NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation document

SEM Scanner 200 for preventing pressure ulcers

The National Institute for Health and Care Excellence (NICE) is producing guidance on using SEM Scanner 200 in the NHS in England. The medical technologies advisory committee has considered the evidence submitted by the company and the views of expert advisers.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the public. This document should be read along with the evidence (see the committee papers).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and resource savings reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?

Note that this document is not NICE's final guidance on SEM Scanner 200 The recommendations in section 1 may change after consultation.

After consultation the committee will meet again to consider the evidence, this document and comments from the public consultation. After considering the comments, the committee will prepare its final recommendations which will be the basis for NICE's guidance on the use of the technology in the NHS in England. For further details, see the medical technologies evaluation programme process and methods guides.

The key dates for this guidance topic are:

Closing date for comments: 10 April 2020

Second committee meeting: 24 April 2020

Details of the advisory committee are given in section 5.

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice.

If the case for adopting the technology is supported, the specific recommendations are not intended to limit use of other relevant technologies that may offer similar advantages. If the technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology in the NHS but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

1 Recommendations

1.1 SEM Scanner 200 shows promise for preventing pressure ulcers. However, there is not enough good-quality evidence to support the case for routine adoption in the NHS.

Research is recommended to address uncertainties about the clinical benefits of using SEM Scanner 200 compared with standard risk assessment. This should assess:

- the risk of pressure ulcer formation using SEM scanner without visual skin assessment compared with visual skin assessment alone
- how changes in clinical decision making from using the scanner lead to reductions in the incidence of pressure ulcers
- the clinical benefits and resource impact of using the scanner in different care settings
- the clinical benefits for different skin tones
- how well the scanner works across populations with a range of comorbidities
- patient-related outcome measures.

Why the committee made these recommendations

The SEM Scanner 200 is a device that measures differences in moisture deep under the skin of the heels and the area around the base of the spine (sacrum). Inflammation occurs when tissue is damaged. Increased moisture under the skin is thought to reflect inflammation and may indicate an increased risk of pressure ulcer formation. Using the SEM Scanner 200 could mean that measures to prevent pressure ulcers can be taken before visible or tactile signs of tissue damage develop.

SEM Scanner 200 was used with standard care in studies looking at its effect on pressure ulcer incidence. This makes it difficult to distinguish between the effect of SEM Scanner 200 alone and that of increased awareness of preventing pressure ulcers. Also, standard care is poorly described in the studies. More evidence is needed on how using the SEM Scanner 200 affects clinical decision making and whether this benefits patients.

2 The technology

Technology

SEM Scanner 200 is a portable, hand-held skin assessment device. It detects an increased risk of pressure ulcers developing by identifying early pressure-induced tissue damage at the heel and sacrum. Published evidence suggests that damage to underlying soft tissues can happen 3 to 10 days before tissue damage shows at the epidermis (Moore et al. 2017). Tissue inflammation is the first response to damage and causes increased dilation and permeability of surrounding blood vessels. This leads to leakage of plasma and fluid, creating a layer of subepidermal moisture. As damage increases, so does the level of subepidermal moisture. SEM Scanner 200 measures variation in subepidermal moisture. Healthy tissue has little variation and will give a low numerical reading whereas inflamed or dead tissue has increased variance in subepidermal moisture and will give higher numerical readings. Readings are taken across a small area, the variance in subepidermal moisture between these readings reflects tissue damage. The variation is reported

as a ‘delta’ value, with a subepidermal moisture delta value of 0.6 or more thought to represent clinically significant levels of tissue damage.

Innovative aspects

2.1 SEM Scanner 200 uses a novel method of identifying subepidermal moisture in the tissue of the heels and sacrum. The method is proposed to identify an increased risk of pressure ulcer formation before visible signs of pressure-induced damage are present.

Intended use

2.2 SEM Scanner 200 is intended to be used on the heels and sacrum of people who are at risk or at high risk of developing a pressure ulcer, as defined in NICE’s guideline on pressure ulcers: prevention and management.

2.3 SEM Scanner 200 is used by healthcare professionals on admission, during the patient’s stay and on discharge. Users need training to use the device and interpret the results. For full information on how to use the technology please refer to the SEM Scanner 200 information for use document.

Costs

2.4 The cost of purchasing the SEM Scanner 200 is £5,835 per device.

For more details, see the website for SEM Scanner 200.

3 Evidence

Clinical evidence

The main clinical evidence comprises 7 studies

3.1 The evidence assessed by the external assessment centre (EAC) included 7 studies; 3 were full text peer reviewed publications (Gefan et al. 2018; O’Brian et al. 2018; Raizman et al. 2018) and 4 were abstracts (Hancock and Lawrance 2018; Okonkwo et al. 2017; Okonkwo et al. 2018; O’Keefe et al. 2019). The studies included 2,213 patients at risk of

developing pressure ulcers in secondary care. Two of the studies were before and after comparative studies, the remaining 5 studies were single-arm observational studies. For full details of the clinical evidence, see section 3 of the assessment report.

The 2 before and after studies are relevant to the decision problem and report pressure ulcer incidence

3.2 Both studies compared pressure ulcer incidence before and after using SEM Scanner 200 as a risk assessment tool to be used alongside standard care. Both studies reported reduced pressure ulcer incidence after using the SEM Scanner 200. Neither study included a detailed description of the protocol used for assessment and management in the standard care arm. Also, there was heterogeneity in the reporting of pressure ulcer incidence, with only 1 study including stage 1 pressure ulcers. These limitations made it difficult to be certain about how well SEM Scanner 200 works when used as the only test.

Diagnostic accuracy is reported in 3 of the observational studies but they use an inappropriate reference standard

3.3 All studies reporting the diagnostic accuracy of the SEM Scanner 200 used visual skin assessment (a standard clinical measure for detecting pressure ulcers based on visual signs of skin deterioration) as a reference standard. The SEM Scanner 200 is intended to detect subepidermal moisture changes before visual evidence of pressure ulcers is present and is not a diagnostic test for pressure ulcers. The EAC noted the use of visual skin assessment for measuring the diagnostic accuracy of SEM scanner may underestimate the specificity of the SEM scanner because non-visible damage correctly identified by SEM scanner would be recorded as a false positive.

In 3 of the observational studies SEM Scanner 200 detects subepidermal moisture changes earlier than visual skin assessment

3.4 All 3 studies reported that subepidermal moisture changes indicating pressure-induced damage were detected earlier than visible signs of skin

deterioration reported by visual skin assessment. The studies provided no additional information about the effect of these findings on clinical management or on the clinical benefits of earlier detection.

Cost evidence

The company's model compares the costs of using of SEM Scanner 200 plus standard care with using standard care alone

3.5 The company submitted 10 studies relevant to the economic assessment of SEM Scanner 200. The EAC reviewed the literature and found 1 study (Burns et al. unpublished) that it considered to be relevant to the decision problem. The company used a decision tree, based on NICE's clinical guideline on pressure ulcers: prevention and management, to assess the effect of SEM Scanner 200 on the cost of preventing pressure ulcers, over a 1-year time horizon. In this model, the heels and sacrum of each patient were assessed and categorised as low risk, at risk or at high risk. Patients assessed to be at risk or at high risk had repositioning every 6 or 4 hours, respectively. The key clinical parameters were identified as an assumed pressure ulcer incidence of 4.09% in the at risk group and an incidence rate of 1.637% in the standard care arm and 0.509% in the SEM scanner arm (a 68% reduction). Parameters were from the unpublished Hancock and Lawrance (2018) before and after study.

The EAC updates costs in the company model

3.6 The company used a cost of £18 per hour for band 5 nursing time as stated in the NICE costing statement for pressure ulcers published in 2014. The EAC considered this source to be outdated and updated the cost to £37 per hour (Curtis and Burns 2018). The EAC also added a 3.5% depreciation rate for the device that had not been included in the company submission.

The updated company model results in cost savings of £59 per person from reduced pressure ulcer incidence

3.7 The company model resulted in cost savings of £59 per patient. Sensitivity analyses applied to the assumed percentage pressure ulcer reduction found SEM Scanner 200 to be cost-neutral at a 28% reduction in pressure ulcer incidence. The company model included the costs of 1 scanner per 9 beds for 210 beds. The model showed that the increased costs for preventive measures were offset by cost savings related to the reduced need for pressure ulcer treatment. Results were reported to be robust to sensitivity analyses, however, the results were not presented. The EAC noted there was uncertainty around estimates sourced from an unpublished study used to populate the company model.

The EAC modelled the cost of SEM Scanner 200 using preferred assumptions, the technology was cost incurring by £45 per person

3.8 The EAC used the predicted number of positive stage 1 pressure ulcers, the prevalence of pressure ulcers and the diagnostic accuracy of the combination of SEM Scanner 200 and visual skin assessment to calculate a pressure ulcer incidence of 8.05%. The model assumed that 50% of stage 1 pressure ulcers would progress to stage 2 without diagnosis and treatment and that 36.5% would do so with diagnosis and treatment. The EAC acknowledged that this model did not adequately capture any potential benefit of earlier identification of pressure-induced damage. The EAC's base case resulted in the technology being cost incurring by £45 per person when using SEM Scanner plus visual skin assessment compared with visual skin assessment alone.

4 Committee discussion

Clinical-effectiveness overview

SEM Scanner 200 can reduce pressure ulcer incidence but there are considerable uncertainties

4.1 The committee noted that the published evidence suggested that using SEM Scanner 200 would result in statistically significant reductions in pressure ulcer incidence. But clinical experts explained that the size of this benefit was greater than they would expect from their own clinical experience. One clinical expert commented that using SEM Scanner 200 had substantially reduced pressure ulcer incidence in their hospice, but not to the same degree as reported in the studies. The committee also considered that it was unclear from the studies whether a reduction in pressure ulcer incidence was due to the scanner results guiding care management decisions or the increased nursing care associated with using the scanner. It concluded that the evidence was unclear about how changes in clinical decisions making from using SEM scanner 200 lead to reductions in pressure ulcer incidence.

It is unclear how often the SEM scanner is used in clinical practice and how the results are used to change clinical practice

4.2 Clinical experts considered that SEM Scanner 200 provides information that could affect decisions about when to intensify preventive measures. These measures include improving the specification of the foam mattress, doing more regular repositioning of the patient, or other pressure-relieving measures. One clinical expert said that using SEM Scanner 200 allows nurses to intensify preventive measures earlier than when using clinical judgement alone. The committee acknowledged that using the SEM Scanner 200 may result in preventive measures being introduced or intensified earlier. The committee noted that there was no evidence to show the effect of earlier interventions on pressure ulcer incidence. It concluded that research is needed to assess the impact of introducing preventative measures earlier on pressure ulcer incidence.

There is uncertainty about the diagnostic accuracy of SEM Scanner 200

4.3 The committee heard from the company that SEM Scanner is not intended to diagnose pressure ulcers and diagnoses the increased risk of pressure ulcer development. The committee heard through correspondence with the Medicines and Healthcare products Regulatory Agency that the SEM Scanner 200 is used to identify patients at an increased clinical risk of pressure ulcers and should be seen as a diagnostic risk assessment tool.

4.4 The company acknowledged there is no appropriate reference standard for measuring subepidermal moisture and that this limited the assessment of diagnostic accuracy. Clinical experts also said using visual skin assessment as a reference standard would confound results because SEM scanner is designed to asses risk of pressure ulcer development before reddening whereas visual skin assessment records visible pressure injuries. The committee concluded that further research should be done to assess the use of SEM Scanner 200 without visual skin assessment for pressure ulcer risk assessment and that it should be compared with standard visual skin assessment.

The evidence does not address how SEM Scanner 200 performs across different populations

4.5 The clinical effectiveness of SEM Scanner 200 may vary between people with different comorbidities. Also, the clinical experts explained that part of the visual skin assessment is to identify redness, which may not be visible in people with dark skin. Using a non-visual method such as SEM Scanner 200 for these people may offer advantages and could address an unmet need. The committee also considered that the presence of comorbidities and conditions associated with skin damage or swelling may influence subepidermal moisture levels and affect the clinical accuracy of the SEM Scanner 200 to identify pressure ulcer risk. The committee concluded that further research should be done to assess the efficacy of the SEM Scanner 200 in preventing pressure ulcers for patients with dark skin and for those with comorbidities.

Relevance to the NHS

There is NHS interest in the SEM Scanner 200 because community and hospital-acquired pressure ulcers remain a significant problem

4.6 The NHS safety thermometer report states that from April 2014 to March 2015 approximately 25,000 patients developed new pressure ulcers. The national proportion of people with a stage 2 to 4 pressure ulcer in the UK is estimated to be 5%. The clinical experts explained that in view of the continued clinical challenges of preventing pressure ulcers in the community and in hospitals, there is increasing interest in using the SEM Scanner 200 across the NHS.

Using devices for measuring subepidermal moisture is referenced in global clinical practice guidelines

4.7 The committee noted the recently updated US National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA) global clinical practice guideline in the treatment and prevention of pressure ulcers. This states that healthcare professionals should consider using a subepidermal or oedema measurement device in addition to routine visual skin assessment to assess the clinical risk of pressure ulcers. The committee also noted that, based on evidence, the guideline only proposed a weak positive recommendation for these devices when assessing risk in people with dark skin.

NHS considerations overview

SEM Scanner 200 provides an objective measure of pressure ulcer risk

4.8 SEM Scanner 200 provides an objective measure of variations in subepidermal moisture. Current risk assessment involves the combined use of validated scales and clinical judgement. The clinical experts explained that the availability of an accurate and objective measure of risk would be an advantage, particularly for training staff in pressure ulcer risk assessment.

The rationale for using SEM Scanner 200 needs further clinical testing

4.9 The company explained that the SEM Scanner 200 delta value reflects a measure of relative difference between the subepidermal moisture recorded over the bony prominences and surrounding tissues of the heels or sacrum. The greater the variation in subepidermal moisture (and therefore the delta value), the greater the likelihood of underlying localised inflammation. Although the committee accepted the rationale for this hypothesis, it considered that patients may have oedema from other causes and the principles need to be further tested in well-constructed clinical studies. It further noted that the interrater reliability of the device was reported by the company to be 83%. The committee concluded that further research would help to understand the reproducibility of the result.

SEM Scanner 200 needs cleaning between patients

4.10 The SEM Scanner 200 is classified as having a medium risk of cross-contamination. The company explained that cleaning is described in the information for use and has been shown to be effective in addressing the risk of cross-contamination. Clinical experts advised that cleansing wipes are used to clean the SEM Scanner 200 and this is in keeping with NHS infection and control procedures. The company stated that there have been no reported cross-contamination adverse events with the SEM Scanner 200.

SEM Scanner 200 has a battery life of 3 hours and a lifespan of over 3 years

4.11 The company explained that the SEM Scanner 200 has a 3-year warranty but the battery life of the device may be longer than 3 years. The clinical experts advised that 3-hour battery capacity is adequate because the SEM Scanner 200 is left on a charging station when not being used.

Training

The company provides free training

4.12 The clinical experts explained that the company provides training in the use of the SEM Scanner 200. The device is easy to use, and the clinical

experts described that staff became comfortable and familiar with its use within 2 weeks or so.

Cost modelling overview

Uncertainties about the clinical benefit of SEM Scanner 200 results in uncertain cost-effectiveness

4.13 The committee noted that the key cost drivers, the reduction in pressure ulcer incidence and specificity of the device, were subject to considerable uncertainty. It concluded that more research was needed to establish the clinical and cost benefits of the SEM Scanner 200.

Further research

Further research is needed to address the uncertainty about the efficacy of SEM Scanner 200 in reducing pressure ulcer incidence

4.14 The committee concluded that further research was needed to address uncertainties about the efficacy of SEM Scanner 200 in reducing pressure ulcer incidence. This research should assess using the SEM Scanner 200 (without visual assessment) for assessing the risk of pressure ulcers compared with standard risk assessment using validated scales and skin assessment. Pressure ulcers occur in acute and community care so research should address the effect of adopting SEM Scanner 200 in each of these settings independently. Research should be sufficiently powered to include subgroups of people with dark skin and those with a range of comorbidities known to influence fluid levels in the subepidermis and underlying tissues. Clinical studies using the SEM Scanner 200 should be clear about how it affects clinical decision making; what effect it has on clinical outcomes and patient-related outcome measures; and the cost implications of its use.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technology advisory committee which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technology advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

Rebecca Owens
Technical analyst

Lizzy Latimer
Technical adviser

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Project manager

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