Modelling the cost-benefits arising from technology-aided early detection of pressure ulcers

Hospital-acquired pressure ulcers (HAPUs) cause pain and discomfort to patients, and use unnecessary health resources. In this study, implementation of the new SEM Scanner™ (Bruin Biometrics, CA, US) technology as an adjunct to the current standard of care practice of visual skin assessments has been tested from probabilistic and cost-benefit perspectives. The authors developed probabilistic (decision-tree) modelling and Monte Carlo simulations representing pathways of care that 10,000 patients, admitted to NHS hospitals in the UK, may undergo. They tested two alternate acute hospital scenarios, of lower (1.6%) and higher (6.3%) HAPU incidence rates. Under a conservative range of assumptions and input parameters, they found that implementation of the SEM Scanner technology as an adjunct to the current standard of care is highly likely to lead to significant financial benefits and cost savings.

Pressure ulcers are a growing threat to the global healthcare economy. From an organisational perspective, hospital-acquired pressure ulcers (HAPUs) are detrimental for multiple reasons, including patient harm, lower perception of care quality provided by the healthcare institution, patient-initiated litigation, rise in insurance premiums (e.g., NHS Resolution Premiums) and increased direct expenditure. The scale of the problem is increasing, with an aging population that is typically less mobile and rising diabetes and obesity. Currently, the number of patients affected by HAPUs is 2.5 million and 700,000 in the US and UK, respectively, of whom 60,000 US patients and 29,000 UK patients die each year due to HAPUs (Padula et al, 2018). In the US, statistics showed that HAPUs were the only hospital-acquired condition where the incidence worsened during 2014–17 (Agency for Healthcare Research and Quality, 2019).

A recent Markov modelling study found that in the US, direct costs of HAPUs (excluding damages or settlements resulting from litigation, lawyer fees and insurance premium charges) could exceed $26.8 billion/year for the adult population (Padula and Delarmente, 2019). Indirect costs are more difficult to evaluate. However, it has been reported that 17,000 HAPU-related lawsuits are litigated in US courts annually (HAPUs are the second most common lawsuit claim after wrongful death) and the average settlement fee is approximately $250,000; settlements favouring patients occur in up to 87% of court cases (Cunningham, 2018). Clinician time is difficult to estimate, but Padula and Delarmente (2019) found that about 59% of the direct HAPU costs are disproportionately attributable to a small number of deep and full-thickness injuries, which occupy most of the clinician’s time and other hospital resources.

The process by which HAPUs form under intact skin, spread in deep tissues and eventually present themselves as full-thickness wounds has been rigorously described, with an overview provided in the international best practice guidelines (Gefen et al, 2019). The mechanobiology of HAPUs is such that soft tissue damage initiates near bony prominences — typically the sacrum and heels — where the force of concentrated bodyweight causes intensified and sustained cell and tissue deformations, which compromise cell integrity and transport function, leading to tissue death (Gefen et al, 2019). Since HAPUs may not...
In hospitals.

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This flaw in classic pressure ulcer prevention
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International best practice guidelines for PUP
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It is the lack of cost-effective, bedside
diagnostic technology for early detection
of HAPUs that hinders the much needed,
significant clinical improvement in PUP
in hospitals.

The SEM Scanner for early pressure ulcer detection
A new technology for early detection of HAPUs
is the SEM Scanner™ (Bruin Biometrics, CA, US).
The SEM Scanner is CE- and FDA-authorised
technology, and is progressively being
integrated into advanced PUP strategies and
protocols in hospitals in Europe and the US. It is
able to indirectly detect cell and tissue damage
during the initial stages of HAPU development,
even if the damage occurs under intact skin,
which would be invisible to the unaided eye
(through the inflammatory changes associated
with the evolving damage). Furthermore, it
can detect an injury where tissue damage may
still be reversible and clinically insignificant, by
focusing on the inflammatory (physiological)
response to the initial, deformation-inflicted cell
death (Gefen, 2018a; 2018b).

When the inflammatory response to cell death
events is triggered, blood vessels adjacent to the
micro-damage site become more permeable,
which allows immune cells to escape the
vasculature and migrate towards these cell
death sites, as a first step in the process of tissue
repair. As a result, plasma also leaves the leaky
vasculature and accumulates gradually in the
interstitial space, eventually forming oedema.
This buildup of plasma fluids progressively
increases the biocapacitance physical biomarker
of the affected tissues, as their dielectric
constant approaches that of water (Gefen, 2018;
Gefen, 2019; Gefen et al, 2019; Peko Cohen
and Gefen, 2019; Ross and Gefen, 2019). This
biocapacitance property is the inflammatory
marker measured by the SEM Scanner. This
marker is highly sensitive to fluid volume
changes as low as 1 ml (Peko Cohen and Gefen,
2019). The particular measurement of clinical
interest is the SEM-delta. This is the difference
between the highest and lowest regional
biocapacitance readings, which quantifies
potentially abnormal localised deviations in
tissue fluid contents.

The SEM Scanner facilitates clinical decision
making by detecting likely reversible damage,
termed a pre-category 1 HAPU. Timely
intervention can halt the progress to a category
1 HAPU or a more clinically significant injury
(Halfens et al, 2001; Swisher et al, 2015). This
model assumes that patients are scanned
alongside VSAs as an adjunct to the current
standard care, and that a patient visit takes
5 minutes.

Subepidermal moisture and the SEM Scanner
have been evaluated in multiple different
settings and countries, including laboratory,
Outcomes and costs incurred depending on detection

The SEM Scanner provides clinicians with the ability to detect an evolving injury under intact skin, much earlier than when damage appears on the skin, by which time it is a more significant injury (Okonkwo et al, 2020). Introduction of this technology calls for a methodological analysis of how PUP practice may be affected. In particular, it is important to understand the extent by which the costs of HAPUs could be reduced.

This paper uses probabilistic modelling to evaluate the expected financial impact of introducing the SEM Scanner in the wound care market, especially in hospital systems.

**Decision tree models**

A probabilistic model is a graphical map and mathematical representation of all the possible outcomes of a series of related choices in a process, e.g., a pathway of care. The map weighs possible actions against one another, at junctures of decisions, based on the probabilities that these actions will be taken in real-world conditions. Each juncture in the map branches into further possible outcomes, which lead to additional nodes that also branch off. A map of a probabilistic model is called a decision tree.

We used decision trees to model the financial benefit of utilising the SEM Scanner in a PUP strategy through an increase in the probability of early detection of a HAPU allowing earlier prescription of targeted interventions, versus conventional practice. We selected the probabilistic modelling approach as it required the fewest assumptions, and we could tailor the model to an analysis more suited to PUP.

Two different decision trees were needed for the probabilities of detection and treatment, one for the current standard care, the other for the SEM Scanner as an adjunct to standard care [Figures 1 and 2]. The decision tree structure is the same in both analyses, with only the detection probabilities [Table 1] and costs [Table 2] differing at the relevant nodes.

**Assumptions for incidence and treatment costs**

The parameters for our modelling included the detection rates of different patient states (no damage, sub-clinical damage, category 1 or later damage) under standard care or care aided by the SEM Scanner [Table 1], incidence levels under the current clinical protocol [Table 3], treatment costs [Table 2] and costs per patient [Table 4]. Note that we have used data from the UK consistently in this work.
Table 1. Key model inputs and the probabilities for detection of the different hospital-acquired pressure ulcer categories with the current standard of care versus with the SEM Scanner.

<table>
<thead>
<tr>
<th>Model input</th>
<th>No damage</th>
<th>Non-visible tissue damage</th>
<th>Category 1 (broken skin)</th>
<th>Category 2 (broken skin)</th>
<th>Category 3 (broken skin)</th>
<th>Category 4 (broken skin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distribution of HAPUs*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of treatment per case*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probability rates for correct detection of tissue status by current clinical standards*†‡§</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probability rates for correct detection of tissue status with the SEM Scanner as adjunct†</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Dealley et al, (2012); †Pancorbo-Hidalgo et al (2006); ‡Okonkwo et al (2019). *Erythema is difficult to detect using the unaided eye if the skin is darkly pigmented, or in clinical cases where skin has abnormal color such as in jaundice or rosacea (Clark, 2010). Conducting good-quality visual skin assessments also requires prolonged and thorough training, e.g. to distinguish between a category-1 HAPU and incontinence-associated dermatitis. Visual skin assessments are somewhat reliable for individuals with light skin tones but by the time non-blanchable erythema is evident, subdermal tissue damage may have already occurred (Bates-Jensen et al, 2017). These factors contribute together to an about 50% sensitivity of nurses’ clinical judgement in identifying patients at risk of HAPUs based on VSAs (Pancorbo-Hidalgo et al, 2006). ‡This is the weighted average probability that a clinician using a SEM Scanner can correctly confirm that no heel and sacral ulcers exist in an examined patient (the “true negative”); this value is based on an algorithm that maximises sensitivity at a cost to specificity.

Table 2. Treatment costs of hospital-acquired pressure ulcers.

<table>
<thead>
<tr>
<th>Damage</th>
<th>Treatment costs</th>
<th>Input rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>No HAPU present but non-visible tissue damage detected with SEM Scanner in use (false positive)</td>
<td>£0</td>
<td>There are no treatment costs incurred. Universal prevention pathway marginal costs arising from SEM Scanner detection are included in the model.</td>
</tr>
<tr>
<td>No HAPU present and no damage detected (true negative)</td>
<td>£0</td>
<td>No treatment required.</td>
</tr>
<tr>
<td>Non-visible tissue damage that is detected with SEM Scanner in use (true positive)</td>
<td>£0</td>
<td>There are no treatment costs incurred. Universal prevention pathway marginal costs arising from SEM Scanner detection are included in the model.</td>
</tr>
<tr>
<td>Non-visible tissue damage but no damage detected (false negative when SEM Scanner in use)</td>
<td>£564</td>
<td>The expected cost of treating undetected non-visible tissue damage. The model assumes that 40% of undetected non-visible tissue damage progresses to a category 1 HAPU, the rest remain as non-visible tissue damage. Therefore, the expected cost is calculated by the sum of 60% of the treatment cost of non-visible tissue damage and 40% of the treatment of category 1 HAPUs.</td>
</tr>
<tr>
<td>Detected category 1 HAPU</td>
<td>£1,211</td>
<td>Reflects the expected cost based on the progression of HAPUs under standard clinical interventions (Halfens et al, 2001).</td>
</tr>
<tr>
<td>Undetected category 1 HAPU</td>
<td>£3,725</td>
<td>Weighted average of treating category 1–4 HAPUs, using the probability that an undetected HAPU will progress during hospital stay according to the distribution rates as weights (Dealley, et al, 2012).</td>
</tr>
<tr>
<td>Broken skin (category 2–4 HAPUs)</td>
<td>£7,493</td>
<td>Weighted average cost across the three categories of HAPUs, using the distribution rates as weights (Dealley, et al, 2012).</td>
</tr>
</tbody>
</table>

Econometrics analysis on the clinical trial data via logistic regression models was performed to test whether any patient characteristics in the clinical trial sub-datasets are statistically significant predictors of PU detection by the SEM Scanner. The key result from this analysis suggested that the sensitivity and specificity rates from the clinical trials can be applied without adjustment for patient characteristics when estimating the expected benefits.

Our assumptions were conservative throughout the development of the modelling to provide a prudent evaluation of the financial benefits in implementation of the SEM Scanner. Specifically, where the SEM Scanner is implemented in a real-world setting where the average incidence rate of HAPUs across all admissions is greater than the assumed 6.3% (the worst-case-scenario in Table 3), then the expected saving per patient in that setting would be even greater than those presented here. The asset cost of the SEM Scanner has been amortised over a 3-year period, although its useful life is expected to be 7 years, according to the manufacturer. All staffing costs use the NHS band 5 pay level, although in practice basic wound care is likely to be carried out by less experienced and less costly nursing staff [Table 4]. The data in Tables 2, 3 and 4 and the analyses are based on an acute NHS hospital setting, so the present analysis is relevant to HAPUs in the UK.

Furthermore, it has been assumed that broken skin (categories 2–4) is always detected accurately, with or without the SEM Scanner. Lastly, given the nature of VSAs, it was surmised that non-visible tissue damage cannot be detected without the SEM Scanner.

Monte Carlo simulations to evaluate the benefits of preventative technology

To test the sensitivity of the estimated financial benefit to the key assumptions, Monte Carlo simulations (generating a series of random values of parameters within pre-defined ranges via specialised computer software) were used.
Non-visible tissue damage has been assumed. The incidence rate of HAPUs (6.3%) multiplied by the incidence rate of non-visible tissue damage (1.6%) multiplied by the incidence rate of broken skin (category 2–4) is 0.56%. This rate is adopted from Lester (2017).

Table 3. Incidence levels under the current clinical protocol in the UK.

<table>
<thead>
<tr>
<th>Scenario variables</th>
<th>Input</th>
<th>Input rationale/source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower incidence of HAPUs: a scenario of 1.6% incidence rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incidence rate of HAPUs in the UK, excluding non-visible tissue damage</td>
<td>1.6%</td>
<td>Minimum is based on average incidence rates in England (NHS Safety Thermometer 2012-2018).</td>
</tr>
<tr>
<td>Incidence rate of non-visible tissue damage</td>
<td>1.52%</td>
<td>Non-visible tissue damage has been assumed to be when the SEM delta reading of the SEM Scanner is greater than or equal to 0.6, according to manufacturer guidelines for use.</td>
</tr>
<tr>
<td>Incidence rate of broken skin (category 2–4)</td>
<td>1.04%</td>
<td>Incidence rate of HAPUs (1.6%) multiplied by the proportion of HAPUs in the UK that are categories 2, 3 or 4 (Dealey et al, 2012).</td>
</tr>
<tr>
<td>Incidence rate of category 1 HAPUs</td>
<td>0.56%</td>
<td>Incidence rate of HAPUs (1.6%) multiplied by the proportion of HAPUs in the UK that are category 1 (Dealey et al, 2012).</td>
</tr>
<tr>
<td>Higher incidence of HAPUs: a scenario of 6.3% incidence rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incidence rate of HAPUs, excluding non-visible tissue damage</td>
<td>6.3%</td>
<td>Adopted from Lester (2017).</td>
</tr>
<tr>
<td>Incidence rate of non-visible tissue damage</td>
<td>5.99%</td>
<td>Non-visible tissue damage has been assumed to be when the SEM delta reading of the SEM Scanner is greater than or equal to 0.6, according to manufacturer guidelines for use.</td>
</tr>
<tr>
<td>Incidence rate of broken skin (category 2–4)</td>
<td>4.10%</td>
<td>Incidence rate of HAPUs (6.3%) multiplied by the proportion of HAPUs in the UK that are categories 2, 3 or 4 (Dealey et al, 2012).</td>
</tr>
<tr>
<td>Incidence rate of category 1 HAPUs</td>
<td>2.20%</td>
<td>Incidence rate of HAPUs (6.3%) multiplied by the proportion of HAPUs in the UK that are category 1 (Dealey et al, 2012).</td>
</tr>
</tbody>
</table>

Universal prevention costs and potential savings of SEM Scanner

Using the decision trees, assumptions and input parameters described above, the expected saving per patient by implementing the SEM Scanner in a facility with a low incidence rate (1.6%) is £15.23 per admission. This saving is the difference between the estimated cost under the current standard of care (calculated using the decision tree in Figure 1), which is £168.35 per admission, and that with the SEM Scanner as an adjunct to the current standard of care (using the decision tree in Figure 2), which is £153.12 per admission. For an average NHS Trust with 40,802 admissions per annum excluding day cases (NHS England, 2018b), the estimated total savings from implementing the SEM Scanner would be £0.6 million per annum for a low incidence (1.6%), and £3.3 million for a higher incidence rate (6.3%).

It is possible to use the modelling to consider the benefits of a growing acceptance of the SEM Scanner technology. The computed savings are shown in Figure 3a, using NHS data on admissions between 1 April 2016 and 31 March 2017, which was 7,303,491 patients (NHS England, 2018b). The models assume that VSA and the SEM Scanner are only applied to patients at risk of pressure ulceration, not on all admitted patients. The percentages assigned to each shade of grey in the figure are year-by-year diffusion rates of SEM Scanner use over 5 years. Under the lowest rate, the SEM Scanner will be used on 5% of patients in the first year and then 10% of patients in the second year, etc (Figure 3a). The maximum saving predicted by this analysis for the low incidence rate is £111 million per annum, so a saving of £15.23 per admission is achieved at the end of a 5-year adoption phase. Importantly, for the lowest
Figure 3b). Again, even the most conservative assumption of diffusion rate of 5% results in savings of £147 million per annum after 5 years [Figure 3b].

To further test the effects of random variance in HAPU incidence rates and damage costs, we used Monte Carlo simulations. Specifically, we allowed the values in Tables 1–4 to fluctuate by ±15% from the nominal values listed in these tables, by assuming triangular distributions of values around these nominal values. The results of the simulations representing repeated trials in 10,000 simulated patients, incorporating the above variability which is expected in real-world conditions, were similar to the ones reported above. Specifically, for the lower (1.6%) incidence rate, the average expected saving per admission was £19 and the median

<table>
<thead>
<tr>
<th>Scenario variables</th>
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<th>Input rationale/source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs of implementation of the SEM scanner technology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Useful life of SEM Scanner</td>
<td>3 years</td>
<td>The number of years that the cost of the SEM Scanner is amortised (prudent estimate because the useful SEM Scanner life is 7 years).</td>
</tr>
<tr>
<td>Cost per scanner</td>
<td>£5,835</td>
<td>Framework cost of the SEM Scanner as proposed in the NHS's Shared Business Services.</td>
</tr>
<tr>
<td>Total number of beds per scanner</td>
<td>9</td>
<td>It was assumed that there is one nurse station for every nine beds, and each nurse station will have a SEM Scanner.*</td>
</tr>
</tbody>
</table>

Table 4: Variables for calculating fixed hospital-acquired pressure ulcer costs per patient.

<table>
<thead>
<tr>
<th>Scenario variables</th>
<th>Input</th>
<th>Input rationale/source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average length of stay (NHS)</td>
<td>5.6</td>
<td>Per NICE pressure ulcer costing statement (NICE, 2014). Average length of stay of an inpatient in the UK.</td>
</tr>
<tr>
<td>Average number of patients per bed per year</td>
<td>58</td>
<td>Bed utilisation rate multiplied by the number of days in a year, divided by the average length of stay.</td>
</tr>
<tr>
<td>Fixed scanner cost per patient</td>
<td>£3.73</td>
<td>Cost of the SEM Scanner divided by the product of: total number of beds per Scanner; the average number of patients per bed year; and the useful SEM Scanner life.</td>
</tr>
</tbody>
</table>

Table 4: Variables for calculating fixed hospital-acquired pressure ulcer costs per patient.

<table>
<thead>
<tr>
<th>Scenario variables</th>
<th>Input</th>
<th>Input rationale/source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training per nurse (hours)</td>
<td>1</td>
<td>Assuming that training will be provided to all nurses covering the number of beds in the base scenario in the first year of implementation. Training costs in subsequent years will be for those nurses who have joined a ward with a SEM Scanner and had not been previously trained.</td>
</tr>
<tr>
<td>Bed/nurse ratio</td>
<td>5</td>
<td>Variable used to calculate number of nurses that require training. Ratio is based on prior UK implementations of SEM Scanners (data provided by the manufacturer).</td>
</tr>
<tr>
<td>Number of wards</td>
<td>10</td>
<td>Representative scenario within a hospital.</td>
</tr>
<tr>
<td>Beds per ward</td>
<td>21</td>
<td>Based on prior UK implementations of SEM Scanners in acute settings.</td>
</tr>
<tr>
<td>Number of beds</td>
<td>210</td>
<td>Beds per ward multiplied by the number of wards.</td>
</tr>
<tr>
<td>Number of nurses</td>
<td>147</td>
<td>(Total Number of Beds / Bed to nurse ratio) × 3 shifts per day / (1 - 14% headroom).</td>
</tr>
<tr>
<td>Nurse Band 5 wage (NHS)</td>
<td>£18</td>
<td>Assumed that HAPU assessment and prevention activities will be carried out by a band 5 nurse on average. Cost per NICE pressure ulcer costing statement (NICE, 2014).</td>
</tr>
<tr>
<td>Fixed training costs per patient</td>
<td>£0.22</td>
<td>Product of: number of nurses; training time per nurse; and nurse wage, divided by the total number of admissions.</td>
</tr>
<tr>
<td>Total fixed costs per patient</td>
<td>£3.94</td>
<td>Fixed Training Costs per Patient + Fixed Scanner Cost per Patient.</td>
</tr>
</tbody>
</table>

* The number of beds per nurse station varies across facilities and ward types. Typically, US/UK hospitals have 4 to 25 beds per station (Cai, 2012), hence 9 beds is a mid-value. If resources for implementing the SEM Scanner technology are more limited than has been assumed here, leading to sharing of devices between nurse stations, the cost of SEM Scanners per total beds would decrease, however, in real-world conditions, the logistics in coordination of devices, which translates to extra cost of nursing time, will be added..
expected saving per admission was £18 (the 95th percentile expected saving per admission was £26 and the 5th percentile was £11. The higher, 6.3% HAPU incidence rate, the average expected saving per admission was £95 and the median expected saving per admission was £94 (the 95th percentile expected saving per admission was £122 and the 5th percentile was £73).

Summary
Using probabilistic modelling and under a conservative range of assumptions and input parameters, we found that implementation of the SEM Scanner technology as an adjunct to the current care practice of VSAs is highly likely to lead to significant financial benefits and cost savings. For an average NHS Trust with 40,802 admissions per annum (NHS England, 2018b), the estimated total savings from implementing the SEM Scanner would be in the range of £0.6 million–£3.3 million per annum. These cost reductions reflect:

- Detection and treatment of non-visible tissue damage (a pre-category 1 injury; Figures 1 and 2) which is not possible without the SEM Scanner, and accordingly, implementation of the SEM Scanner allows prevention of some category 1 HAPUs at lower costs than treatment of category 1 HAPUs.
- A higher rate of detection of category 1 HAPUs than is possible without the SEM Scanner and, therefore, prevention of potential category 2–4 HAPUs.
- Avoidance of some unnecessary interventions for patients with HAPUs, due to higher confidence by clinicians to rule out HAPUs with the SEM Scanner readings.

The approach and methodology described here can be translated to any scenario — including in other medical fields — where a new technology is introduced in the market. The investments required to implement the new technology can be weighed against the current costs of treatment of a condition that, in a substantial number of cases, becomes avoidable with the aid of this new technology. If the quality of the input parameters for the modelling, such as incidence rates and current costs of treatment, is adequate, then the cost–benefit calculations based on the present method provide the critical information for decision makers.

It is clearly not sufficient that a technology is clinically effective; it must also be financially justified. These models suggest that increasing diagnostic accuracy through the use of this technology to aid clinical decision making results in measurable, material financial savings for healthcare providers.

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