

The Health Technology Assessment Of Medical Devices: What Have We Learnt? A NICE External Assessment Centre Perspective

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Disclosure

- My employer, York Health Economics Consortium, has been paid by NICE to undertake work as an External Assessment Centre for its Medical Technologies Evaluation Programme (MTEP)
- My employer, York Health Economics Consortium, has also been paid by various device companies to undertake work including submissions to MTEP
- The views in this presentation are my own and do not reflect those of NICE or device companies



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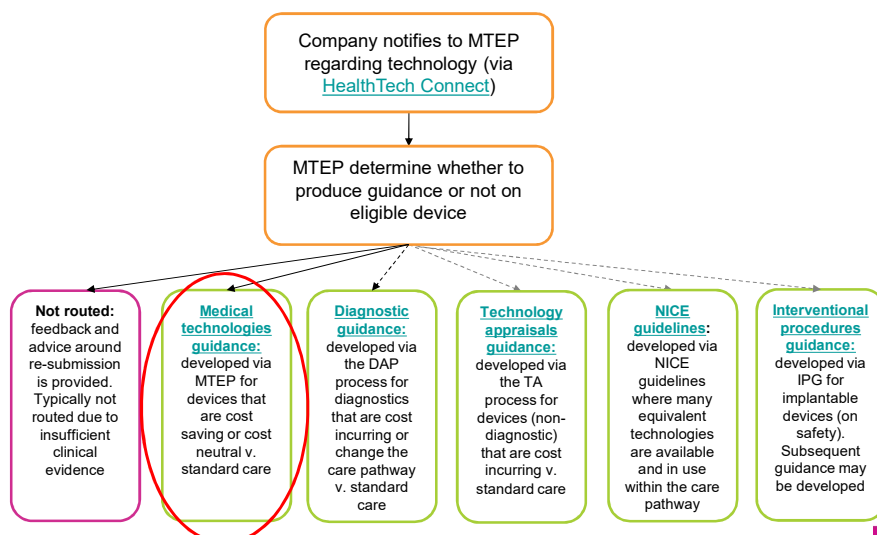


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NICE process for devices



Medical Technologies Evaluation Programme (MTEP)

- The MTEP Programme at NICE was set up in 2009 “to identify and, subject to evaluation, encourage adoption of new or novel medical devices and diagnostic technologies with potential to improve the experience and outcomes of patients and/or to drive efficiencies in the use of health-service resources.” (Campbell and Campbell, 2012)
- To date has published 50 Medical Technologies Guidance (MTG), of which, 45 remain on the NICE website
- Decisions are made based on clinical and economic evidence as well as expert/patient input
- This presentation will highlight examples of submissions where lessons may be learned to inform future submissions to MTEP and provide some tips for good practice



Clinical evidence

- Insufficient quality, quantity and generalisability of clinical evidence is the most common reason for NICE not issuing a positive recommendation

MTG	Title	Issues with clinical evidence
MTG48	PneuX to prevent ventilator-associated pneumonia	- Not related to the full scoped population Comparator was not current NHS clinical practice - Criteria for measuring outcomes unclear
MTG47	Episcissors-60 for mediolateral episiotomy	- Not enough evidence – limited in quality and quantity - Only relates to the reusable version of the device
MTG44	Curos for preventing infections when using needleless connectors	- Studies not controlled and device introduced as part of a bundle - Outcomes and patient groups inconsistent across studies



Clinical evidence (2)

MTG	Title	Issues with clinical evidence
MTG40	Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers	- US based clinical studies were not generalisable to the NHS Patient selection in the NHS unclear
MTG22	VibraTip for testing vibration perception to detect diabetic peripheral neuropathy	Comparator was not current NHS clinical practice
MTG20	Parafriacta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers	- Comparative evidence against standard care in a hospital setting required - Patient selection in the NHS unclear
MTG5	The MIST Therapy system for the promotion of wound healing	- Study population sizes too small - Comparator not appropriate



Selecting the correct population

- Where positive clinical evidence is only robust in a subgroup of the overall population or the device is estimated to be cost saving in a subgroup of the overall population then recommendations will be limited

The ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury
Medical technologies guidance [MTG21] Published date: 12 November 2014 [Register as a stakeholder](#)

GreenLight XPS for treating benign prostatic hyperplasia
Medical technologies guidance [MTG29] Published date: 14 June 2016

Endocuff Vision for assisted colonoscopy
Medical technologies guidance [MTG45] Published date: 14 June 2016

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1 Recommendations

1.1 Evidence of detection (screening)

1.2 Endocuff's cancer screening following a positive stool test. There is limited evidence Vision in a non-screening population.

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1 Recommendations

1.1 The case for adopting Memokath-051 for evidence. The evidence is limited but suggests reducing ureteric obstruction and improving section 4(b) and in appropriate patients is successful rate and a better patient experience also reduce the number of stent replacement

1.2 Memokath 051 stents should be considered

- malignant ureteric obstruction and an stent
- benign ureteric obstruction who cannot have or do not want reconstructive surgery or
- ureteric obstruction of any kind who cannot have or do not want a double J stent, or for whom repeat procedures are a particularly high risk.

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8 Sources of evidence considered by the Committee

About this guidance

1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. 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. The medical technologies guidance on the ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury recommends further research. This recommendation is 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.

1.1 The ReCell Spray-On Skin system shows potential to improve healing in acute burns. However, there is insufficient evidence on its use in clinical practice, particularly in relation to which patients might benefit most from its use. To support the case for its routine adoption in the NHS.

1.2 Research is recommended to address uncertainties about the claimed patient and system benefits of the ReCell Spray-On Skin system. Clinical outcomes should include time to 95% healing, length of hospital stay, cosmetic appearance of the scar and function of the burn area, compared with standard care. As relevant databases and registers are available, the research might include analysis of data generated from these. NICE will explore the development of appropriate further evidence, in collaboration with the technology sponsor and with clinical and academic partners, and will update the guidance if and when new and substantive evidence becomes available.

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Economic Modelling

- A case must be made to demonstrate that cost savings are likely with the introduction of the new device
- Where clinical evidence is limited or uncertain, economic outcomes are likely to be uncertain too (e.g. in MTG38 for Neuropad)
- In other cases, where there is high uncertainty this will be flagged and will feed into a negative recommendation (e.g. in MTG6 for Ambulight PDT)
- External Assessment Centres typically undertake additional modelling, sensitivity analyses and scenario analyses
- In some cases, where extensive additional modelling is required, a decision may be delayed (e.g. in MTG13 for Watch BP)

Pricing

- Typically, devices assessed through MTEP are assessed at their list price or a pre-specified discounted price
- This value is submitted during the company's submission and will be used throughout to populate the company and EAC's economic models
- The value is published on the NICE website meaning the guidance is only valid at the maximum price shown on the website

Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia
Medical technologies guidance (MTG) **gammaCore for cluster headache**

Medical technologies guidance [MTG46] Published date: 03 December 2019 [Refine as a stakeholder](#)

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Download guidance (PDF)

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Tech 1.1

Inno 2.2

Intes 2.3

2.4

Costs 2.5

The total cost of consumables for the Rezum procedure is estimated at £2,500 (including VAT) per treatment. This includes the generator, which is a one-time charge. The consumable provides a single treatment session and is not reusable. The consumable is provided free of charge. For more details, see the [product information](#).

Guidance

2 The technology

Technology

gammaCore (gammaCore) is a non-invasive vagus nerve stimulator used to treat and prevent cluster headaches. It is self-administered by the person or their carer.

After applying conductive gel, gammaCore is held against the neck (over the cervical branch of the vagus nerve) and delivers a small electric current for about 2 minutes. This stimulation should be repeated 3 times. The device is small and portable.

gammaCore requires RFID (radio frequency identification) card activation which is renewed every 2 months (93 days). The RFID card activation allows gammaCore to deliver a maximum of 30 stimulations in each 24-hour period. Conductive gel is provided with each new RFID card. Additional gel can be provided at no extra cost.

Benefit/evidence

gammaCore is currently the only technology that uses non-invasive stimulation of the vagus nerve to treat cluster headache.

Intended use

The instructions for use (gammaCore) state that gammaCore should be used regularly throughout the day to prevent cluster headache attacks and acute to reduce pain during an attack.

gammaCore is intended to be self-administered, or treatment can be administered by a carer. Using gammaCore requires brief training and some manual dexterity. Training for patients and staff is provided by the company for free.

gammaCore should not be used by people with an active implantable medical device, people with heart disease, during pregnancy or in children.

Costs

gammaCore is provided free of charge for the first 3 months (93 days). Subsequent treatment costs £250 for 93 days (including VAT).



So what have we learnt?

- Claimed benefits should be evidence based
- The population within clinical evidence submission should be well defined and aligned with that in which the device is clinically and cost-effective
- Clinical studies should be well conducted, comparative and generalisable to NHS
- Clinical evidence should align with the device being considered
- Economic models should follow the NICE reference case/MTEP methods guide
- Uncertainty should be fully explored with sensitivity and scenario analyses
- Insight from relevant clinical experts working within the NHS is required



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