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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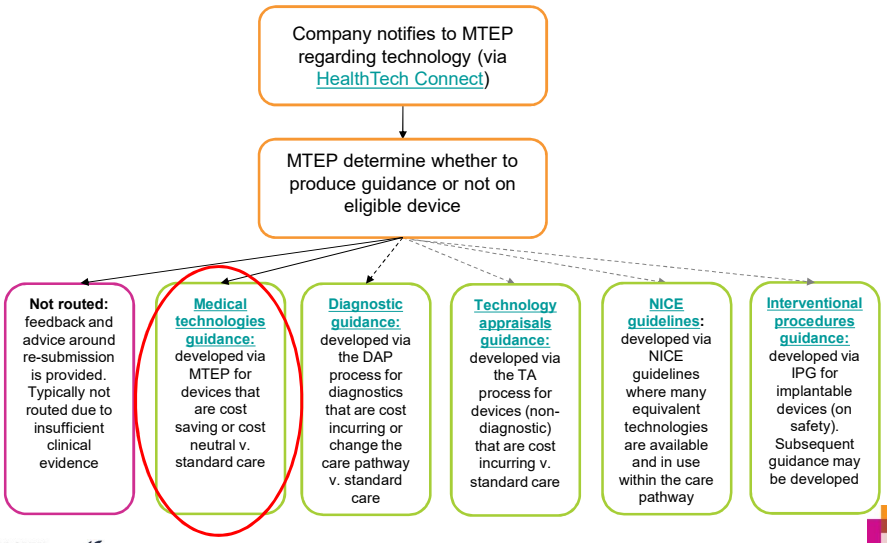
NICE process for devices



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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

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Clinical evidence

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

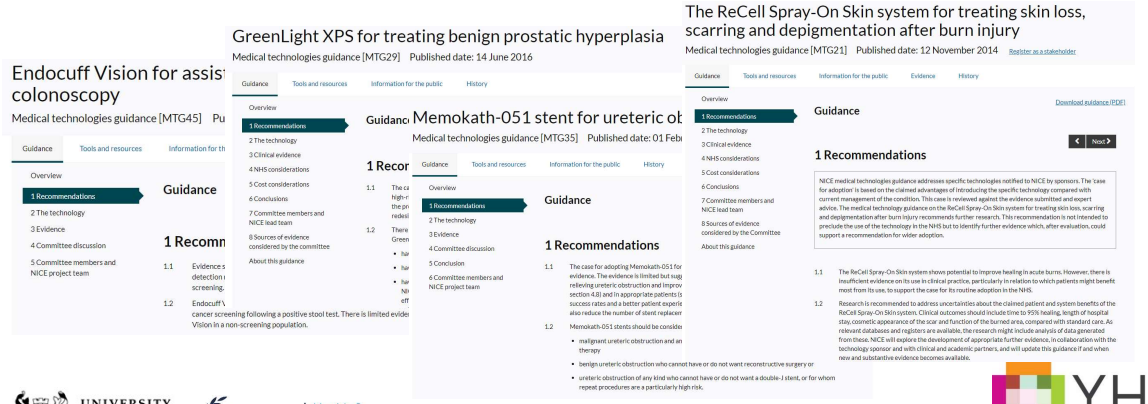
MTG	Title	Issues with clinical evidence
MTG48	PneuX to prevent ventilator-associated pneumonia	• Not related to the **full scoped population** • **Comparator** was not current NHS clinical practice • Criteria for measuring **outcomes unclear**
MTG47	Episcissors-60 for mediolateral episiotomy	• Not **enough** 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	Parafricta 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

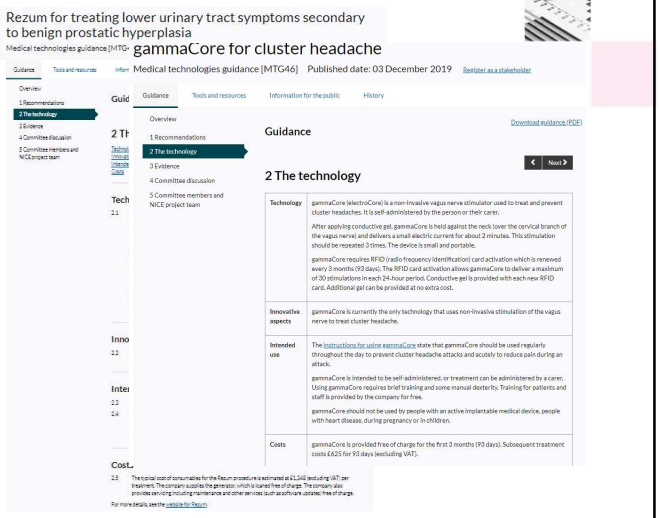


Economic Modelling

- 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



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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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Thank you

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