

Real-world evidence evaluating a novel early-detection device for HAPU reduction

Martin Burns(1), MBA, Rachael Lester(1), MBA, Rachael Lawrence (2); 1. Bruin Biometrics LLC 2. RL Biostatistics, UK

Background & Objectives

The objective of the Pressure Ulcer Reduction Program (PURP) is to provide clinicians with the option to evaluate the clinical impact of implementation of SEM Scanner (for detection of pressure-induced tissue damage) when incorporated into the clinical workflow of pressure ulcer prevention and management care procedures over a 1 to 6-month period.

This program allows clinicians a systematic approach to assess several factors prior to purchasing the technology, including:

1. Clinical Impact – as measured by hospital-acquired pressure ulcers (HAPU) change (e.g., reduction from historical);
2. Financial Impact – as measured by cost-savings and productivity; and
3. Nurse Experience (e.g., Ease of Use, Safety) – as provided in Post-Evaluation Surveys and verbally from the RN users and clinicians

NOTE: This work has been sponsored by Bruin Biometrics, LLC



The SEM Scanner. Bruin Biometrics (BBI)

Materials & Methods

Beginning in 2014, hospitals were selected to participate in the product evaluation programs. Performance was assessed by comparing "pre-" and "post-" HAPU rates. "Pre-" rate was based on the historical monthly HAPU rates (all grades) for up to 1 year prior for the ward in the program.

Phase 1 (Preparation): Clinicians ("participants") were selected by the hospital and consisted of wound care specialists, nurses and clinicians as they represent the intended user profiles. Participants completed a series of training activities including device training provided by the manufacturer ("BBI").

Phase 2 (Evaluation): PURP participants took daily SEM readings and skin assessments on patients (sacrum, heels) identified as "at risk" for the development of PUs. Clinician were instructed to provide preventative interventions when SEM delta scores of 0.6 or above were observed. Patients were intervened upon using hospital's pressure ulcer prevention and management protocol.

Data Collection & Analysis: PURP participants recorded the information on data record sheets they utilized for their respective PURP evaluations. PURP participants also completed a post-evaluation questionnaire regarding their experience. Where possible, incidence during evaluation was compared to baseline HAPU rates provided by the hospitals from the same ward in the previous time period to assess reduction. (summary data was provided with permissions to BBI)

Results

The summary to the right (Table 1) of aggregated data collected from hospitals involved in PURPs from 2014 to 2016 included a variety of departments within the acute care setting. In total, 632 patients are included in this aggregate data from 9 different hospitals.

- PURP results listed in Table 2 show the HAPU incidence rates observed during the PURP evaluation period.
- The summary Table 3 shows that over 50% of the participating hospitals, nurses had observed zero HAPUs during the evaluation period with an additional 2 hospitals who had observed reductions ranging from 87% to 90%.
- According to the aggregated data, the observed HAPU incidence for the entire population of scanned patients was 1.3% (vs 4.8% incidence for all UK NHS Hospitals per 2014-2015 NHS Safety Thermometer).

Table 1: PURP Hospitals & Patients

Department	No. Hospitals	No. Patients
Orthopedic Trauma	3	164
ICU / Trauma	2	33
Elderly Care	2	254
Medical / Stroke	2	181
Total	9	632

Table 2: HAPU Incidence Rates Observed

Hospital No. / Ward	No. Patients Scanned	Duration (months)	No. HAPU	HAPU Incidence (95% CI)
1 – Orthopedic Trauma	99	3	0	0% (0.0%, 3.7%)
2 – Medical	35	2	0	0% (0.0%, 10.0%)
3 – Orthopedic Trauma	34	3	0	0% (0.0%, 10.0%)
4 – Elderly Care	20	1	0	0% (0.0%, 16.8%)
5 – ICU	12	1.5	0	0% (0.0%, 26.5%)
6 – Medical / Stroke	146	1	2	1.3% (0.8%, 4.9%)
7 – Elderly Care	234	6	2	0.9% (0.1%, 3.1%)
8 – ICU	21	2	3	14.3% (3.1%, 36.3%)
9 – Orthopedic Trauma	31	1.5	1	3.2% (0.08%, 16.7%)
Totals	632	21	8	1.3% (0.6%, 2.5%)

Table 3: PURP Observations of HAPU Reductions

HAPU Reduction Quartile	No. of Hospitals	Percent of Hospitals
Reduction: 100%	5	56%
Reduction: 75%-99%	2	22%
Reduction: 50%-74%	0	0%
Reduction: 25%-49%	0	0%
Reduction: 1%-24%	0	0%
No Reduction	2	23%
Total	9	100%

Discussion & Conclusions

PURP users shared similar findings and have observed benefits from implementation of SEM scanning technology.

- A reduction of HAPUs
- Measurement and assessment of SEM values enable early detection of PUs.
- Cost-savings in pressure ulcer care

In real-world clinical settings, the use of SEM measurements has demonstrated meaningful clinical benefit from the ability to detect the early development of pressure ulcers. The data suggest that utilization of SEM values aids in clinical assessment and decision making for prevention of pressure ulcer by providing quantitative, real-time information about patient's tissue health to facilitate earlier intervention. Implementation of the device provided facilities with a first-time opportunity to use objective "trigger" to initiate care team dialogue and decision-making for targeted patient care. This challenges the pre-existing belief that "React to Red" is sufficient for preventing PUs.

Clinicians from three of the nine hospitals have presented their PURP experiences at international scientific congresses. These case experiences are summarized below.

Poster Title	N	Author	Findings
Improved Patient Safety With the Use of the SEM Scanner (<i>Wounds UK 2016</i>)	35	G. Smith	<ul style="list-style-type: none"> •100% reduction in HAPU incidence. Early detection allowed clinicians to put in place the necessary measures to avoid development, or progression of, PUs. •Cost savings estimates of £600,000 per annum •Improved productivity of 1420 (36 weeks) of nursing time
Hand-held device to decrease HAPUs: from theory to practice (<i>EWMA 2017</i>)	235	R. Raizman M. MacNeil	<ul style="list-style-type: none"> •Reduction on HAPU incidence by 90% as compared to baseline conducted •Study design controlled for Hawthorne effect
Chasing Zero Results from a New Pressure Ulcer Prevention Bundle (<i>Wounds UK 2016</i>)	234	S. Littlefield N. Kellett	<ul style="list-style-type: none"> •Reduction of grade II-IV HAPUs)at Farnham Community Hospital by more than 95%, which was maintained for 6+ months following the full introduction of the PU Bundle. •75% of nurses described the new technology as easy to use and 88% reported that the technology provided valuable information to support clinical decision making.