Bruin Biometrics, LLC (BBI) is pleased to provide this series of white papers to help lay readers understand commonly debated topics in pressure ulcer research and clinical practice. These papers are the distillation of a comprehensive literation search and review, rather than the result of primary research.

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White Paper

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Can Pressure Ulcers Be Prevented?

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Introduction

A health care facility's pressure ulcer prevalence rate is generally considered an indication of the quality of care that facility provides. Accordingly, reducing pressure ulcer prevalence is an urgent need for providers across all care settings. Unfortunately, pressure ulcer rates are stubbornly persistent; the number of hospitalizations in the United States with a secondary diagnosis of pressure ulcers increased by 80% between 1993-2006.[i] By 2008, the overall pressure ulcer prevalence in U.S. hospitals was 13.5% in acute care settings and 22% in long-term care facilities.[ii]

Since October 1, 2008, the Center of Medicare and Medicaid Services (CMS) has classified advanced Stage III and Stage IV pressure ulcers as avoidable hospital acquired conditions, or "never events." Likewise, the National Health System in the United Kingdom adopted a zero tolerance approach to pressure ulcers in 2010.[iii] Avoidable pressures ulcers are defined as those a patient develops as a result of the facility caring for the patient failing to:

- evaluate the resident's clinical condition and pressure ulcer risk factors;
- define and implement interventions consistent with resident needs, goals, and recognized standards of practice;
- monitor the impact of interventions; or,
- revise interventions as appropriate.[iv]

Effective October 1, 2013, CMS and other private insurers in the United States will no longer reimburse hospitals for advanced pressure ulcer cases that are not identified as present on the patient's admission to the hospital or that develop due to negligent care described above. However, because pressure ulcer incidence in hospitals, long-term care facilities, and nursing homes continue to persist[ii] despite employing prevention techniques, many clinicians have wondered, "Are pressure ulcers truly avoidable?"

Most – But Not All – Pressure Ulcers are Avoidable

To address this question, the National Pressure Ulcer Advisory Panel (NPUAP) hosted a multidisciplinary conference in 2010. The NPUAP convened a group of 24 clinicians: nurses, physicians, dieticians, therapists, and other professionals in pressure ulcer prevention and treatment. 80% of the panel agreed that most but not all pressure ulcers are avoidable.[v]

Numerous organizations, including the United States Agency for Health Care Policy and Research (AHCRP), publish and advocate the adoption of various best practices in pressure ulcer prevention. Fundamental components of all

pressure ulcer prevention programs include conducting comprehensive assessments to identify patients at the highest risk, performing and documenting regular skin inspections, ensuring patients maintain a proper diet, and minimizing moisture along the skin caused by urinary and fecal incontinence. [vi] Other effective preventative measures include frequent repositioning, regularly exercising, and employing proper support surfaces.

Risk Assessment

The current standard of care in pressure ulcer prevention begins with a comprehensive risk assessment. Clinicians evaluate patients in an effort to identify risk factors that increase a patient's likelihood of developing a pressure ulcer. One of the most widely used tools in pressure ulcer risk assessment is the Braden Scale.[vii] Developed in 1987 by Barbara Braden and Nancy Bergstrom, the scale is composed of six subcategories: sensory perception, skin moisture, activity, mobility, friction and shear, and nutritional status. Clinicians evaluate patients against each subscale, assigning a score on a numeric scale from 1 through 4, where 1 is the lowest score possible and 4 is the highest score possible. Scores are then totaled to quantify the patient's overall pressure ulcer risk level. Patients with a score in the range of 15-18 are considered low risk, 13-14 moderate-risk, 10-12 high risk, and 9 or below highest risk.[vii]

Despite its widespread use, the Braden Scale has its limitations. Issues that can arise when using the Braden Scale include subjective and inaccurate scoring for each subcategory, poor visual inspection technique, insufficient time to conduct an assessment, unclear wording within the instrument, and undervaluing the importance of accurate measurement.[vii] However, despite its limitations, the Braden Scale shows the best sensitivity/specificity balance when compared to alternative tools such as the Norton and Waterlow scales, which are routinely used in Europe.[viii] As displayed in the table below, the Norton Scale has less sensitivity and specificity than Braden;[viii] the Waterlow Scale offers a high sensitivity score, but low specificity.[viii] Finally, nurses' clinical judgment gives moderate scores for sensitivity and specificity; but is not a good pressure ulcer risk predictor.[viii]

Tool	Sensitivity	Specificity	Odds Ratio	95% Confidence Interval
Braden Scale	57.1%	67.5%	4.08	2.56-6.48
Norton Scale	46.8%	61.8%	2.16	1.03-4.54
Waterlow Scale	82.4%	27.4%	2.05	1.11-3.76
Clinical Judgment	50.6%	60.1%	1.69	0.76-3.75

Table 1: Risk Assessment Tool Comparison[ix]

The sensitivity, specificity, and positive predictive ability of risk-assessment tools are problematic in long-term care settings, because none of the tools account for all known risk factors. Nurses frequently combine use of a risk scale with their clinical judgment, and many patient risk factors often go unnoticed.[x] Worse, sometimes the tools often over-predict risk, leading to inefficient allocation of resources.[xi]

Skin Inspection

Following completion of patient risk assessment, clinicians are advised to conduct a thorough, visual inspection of the patient's skin, focusing on areas where pressure ulcers most commonly develop: the sacrum (43.9%), followed by the trochanters (17.9%), and the heels (13.7%).[xii] The presence of thin, fragile, warm, clammy, or oedematous (excessive swelling due to the accumulation of watery fluid in tissues) skin indicates increased pressure ulcer risk. Identifying scar tissue, dry patches or cracks, as well as areas where pressure ulcers previously formed also suggest that a patient is at an elevated risk for future pressure ulcer development.

Most importantly, proper skin inspection includes assessing the presence of nonblanchable erythema (redness of the skin surface that persists when pressure is applied) which is often the first sign of tissue destruction. Nonblanchable is indicative of a Stage I pressure ulcer.

Unfortunately, the quality of visual skin inspection is highly dependent on the skill of the caregiver, and wide and varying results are common. There are three significant problems with visual assessment:

- Visual assessment is **subjective**; differentiating between epidermal irritation and sub-epidermal injury is often more art than science. One research study showed that inter-rater agreement for the presence of erythema at the sacrum, right and left ischium, and buttocks resulted in kappa statistics (indicating degree of inter-rater agreement) ranging from 0.73 to 1.00.[xiii]

- Visual assessment is **unreliable**; surface discoloration associated with Stage I pressure ulcers is less evident in patients with dark skin tones. Studies indicate that African Americans experience a higher incidence of PU when compared to Caucasians (0.56 per person year compared to 0.35 per person year).[xiv]

- Visual assessment is **untimely**; pressure ulcers often occur suddenly without visual cues appearing in time to prevent them. In patients at high-risk for pressure ulcer formation, nonblanchable erythema can develop in as little as 2 hours.[xv]

- Visual assessment is **ineffective**; it is impossible to detect Deep Tissue Injury (a localized area of discolored, intact skin or a blood-filled blister indicative of damage to underlying subepidermal tissue) that develops according to the "Bottom to Top" pressure ulcer formation model. This model suggests that mechanical loading, friction, or shear impart an injury first to tissue closest to the bone, which then moves outward towards the skin's surface.[xvi] This Deep Tissue Injury (DTI) occurs.[xvii]

Ultimately, by the time tissue damage is visually evident at the skin's surface, significant damage has already occurred.

High Pressure Ulcer Incidence is a Systemic Problem

Effective risk assessment, comprehensive skin inspections, proper nutrition, adequate moisture management, regular movement, and specialized supportive surfaces are all necessary components to pressure ulcer incidence reduction. However, successfully and consistently implementing interventions in each of these domains is challenging. Research indicates that overall adherence to best practices in pressure ulcer prevention is low,[xviii] because best practices only address one aspect of pressure ulcer prevention. In reality, multiple, interrelated factors contribute to and increase the probability that a patient will develop a pressure ulcer, and high pressure ulcer incidence is a systemic problem.[xix]

To reduce pressure ulcer incidence and overall prevalence, a systems approach that addresses the external, institutional, execution, and patient factors (portrayed in the diagram below) that contribute to pressure ulcer development is needed.

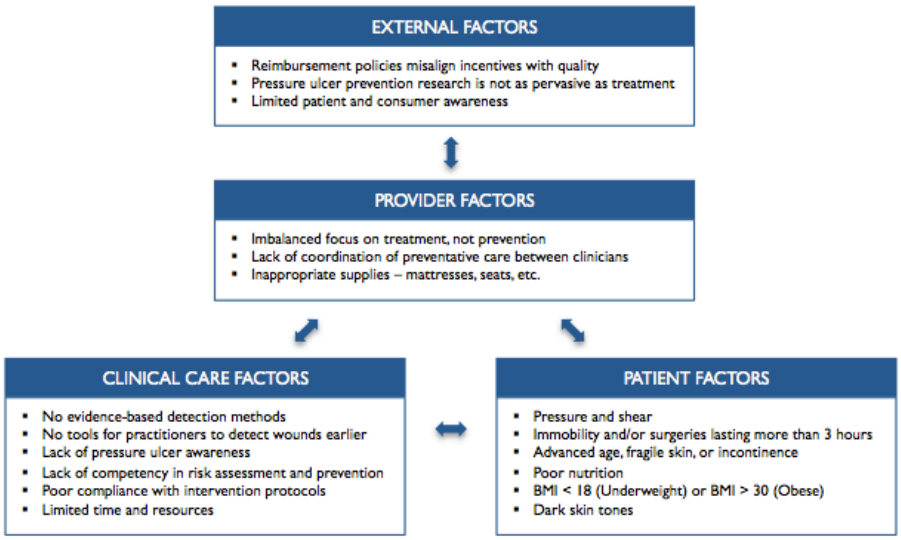

Figure 1: The Systemic Problem

The Bruin Biometrics Solution

Several pressure ulcer prevalence studies have been conducted demonstrating that almost half of all pressure ulcers are categorized as Stage I.[xx] This finding suggests that interventions to significantly decrease pressure ulcer incidence must occur before non-blanchable erythema – the definition of a Stage I pressure ulcer – is present on the skin's surface. Furthermore, the 2001 National Pressure Ulcer Advisory Panel Task Force acknowledged that there is no way to know what changes in tissue health occur beneath intact skin;[xxi] therefore, to improve both pressure ulcer prevention techniques and associated outcomes, a tool that can accurately identify and define deep tissue injury under intact skin is needed.[xxi]

To address this unmet need, Bruin Biometrics, LLC (BBI) has developed the SEM Scanner. SEM (subepidermal moisture) is a biophysical marker associated with the inflammatory response to injury indicative of tissue damage and incipient pressure ulcer formation.[xxii] In clinical studies, SEM has been found to reliably identify local tissue edema related to inflammatory changes that occur up to 10 days before damage is visible on the skin's surface.[xxiii] As researched and concluded by Barbara Bates-Jensen, PhD, RN, CWOCN, FAAN, one of the world's leading wound care experts, "SEM was higher (indicating increased edema and inflammation) when there was no

visible skin damage at the time, but erythema or Stage I pressure ulcer was visible on the skin one week later."[xxiv] By detecting SEM build-up and thus pressure ulcer formation before it surfaces, detecting SEM enables clinicians to prevent the formation of pressure ulcers. Bates-Jensen's studies also indicate that SEM is capable of differentiating between erythema and Stage I pressure ulcers, even in subjects with dark skin tones.[xxiv]

The SEM Scanner, conceived by Bates-Jensen and developed by the UCLA Wireless Health Institute, is a hand-held, portable device that noninvasively detects changes in subepidermal moisture. The device employs sensor technology to measure relative tissue surface electrical capacitance through application of low amplitude signals emitted by electrode structures placed on the subject's skin. The surface electrical capacitance value can be used to indicate the presence of subepidermal moisture, an indicator of, tissue damage.

Incorporating the SEM Scanner™ as an adjunct to the current standard of care in pressure ulcer prevention fosters early detection that can lead to effective interventions and decreased pressure ulcer incidence. The SEM Scanner's advantages over other diagnostic modalities include:

- Objective, evidence-based measurements
- Non-invasive, low risk, rapid results
- Relative low cost
- Applicability across all skin colors
- Clear risk assessment documentation
- Can be used in any clinical setting by nurse technicians and medical assistants
- Minimal technical skills for operation: 94% of nurses who tested the SEM Scanner were able to accurately use the device with only 10 minutes of training.

Providers can easily adopt the SEM Scanner into existing workflows. After conducting a holistic risk assessment (with the Braden, Norton, or Waterlow scales) and then performing a visual skin inspection within two hours of each patient admission, the SEM Scanner can be used to measure a patient's subepidermal moisture levels. These readings can then be used to target patients at the highest risk for pressure ulcer development, and thus efficiently deploy interventions to prevent ulceration.

Most importantly, incorporating the SEM Scanner into facility practice employs a comprehensive, systems solution to the systemic problem of high pressure ulcer incidence:

- **External factors:** The SEM Scanner is the only evidence-based pressure ulcer detection method, capable of identifying patients at

risk of developing a pressure ulcer up to one week before damage is visible at the skin's surface.

- **Institutional factors:** The SEM Scanner reporting tools enable providers to quickly and easily document pressure ulcer risk assessment, enabling transparency and driving compliance with hospital pressure ulcer prevention protocols.
- **Execution factors:** The SEM Scanner is quick and easy to use; it takes the "art" out of pressure ulcer risk assessment, thereby efficiently utilizing clinician's time.
- **Patient factors:** Current patient risk profiles are broad; but the SEM Scanner enables refined risk management and monitoring of patients who are at the highest risk for pressure ulcer development.

With the SEM Scanner, hospital leadership can engage hospital staff in driving hospital acquired pressure ulcer incidence to zero through improved awareness and compliance, targeted identification, and effective risk management. For the first time, preventing pressure ulcers is finally possible.

Endnotes

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