUSH Tool,43 which may improve in value by adding validated size and depth scales.49 Recommendations to revise treatment plans if no significant reduction in wound area occurs after 2 to 4 weeks or to address patient issues in response to complications or non-adherence to care plans also require a stronger research base.

Palliative care for qualifying individuals is a key area in need of research on skin, pain, and PU assessment and management. An operational definition with good predictive validity is needed for terminal ulcers. Research is needed to refine methods for establishing and achieving individualized care goals consistent with medical condition and patient and family wishes, needs, and capabilities; and for protecting the skin, maintaining patient hydration and nutrition, preventing skin breakdown, and stabilizing and managing the PU and surrounding skin as much as possible while optimizing patient comfort. Research is needed to support effective pain management strategies, including analgesics and dressings that keep wounds moist with intermittent dressing changes, while implementing all PU and infection prevention and management principles acceptable to the patient and family.

Guideline recommendations not ready to implement without further research or content validation. Recommendations not accepted as evidence-based practice or relevant to PU management or prevention are summarized below and in Table 6. These were evenly distributed among PU debridement or cleansing interventions, adjunctive therapy, aspects of individual risk, or skin color assessment. One recommendation, obtaining fall history, would have been in this category, but was moved from the section on environmental assessment to the section on medical history at Content Validity Survey respondent’s suggestions.

Eighteen recommendations no longer are included in the final guideline because they require more evidence and content validation (see Table 6).

Discussion

As with many areas of medical practice, most PU recommendations supported by strong opinion (CVI >0.75) have become usual and customary practice, even though 68.8% require more evidence to qualify as A-level, evidence-based care. If genuine knowledge is science based,44 these results mean clinicians think they know much more than they do. The good news is that the percent of PU management recommendations based on A-level evidence rose to 26.4% from about 20% with A-level supporting evidence when the AH-CPR (now AHRQ) Pressure Ulcer Prevention and Treatment Guidelines15,16 were first created.

All evidence-based PU efforts continue to be limited by incomplete understanding of PU etiology and the multiple interacting factors that cause a PU or delay its healing. As long as the words used to describe PU, treatment or prevention interventions, or responses to treatment mean different things to different people, understanding the safety and efficacy of interventions to prevent or treat a PU will have limited clarity. Operationally defined quality measures and indicators45 can help standardize PU management. RCTs that test hypotheses need to use clear operational definitions of interventions such
as offloading, pressure redistribution, and moist wound healing or outcomes such as healing, pain, or infection to avoid confusing the field. This work is but a tentative step toward encouraging those much-needed definitions and RCTs.

Research considerations.

Diagnosis. Some aspects of individual care seem too obvious to test. Others are difficult to test for diagnostic or screening validity in cohort studies or for comparative efficacy and safety in RCTs. Many diagnostic or screening recommendations would benefit from well-designed clinical research, mining electronic medical record databases to establish their respective clinical diagnostic or predictive validity. Such actions could be refined if they were subject to systematic study.

Systematically studying clinical judgment certainly would be complex, but could enlighten wound care practices. For example, guideline statements address the need for clinical-decision making based on clinical, nutritional, psychosocial, and environmental assessments were seen as clinically important, but lack evidence to support their utility. The thorough examination of an individual’s health condition and ability to comply with therapies is fundamental. Research in this area could address data collection, retrieval, and validation.

Research on the natural history of PU healing — eg, the PU healing rate in individuals with various comorbidities or receiving various treatments — would be informative for policy makers. Although research in PU healing may seem too complex due to confounding comorbidity factors, most chronic illnesses have similar patterns of comorbid conditions. Valuable warning patterns can be found by mining appropriate databases, which could prepare PU professionals to heed and address risk for slow healing before it becomes a serious problem.

Assessment. Accurate depth assessment of partial- or full-thickness PU predicts healing time. Accurate PU area assessment provides advance warning that the ulcer is not on a healing trajectory. Yet concerns related to accuracy of PU size, depth, and stage assessment remain. Staging systems are used to support reimbursement in some countries, including the US, yet only one cohort study (reporting diagnostic validity of but a single stage: blanchable erythema) was found. Much work remains to establish the true value of using staging systems in documenting the extent of a PU or to develop plans for care. Research should focus on how to improve accuracy and reliability of PU assessment, as well as diagnostic and predictive validity of assessment parameters used in diagnosing and screening nonhealing wounds. For example, Kurd et al reported improved healing outcomes in RCTs for venous leg ulcers and diabetic foot ulcers if wound care providers received feedback of 4-week healing rates, a procedure supported by A-level evidence. However, no similar RCTs have been conducted for PUs, although technology could easily facilitate accurate staging and surface area and volume measurement. Likewise, educational research methods could facilitate recognition of PU complications.

Documentation. Accurately recording PU etiology, duration, and prior treatments has great utility in clinical settings. Data are cumbersome to find and often are lost when individuals change healthcare systems or providers. Interactions between skin moisture and resulting fragility and pressure, friction, or shear damage may blur distinctions between etiologies.

Skin health. Maintaining skin health is a vital yet barely researched area. Clinical trials on skin care regimens would be informative and reduce costs if one regimen were shown to be more efficacious. The relationship of moist skin to PU development, particularly regarding the microclimate (temperature and humidity) at the interface between the bed and the body, is not well studied and remains poorly understood. Animal studies to clarify how moisture injures skin, as well as how to keep skin properly moisturized and clean while protecting it from excess moisture, would provide supportive data for clinical care because it would be unethical to subject individuals to injurious situations. Related studies on the use of incontinence containment devices and associated incidence of PU formation also are needed.

Research could help identify the best educational methods to teach skin inspection. Clinical issues with skin inspection often coincide with the inability to see all the skin due to immobility, obesity, or the presence of splints, dressings, and the like. Developing systems that could sense changes in skin condition beneath opaque devices would be a good use of technology.

Nutrition and hydration. The hydration/protein-calorie connection to PU development is fairly well understood, but the need to determine the doses needed to maintain skin health and promote healing, especially in individuals with significant bowel and/or liver disease, remains unaddressed. An ethical analysis and qualitative research of enteral and parenteral nutrition would help guide discussions with families on this sensitive topic.

Restorative care. Although frequently used in long-term care when individuals no longer show improvement toward goals, restorative care with regard to PU formation needs to be better explored, perhaps by examining time to ulceration in individuals of similar risk. The effect of splinting and range-of-motion exercises on the time to ulcerate could also be examined.

Shear. Knowledge is increasing regarding the effect of shear on PU formation and the development of undermining in existing PUs. Research is needed on how to protect skin from shear when the head of the bed must be elevated, as for individuals on ventilators and persons who are tube fed. For too long, the skin has been sacrificed for the lungs. Clinicians need to find methods to meet the needs of both body systems.

Pressure redistribution. Although interventions to change the position of a bed-ridden individual are supposed to be based on individual needs, there is little information to guide
this decision process. Should everyone be turned every 2 hours? How does the surface the individual is lying on affect turning schedules? Should turning/repositioning frequency increase when Stage I PUs develop or is that too late? At the very least, studies to examine individual conditions that predict an ideal turning frequency could be helpful in determining staffing ratios in many institutions.

The design of wheelchairs and bedside chairs has not changed in decades. Technology may be able to assist with the development and testing of “smart surfaces” that either inform the staff or move the individual when tissue is becoming hypoxic. In the interim, studies of staff training methods on how to reposition individuals in wheelchairs and bedside chairs would assist in meeting the need for prevent PUs in the chairbound individual.

**Education considerations.**

Assessment of non-Caucasians. Assessing the skin in darkly pigmented individuals remains a clinical concern. Erythema and blanching in darkly pigmented skin is difficult to see, so techniques are needed to advance the ability to note early signs of pressure damage or predict healing delay.

Wound measurement. Whether a wound is healing often is determined by wound measurements. The PUSH Tool measures ulcer length. Langemo et al reported that this form of wound measurement was not the most accurate, but serves as a repeatable measure of changes over time. Simple longest length x longest perpendicular width is most strongly correlated with planimetric chronic wound area and has been validated as a predictor of delayed healing.

Growth factors. Growth factor use currently is indicated only for the treatment of lower extremity diabetic neuro-pathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply. In addition, the Food and Drug Administration (FDA) has added a warning for becaplermin gel (Regranex®, Systagenix Wound management, Quincy, MA) that describes an increased risk of death from cancer in individuals treated with three or more tubes of the product compared with those individuals who did not use the product. Although ulcers severe enough to require three or more tubes of growth factor may impact health sufficiently to correlate with cancer deaths, causal relationships remain to be explored. The FDA recommends that growth factors be used only when the benefits can be expected to outweigh the risks.

**Conclusion**

Using currently available evidence-based guidelines of care, supplemented with the best available additional research as needed, the AAWC GD developed a “Guideline of Pressure Ulcer Guidelines”. Content validity of the 368 individual recommendations was tested (N = 32 volunteers) and the strength of evidence supporting each recommendation was tabulated, reviewed, and compared to the CVI. Eighteen recommendations did not meet the criteria for inclusion (C-level evidence and low CVI), leaving a total of 350 recommendations meriting inclusion in the evidence-based, content-validated PU guideline. Of those, 90 were found to be ready for implementation (A-level evidence and good content validity). However, most recommendations (63%) continue to have C-level evidence, and discrepancies between levels of evidence and CVI ratings were observed. Specifically, for 68.8% of recommendations, survey participant ratings were higher than existing levels of evidence, suggesting a need for research. At the same time, the CVI for a few recommendations (1.9%) was low, while their level of evidence was high, indicating a need for education.

The consistency and quality of current PU protocols of care will improve only if existing science-based knowledge is used and research required to replace opinion with evidence is conducted. Education, learning, and organized implementation programs are vital to foster attitude and behavioral changes required to implement the evidence-based principles identified. Hopefully, present healthcare professionals will use this content-validated, evidence-based AAWC “Guideline of Pressure Ulcer Guidelines” to inform their PU practice and educate colleagues, staff, care givers, and all who affect persons with or at risk for PU about ulcer assessment, prevention, and treatment principles and strategies.

Organizations are working together to highlight this unified approach; generating one consistent “guideline of PU guidelines” is a pioneering step. Now clinicians can be united in understanding what is known (ready to implement), what is not known (research needed), and what should be known (education needed). Placing this work in clinical perspective, the content validation process is a slice in time of recommendations that healthcare professionals believe are relevant to PU management. The evidence is but a summary of best evidence available while this AAWC “Guideline of Pressure Ulcer Guidelines” was being developed. Ideally, clinical opinions and evidence already have improved as these results are being reported. The guidelines are but a signpost along the path to improving consistency and quality of PU care and related outcomes. Education is the key to implementing good evidence-based practice. Research is needed to forge new knowledge in areas where ignorance still prevails. The authors hope that future PU professionals will not stop at this signpost, but will build on this work to conduct the research needed to create future complete, comprehensive A-level PU protocols.

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Additional Disclosures

Dr. Contreras-Ruis and Whitney have nothing to disclose. Ms. Girolami is the Clinical Manager, Therapy Support, Inc, Cincinnati, OH. Dr. Woodbury is a consultant and/or paid advisory board member of the Canadian Association of Wound Care. Dr. Bolton is a former employee of Johnson & Johnson Wound Management (Somerville, NJ) and Convatec (Skillman, NJ); Chief Scientific Advisor, Derma Sciences, Inc (Princeton, NJ); and a member of the Medical Advisory Board, Systagenix Wound Management (Quincy, MA).

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