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## Pressure ulcer management and research priorities for patients with spinal cord injury: Consensus opinion from SCI QUERI Expert Panel on Pressure Ulcer Research Implementation

### OVERVIEW

Pressure ulcers (PUs) are a serious and costly complication for many individuals with reduced mobility and sensation. Some populations, such as those with spinal cord injury and disease (SCI/D), remain at high risk throughout their lifetimes. Clinical observations and research have demonstrated staggering costs and human suffering because of PUs, including profound negative effect on general physical health, socialization, financial status, body image, and level of independence and control [1–2]. The International Pressure Ulcer Prevalence Study from 2006 to 2009 demonstrated a change in PU prevalence in the U.S. healthcare facility population. Overall, PU prevalence was slightly lower in 2009 than in 2006, but prevalence of suspected deep-tissue injuries (DTIs) increased during the same period [3]. Further investigation into the cause of these changes is warranted. DTI diagnosis frequency may have been affected by the addition of suspected DTI to the revised National Pressure Ulcer Advisory Panel (NPUAP) staging definitions in 2007 and rule changes for Centers for Medicare and Medicaid reimbursement.

Consideration of current evidence-based practice (EBP) is vitally important in the development and implementation of prevention, treatment, and rehabilitation strategies for PUs. A wealth of basic science is available, and early clinical trials are being carried out in the field of PU research; many of these trials were presented at the inaugural International Evidence Based Practice in Wound Care conference in 2006. The focus of the 2nd International Conference on Evidence Based Practice in Wound Care: The Effective Implementation of Pressure Ulcer Clinical Practice Guidelines (held in 2009) was the apparent “disconnect” between these early-stage research efforts and their implementation as routine clinical practice, as documented in current clinical practice guidelines (CPGs).

EBP and expert opinion are frequently combined during the formulation of CPGs. The balance of expert opinion and EBP in a given CPG depends on the maturity and depth of the research base. Currently, there are multiple CPGs for ulcer prevention and treatment, including the Consortium for Spinal Cord Medicine Clinical Practice Guidelines on Pressure Ulcer Prevention and Treatment (SCICPG) [4]. The common goal of these CPGs is to reduce the incidence and prevalence of PUs. Unfortunately, Thomason et al. found that although SCI physicians and nurses generally agreed with the SCICPG recommendations as written, they did not believe that these recommendations were

fully implemented in their respective clinical settings. Furthermore, clinical personnel identified lack of knowledge and organizational factors—such as communication difficulties across teams, shifts, and hospital departments—as the biggest barriers to implementing CPGs [5]. The effective selection and implementation of evidence-based guidelines for PU are critically important to improving rehabilitative and lifetime outcomes for people at risk for PU development. Education in the use and implementation of CPGs is an ongoing need. Additionally, a critical need exists to identify the remaining research gaps and pathways to effective implementation of research efforts in clinical practice.

An invited expert panel met in Cleveland, Ohio, on June 4, 2009, in conjunction with the 2nd International Conference on Evidence Based Practice in Wound Care, to develop a research agenda based on critical knowledge gaps regarding PUs in individuals with SCI and on implementation of advanced clinical practice. We report a literature-based discussion of the consensus panel conclusions. The meeting was sponsored by the Department of Veterans Affairs (VA) SCI Quality Enhancement Research Initiative (SCI QUERI).

The SCI QUERI works closely with the VA's SCI/D Strategic Health Group to identify the critical, time-sensitive issues important for Veterans Health Administration operations as part of the SCI QUERI mission: promotion of patient health, functioning, and quality of life through the implementation of evidence-based methods for enhancing patient self-management and disease prevention in the context of multidisciplinary care. PUs are a significant clinical problem in the SCI population and are a primary area of research focus.

## PANEL FORMAT

The multidisciplinary expert panel consisted of a balanced mix of clinicians and researchers, integrating physicians, nurses, engineers, and physical therapists with both health services and rehabilitation researchers. VA research leaders attended, and the VA Rehabilitation and Research Service and the VA

Office of Nursing Service were also involved since a critical need remains for preclinical and clinical pilot-phase research in PU management (see **Appendix** for panel membership, available online only).

The panel's mission was to develop consensus on a focused research agenda to address the critical gaps extant in evidence-based knowledge of PU care and to facilitate large-scale implementation of advanced clinical practice.

Panel discussions were divided into three sessions: (1) primary prevention—reducing the incidence of PUs, identifying high-risk patients, and developing models of rehabilitation and education; (2) secondary prevention—performing early/routine assessments and reducing recurrence of PU; and (3) tertiary prevention—treating and reducing disease-related complications [6]. Panel discussions used the SCICPG as an underlying guide.

While panel discussions were segregated by prevention level, several topics are clearly relevant to more than one aspect of PU prevention and/or management. For example, heterotopic ossification (HO) is potentially important in both primary and secondary prevention. Therefore, our discussion in this article is organized by the overarching categories of risk factors (ranging from the cellular level to the patient and environment), clinical management (at the patient, clinical microsystem, and clinical macrosystem level), education (of patient, caregivers, clinicians, and administrators), and environment of care (macrosystem).

The expert panel conducted a follow-up survey to prioritize the research gaps identified during panel discussions. Panel participants were asked to prioritize research topics, from the perspective of their individual expertise, in the four domains discussed. Panelists ranked what they considered the most urgent research areas using a multiple selection format. Selections were limited to the top three research themes in the domains of risk factors and clinical management and the top two research themes in the domains of education and environment of care. Validation measures were employed to ensure survey integrity. The survey was hosted on the online survey provider Question Pro (<http://www.questionpro.com/>). High-priority research topics were designated based on percentage of panel responses.

## PANEL FINDINGS

### Risk Factors

Reducing PU incidence and recurrence (primary and secondary prevention, respectively) depends on reliably identifying the risk factors that contribute to PU formation. It is well recognized that PU development involves multiple factors, and although many risk factors have been identified, many key questions in PU development remain unanswered and are in need of further research. Clinically, it is not known why some individuals develop recurrent PUs while others with similar predisposing risk factors remain PU free. This may be due to genetic predisposition, intrinsic inflammatory states, baseline nutritional status, or other unknown reasons. For example, the duration of applied pressure is known to be important, but anecdotal information suggests that some people can sit for many hours a day and not exhibit tissue damage while others may experience skin breakdown if they do not rigorously adhere to a frequent pressure-relief regime. Clearly there is no “magic number” for a single universal “safe loading” period or applied pressure that will not cause tissue damage [7].

Risk factors are organized by the SCICPG into the following categories: demographics (e.g., patient age, time since injury, and education), physical/medical (e.g., level and completeness of injury, mobility, incontinence, and comorbidities), and psychosocial (e.g., psychiatric disorders, cognitive impairments, substance abuse, and compliance). The panel emphasized that, in addition to the more easily quantifiable physical and biomechanical factors, it is important to review the psychosocial aspects of PU risk status. As described in the CPG, psychosocial includes aspects of both patients’ mental status (with specific emphasis on depression and anxiety) and psychosocial resources such as support networks and living situation.

### *Population Risk Disparities*

Several disparities in PU risk based on population warrant further research. While risk factors are widely agreed upon, the relative weight of these factors and their importance with respect to recurrence have not been established and probably vary across

patient groups [8]. The panel considered that further research is needed to establish whether factors that predict PU recurrence in the SCI/D population are similar to those in other high-risk populations, such as the older population and individuals with multiple sclerosis. Even within the SCI/D population there are differences between veterans and other SCI/D groups [9]. Much of the published research on risk factors for PUs focuses on either nursing home residents or on the population with acute SCI/D; the degree to which these risk factors apply to other populations has not been established. VA hospitals have a high proportion of individuals with long-term, chronic SCI (time since injury approximately 20 years) [10–11] who receive life-long care in both urban and rural areas, whereas Model SCI Systems Centers focus primarily on acute traumatic SCI in the urban areas. PU risk factors may possibly differ between these populations. Recurrence rates are known to be significant, ranging from 31 to 79 percent [12–16]. Data exist on possible risk factors for recurrent PUs; however, there is little information on characteristics of recurrence [17].

### *Mechanical Risk*

The etiology and biomechanics of PU development remain topics for further investigation. Clinically, it is known that tissue breakdown can originate both at the skin surface and in deep tissues [18–19]. Histological studies have shown that deep tissue often shows significant damage before any superficial damage is visible [20]. Recent preclinical studies indicate that deep-tissue loads, in particular internal strains, may be important factors [21–22]. Further preclinical studies are in progress to fully characterize these models. Research is also needed to establish the pathway for translation and clinical practice implementation of biomechanical interventions to prevent skin breakdown.

### *Cellular-Level Risk*

Biomolecular aspects of PU development are incompletely characterized and need further research. The effects of mechanical loading on cytokine release from the skin surface have been investigated in an in vitro model [23–24]. A pilot study by Sari et al.

evaluated creatine phosphokinase levels in wound exudate as a potential indicator of DTI in an animal model [25]. In the field of diabetic ulcer management, nitric oxide levels in wound fluid have recently been proposed as indicators of wound healing [26]. While using wound exudate as the source for biomarkers [27] could increase knowledge of the processes involved in tissue breakdown and/or healing, implicitly this approach could not facilitate primary or secondary prevention. The panel considered that centralized banking of wound tissues could provide a resource to advance the basic research still required to understand the biochemical precursors to PU development. Several commercial tissue banks exist that can provide a variety of tissues. The National Disease Research Interchange (NDRI) is a not-for-profit corporation, supported by the National Institutes of Health, that provides human cells and tissues for research. Currently these tissue banks tend to focus on specific disease etiologies, such as cancer, arthritis, and heart disease; however, NDRI could act as a broker to obtain wound tissues [28]. In addition, tissue from PU surgeries could be a valuable resource for tissue banking.

#### *Risk Assessment*

The panel recognized a continuing need for standardized assessment tools that would enable practitioners to identify PUs before tissue damage becomes clinically noticeable. Such tools are needed for all patient groups. The challenge of detecting early skin damage, i.e., stage I PUs, in individuals with darker skin is even greater than in the overall at-risk population. Advanced imaging techniques are being investigated that have the potential to improve primary prevention for these individuals [29–30]. Measurement of subepidermal moisture has been reported as a potential technique for detecting early PUs in individuals with dark skin [31], thus improving care for this patient population. Multispectral imaging has been reported as a potential method for detecting erythema in individuals with dark skin pigment [32]. Initial evaluations have been performed of diagnostic ultrasound [33–36], three-dimensional elastography [37–38], and methods to assess tissue viscoelasticity [39] for identifying and predicting

progression of DTI to fulminant PUs and assessing deep tissue strains in individuals with SCI. Further research is needed to establish reliability and efficacy in order to provide a sound basis for clinical implementation of interventions utilizing newer technologies for all individuals at risk for PU development.

#### *Physiological Risk*

The panel considered specific clinical factors within the SCI/D population that significantly affect PU risk status. For example, individuals with tetraplegia frequently have uncompensated hypotension combined with poor or absent venous return. These population-specific cardiovascular changes may be significant risk factors in PU development [40].

HO is also a well-known complication of SCI and has been linked to PU incidence [41–43], but the mechanism driving uncontrolled promotion of osteogenesis following SCI has not been investigated. A recent study in patients with traumatic brain injury (TBI) indicated that both osteoblast proliferation and differentiation are increased acutely following TBI [44]. Increased osteoblast activity is an indicator of HO, suggesting that further research in the SCI population may be warranted. The precise relationship between HO and PU formation remains to be determined.

Although specific patient groups have been defined as being at high risk of PU development, the effect of comorbidities has not been investigated in the population with SCI. For example, chronic obstructive pulmonary disease (COPD) was found to be associated with PUs in an outpatient geriatric population [45]. This area of research may benefit from preclinical modeling using the large databases available to VA researchers through the VA Information Resource Center [46] or the National Surgery Quality Improvement Program [47]. Additionally, the panel considered that clinical studies are needed regarding the effect of factors such as diabetes and obesity on PU development and/or recurrence.

#### *Aging-Related Risk*

The risk of PU development and/or recurrence may also be affected by comorbidities that develop over time. Extensive longitudinal cohort studies have

shown that aging with an SCI accelerates degenerative changes in health status [48–49]. Reports of the relationship between PU and time since injury are less consistent [8,50–51]. The panel considered that research in the SCI veteran population would be valuable in addressing these questions.

### *Environmental Risk*

Knowledge of how extrinsic environmental factors contribute to formation and recurrence of PUs remains incomplete. Environmental risk factors include the local skin environment (e.g., moisture level secondary to sweating and bowel or bladder incontinence), interface pressure and shear force between the skin and the support surface, friction [52], residential situation, and psychosocial support. These factors may interact with intrinsic physical/medical risk factors to increase PU risk. Certain environments are known to be associated with higher incidence of PUs, e.g., intensive care units (ICUs) and surgery. Recent VA quality improvement data from the VA Nursing Outcome database\* (second quarter of fiscal year 2008–final quarter of fiscal year 2010) indicate that the average rate of hospital-acquired ulcers is low (2.2%) in VA SCI Centers. Further research into high-risk settings for PU development, especially for community-dwelling individuals with SCI/D, is warranted.

### *Nutritional Risk*

The SCICPG suggests that general nutritional status is important in PU development and healing. In addition, the NPUAP White Paper on the role of nutrition in preventing and treating PUs advises that early nutrition screening provides a window for identification of PU risk. However, although the NPUAP provides guidelines for nutritional assessment and management of individuals with pre-existing PUs [53], there is little evidence supporting use of specific nutritional therapies for preventing and treating PU. Our panel deemed that further

research is needed into the effects of specific dietary elements in individuals with SCI/D, e.g., the potential role of proinflammatory diets in both acute and chronic SCI/D.

### *Pressure Ulcer Risk Assessment*

As noted previously, it is well recognized that prevention of PUs involves many factors. The correction of all risk factors for an individual with SCI/D can be both overwhelming and impractical to implement in clinical practice. The relative importance of both independent and dependent risk factors for PU prevention has not been investigated. A pilot study to differentiate degrees of risk in critically ill people was reported over 15 years ago [54] but has not been further developed. The Salzberg risk assessment scale, developed for SCI, focused on 15 risk factors, including urinary incontinence, autonomic dysreflexia, cardiac/pulmonary/renal/diabetic comorbidities, impaired cognitive function, cigarette smoking, residence in a nursing home or hospital, hypoalbuminemia, and anemia [55–56] but has not been further evaluated for validity and reliability [3]. The panel suggested that research is needed to develop weighted models of risk factors to enable efficient direction of clinical resources for effective primary PU prevention in the population with SCI/D.

The panel concluded that standardized and comprehensive documentation of PU risk factors and treatments could potentially help reduce both PU development and recurrence rates. Clinical and health services research is needed to develop and implement appropriate and effective documentation.

### **Education**

Education and awareness are critically important to prevent PUs. Educational programs may be directed to healthcare professionals, i.e., physicians, nurses, and nursing assistants, as well as to individuals with SCI, their families, and caregivers. The SCICPG recommend providing these individuals with information on effective strategies to prevent and treat PUs [4]. The panel discussed the continuing need for research regarding the most effective ways to educate all groups involved in PU prevention.

\*Internal communication: Office of quality and performance. VA Nursing Outcome database (VANOD). Washington (DC): Department of Veterans Affairs; 2010.

Knowledge of how best to educate patients and providers is necessary for the development of comprehensive and effective tools tailored to the individual's learning style. To be effective, education must motivate the at-risk individual and his/her provider to both learn and act on the information.

Effective primary prevention requires accurately identifying at-risk individuals, implementing appropriate preventative measures, and identifying early-stage tissue damage. Continuing education and collaboration is required to maintain the knowledge needed to perform these tasks. In the acute setting, education of clinical staff is important to improve PU awareness and to promote primary prevention strategies. Studies have shown that there is wide variation in nursing knowledge and implementation of PU preventive measures [57]. A significant drop in PU knowledge retained by critical-care and medical-surgical nurses was found 3 months after participation in a targeted learning activity [58]. Quarterly continuing education on PU prevention for all clinical staff involved with care of persons with SCI may be beneficial. Further research is needed to elucidate best practice for continuing education regarding primary prevention of PUs in the acute period post-SCI.

Nosocomial development of primary and recurrent PUs also varies in different healthcare settings and/or populations. In particular, serious illness requiring ICU admission and prolonged surgical procedures will both affect overall risk status. However, the primary risk factors involved will vary by patient and by setting. The panel considered that specific guidelines are needed for healthcare professionals working in these settings. Research is needed both to develop appropriate guidelines and to increase awareness amongst acute-care providers who traditionally may not regard PU prevention in populations with SCI/D as a priority.

Many clinical programs have recognized the need for early and comprehensive patient education during SCI rehabilitation. Sheppard et al. found that patients who had developed skin breakdown had poor knowledge about skin care [59]. This suggests that reinforcement of patient education at every practical opportunity would be highly beneficial. The panel considered that it was also important for

nonprofessional caregivers, such as family members, to be included in the educational process.

The SCICPG suggest that appropriate educational programs, which empower patients to take responsibility for skin care, are valuable for decreasing recurrence. However, research is needed to determine which approaches work best for different populations of individuals with SCI. Some research suggests that incentives can improve patient and provider participation in skin protective behaviors [60–61]. Determining of which incentives are effective, sustainable, and reproducible remains an area for future research.

Tertiary prevention of PUs is focused on minimizing the incidence of further related complications. The VA "Hub-and-Spoke" system was designed to ensure that all veterans with SCI have access to relevant clinical expertise. Within the veterans healthcare system, the SCI Center is the hub, with some less specialized PU care provided at the spoke facilities within the hub's associated SCI service areas. The educational goals for clinical teams at VA spoke facilities include knowledge of PU risk factors and potential complications. The panel considered that further research is needed to evaluate how to effectively disseminate information on best practices to spoke site community providers.

### **Clinical Management**

Clinical management of PU prevention and treatment is complex because of the many risk factors and environmental contributions to their formation. The SCICPG includes 32 separate recommendations. It would be very challenging and unrealistic to expect all recommendations be implemented concurrently. Providers and patients may feel overwhelmed by the numerous instructions for managing PUs. Moreover, few of these recommendations are evidence-based.

The clinical decisionmaking process is further complicated by the fact that the SCICPG weight all recommendations equally, which does not aid clinicians during a clinical decisionmaking process that is characterized by multiple competing priorities. The panel recommended further evaluation of the effect of adhering to all CPG-recommended behaviors. The effect can be studied from several angles, including

clinical outcomes such as decreased incidence and reduced recurrence rates.

### *Planning for Prevention*

The SCICPG support tailoring PU prevention programs to specific patient populations. Key differences exist between the population of persons with SCI/D and other at-risk groups (such as elderly nursing home residents) in muscle remodeling and atrophy [62–64]. For example, the primary diagnosis of SCI/D is a much more stable condition than the degenerative aging process, and loss of appetite is more frequent in the older population than in the SCI/D population. Thus, patient-specific risk factors and overall treatment needs are different.

The panel determined that additional research is needed in clinical care planning for PU prevention. The majority of at-risk patients, particularly individuals with SCI/D, can never be considered risk-free, although the absolute level of risk for an individual may vary over time. Furthermore, the predominant risk factors in the acute-care setting are different from those in community-dwelling population or long-term-care settings. The panel considered that research is needed to determine the need for different clinical care planning to address the different effects of episodically varying risk factors such as infection and chronic risk factors such as muscle atrophy.

The panel discussed clinical-care planning for continuous PU prevention and unanimously agreed that all PUs may not be preventable. A 1-day consensus panel on this issue was hosted by the NPUAP in February 2010 [65]. Given that the strongest predictor of PU development is having had a previous ulcer, anyone with a previous PU has to be considered at high risk for recurrence [66]. At present, the long-term follow-up of individuals whose PUs are healed varies. No evidence is available to guide clinical practice on what types of follow-up interventions these high-risk individuals should receive once their ulcer is healed. In many cases, clinical staff is so busy treating PUs that prevention may not receive attention or resources adequate to address the magnitude of the problem. It may be more effective to manage individuals with SCI/D and a history of PUs as if

they have a chronic systemic disease, similar to diabetes or COPD. For example, to optimize skin health, continuing risk-factor management and patient/care-giver awareness training should be provided to reduce both recurrence and further complications. The panel discussed whether a patient-centered or wound-centered approach would be more effective for long-term prevention. Patient-centered treatment models are relatively novel in PU management, and the panel considered that clinical research studies are needed prior to implementation.

### *Acute Care and Bed Rest*

The SCICPG recommend universal precautions for PU prevention, including turning every 2 hours while in bed for at-risk individuals. While this is a standard practice in the United States, the clinical practice in Europe (guided by the European Pressure Ulcer Advisory Panel guidelines) recommends individualized repositioning frequency based on patient factors and support surface [67]. The research basis for the 2-hour recommendation is inadequate [68]. Moreover, a recent meta-analysis by Krapfl and Gray found limited evidence that 4-hourly turning, when combined with an appropriate pressure redistribution surface, is equally effective as a 2-hourly turning regime [69]. The panel agreed with the SCICPG authors in recommending that further research is needed to determine optimal turning intervals.

The SCICPG recommend implementing PU prevention strategies during acute SCI to avoid prolonged immobilization. Unfortunately, implementation can be difficult during the acute postinjury period in the presence of bulky but medically necessary devices such as ventilators and external fixation devices. Optimally identifying at-risk individuals and early tissue damage and implementing preventive measures require an interdisciplinary team that brings together many different clinical skills. The implementation of interdisciplinary wound teams and specialized “turn teams” has been correlated with reduced incidence of PUs at all levels of patient care [70–73]. However, these teams were frequently implemented at the same time as other interventions. Therefore, the specific effect of the wound teams is difficult to ascertain without further research.

Determination of best practices for team composition and interaction is likely to be critically important [74]. It is recognized that not all disciplines will have the same professional education background or educational approach to PU management. It is not clear what knowledge the team leader should have, what disciplines ought to be represented on the team, or what frequency of rounding is needed for optimal management of PUs. In addition to team structure, it is necessary to establish guidelines for team interactions and communications, such as using digital images to monitor wound healing and implementing wound-care templates in the electronic medical records. Research is needed to determine the most effective techniques to promote interdisciplinary knowledge sharing and long-term implementation into routine practice.

#### *Skin Assessment*

Best practices for conducting skin inspections and wound-care rounds in hospitals have not been established. Likewise, the frequency and techniques for skin inspection in either the home or long-term-care setting are ill-defined. Despite the SCICPG recommendation for daily visual and tactile skin inspections, the expert panel agreed that visual skin assessment (VSA) remains an inadequate method for accurate prediction of PU development. There is evidence that VSA is difficult to carry out routinely for patients and providers. Although several risk assessment tools are currently in use, most of these tools demonstrate inappropriate sensitivity and specificity when applied to individuals with SCI/D. In addition, there appears to be some disagreement on the clinical effect of implementing routine risk assessment [75–77]. The expert panel considered that further research on how to provide timely and accurate feedback about risk factors to individuals with SCI/D and their caregivers is sorely needed.

#### *Tissue Health Assessment*

Although the assessment of PU risk is the goal of the SCICPG, several known risk factors currently cannot be assessed practically. For example, both normal and shear forces are known to be significant risk factors. Clinical pilot studies have

shown a strong association with duration of loading, particularly acutely following traumatic SCI [78–80]. Assessing shear directly would aid risk assessment. While theoretical models of the effect of shear stresses have been developed [81–83], appropriate sensors are at an early stage of development for clinical use [84]. The panel considered that research is needed to validate mathematical models incorporating the effects of shear stresses and to develop shear measurement devices. This preclinical research is needed prior to implementation as a component of clinical management.

#### *Support Surface Technology*

Although the SCICPG recommends many support surface and positioning methods for preventing and treating PUs, no uniform method or schedule for conducting a seating/support surface evaluation is available. Variability in data collection, interpretation, and use of quantitative measures is a barrier to the development of evidence-based guidelines for seating prescriptions [85–86]. For example, the best way to use the information obtained through interface pressure mapping is unknown [87]. The panel considered that further research is needed on support surface technologies and their implementation.

The standard of care for PU healing remains prolonged bed rest. In individuals with SCI/D, this is associated with other comorbidities, loss of function, and social isolation. Although prone carts are routinely used in the rehabilitation hospital setting, they remain impractical for use in most community settings. Current research into alternating-pressure support-surface technologies may redirect the PU prevention and treatment approach to pressure relief [88]. Ultimately, however, despite all improvements in support surface technology a universal optimal therapy is unlikely. Research-based principles that would allow individualized treatments based on each person's array of risk factors and environment have yet to be developed.

#### *Pressure Ulcer Treatments*

PU management can be classified broadly as either conservative or surgical. Conservative management can include both systemic (e.g., nutritional) and topical interventions (e.g., dressing change).



Treatments for PUs vary widely based on the stage and characteristics of the wound, e.g., amount of drainage, bacterial load, and presence of slough or eschar. The multiplicity of factors makes determining the standard treatment protocol for PUs difficult. Good data on which patients would benefit from conservative as opposed to surgical treatment are lacking. It may be beneficial to develop an algorithm or decision tree for PU treatment. Further research is needed to determine which treatments best promote complete healing under what circumstances. Ultimately, the development of evidence-based guidelines for the personalization of PU care would be beneficial.

Even when certain PU principles are commonly accepted, further research is required to determine best practices. For example, provision of a moist healing environment is known to promote ulcer healing [89–91], but optimal conservative methods for controlling moisture in the wound require further research. Controlled clinical studies of topical agents in PU management, a commonly accepted practice, have tended to use pre-post test study designs, focusing on interventions involving a single product [92–93]. A comparative effectiveness trial would be large and likely to become rapidly obsolete since new agents and dressings are continuously being released. A standardized assessment methodology based on quantitative benchmarks for wound healing would facilitate direct comparison of different types of intervention.

Another commonly accepted principle for wound healing is debridement. Debridement is a technique employed to remove necrotic materials from the PU and to promote healing. It can be divided into three major categories: enzymatic, mechanical, and sharp debridement. There are currently no standardized guidelines for best clinical practices in debridement to facilitate PU healing. The panel considered that clinical research is needed to determine both selection of technique and timing of debridement.

The surgical management of PUs remains controversial because of the high rate of recurrence after flap closure [16,94–96]. Further research is needed to clarify the role for surgery in PU treatment, because many questions remain. For example, it is unknown

whether surgical intervention decreases recurrence of PUs compared with more conservative treatments or whether it may increase incidence of PUs in other locations during the recovery process. There are other important postoperative practices for individuals with SCI/D for which there is little evidence to guide care, such as length of bed rest and progression of seating trials, which remain largely based on clinician practice and preference rather than empirical evidence. Collaboration between surgeons and rehabilitation teams in postoperative care may improve outcomes [97]. Further research is needed to determine the best clinical pathways for surgical management of PUs. Topics of interest include management of the pre- and postoperative risk factors, identification of the patient and provider factors that are most predictive of surgical success, determination of the intraoperative precautions that should be taken to prevent additional skin breakdown, and establishment of the best practices for closure surgeries to improve success rates and decreased recurrence. Additionally, the panel is still concerned regarding how to sustain adequate surgical support to perform these challenging surgeries in the future.

### *Home Management*

PU prevention and treatment for the person with SCI/D living at home vary widely depending on a number of factors, including the individual's level of injury and functional ability; availability of support services such as home nursing and health aides; and caregiver availability, clinical skills, and physical abilities. Demands on patients and caregivers dealing with a PU at home can be overwhelming, especially when external resources are limited. The panel recommended further research on best practices for helping caregivers manage at home.

The panel discussed the role that communications or distance technology could play in improving patient home care by continuing patient education and interactions with clinicians. Patient-specific information on PU risk factors could be made available to individuals, either on demand or regularly. In turn, the individual with SCI/D could have improved remote access to relevant information and expert clinical advice. The enhancement of patient/clinician

interactions, with personalized near-real-time feedback, could facilitate secondary prevention of PUs. Research is needed to evaluate whether technologies such as home telehealth, social messaging platforms, text messages, or “blogs” would promote adoption of protective behaviors and/or early notification of tissue damage, i.e., stage I PUs [98–99] when potentially, clinicians have an opportunity to make a difference in the course of the ulcer.

### *Recurrent Pressure Ulcers*

The NPUAP staging model states that once a PU develops, it is always described as at the maximum stage [100]. For example, if an individual has a grade IV right ischial PU during acute rehabilitation, any further right ischial breakdown should always be classified as grade IV. The current NPUAP terminology implies that this grading system should be applied even if the second event is 20 years later and only involves superficial breakdown. However, the panel deemed that the lack of a reliable and valid classification system for staging recurrent PUs is problematic. Should a wound returning a month later in a person with a healed PU be considered new or old? If a wound develops elsewhere but tunnels to a previous PU site, is this classified as the same ulcer? These issues should be systematically addressed to determine the true prevalence and incidence of recurrent PUs.

### *Characterization of Wound Healing and Chronic Wounds*

The current staging model also lacks clarification of the various physiological phases of wound healing. It is important to clearly develop a standardized definition of healing and a reliable way to determine if a wound is fully healed. The relationships between the clinical appearance of a healing wound, the physiological properties of the wound, and clinical outcomes are not well understood. Current definitions of wound healing include epithelialization or covering over of the wound area and require a temporal component to be clinically relevant. It would be beneficial to determine whether biomechanical information, similar to studies of tensile skin strength following surgical incisions, may be applied to healing ulcers to help quantify healing. This would require

development of both a precise clinical definition of wound closure, e.g., wound epithelialization, and a physiological definition based on the tensile strength of wound tissue and collagen organization. At this time, we lack cost-effective and noninvasive techniques that can be applied clinically to determine whether a wound is fully healed. Research in these areas would help determine which treatments promote complete healing.

Complicating the staging of PUs in individuals with SCI/D are those patients who develop chronic nonhealing ulcers. Further study is needed to determine at what point a wound should be categorized as nonhealing. It is unclear whether patients can live safely with prolonged open wounds because of a lack of longitudinal studies of nonhealing PUs. We need a more rigorous clinical definition of recurrence in nonhealing wounds. Clinical approaches to managing patients with chronically nonhealing wounds remain ill-defined and should be further investigated.

### *Tertiary Prevention of Complications*

Conventionally, long-term bed rest has been an important component of conservative management for PU healing. In individuals with SCI/D, bed rest is associated with loss of function and other comorbidities such as deconditioning, respiratory compromise, and social isolation [101]. Deconditioning, in turn, increases the risk of further complications such as pneumonia, with a highly deleterious effect on patient recovery. It may therefore be beneficial to allow patients to mobilize before a PU is fully healed. Questions remain regarding the appropriate therapy regimen to prevent complications of immobility. For example, should bedside cardiovascular exercise be used routinely to prevent deconditioning? If so, how should it be implemented such that worsening of the pressure ulceration is prevented? There is no evidence to guide clinical practice in determining activity levels to protect respiratory and functional health during conservative PU management. The panel considered that clinical studies are needed to evaluate whether PUs can heal effectively without complete bed rest. As a corollary to this approach, development of evidence-based activity criteria would be invaluable

for safely increasing sitting time and patient discharge to the community prior to healing.

Comprehensive assessment of the patient is important, as emphasized in the SCICPG, because PU development is considered a serious complication of SCI/D, which is associated with additional life-threatening complications. The most frequent cause of death among veterans with SCI/D was sepsis associated with genitourinary and PU sequelae [102]. However, the current mortality rate for PU-related complications in the population with SCI/D is not well characterized.

Multiple morbidities are associated with presence of PUs, such as osteomyelitis, bacteremia, and sepsis [103–104]. PU surgeries have been associated with wound dehiscence, postoperative hematoma/seroma, necrotizing fasciitis [105], and development of new intraoperative PUs. The incidence and prevalence of these complications are variably defined. The best means for tertiary prevention of such complications also remain unclear. Once complications develop, treatments remain largely provider-dependent rather than being primarily evidence-based. Additional research is recommended in these areas.

As previously stated, individuals with SCI/D are always at some level of risk for developing PU and subsequent infection. There is particular concern for patients with chronic nonhealing wounds, who typically have polymicrobial wound colonization associated with slowing of the wound healing process [106]. Colonization may eventually lead to local osteomyelitis or systemic infections. Though not the current practice, long-term prophylactic antibiotics have been used in the prevention of urinary tract infections and other complications of SCI/D [107]. Some clinicians believe these antibiotics may be useful for treating chronic osteomyelitis. However, it is unclear whether long-term prophylactic antibiotics are beneficial in tertiary prevention of morbidity and mortality due to SCI/D-related wound infection. Unfortunately, this strategy may also lead to the evolution of antibiotic-resistant bacteria and cause difficulty in identifying effective therapy [108–109]. The panel considered that additional research is needed to evaluate the relative benefits of long-term antibiotics with respect to tertiary prevention of PU complications in SCI.

## Environment of Care

The provision of care for preventing and treating PU in persons with SCI/D occurs in a variety of settings, from the acute to chronic, from inpatient to the community. Patient needs and the resources available for care vary based on level of injury and socioeconomic factors: level of education, insurance availability, and family support structure, to name a few. Consequently, there are significant challenges to care planning in this population, such as how to optimize provider team awareness, personnel/care-giver planning and stability, and administrative support of care systems in the population with SCI/D.

The SCICPG support tailoring PU prevention programs to specific patient populations. Facilities need to determine the best way to implement and maintain the SCICPG. However, all recommendations are given equal weight of importance, which is impractical for clinical implementation and may impair the capability of healthcare systems to prioritize how limited resources are allocated. As mentioned, the effect of adhering to CPG-recommended behaviors can be studied from several perspectives, which may include outcomes such as cost-benefit analysis, quality improvement, risk management, and patient satisfaction. Research is needed to develop appropriate and weighted guidelines that would optimize allocation of resources for all levels of prevention.

It is believed that current distribution of healthcare resources focuses more on treatment of PUs and their morbidities than on primary prevention. Unfortunately, the complete true costs of PU prevention and care—ranging from direct clinical expenses such as treatments and durable medical equipment to indirect costs such as loss of income, mobility, and independence—remain unknown. From the system standpoint, desire for lower costs and decreased liability may drive calls for the derivation of evidence-based-care algorithms from weighted CPGs, e.g., implementation of multidisciplinary wound teams in the acute and long-term acute care facility. It is important, therefore, to determine the cost-effectiveness of specific treatments and prevention activities [110–111]. Further research is needed in this area.

The exact circumstances under which veterans with SCI/D continue to receive care for skin breakdown at VA spoke sites versus being transferred to the hub site for PU care are not well understood. If PU care was more formally comanaged between the hub and spokes, real-time information on the number of stage II or greater ulcers and available resources to manage them could be shared. There would be better information about the magnitude of the problem within the system of care and there could be more centralized discussion about how best to deploy resources under this scenario. Technology, including video conferencing or other telehealth applications, may facilitate such clinical collaboration on care for patients at remote sites.

Recent External Peer Review Program data<sup>\*</sup> suggest that in the population of veterans with SCI/D, the majority of PUs are acquired at home. Most prevention strategies address the role that institutions play in prevention. However, very few large scale studies address how best to help community-dwelling persons with SCI prevent skin breakdown. Further implementation research is needed in this area. For example, studies focused on the discharge planning interface between hospital care and home care would be beneficial. Research is needed on best practices for providing continuity of home care to meet the PU prevention and treatment needs of patients with SCI.

## RESEARCH PRIORITIZATION SURVEY RESULTS

Panel participation in the survey was 81.8 percent. In the area of risk factor research ( **Figure 1**), the panel's highest-priority research topics are advanced imaging for early PU detection (18.5%), biomarkers for PU development (18.5%), deep tissue load and internal-tissue strains (11.1%), nutritional status and management (11.1%), and weighted risk

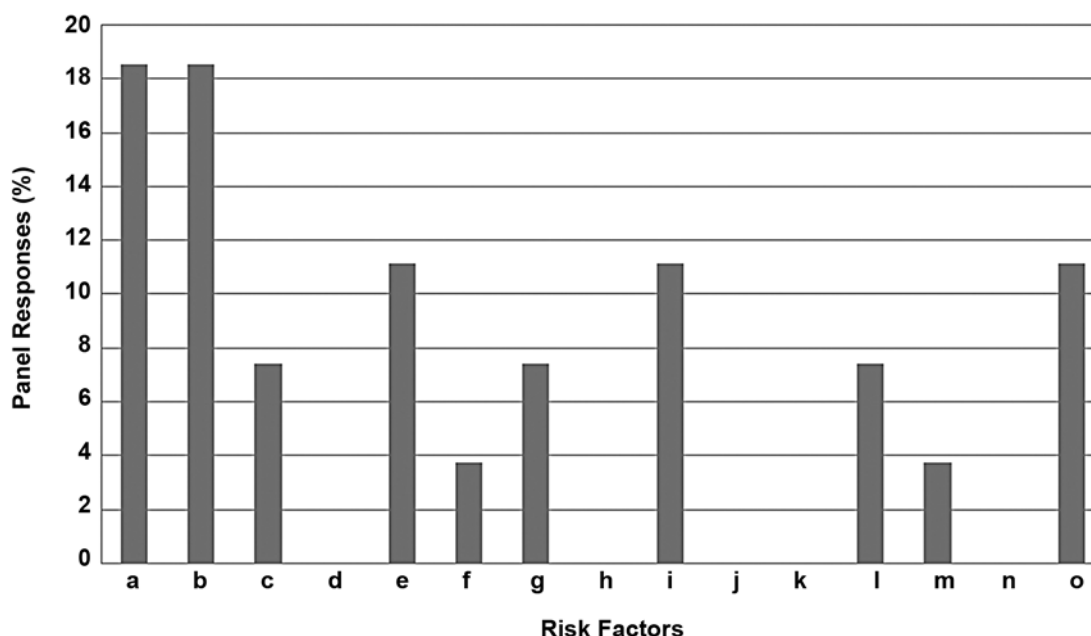
factor models (11.1%). For education ( **Figure 2**), the panel's highest-priority research topics are the development of efficacious learning tools for patients (33.3%), development of efficacious learning tools for caregivers (22.2%), and promotion of interdisciplinary team knowledge (22.2%). In clinical management ( **Figure 3**), the highest-priority research topic is the pathway for conservative and surgical management (18.5%), followed by the effect of interdisciplinary wound teams (11.1%), standardization of seating/support surface evaluation (11.1%), and telehealth assessment (11.1%). Highest-priority research topics in environment of care ( **Figure 4**) include the systematic implementation of standardized PU care programs (38.9%), methods for effective transition of PU care from the inpatient to home settings (22.2%), and best practices for the management of patients with SCI and PU who reside far from an SCI Center (16.7%). The panel hopes that the coordinated development of this prioritized research agenda will spur future PU research and increase funding sources to finance such endeavors.

## CONCLUSIONS/RECOMMENDATIONS

The consensus of the panel is that several critical knowledge gaps exist in the PU research base. One of the largest issues is our current inability to predict when an individual with SCI/D is developing an occult PU. Research on biomarkers of PU formation and healing and advanced imaging techniques for early PU detection are very high-priority items. Better understanding of nutritional risk factors and therapies, as well as enhanced insight into the relationship between internal tissue forces and PU formation, will also aid us in the principal goal of primary prevention.

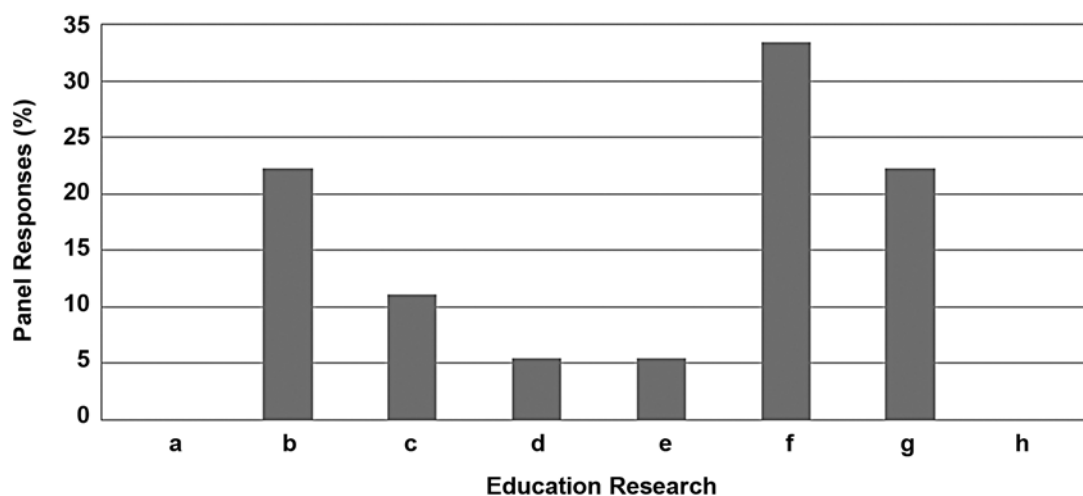
The panel also opined that we are falling short in our efforts to educate patients, families, and caregivers about optimal PU prevention and care in community settings. Developing effective learning tools for patient, family, and caregiver education on both prevention and treatment of PUs is a high priority. There also remains room to improve our utilization

<sup>\*</sup>Internal communication: Performance measurement reports. Washington (DC): Veterans Health Administration Office of Quality and Performance; 2010.



**Figure 1.**

Highest priority risk factor research. **(a)** Advanced imaging for early pressure ulcer (PU) detection, **(b)** biomarkers for PU development, **(c)** biomarkers for PU healing, **(d)** chronic systemic inflammatory states, **(e)** deep-tissue load/internal tissue strains, **(f)** genetic predisposition, **(g)** effect of comorbidities on PU risk in spinal cord injury (SCI), **(h)** microenvironment, **(i)** nutritional status and management, **(j)** physiology of PU, **(k)** psychosocial risk factors, **(l)** risk assessment tools for SCI, **(m)** risk factors for recurrent PU, **(n)** factors associated with aging with SCI, and **(o)** weighted risk factor models. Research topics **d**, **h**, **j**, **k**, and **n** had 0% response rate.



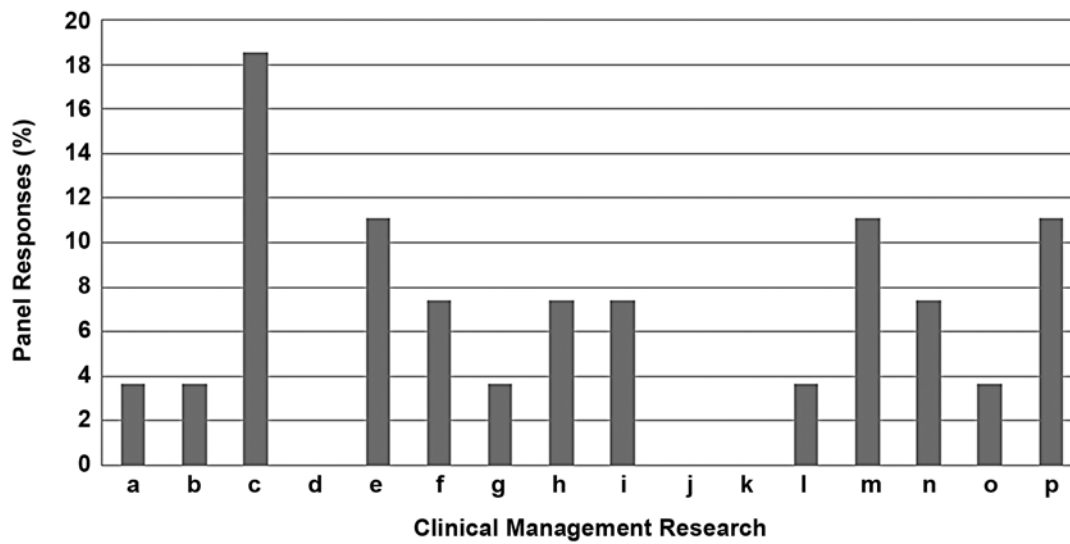
**Figure 2.**

Highest priority education research. **(a)** Continuing clinical education content/frequency, **(b)** development of efficacious learning tools for caregivers, **(c)** development of efficacious learning tools for families, **(d)** development of efficacious learning tools for inpatient clinical staff, **(e)** development of efficacious learning tools for outpatient clinical staff, **(f)** development of efficacious learning tools for patients, **(g)** promotion of interdisciplinary team knowledge, and **(i)** telehealth education. Research topics **a** and **h** had 0% response rate.

of interdisciplinary teams for preventing and treating PUs in the inpatient setting.

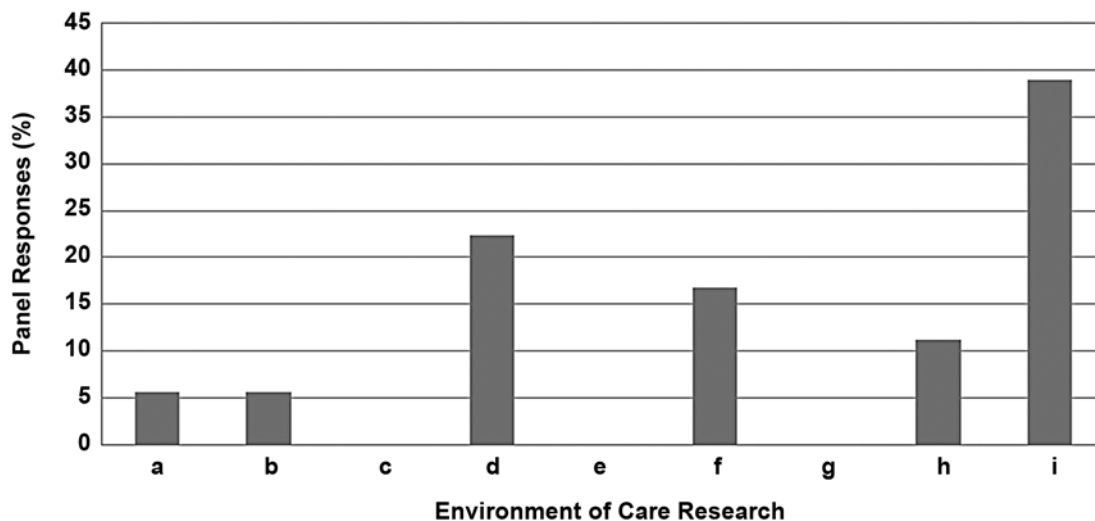
From the clinical management perspective, the panel considered that research to more rigorously

define pathways for both conservative and surgical management of PUs is most important, together with the need to standardize of evaluation methods for seating and support-surface interfaces. The effect of



**Figure 3.**

Highest-priority clinical management research. **(a)** Avoidance of deconditioning during bed rest, **(b)** best practices for home care management, **(c)** clinical pathway for conservative and surgical management, **(d)** effect of “Turn Teams”/turn frequency, **(e)** effect of interdisciplinary wound teams, **(f)** long-term surgical outcomes, **(g)** monitoring frequency of turning, **(h)** patient-centered treatment models, **(i)** personalized treatment planning, **(j)** selection of conservative pressure ulcer interventions, **(k)** staging of recurrent PU, **(l)** standardization of clinical documentation, **(m)** standardization of seating/support surface evaluation, **(n)** support surface technologies, **(o)** surgical techniques for PU treatment, and **(p)** telehealth assessment. Research topics **d**, **j**, and **k** had 0% response rate.



**Figure 4.**

Highest-priority environment of care research. **(a)** Allocation of resources for pressure ulcer prevention, **(b)** cost-effectiveness of PU prevention, **(c)** cost-effectiveness of PU care and treatment, **(d)** effective transition of PU care from inpatient to home settings, **(e)** high-risk settings for PU development, **(f)** management of geographically distant persons with SCI and PU, **(g)** optimizing inpatient care, **(h)** optimizing outpatient care, and **(i)** systematic implementation of standardized PU care programs. Research topics **c**, **e**, and **g** had 0% response rate.

interdisciplinary wound teams is also of high interest because they are believed to improve both prevention and healing of PUs in hospital settings. Furthermore, improved understanding of the appropriate implementation of telehealth evaluation methods may help pre-

vent and treat PUs in individuals with SCI and PU(s) in the community setting.

Research on the environment of care ranging from inpatient to community settings remains underdeveloped. The panel deemed systematic implementation of

standardized PU prevention and care programs the highest priority.

Clearly, many critical multidisciplinary targets remain for PU research, ranging from primary to tertiary prevention, from cellular mechanisms of healing to treatment methodologies. Extensive research is needed in the basic sciences and clinical applications, as well as on the large scale implementation of evidence-based clinical practice. The panel identified several important areas of research within the CPGs. The panel also concluded that certain evidence-based research on SCICPG topics, such as tissue-imaging technology, is nearing readiness for implementation trials.

It is also important that research addresses pathways to change in the healthcare system to effectively put new findings into operation. Effective change requires a culture of continuous education and improvement, complimented by a willingness to change when new evidence becomes available. It may be beneficial to model our efforts on VA National Systems Redesign techniques [1–12] to expedite timely adoption of EBP for preventing and treating PUs. Successful advancement of PU prevention across the VA system will decrease treatment costs and improve quality of life for our veterans with SCI/D. It may also serve as a model for care system changes for individuals with SCI/D across the country and throughout the world.

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