



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Subepidermal moisture scanners for prevention of pressure ulcers
Topic exploration report number:	TER270

Introduction and aims

Subepidermal moisture (SEM) scanners are hand-held devices used to assess the skin on the heel and sacrum. They detect early pressure-induced tissue damage, thereby identifying increased risk of pressure ulcers. Underlying soft tissue damage can occur over a week before damage becomes visible at the outer skin layers. Early detection of damage would allow preventative measures to be put in place earlier and potentially reduce the incidence of pressure ulcers and the associated treatment costs.

Health Technology Wales (HTW) researchers searched for evidence on the clinical and cost-effectiveness of SEM scanners to identify increased risk of pressure ulcers in any setting (including hospital admissions, inpatients, discharge patients and those in the community).

Summary of evidence

The National Institute for Health and Care Excellence (NICE) published multiple technology guidance (MTG51) in October 2020. It was concluded that the SEM Scanner, with visual skin assessment, showed promise for preventing pressure ulcers. However, NICE reported that there was not enough good-quality evidence to support the case for routine adoption in the NHS, recommending a randomised controlled trial (RCT) to address uncertainties about the clinical benefits of using the scanner compared with standard risk assessment.

HTW has identified little relevant additional evidence following NICE MTG51 that would address the aforementioned uncertainties. One study (Musa et. al. 2021) of 1,478 patients used a pragmatic 'real-world' approach, obtaining pressure ulcer data (before and during SEM Scanner use) through routine audit. SEM analysis reportedly fitted into routine skin assessment well. All sites reported a reduction in mean pressure ulcer incidence: 87% in acute care settings; 47% in the palliative care setting and 27% in the community care setting. Furthermore, 67% of sites reported a 100% incidence reduction. Another study suggested that the sensitivity and

specificity would allow for augmentation of clinical decision making (Gershon and Okonkwo 2020).

The SEM scanner is a digital health technology and was determined to be a Tier C technology according to the [Evidence Standards Framework for Digital Health Technologies](#). This classification covers technologies with measurable user benefits, including tools used for treatment and diagnosis, as well as those influencing clinical management through active monitoring or calculation. For technologies of this classification, it is recommended that high quality RCTs are produced to demonstrate effectiveness of the technology.

Areas of uncertainty

NICE MTG51 stated that there was not enough good-quality evidence to support the case for routine adoption in the NHS. Clinical experts reported that the magnitude of reduction in incidence of pressure ulcers was greater than they would anticipate based on their clinical experience and there were concerns that benefits may be in part due to increased awareness of preventing pressure ulcers. An RCT comparing to standard risk assessment was advised, but has not yet been carried out. Uncertainties regarding clinical benefit (and therefore cost benefit) remain.

Conclusions

Published evidence suggests SEM scanners detect early pressure-induced tissue damage and they show promise for preventing pressure ulcers. However, the uncertainties regarding clinical benefit (and therefore cost benefit) reported in NICE MTG51 remain. An RCT comparing to standard risk assessment would help to address uncertainties.

Brief literature search results

Resource	Results
HTA organisations	
	Innovative Medical Technology Overview: 007-2016 SEM scanner. October 2016:
Healthcare Improvement Scotland	http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/topics_assessed/imto_007-2016.aspx
Health Technology Assessment Group	We did not identify any relevant evidence from this source
Health Information and Quality Authority	We did not identify any relevant evidence from this source
EUnetHTA	We did not identify any relevant evidence from this source
International HTA Database	We did not identify any relevant evidence from this source
UK guidelines and guidance	
SIGN	We did not identify any relevant evidence from this source
NICE	Medical technologies guidance (MTG51). SEM Scanner 200 for preventing pressure ulcers. October 2020: https://www.nice.org.uk/guidance/mtg51
Secondary literature and economic evaluations	
https://www.epistemonikos.org/en/	We did not identify any relevant additional evidence from this source
https://www.tripdatabase.com/	We did not identify any relevant additional evidence from this source
Cochrane library	Moore Z. and Patton D. Risk assessment tools for the prevention of pressure ulcers. Cochrane Database of Systematic Reviews 2019, Issue 1. Art. No: CD006741. DOI: 10.1002/14651858 https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006471.pub4/epdf/full
Medline	Budri AMV, Moore Z, Patton D, O'Connor T, Nugent L, Avsar P. Sub-epidermal moisture measurement: an evidence-based approach to the assessment for early evidence of pressure ulcer presence. Int Wound J. 2020 Dec;17(6):1615-1623. doi: 10.1111/iwj.13437. Epub 2020 Jul 19. PMID: 32683789: https://onlinelibrary.wiley.com/doi/10.1111/iwj.13437 Gefen A, Ross G. The subepidermal moisture scanner: the technology explained. J Wound Care. 2020 Sep 1;29(Sup9a):S4-S9. doi: 10.12968/jowc.2020.29.Sup9a.S4. PMID: 32931371: https://www.magonlinelibrary.com/doi/full/10.12968/jowc.2020.29.Sup9a.S4?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org
Primary studies	
https://www.epistemonikos.org/en/	We did not identify any relevant additional evidence from this source
https://www.tripdatabase.com/	We did not identify any relevant additional evidence from this source
Cochrane library	We did not identify any relevant additional evidence from this source
Medline	Gershon S. Using Subepidermal Moisture Level as an Indicator of Early Pressure Damage to Local Skin and Tissue. Adv Skin Wound Care. 2020 Sep;33(9):469-475. doi: 10.1097/01.ASW.0000655380.86380.7b. PMID: 32132363: https://journals.lww.com/aswcjournal/Fulltext/2020/09000/Using_Subepidermal_Moisture_Level_as_an_Indicator.4.aspx

	<p>Gershon S, Okonkwo H. Evaluating the sensitivity, specificity and clinical utility of algorithms of spatial variation in sub-epidermal moisture (SEM) for the diagnosis of deep and early-stage pressure-induced tissue damage. J Wound Care. 2021 Jan 2;30(1):41-53. doi: 10.12968/jowc.2021.30.1.41. PMID: 33439080: https://www.magonlineibrary.com/doi/full/10.12968/jowc.2021.30.1.41?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org</p> <p>Musa L, Ore N, Raine G, Smith G. Clinical impact of a sub-epidermal moisture scanner: what is the real-world use? J Wound Care. 2021 Mar 2;30(3):198-208. doi: 10.12968/jowc.2021.30.3.198. PMID: 33729842: https://www.magonlineibrary.com/doi/full/10.12968/jowc.2021.30.3.198?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org</p>
Ongoing primary or secondary research	
PROSPERO database	We did not identify any relevant additional evidence from this source
Clinicaltrials.gov	We did not identify any relevant additional evidence from this source

Date of search:	May 2021
Concepts used:	SEM scanner, subepidermal moisture, pressure ulcers, tissue damage, risk assessment, prevention.