

A Pressure Injury Prevention (PIP) Quality Improvement Pilot Of Sub-Epidermal Moisture Scanning In Acute Care

By Marlene Varga MSc BScN, Misha Jadoo BScN, Sebastien Normandin BHK ARJO and Jacqueline Brayshaw BN RN

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Introduction

A pressure injury is defined as localized damage to the skin and/or underlying tissue, due to pressure or pressure in combination with shear.¹ Patients with activity/mobility impairment are

at highest risk due to their inability to safely reposition or mobilize themselves, leaving them exposed to prolonged unrelieved pressure and/or shear.^{2,3} In Canada, the prevalence of pressure injuries is 26% with 25.1% acute care, 29.9% non-

acute care, 22.1% mixed health-care settings and 15.1% in community care settings.⁴ Hospital-acquired pressure injury treatment costs range from \$44,000 for Stage 2 to \$90,000 for Stage 4.⁵ The cost to treat pressure injuries is substantially higher than prevention.^{6,7} The burden on those living with pressure injuries⁸ and those engaged in efforts to prevent and treat them is enormous.⁹ While a zero-pressure injury rate is desirable, it also is very unlikely,¹⁰ however there is consensus that most pressure injuries are preventable.¹¹

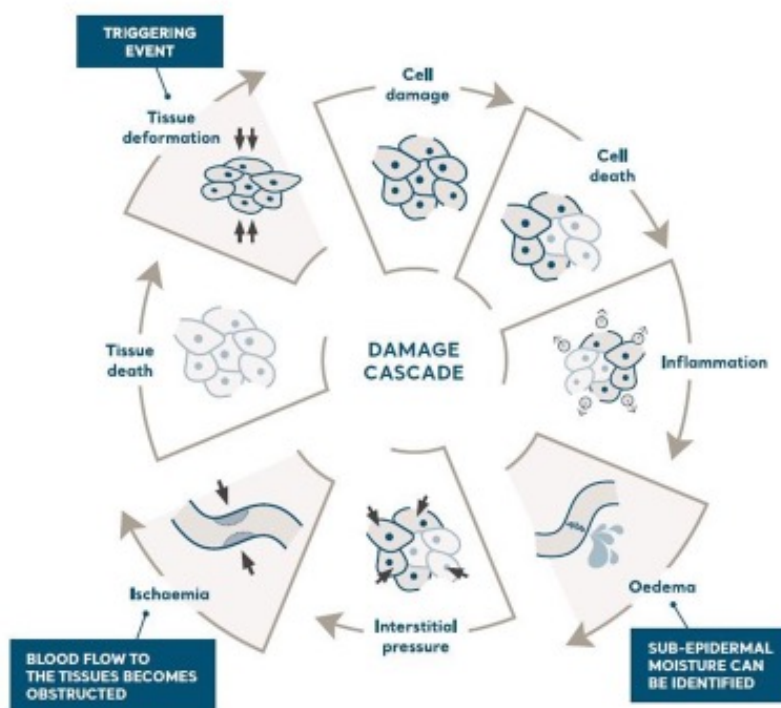
Risk And Skin Assessment

The use of a validated risk assessment tool is recognized as the initial crucial step in prevention.¹ Risk assessment tools are subjective and not anatomy specific, with low sensitivity and specificity (50.6% and 60.1%), depend on independent factors such as age, nutrition, activity, mobility, and skin status¹²⁻¹⁴ and are weighted the same, diluting the impact of immobility on pressure injury development.¹⁵ Visual skin assessments offer limited predictive validity¹⁶ and are limited to visible and palpable changes to the skin, and are expertise dependent.¹⁷ Darkly pigmented skin rarely shows a blanching response, and erythema may be hard to detect,¹⁸ potentially contributing to more severe outcomes in these populations.¹⁹ Risk and visual assessments are not intended to assess or identify existing pressure damage^{16, 20-22} and risk assessments do not provide information on how patients are responding to adverse events of pressure and shear forces. The visual and physical signs of tissue damage are usually only visible on the skin surface 3-10 days after damage occurs²³ suggesting that skin health can significantly deteriorate before interventions. The current approach of visual skin assessment is a macroscopic observation attempting to identify microscopic changes and identifies existing damage rather than preventing it.²⁴⁻²⁶ Relying solely on the current standard of care means that early detection and timely appropriate, anatomy specific interventions are often impossible.

Pressure Injury Damage

Early pressure-induced cell and tissue damage begins at the cellular level (Figure 1).²⁷ Ischemic damage caused by occlusion of blood vessels can take several hours to develop, however, cell deformation occurs within minutes when tissue is exposed to high pressure strains.²⁷⁻³⁰ There may be clinically significant tissue damage before visual or tactile manifestations are observed. The contemporary understanding of the pathophysiology of pressure injuries reveals that tissue inflammation, the first response to damage, causes increased dilation and permeability of surrounding blood vessels.³¹ Increased vascular permeability allows fluid to enter the extravascular space causing a build-up of edema or sub-epidermal moisture (SEM) which is invisible to the naked eye.³¹ SEM is therefore a biophysical marker, which if raised, enables the detection of pressure injuries before visual manifestation.^{23, 26}

Figure 1: Damage Cascade



Cycle of Pressure Injury: adapted from Gefen A, 202038. The SEM Scanner for Early Pressure Ulcer Detection: A 360-degree Review of the Technology. Wounds International. Vol 11, Issue 3: p22-30.

Method

The Provizio™ SEM Scanner (Bruin Biometrics LLC, USA), a CE marked class 11a, FDA approved, non-invasive, handheld skin assessment device, is recognized as an objective method for detection of early invisible tissue damage,³²⁻³⁵ and was selected based on a review of available technology.³⁶ (See Figure 2.)

The current clinical practice guidelines recommend the use of SEM as an objective biomarker of risk in adjunct to clinical skin assessment and when assessing individuals with dark pigmented skin¹ given the inherent subjectivity of these methods.

Clinical studies have determined that a SEM Delta (Δ) <0.6 can indicate lower risk for pressure injury while a SEM Delta (Δ) >0.6 is suggestive of increased risk.³² The device supports identification of specific anatomical areas at increased risk of pressure injury development on average of five days earlier than visual skin assessment.^{25,26,32,37,38} By implementing targeted prevention strategies earlier to specific areas of concern, tissue damage identified in the preventable stage may cease progression to tissue death.²⁴

The six-week pilot was designed as a quality improvement (QI) process to be used with minimal modifications to existing care pathways and was not required to be subject to institutional review board oversight and ethics committee approvals. Local operational approval was obtained to conduct the pilot on one Medicine unit at a large urban acute facility in Alberta, Canada. The pilot was guided by the *Promoting Action on Research Implementation in Health Services* framework,³⁹ which proposes that successful implementation is dependent on the interplay of evidence, implementation context

Figure 2: SEM Scanner



Source: Bruin Biometrics LLC

and facilitation. Local pressure injury data was collected by the local team using the standardized provincial audit tool. A medical unit with at-risk patients and strong leadership engagement in prevention was chosen for the pilot. The pilot was facilitated by one Clinical Nurse Specialist (CNS) and one Clinical Nurse Educator (CNE) implementation lead. A team comprising six front line nursing champions was identified in collaboration with the CNE and Unit Manager to facilitate implementation.⁴⁰ Additional implementation strategies included engaging with participants at multiple levels, fostering local ownership, employing improvement tools to generate practice-based evidence, conducting Plan-Do-Study-Act cycles to develop and refine implementation strategies and support capacity to implement evidence-based intervention.⁴¹

Six in-person 45-minute training sessions were offered to participants to choose from. Training was supported by industry in collaboration with the CNE and CNS and included a PowerPoint presentation detailing the technology, the standard operating procedure, the significance of SEM Delta (Δ) values and a review of the SSKIN+ bundle. Participants completed one scan on sacrum (Figure 3) and heel locations (Figure 4) of an anatomical model and one supervised return demonstration with a consenting patient. Three scanners and the single patient use sensors were placed in accessible locations on the unit. Pressure injury prevention pamphlets were made available for patients and families in a public area on the unit.

Figure 3: Sacral Scanning Locations

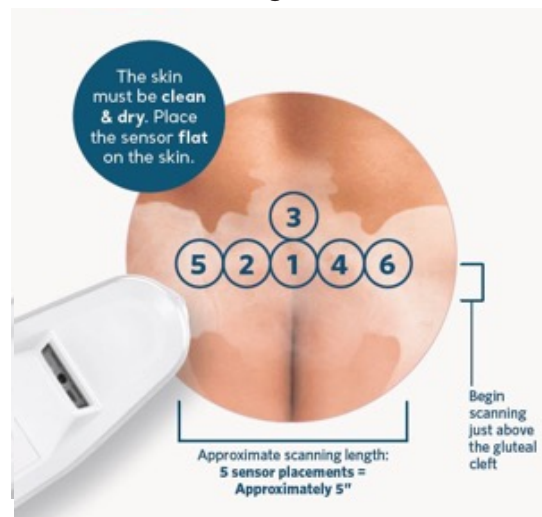


Figure 4: SEM Scanner Applied To Heel



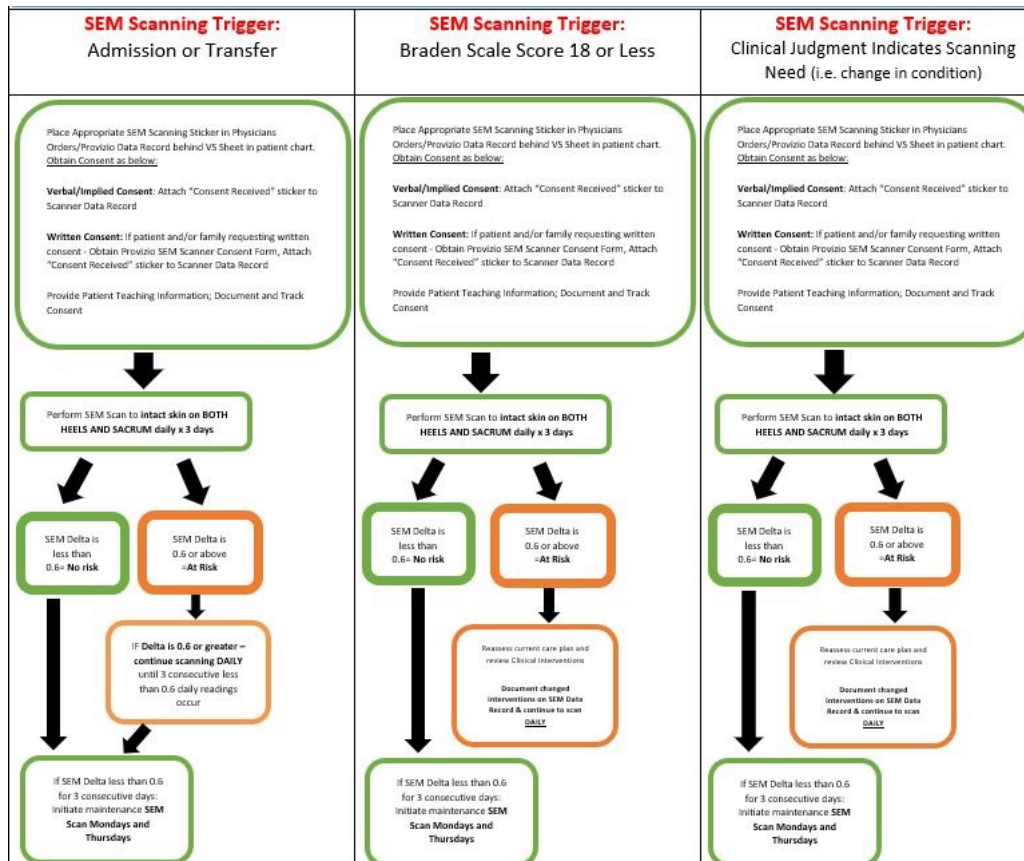
Scans were conducted according to the manufacturer's instructions. A process map (Figure 5) and inclusion criteria (Figure 6) were developed based on review of the literature and in collaboration with the distributor of the device and pilot team. Inclusion criteria included: minimum age 18, Braden Score ≤ 18 , implied consent, scanning locations accessible to scanning and intact skin. Exclusion criteria included Braden score > 18 , non-intact skin, safety risk to provider for restless or combative patients, patient conditions not appropriate for scanning, sites not accessible to scanning and refusal to participate. Written consent was available if desired from patients or families, otherwise implied consent was obtained.

SEM assessments were performed on the sacrum and both heels daily, in the morning during assessments. Standard of care was followed during SEM assessments including risk assessment with the Braden Scale and skin assessment to determine skin changes or redness. Assessments were documented on a data collection form. Scans were completed on included patients daily until three consecutive SEM Delta (Δ) < 0.6 were achieved at the sacrum and both heels. Then patients were transitioned to maintenance scanning Mondays and Thursdays. Following assessments, staff determined if the SEM scanner changed their clinical decision-making and documented subsequent interventions.

Figure 6: Inclusion/Exclusion Criteria

INCLUSION CRITERIA	EXCLUSION CRITERIA
<ul style="list-style-type: none"> • Minimum age 18 • New admission to unit • Braden Scale Total Score 18 or less, or if clinical judgment indicates • Patient, family, or legal representative able to provide verbal implied consent (written optional) • Heels and sacrum accessible to scanning and skin is intact 	<ul style="list-style-type: none"> • Physical act of performing inspections and measurements contraindicated due to patient condition (for example, safety risk or end of life)

Figure 5: Initial Process Map



SEM Delta (Δ) readings were documented on a communication board, and nursing report for facilitated communication. Data was anonymized, scanned, removed from the unit and stored in a locked room. Anonymized data was sent to industry for analysis. During the first four weeks, one ARJO representative was on site for staff support for additional education for staff who did not attend the pre-education. A paper and electronic evaluation form was collected from the team, patients and families to obtain feedback on the experiences with the technology. The Clinical Sustainability Assessment Tool (CSAT)⁴² was administered to the implementation team one week after the pilot to obtain feedback.

Results

A total of 78 nursing staff attended the training sessions representing 75% of the unit level nursing program workforce. Two members of the leadership team attended the education; Nursing was the only discipline who attended education sessions, conducted scans and implemented interventions. Allied health teams were provided one education session upon request during week four of implementation but did not participate in the pilot. A total of 97 patients were evaluated over the six-weeks with a total of 2,039 scans completed. Seventy-four per cent of clinical decision-making was changed during assessments (Figure 7 and 8). SEM Delta (Δ) results in the sacral and heel locations trended downwards throughout the pilot (Figure 9). A total of 1,119 total scans had a SEM Delta (Δ) < 0.6 indicating raised SEM levels detected, yet 73% of those patients were identified at low risk with the Braden Scale (Scores 15-18).

Figure 7: SEM Delta Results

Anatomical Site	SEM Δ \geq 0.6	SEM Δ \geq 0.6 (%)	SEM Δ \geq 0.6 at anatomical site, with no discoloration (%)	SEM Δ \geq 0.6 at anatomical site, identified as 'low risk' via Braden score* (%)	Total scans
Sacrum	437	65.5%	68.6%	73.7%	667
Heels	682	49.7%	78.0%	53.5%	1372
All sites (total)	1119	54.9%	41.0%	73.0%	2039

71% (69) total patients with SEM Δ \geq 0.6 Identified as 'low risk' via Braden Score, AND had no skin discoloration

Figure 8: Clinical Decision-Making

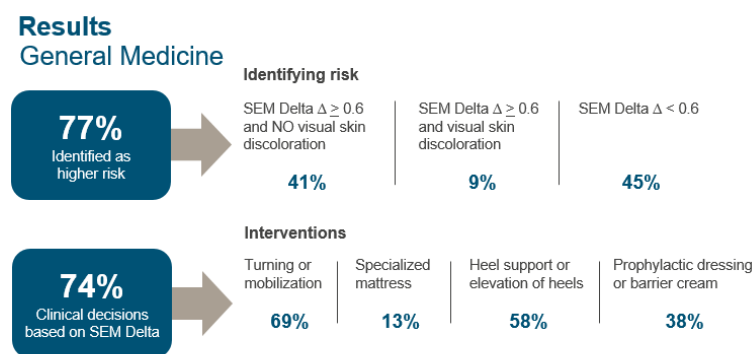


Figure 9: SEM Delta Trending

% Scans With Elevated SEM Delta



The baseline facility-acquired pressure injury rate was 9% and after the pilot was 0%: a 100% reduction rate. This was translated in collaboration with the distributor into an annual cost savings of \$426,903 for the unit. Cost savings was modeled based on predicted facility acquired rate from historical data from two previous audits, the estimated cost of pressure injuries in Canada,⁵ daily scanning and a conservative estimate of 75% reduction of heel and sacrum hospital-acquired pressure injuries from a baseline estimate of 54 HAPI's per year (SEM scanning averages a 90% reduction in acute care,⁴³ of which would yield a cost savings of \$563,099).

The estimated cost savings were indicative of material costs.

Upon review of the data from week one-three, the implementation team observed that prophylactic dressings were the first choice for interventions. The implementation team encouraged

*Where risk scores were provided

basic preventative interventions first, such as increasing turning frequency, repositioning and mobilization prior to application of prophylactic sacral dressings. Some scans were not completed, typically on weekends, and there was a lack of documentation related to skin assessment and skin tone. When there was no documentation on skin assessment, these values were not included in the data analysis. Although the technology appeared to integrate into the current workflow processes, staff suggested that the timing of the scans be changed to reduce workload during day shift. Scan times were changed to one side of the unit scanning patients on day shift and the other side on evening shift during week five. The implementation team recognized self organization⁴ by the local team as modifications were recommended by participants and changes were made. Adaptations were made to the process map during week five. The threshold of three consecutive days of normal SEM Delta (Δ) was reduced to two consecutive days to limit sensor consumption and sensor cost within the local pilot budget.

with mobility issues and is recommended for future process maps.

Twenty evaluations were completed by participants, eight by students (Figure 10) and one by a patient (Figure 11) with positive results indicating acceptability of technology. The CSAT identified organizational readiness as a domain with the largest variability, highlighting opportunities to support future implementation including establishing systems to support various practice needs, ensuring that the practice is feasible and has sufficient resources to achieve goals, adequate staffing to achieve goals and integration into operations. This feedback supported a greater practical and scientific understanding of critical contextual factors that support clinical practices over time.

Adverse Events

No adverse or serious adverse events were reported during the pilot relating to the use of the Provizio™ SEM Scanner. Two patients developed pressure injuries during the pilot, but these were determined to be unavoidable through non-adherence to interventions due to

Figure 10: SEM Participant Survey

Provizio SEM Scanner Feedback	Healthcare Providers (Total =20)			Students (Total =8)		
	Yes (%)	No (%)	Blank/NA (%)	Yes (%)	No (%)	Blank/NA (%)
In my experience, it was easy to learn to use and operate the device.	100%			100%		
Scanning each patient was quick and I was able to scan each patient easily.	80%	20%		100%		
Assessing patients with a deviation (delta) of 0.6 alerted me to take appropriate clinical action.	100%			100%		
The device adds value and provides additional information to support my decision-making about my patient's pressure injury prevention care.	90%	10%		100%		
The device gave me immediate feedback as to whether the area was improving or not.	90%	10%		100%		
The device provides clinically meaningful data about tissue damage.	85%	15%		100%		
The device can replace risk assessments.	45%	55%		12%	88%	
The pilot increased awareness and engagement of the problems and solutions around pressure injury prevention with Physicians.	80%	15%	5%	100%		
The pilot increased awareness and engagement of the problems and solutions around pressure injury prevention with NPs.	25%		75%	100%		
The pilot increased awareness and engagement of the problems and solutions around pressure injury prevention with Allied Health teams.	90%	10%		100%		
Would you adopt the device into your clinical practice?	85%	15%		100%		
Do you believe the pilot was successful?	80%	20%		88%	12%	
Do you believe the pilot was worth the implementation effort on your part?	85%	15%		75%	12%	12%

The scanning trigger of a Braden Score of 18 or less was amended to <18. A queue for referral to the allied health team was added for independent patients with a SEM Delta (Δ) <0.6 on admission. This change should also have included patients

complexity of the individual patients.

Discussion

The introduction of SEM scanning illuminated

Figure 11: SEM Patient Survey

Provizio SEM Scanner Feedback	Patients (Total = 1)	
	Yes (%)	No (%)
I know more about what pressure injuries are and how they can happen.	100%	
I know more about the factors that increase my risk of developing a pressure injury.	100%	
I know more about strategies to help me prevent a pressure injury from developing.	100%	
I have learned about the Provizio™ SEM Scanner technology and how that can help prevent pressure injuries.	100%	
After learning about the Provizio™ SEM Scanner technology I am confident that my care team can help prevent pressure injuries from developing while I am in care.	100%	
I know that I or my family or caregivers can actively participate in pressure injury care planning if able to keep my skin safe.	100%	
I know who to communicate with on my care team if I have concerns or questions about pressure injury prevention.	100%	

educational opportunities to strengthen documentation and critical thinking surrounding the SSKIN+ bundle application, and the importance of multidisciplinary engagement and management of front-line resources. Risk and skin assessments, including skin tone variance, were not consistently documented. The Provizio™ SEM scanner can upload data results into the Electronic Medical Record system, mitigating challenges with consistent documentation. Support surface selection was based on a list of current available support surfaces prompting the need for an up-to-date algorithm to support decision-making. Turning and repositioning was identified as an intervention, however on the ground support identified opportunities for additional education related to turning frequencies and side-lying positioning, which is significant for appropriate offloading of pressure. Incontinence associated dermatitis (IAD) on two occasions observed by the project lead were not diagnosed. IAD is frequently misdiagnosed as a stage one or two pressure injury⁴⁵ as

visual skin assessments are unreliable.¹⁶

Prior to the pilot, the current standard of care of risk assessments and skin assessments led to inconsistencies in SSKIN+ bundle utilization. This was apparent with the introduction of the SEM assessment as well; however, clinical participants increased their clinical decision-making by 74% after scanning with the addition of objective SEM Delta (Δ) assessments. Participants developed care plans using the SSKIN+ bundle and reliable objective SEM assessments and were able to focus their time and resources amongst the patient groups with elevated SEM Delta (Δ) scores. There were challenges with participants reviewing previous SEM Delta (Δ) scores and SSKIN+ interventions to either increase or decrease the interventions. The implementation team communicated this gap to participants during week four and reinforced the SSKIN+ bundle to the participants by providing a new reference tool to stratify the interventions on a continuum of low, moderate and high risk to aid in decision-making.

This change shifted participants from choosing sacral prophylactic dressings as a first line of intervention to considering other options, such as mobilization or turning and repositioning. Health-care provider compliance rates to prevention strategies and guidelines in acute care vary, suggesting that there is opportunity to improve the implementation of basic strategies including repositioning, heel elevation, nutrition support, and moisture management.⁴⁶ Future education for subsequent implementation should include documentation, reinforcement of landmarking, scanning technique, SSKIN+ bundle implementation, evaluation of care planning and a review of maintenance case studies to support evaluation of interventions.

There was limited discussion of abnormal SEM assessments at rapid round discussions, which was an opportunity for improvement. An inter-professional approach is required to mitigate risk factors such as mobility, nutrition and moisture management as part of a comprehensive pressure injury prevention care plan.⁴⁷ Health-care leaders must consider the importance of interprofessional collaboration and role clarity to ensure patients are receiving the necessary care from the care team. Developing team skills and interprofessional relationships can positively impact pressure injury prevention.⁴⁷ The implementation team observed that participants and student discussion of SEM Delta (Δ) results with patients and families raised awareness of pressure injuries and the technology for early detection.

The pilot started with two hundred sensors that needed to be reordered weekly, which was a stressor for the implementation lead to coordinate. The team did not project sensor consumption, therefore weekly incremental sensor costs were a concern for the operational leadership team, prompting discussions related to reducing sensor consumption prompting better adaptation into staff workflow, and enhanced interventions including consultations to allied health. Full implementation could alleviate challenges with re-ordering sensors, as the unit could see increased financial and quality of care benefit through the reduction of facility-acquired pres-

sure injuries. Imbedding innovation requires people to work together to solve problems using give-and-take and this was achieved through open dialogue, strong leadership and openness to change.⁴⁴ The implementation team harnessed feedback productively and viewed differing perspectives as the raw ingredients for multifaceted solutions.⁴⁴

Additional opportunities identified through team communication and voluntary written evaluations included needing more time dedicated to addressing pressure injury risk factors through implementation of strategies with a team approach, workload challenges limiting ability to attend to prevention due to competing priorities and confidence in technology. The pilot took place September 2022 when the team was experiencing post-pandemic fatigue, which may have translated into a task-focused approach to care. Staff were positive during the pilot as the technology was, “motivational, helped us to make a difference and took our mind off the pandemic.” Third year nursing students were eager to learn about the technology and brought positive energy while integrating SEM into their practice.

There is a constant and large drive to implement changes without a thorough assessment of the environmental and establishment organizational readiness,⁴⁸ a critical step in the implementation process.⁴⁹ Organizational readiness refers to the extent to which organizational members are psychologically and behaviourally prepared to implement organizational change including internal support and resources to effectively manage the practice change.⁵⁰ Leadership, facilitation, organizational and staff commitment, evaluation and feedback and resources dedicated to the pilot were significant contextual factors identified as important facilitators. Staff recognized the impact on decision-making through measuring SEM and interpreting and implementing the SSKIN+ bundle to support resource stewardship while improving quality care.

Limitations

Innovation may be hindered by tensions in the innovation process inherent to health care, such

as risk aversion, lack of agility and nimbleness, along with challenges with testing innovations.⁵¹ Within the current pilot, our implementation and leadership teams took this opportunity head-on to test out innovation to improve pressure injury prevention and are exploring the multi-factorial resources for future implementation. Documentation of risk and skin assessments and communications related to the transitions to maintenance scanning were inconsistent limiting analysis. The implementation of the SSKIN+ bundle was limited to the nursing discipline.

Conclusion

Current literature suggests the use of SEM to objectively assess the skin and underlying tissues for early pressure damage.^{1, 24} The results demonstrated that targeting elevated SEM Delta (Δ) with early and anatomy-specific, evidence informed prevention strategies, reduce SEM Delta (Δ) and could eliminate preventable facility-acquired pressure injuries resulting in improved patient outcomes and higher quality care. The seamless inclusion of an objective assessment into the current standard of care, along with adaptations, were successfully implemented. An understanding of contextual factors is necessary for supporting the translation of evidence into practice. Future work will focus on sharing results with teams and consideration of future adoption of SEM technology.

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Marlene Varga (She/Her) MSc BScN, Pressure Injury Prevention Lead, Covenant Health, AB.

Misha Jadoo (She/Her) BScN RN, National Wound Care Specialist ARJO.

Sebastien Normandin, BHK ARJO.

Jacqueline Brayshaw BN RN, Covenant Health, AB.

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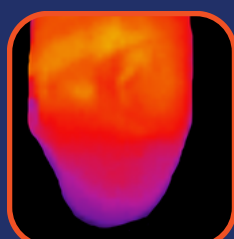
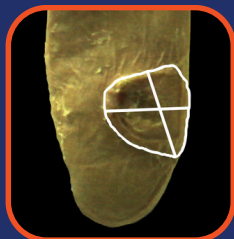
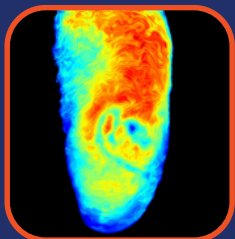


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