

Assessing the Need for Developing a Comprehensive Content-Validated Pressure Ulcer Guideline

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Healthcare professionals need evidence-based strategies and guidelines for care to optimize pressure ulcer prevention and management. Differences among pressure ulcer guidelines confuse caregivers, reducing consistency of care. To assess the need for a comprehensive content-validated guideline document, the Association for the Advancement of Wound Care Guideline Subcommittee evaluated current pressure ulcer guideline recommendations by compiling 10 pressure ulcer-specific guidelines existing before June 2008 on the National Guideline Clearinghouse website along with the National Pressure Ulcer Advisory Panel (draft), European Pressure Ulcer Advisory Panel (draft), and Wound Healing Society guidelines. Steps for each aspect of pressure ulcer management were compiled and inconsistent recommendations identified. Currently available pressure ulcer guidelines were found to differ in definitions, aspects of care, validation, evidence criteria, and procedural recommendations, potentially affecting consistency and quality of all aspects of pressure ulcer management, including diagnosis, prevention, treatment, and outcomes measurement. To address these inconsistencies, a comprehensive list of Pressure Ulcer Care Initiative (PUCI) steps was prepared for content validation and posted on www.aawconline.org, enabling healthcare professionals interested in improving the consistency and quality of pressure ulcer prevention and care to participate in this process. All steps with a content validity index >0.75 (rated clinically relevant by survey respondents) and/or with A-level standardized clinical evidence support will be included in the comprehensive PUCI guideline. Content validation of recommendations is an important first step to improving the consistency of pressure ulcer care.

KEYWORDS: *pressure ulcer, guideline, evidence, development, content validity*

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Pressure ulcers (PU) place major social, clinical, and economic burdens on society. They lengthen hospital stays, increase morbidity and mortality, and decrease patient quality of life.¹ In the US, PU-related hospital stays increased from 280,000 cases in 1993 to 455,000 cases in 2003. Pressure ulcer treatment costs increased from an estimated \$1.3 billion in 1992 to \$17.2 billion in 2003, resulting in an average cost of \$37,800 per person with a PU.² Likelihood of developing a PU increases with length-of-stay in a care setting, immobility, and increasing age.¹ United States PU point prevalence (ie, the percentage of at-risk patients having a PU at any point in time) has been reported as 3% to 10% in home care and approximately 15% in acute care.² In the UK General Practice setting from 1988 to 1996, annual period PU prevalence (percentage of patients reported with a PU during 1 year) increased with age from <1% of those 65 or older to 3.3% for persons >95 years of age.¹ Prevalence, incidence, and cost reporting methods vary within different healthcare systems, so the true magnitude of the burden of these wounds is difficult to estimate.

Evidence-based patient, skin, and wound care guidelines have been shown to reduce PU incidence³⁻⁶ as well as healing time and costs of caring for existing ulcers.⁷⁻¹⁰ Currently, 10 guidelines on the US Division of Health and Human Services Agency for Healthcare Research and Quality (AHRQ) National Guideline Clearinghouse (NGC) website focus on prevention and treatment. Healthcare professionals depend on these guidelines to help them standardize care, prevent and manage these ulcers, and meet reimbursement requirements or litigation challenges. In many US settings, if a patient develops a preventable PU or has a PU with poor outcomes, providers may face negative reimbursement consequences.

Clinical practice guidelines are designed to meet the need for “systematically developed statements to facilitate practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.”¹¹ A guideline

best enables translating knowledge into decisions if it is clear and precise with unambiguous language and logical, easy-to-follow recommendations annotated with the best available evidence.¹² Such guidelines inform healthcare professionals about best clinical practices, which are simultaneously 1) supported by the best research evidence available, linking guideline decisions to desired outcomes, 2) designed to supplement clinical skill and expertise for appropriate selection and application, and 3) responsive to patient desires, values, capabilities, and preferences.¹³ For example, the Joint Commission uses evidence-based standards, clinical guidelines, and quality measures¹⁴ in its Disease-Specific Care Certification Program.¹⁵

It can be unclear which documents have been agreed on by a panel of experts (consensus statements), which have been validated by formal peer review (guidelines), or whether clinically relevant guideline outcomes have been confirmed in a prospective controlled clinical trial (standards).¹⁶ As a result, selecting a guideline or specific guideline recommendation to optimize PU outcomes in a clinical setting can be a confusing process. A guideline summarizing all clinically relevant (ie, with formal measured content validity) PU steps with best available evidence supporting each step would improve patient-oriented care decisions. Evidence for each step of PU care could give professionals a tool both to reduce

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KEY POINTS

- Healthcare professionals looking for guidance on how to optimize pressure ulcer prevention and care by reviewing existing guidelines may find less clarity and more ambiguity than anticipated.
- In addition to a general lack of underlying evidence to support certain recommendations, the AAWC Wound Care Guideline Subcommittee found important differences between currently available pressure ulcer guidelines.
- To help improve the consistency of pressure ulcer care, the subcommittee developed clinical evidence criteria, including a comprehensive list of Pressure Ulcer Care Initiative steps for content validation by interested healthcare professionals.
- All interested healthcare professionals are encouraged to visit www.aawconline.org and participate in this important process by December 15, 2008.

patient risk for PU development and to treat an existing PU. Increasing use of such evidence to supplement clinical expertise and optimize institutional PU protocols can improve outcomes and support reimbursement of PU prevention and care while limiting PU-related costs, litigation, and fines. To this end, the Association for the Advancement of Wound Care Guideline Subcommittee (AAWCGS) reviewed existing PU guidelines to assess the need for a comprehensive content-validated PU guideline annotated with summaries of best available evidence supporting each step of current PU guidelines.

Methods

Participants: the AAWCGS. The multidisciplinary, all-volunteer AAWCGS included five Certified Wound Ostomy Continence Nurses (CWOCNs) — one also is an APRN; one physician with a specialty in General Surgery; two Physical Therapists — one additionally qualified as a DPT, CWS; and two PhDs. Authorized by the AAWC in October 2007, the team first met January 15, 2008 by teleconference and adopted a goal of providing a comprehensive, clear list of content-validated steps of PU care with a succinct summary of best available evidence supporting each step. Assessing professional needs for such an initiative was the first step toward that goal.

Compiling PU recommendations via a guideline literature search. The AAWCGS compiled a comprehensive list of treatment recommendations for PU patient and wound management, including diagnosis, risk assessment, treatment, and prevention from guidelines in the NGC as of June 1, 2008, plus those of the Wound Healing Society and current drafts of European Pressure Ulcer Advisory Panel (EPUAP)^{17,18} and National Pressure Ulcer Advisory Panel (NPUAP)¹⁹ guidelines. This comprehensive list of PU management recommendations became the Pressure Ulcer Care Initiative (PUCI), designed to guide professionals toward a content-validated, comprehensive PU guideline. Redundant steps were combined and the language of each step of care was simplified and clarified. All PUCI steps of prevention and care then were prepared for a content-validation survey,^{23,24} accessible online at the AAWC website, www.aawconline.org.

Results

Pressure ulcer guidelines evaluated by the AAWCGS included the NPUAP PU guidelines draft, 10 articles from the NGC website,^{20,21,30,33-37} and documents published by the Wound Healing Society.³⁸ Guidelines varied in definitions, procedures, content, professional focus, evidence basis, and degree or methods of validation. For example, definitions of PU severity differed between expert panels from Europe and the US (see Table 1), although the pathophysiology of PU appears similar in patients around the world.

Recommended PU assessment procedures also differed among guidelines. Reliable, valid, accurate PU assessment is vital for appropriate PU management because it guides clinical decisions,²⁵ helps track PU progress over time, supports reimbursement, and alerts healthcare professionals when a PU is not responding to care.²⁶ Table 2 compares two common PU assessment scales^{27,28} — only one records several parameters that signal infection or new tissue damage, as well as wound depth,²⁷ a strong predictor of healing time.³⁹ One uses geometric measurement of wound length and width²⁷; the other uses anatomic measurements.²⁸ Neither geometric nor anatomic length x width is perfectly accurate in measuring wound area, but geometric clinical wound measures have been shown to be more reliable than anatomic measures³¹ and have been validated in a clinical cohort³² of 260 wound patients as an effective measure of wound area consistently predicting healing ($P < 0.05$).

In addition, simple geometric measures provide accurate reliable estimates of percent reduction in wound area over time because they minimize error of area estimation during successive clinical assessments as wounds change in shape and orientation along the body axis during healing or deterioration. Evidence³² validated geometric length x width to estimate wound area percent change over time. Low percent change identifies nonhealing PUs after as few as 2 weeks.²⁶ Thus, simple geometric length x width can help identify a nonhealing PU, supporting clinical decision-making.

Guidelines for PU prevention also differed in recommendations for patient skin care and protection, positioning, and pressure-relieving devices. A National Guideline Clearinghouse™ synthesis¹¹

TABLE 1
NPUAP AND EPUAP PRESSURE ULCER (PU) CLASSIFICATION DEFINITIONS

NPUAP Stage	Defining Characteristics NPUAP⁴⁴	EPUAP Grade	Defining Characteristics EPUAP⁴⁵
Suspected deep tissue injury	Purple or maroon discolored skin or blood-filled blister; may be painful, warm or cool, boggy or firm Difficult to detect if skin tone dark <i>Further description:</i> Evolution may include thin blister over dark wound bed; may progress to thin eschar cover; may evolve rapidly exposing additional layers of tissue, even with optimal treatment	Not graded	None specified
Stage I	Intact skin with non-blanchable redness Localized usually over bony prominence. Darkly pigmented skin may not blanch visibly. Color may differ from surrounding area <i>Further description:</i> May be painful, firm, soft, warmer or cooler than adjacent tissue; may indicate PU risk	1	Intact skin with non-blanchable erythema; difficult to identify in darkly pigmented skin
Stage II	Partial-thickness loss of dermis; shallow open ulcer; red or pink wound bed without slough or bruising. May be intact or open serum-filled blister <i>Further description:</i> Shiny or dry shallow ulcer; if bruised, suspect deep tissue injury; not skin tear, tape burn, perineal dermatitis, maceration, or excoriation	2	Partial-thickness skin loss involving dermis and/or epidermis superficial, presents clinically as abrasion, blister or shallow crater
Stage III	Full-thickness tissue loss Subcutaneous fat may be visible. No tendon, muscle or bone visible or palpable. Slough does not obscure depth of tissue loss; may be undermined or tunneled <i>Further description;</i> Depth varies with location: shallow on bridge of nose, ear, occiput or malleolus or deep where fat layer is thick	3	Full-thickness skin loss involving damage or necrosis to subcutaneous tissue. Down to but not through fascia. Deep crater with or without undermining of adjacent tissue
Stage IV	Full-thickness tissue loss; exposed bone, tendon or muscle visible or palpable. Slough or eschar may be present on parts of ulcer. Often includes tunnelling or undermining. <i>Further description:</i> Depth varies with location: Shallow on bridge of nose, ear, occiput or malleolus; may extend into muscle and/ or supporting structure; osteomyelitis possible	4	Extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures with or without full-thickness skin loss
Unstageable	Full-thickness tissue loss. Base of ulcer bed covered by: slough (yellow, tan grey, green) or eschar (tan, brown or black) <i>Further description:</i> Until enough slough or eschar is removed to expose wound base cannot determine stage. Do not remove stable dry black heel eschar	No grade	None specified

reported similar categories of interventions covered by the two PU prevention guidelines as well as differences in procedure details. For example, the Registered Nurses Association of Ontario (RNAO) guideline³⁰ recommends turning every 2 hours only for high-risk patients but the Hartford Institute for Geriatric Nursing³⁵ recommends this approach for all at-risk patients. Only high-density foam was mentioned to reduce interface pressure by the RNAO guideline; the Hartford guideline makes no mention of foam but describes RNAO Level II (corresponding to research level B) evidence supporting other pressure-reducing devices such as static air, alternating air, gel, or water mattresses. Such discrepancies can cause confusion and increase liability.

In terms of professional focus, some guidelines focused on nursing aspects of pressure ulcer management while others included more physician-oriented elements. Also, the PU guidelines evaluated differed in the quality of evidence criteria supporting their recommendations. The highest level of evidence usually required at least two clinically relevant PU randomized controlled trials (RCTs) or a systematic review or meta-analysis including at least two RCTs.^{30,33} Occasionally, the highest level of evidence included consensus opinion or preclinical research not necessarily validated for PU.³⁸ This is consistent with findings of a recent systematic review⁴⁰ of 24 guideline appraisal tools, all of which lacked standardized criterion for rating guideline evidence. Clear, universal criteria for evidence quality for all PU guidelines would improve evidence-based PU care and patient outcomes and improve confidence in guideline use.

Discussion

The comprehensive list of PU management recommendations (the PUCI) compiled by AAWCGS confirmed the need for a comprehensive content-validated PU guideline. The AAWCGS proposes two steps to remedy the confusion resulting from PU guideline differences. By crafting and content-validating one comprehensive guideline for all steps of PU care (the PUCI), the AAWCGS intends to increase clarity and clinical relevance of all PU recommendations. Hopefully, summarizing the best available evidence supporting each step will forge construct validity to

underscore the efficacy of each recommendation of PU management or identify the need for further research to support its efficacy.

Content validity testing. Establishing content validity is crucial for any instrument that affects patient care decisions.²³ The PUCI included aspects of PU risk assessment and management, diagnosis and documentation, prevention, treatment, and palliative care options. To establish content validity of each PUCI recommendation, a judgment quantification process²³ will be used by a multidisciplinary convenience sample of volunteer wound care professionals responding to this publication. An Item Content Validity Index (CVI) will be calculated as the percent of respondents rating the clinical relevance or validity of that item as 3 or 4 using the 4-point Likert scale below:

- 1 = Not relevant
- 2 = Unable to assess relevance without further information
- 3 = Relevant but needs minor attention
- 4 = Very relevant and succinct.

Solicitation of Input

Professional, patient, or patient advocate readers are invited to participate as peer reviewers in this PUCI content validation to determine clinical relevance for each step. The content validation form may be accessed at www.aawconline.org. With permission, each participant will be credited as participating in this historic initiative. As an added token of AAWCGS appreciation, returning a completed PUCI content validation survey will qualify respondents for a drawing for one free new or renewed membership to the AAWC.

Corresponding CVI values + standard deviation from the content validation study will be published along with the evidence level for each PUCI item and a list of items that did not meet at least one of the two content or evidence-based construct validity criteria will be deleted. Content validity²⁴ data from all respondents, received by December 15, 2008, will be entered into an EXCEL[®] database and analyzed using the program's automatic functions for descriptive statistics. Mean content validity score and the proportion of respondents rating each item a 3 or 4 (on the CVI) will be calculated for each aspect of care.

TABLE 2
PRESSURE ULCER (PU) PARAMETERS ASSESSED IN TWO COMMONLY USED SCALES

Parameter	Pressure Sore Status Tool²⁷	Pressure Ulcer Scale for Healing²⁸
Location	Identified by bony prominence underlying the PU – eg, sacrum	Not recorded
Size	Longest geometric length (cm) x longest geometric perpendicular width (cm) rated on a 1-5 scale	Greatest anatomic head-to-toe length x greatest side-to-side width rated on a 0 to 5 scale
Depth	1 = Nonblanchable erythema on intact skin 2 = Partial-thickness skin loss 3 = Full-thickness skin loss 4 = Obscured by necrosis 5 = Full-thickness skin loss with damage to muscle, bone, or supporting structures	Not recorded
Edges	Rated based on distinctness, clear visibility, and attachment to wound base	Not recorded
Undermining	Longest zone of undermining found by gently probing PU perimeter with a sterile swab; rated on a 1 to 5 scale	Not recorded
Necrotic tissue type	Rated on a 1 to 5 scale based on visibility, adherence, and color	Rated on a 0 to 4 scale as tissue type: 4 = necrotic tissue (black, brown) 3 = slough (yellow or white) 2 = granulation tissue 1 = epithelial tissue 0 = closed/resurfaced
Necrotic tissue amount	Rated on a 1 to 5 scale as % of wound covered with necrotic tissue	Not scored
Exudate type	Rated on a 1 to 5 scale from none or bloody to foul, purulent	Not scored
Exudate amount	Rated 1 to 5 as none, scant, small, moderate, large	Rated 0 to 3 for none, light, moderate, or heavy
Skin color surrounding wound	Rated 1 = normal for ethnic group 2 = bright red and/or blanches to touch 3 = white or gray pallor or hypopigmented 4 = dark red or purple &/or non-blanchable 5 = black or hyperpigmented	Not scored
Peripheral tissue edema and induration	Each separately rated on 1 to 5 scales based on firmness of tissue and distance edema or induration extends from wound edge	Not scored
Granulation tissue	Rated 1 to 5 based on % of wound covered with granulation tissue	Rated under necrotic tissue type above
Epithelialization	Rated 1 to 5 based on % of wound covered with epithelium	Rated under necrotic tissue type above

Supporting evidence for PU care: construct validity. In addition to content validation, each AAWCGS member will search the MEDLINE, CINAHL, and EMBASE databases to identify and summarize three or more studies providing the best available evidence supporting each aspect of PU patient and wound management. Standardized strength of evidence ratings (see Table 3) adapted from prior AHRQ guidelines for PU care^{20,21} will be utilized along with diagnostic and prediction criteria adapted from the American Society of Plastic Surgeons (ASPS) Scales for Rating Levels of Evidence and Grading Practice Recommendations.²²

When complete, all PUCI recommendations that meet the standardized content validity and/or strength of evidence criteria will be made available for free public use on the AAWC website, www.aawconline.org and, if accepted, on the NGC website, www.guideline.gov. Other content-validated algorithms have been published for venous ulcers⁴¹ and general wound care.²⁹ In addition, the need for professional education to prevent PUs has been validated.⁴² The sole wound care guideline identified in this literature search with outcomes of its use validated as a standard in two prospective controlled clinical trials addressed venous ulcers.⁴³

Although still far from becoming a standard, the PUCI can grow and improve in content validity with input and review of the *Ostomy Wound Management* readership — people who qualify as having the interest and knowledge to rate the clinical relevance of these steps of PU care. *Ostomy Wound Management* readers, therefore, are encouraged to assist in PUCI development and content validation by rating clinical relevance of guideline items. This task should take less than 1 hour and may be done in intervals at the reader's convenience by downloading the virus-free file. Evaluating the clinical relevance of PUCI items will serve as preparation for the final construct validation step of the process — ie, determining the level of best available evidence supporting each item. Participants also are invited to share Level A evidence with the authors for any aspect of PU care. The final validated guideline will be updated regularly to incorporate new evidence, offering a benchmark for professional PU care and reimbursement.

Conclusion

Guideline quality is characterized by clear, precise, unambiguous language with logical easy-to-follow recommendations annotated with the best available evidence.¹² In addition to previously published differences in existing PU guidelines,¹¹ the authors review of 11 published guidelines, including 10 on the NGC website and two draft guidelines, showed important variations in definitions, procedures, content, professional focus, evidence basis, and degree or methods of validation. By crafting and content-validating one unified guideline for all steps to PU care (the PUCI), the authors hope to increase clarity and clinical relevance of all PU steps of care. Finally, by summarizing the best available evidence supporting each step, construct validity that supports the efficacy of each step of PU management will be forged and will clarify which components of care or recommendations need further research.

The resulting PUCI guideline will be neither a consensus-based document nor a comprehensive systematic review of all literature supporting each aspect of care. As a compendium of objectively rated, best currently available evidence supporting all recognized aspects of PU care, the guideline will reduce confusion. This “guideline of all guidelines” is designed to help wound care professionals provide consistent, high-quality PU care and improve patient and PU outcomes, professional satisfaction, and reimbursement while decreasing liability and costs of care. Absence of compelling evidence (B or C level) supporting a specific step suggests the step may not be better than preferred current practice and highlights opportunities for controlled research before that recommendation qualifies as recommended PU care. Periodic PUCI updates based on new evidence will perpetuate a continuously improving framework within which efficacy and clinical relevance of PU care can be further validated. - OWM

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TABLE 3
PRESSURE ULCER CARE INITIATIVE (PUCI) GUIDELINE EVIDENCE CRITERIA

- Level A.** Results of two or more RCTs related to pressure ulcers in humans provide support for efficacy or cohort studies to support diagnostic or prognostic aspects of care
- Level B.** Results of two or more HCTs or CCTs or a CCT and a RCT related to pressure ulcers in humans provide support. When validated as clinically relevant to pressure ulcer management, results of two or more controlled trials in an animal model provide indirect support
- Level C.** This rating requires one or more of the following:
 C1: Results of one controlled trial – eg, RCT or CCT or HCT
 C2: Results of at least two clinical pressure ulcer case series (CS) or descriptive studies or a cohort study relevant to pressure ulcers in humans
 C3: Expert opinion (EO)

RCT = randomized controlled trial; HCT = historically controlled trial; CCT = nonrandomized controlled trial with patients assigned according to convenience; CS = clinical case series; EO = expert opinion

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