Innovative Medical Technology Overview: 007/2016

This IMTO summarises a submission by Bruin Biometrics Europe Ltd regarding the following medical technology. It should be read in conjunction with the accompanying IMTO Review Document (RD), which is an impartial review of the strengths and weaknesses of the evidence submission by Healthcare Improvement Scotland.

SEM Scanner

Technology

The SEM Scanner is intended to assist in the detection of pressure induced tissue damage. The scanner is a class IIa, hand-held, portable, tissue assessment device that analyses the skin’s underlying tissue to detect changes in sub-epidermal moisture (SEM). SEM is stated to be a biophysical marker associated with localised oedema and to be indicative of pressure induced tissue damage.

The SEM Scanner is available as an add-on to the standard of care for the detection of pressure ulcers (PU). The SEM Scanner can be used in all care settings where patients are identified as being at risk of developing a PU. However, the focus of the evidence presented is on the acute care, community care and nursing home settings.

Product Performance

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<th>Economic considerations</th>
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<td>The cost of one SEM Scanner unit before discounts is approximately £14,000. A variety of purchase/lease/risk sharing options are available, which serve to reduce procurement risk.</td>
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| The manufacturer submitted a cost comparison model which assessed the costs associated with PUs without the SEM Scanner versus the costs associated with PUs with the SEM Scanner available. The manufacturer’s base case analysis included optimistic assumptions. However, applying more conservative assumptions suggests that the SEM Scanner may contribute to potential ward-level resource reductions in excess of £50,000 per year. This figure was based on the key assumption that the use of the SEM Scanner leads to a 50% reduction in PUs. |

| The model focuses solely on the cost impact of the SEM Scanner, and does not incorporate the potential impact upon patients’ quality of life such as reduced patient |
The manufacturer provided little information regarding study methodology, particularly in relation to patient selection processes and data collection – which leads to concerns surrounding bias. Furthermore, increased focus on PUs alone may affect risk assessments and detection of potential PUs, rather than the SEM Scanner per se.

The SEM Scanner appears to be an innovative and promising technology to help reduce the burden of pressure PUs across NHS Scotland. However, there is a need for further development of the evidence in order to strengthen the manufacturer’s case. A prospective randomised trial using SEM scanner versus current care provision in NHS Scotland would provide a more robust evidence base.

Safety
The SEM Scanner is contraindicated for use on broken skin.

To date, no adverse or serious adverse events have been reported from the use of the SEM Scanner. No reports of complaints have been received.

In the event of false positives or false negatives, it is argued that the patient would be no worse off than under current standard of care. In the event of false positives, patients would receive inexpensive and unobtrusive preventative care, and in the event of false negatives, patients will still be assessed using standard of care.

The SEM Scanner’s cleaning and disinfecting procedure adheres to Scottish requirements outlined in the National Infection Prevention and Control Manual (NIPCM).

Organisational and patient issues
There is variability both in PU incidence reporting across NHS Scotland, and also in the standard of care currently applied in Scotland.

Healthcare Improvement Scotland recently published standards for prevention and management of PUs.

Clinical experts have indicated that the SEM Scanner requires nurse training in order to provide accurate results. Incorrect positioning of the device, can lead to inaccurate results.

Patients requiring pain stabilisation, or with cognitive impairment, agitation or confusion may not be suitable for daily scanning.

What is an IMTO?
Innovative Medical Technology Overviews (IMTOs) summarise the evidence relating to an individual technology that has been submitted by the manufacturer of the technology.

The purpose of IMTOs is to provide information that will contribute to local decision-making by NHS health professionals, NHS managers, and procurement colleagues.

IMTOs do not contain recommendations for NHSScotland and should be considered alongside existing guidance applicable to NHSScotland.

Chair
Scottish Health Technologies Group