

# The impact of NICE's evaluation of innovative medtech products on the development of clinical evidence

Improving the Environment for Medical Device Clinical Research Stakeholder Workshop

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# Role of NICE

NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health

# NICE's current evaluation programmes (clinical)

- **Technology Appraisals Guidance**
  - new treatments with potential significant impact on NHS, or policy priorities (cancer, heart disease, stroke)
  - clinical and cost-effectiveness
  - 3-month funding direction
- **Interventional Procedures Guidance**
  - safety and efficacy of novel procedures
- **Clinical Guidelines**
  - established treatments in the pathway of care
  - clinical and cost-effectiveness

# What evidence does NICE use?



## Medtech evaluation in NICE's current programmes (Devices)

- **Technology Appraisals Guidance, eg**
  - Drug eluting stents
  - ICDs
- **Interventional Procedures Guidance, eg**
  - Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants
  - Transcatheter aortic valve implantation for aortic stenosis
  - Suburethral synthetic sling insertion for SUI in men
- **Clinical Guidelines** as technologies are established and appear in the pathway of care

## Medtech evaluation in NICE's current programmes (Diagnostics)

- **Technology Appraisals Guidance, eg**
  - Liquid-based cytology
  - Myocardial perfusion scintigraphy
- **Interventional Procedures Guidance, eg**
  - Catheterless oesophageal pH monitoring
  - Lumbar infusion test for the investigation of normal pressure hydrocephalus
  - Falloposcopy with coaxial catheter
- **Clinical Guidelines, eg**
  - Preoperative tests
  - Intrapartum care (includes fetal monitoring)

# Current position - pros and cons

<b>Pros</b>	<b>Cons</b>
National evaluation	Limited capacity, restricted to national priorities
Robust, transparent processes and methods, incl. public consultation	Not tailored to determining value early in lifecycle
Strong, well-known “brand”	Several evaluation options within and outside NICE
Funding direction (TA)	Unclear to NHS how other guidance and recs should be prioritised

# Conclusions from our experience

- Recognise there may be aspects of medtech product evaluation (including diagnostics) that need bespoke methods and processes
- Also need to increase capacity for identifying and selecting topics
- Concerns generally about lack of adoption of beneficial products

# “Darzi Review”

*“For new clinical technologies, we will simplify the way in which they pass from development into wider use by creating a single evaluation pathway, and will develop ways to benchmark and monitor their successful uptake”*

Next Stage Review  
Summer 2008

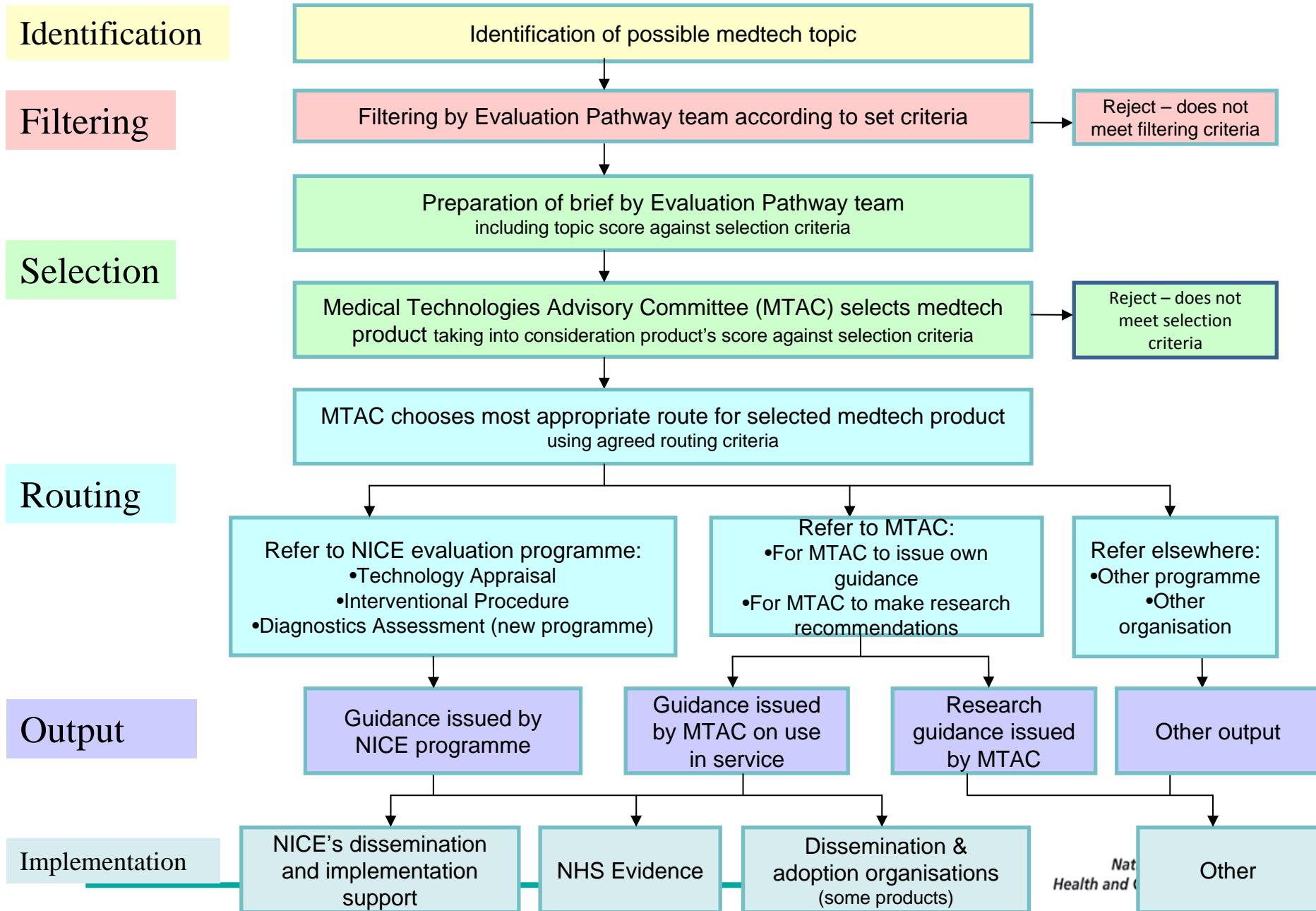
# Medtech evaluation: new developments at NICE

- Evaluation Pathway
- Diagnostics Assessment Programme (pilot)
- Both in planning, with high degree of industry input
- Evidence development questions +++

# Evaluation Pathway for medtech products

- Notification-based system
- Evaluation based on benefits
- Single entry point
- Medical Technologies Advisory Committee (MTAC) routes products to appropriate evaluation (by NICE or others)
- MTAC produces its own guidance on appropriate products
- Single exit point, ie guidance and evidence on all products going through the pathway to be published on NHS Evidence

# Evaluation pathway for medtech products



# Scope – products to be evaluated

- Medical devices as defined in EU directives:
  - 93/42/EEC (concerning medical devices)
  - 98/79/EC (concerning in vitro diagnostic medical devices)
  - 90/385/EEC (concerning active implantable medical devices), as amended
- .....including medical devices used for the purpose of diagnosis
- Genetic tests fall within the scope of 98/79/EC provided they have a medical purpose
- Other products (eg tissue engineered products), on advice from DH

# What does NICE mean by benefits?

- **Patient, eg**
  - Quality and quantity of life
- **System, eg**
  - Facilitates treatment in another location
  - Supports service reorganisation
- **Resources, eg net reduction in:**
  - Recurrent costs
  - Acquisition costs

# Dummy “positive” recommendation

- Product X is recommended as an option for use in the NHS.
- It reduces costs over x years and produces clinical outcomes similar to those of established methods, for the treatment of selected patients with Y.
- Product X results in shorter hospital stay.
- Its acquisition costs, estimated to be £xxx, are offset by the reduced costs of hospital and community nursing care.
- ***But – what if there is insufficient evidence for a positive recommendation?***

# Dummy recommendation requiring further evidence

- The available evidence suggests that product X is more effective in treating Y than other available products, but more information is needed to confirm these findings.
- Data on all patients treated with X should therefore be submitted to the national X register at [www.Xtreatment.uk](http://www.Xtreatment.uk)
- Further guidance will be developed during the last quarter of 2010 after review of these data.

# Types of evidence/data collection (1)

- **“Promising” product where on the current evidence base, few or no conclusions can be drawn on optimal use**
  - Likely to take the form of primary research (?RCTs)
  - Aligns closely with activities of NIHR/HTA
- **Next steps after evaluation by NICE**
  - Formulate research question, tailored to suit HTA’s prioritisation process/methods
  - Refer to HTA
  - NICE to produce recommendations once research is complete

# Types of evidence/data collection (2)

- **Product where some conclusions can be drawn on optimal use but there are specific uncertainties**
  - Specific outcomes
  - Potentially time-limited studies
- **Next steps after evaluation by NICE = broker arrangement for clinical utility study**
  - NHS provide clinical setting
  - Manufacturer provides kit/disposables etc
  - Some outcomes might be addressed by specialist society or manufacturer register
  - NICE produces revised recommendations once research is complete

# Implications

- Evidence produced by product developers should focus on benefits valued by NICE
- Developers should be prepared for post-marketing evaluation to remove uncertainties in the evidence
- NICE needs to make its research recommendations more explicit

# Next steps

- MTAC being recruited, meeting first time in November
- MTAC's methods and processes being developed – public consultation planned for spring 2010
- Discussions with DH R&D re development of clinical utility studies
- MTAC to produce first recommendations in 2010