

NICE Evaluation Pathway for Medical Technologies

Medilink Innovations Day, 8th July 2010

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Agenda

- NICE's experience in medtech evaluations
- New activities in medtech evaluations
- Evaluation Pathway
 - Processes
 - Methods
- How you can get involved

Role of NICE

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

What evidence does NICE use?



NICE's clinical evaluation programmes

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

Medtech evaluation in NICE's current programmes (Devices)

Technology Appraisals Guidance

- Drug eluting stents
- ICDs

Interventional Procedures Guidance

- 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

- technologies are established and appear in the pathway of care

Medtech evaluation in NICE's current programmes (Diagnostics)

Technology Appraisals Guidance

- Liquid-based cytology
- Myocardial perfusion scintigraphy

Interventional Procedures Guidance

- Catheterless oesophageal pH monitoring
- Lumbar infusion test for the investigation of normal pressure hydrocephalus
- Falloposcopy with coaxial catheter

Clinical Guidelines

- Preoperative tests
- Intrapartum care (includes fetal monitoring)

Current position - pros and cons

Pros	Cons
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

Medtech evaluation: new★ developments at NICE

- Evaluation Pathway
- Diagnostics Assessment Programme (pilot)

Diagnosics Assessment Programme pilot

- Pilot topic - Non-invasive tests for liver fibrosis in people with alcohol-related liver disease
- Diagnostics Advisory Committee
- Developing methods and processes

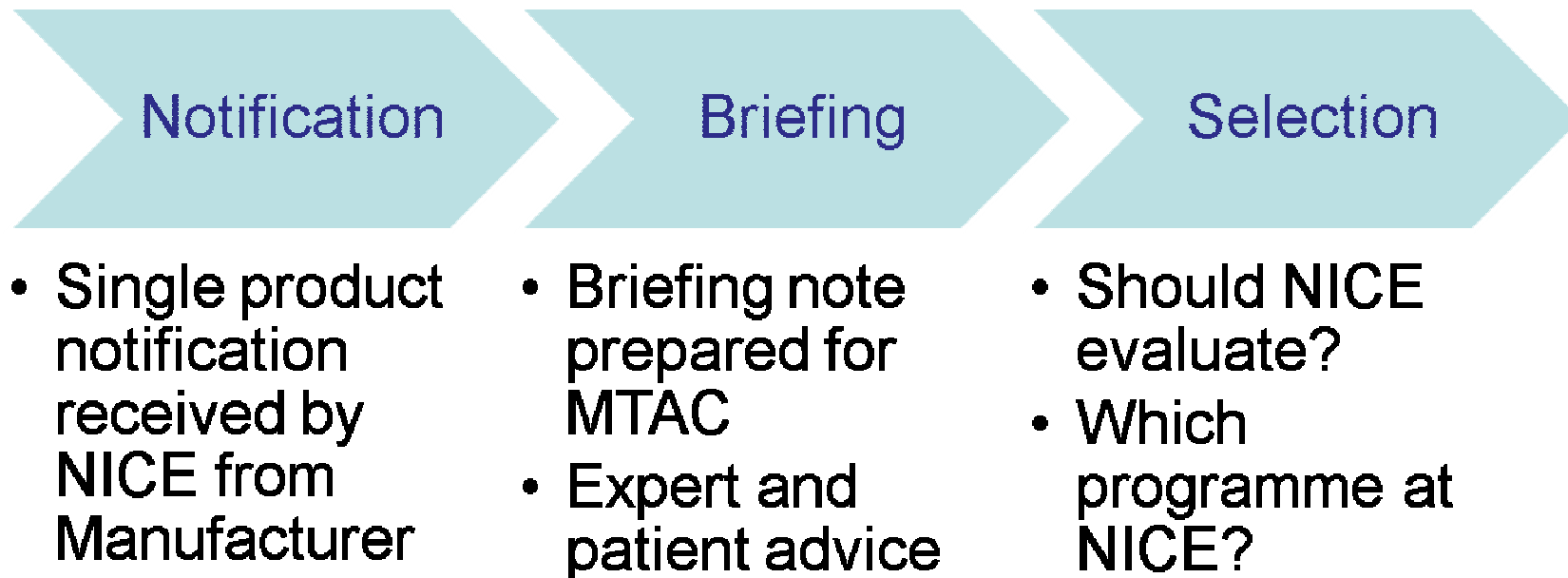
Evaluation Pathway for medtech products

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

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

Stages – identification and selection



Which programme at NICE?

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
- New device in a novel procedure where safety and efficacy are still unknown

Medical Technologies Guidance

- Single product
- **Innovative devices and diagnostics** (early stage evidence)
- **More benefit/same cost**
- **Same benefit/less cost**

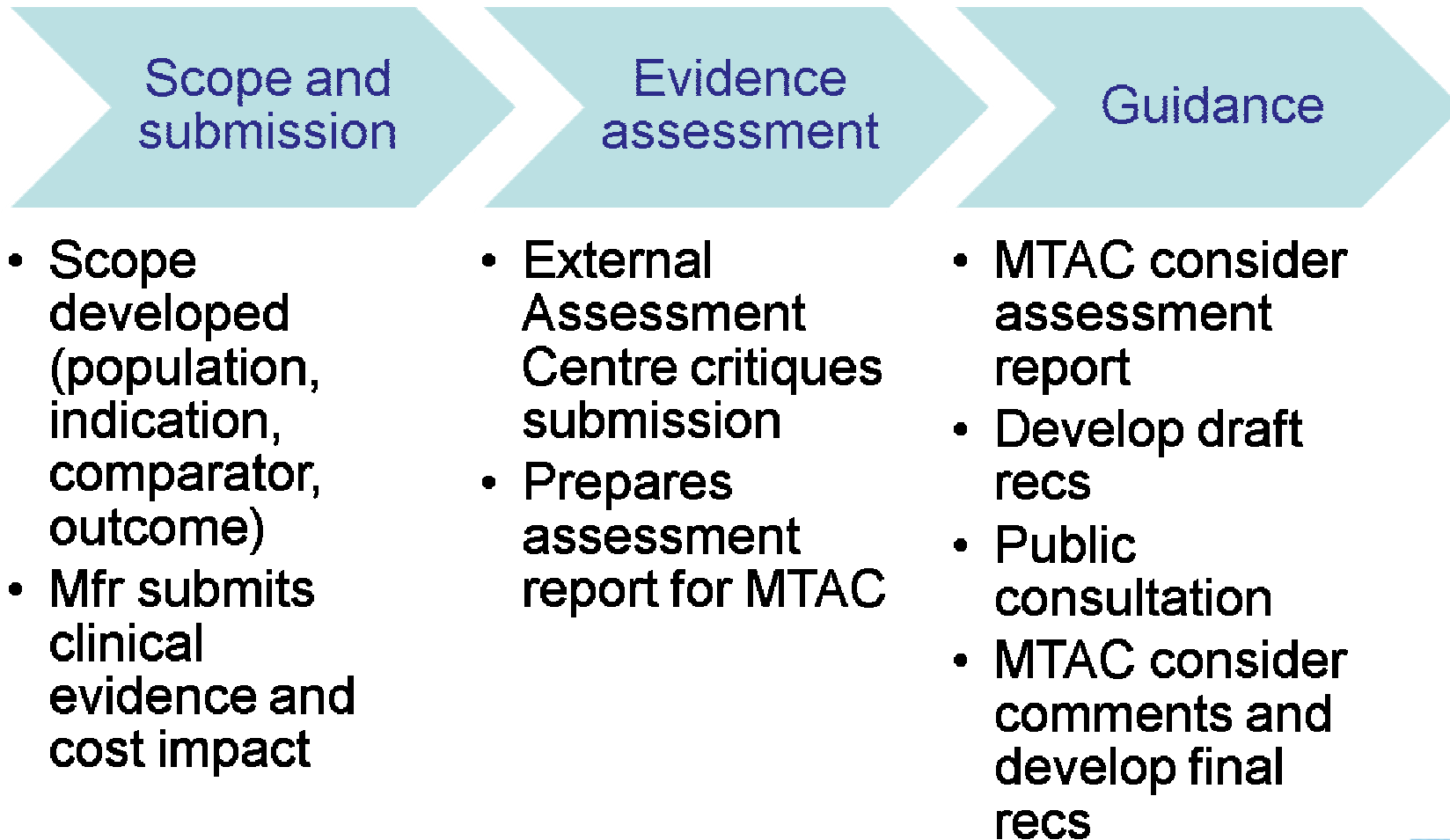
Diagnostics Guidance

- More cost/more benefit
- Complex care pathways
- Multiple or single products

NICE Medical Technologies guidance

- Provide advice on use to NHS (and social care where appropriate)
- Advice on conditions for use in order for benefits to be achieved, eg operator training, service changes
- Advice on further research required.....
- **or** advice that the technology should be used only in context of research

Stages – guidance development



Manufacturer submission

- Clinical evidence submission:
 - 2 weeks after the scope is agreed the manufacturer submits all relevant clinical evidence to NICE.
- Cost model submission:
 - 6 weeks after the scope is agreed the manufacturer submits its model of relevant costs.

Manufacturer submission – clinical evidence

- Published and in-press trials
- Regulatory data
- Post-market register data
- Forthcoming trial results
- Planned trials in a reasonable timeframe

Manufacturer submission – cost model

- **Non-clinical**
 - costs of acquisition and maintenance
 - staff costs
 - infrastructure costs etc
- **Clinical**
 - net costs of service use (eg length of stay, primary care consultations)
 - net costs of outcomes or events avoided (as they affect service use)

Cost-consequence analysis approach

- Expectation technology is therapeutically near equivalent to comparator
- Costs and resource consequences of the technology as well as relevant clinical benefits
- Not required: valuation of patient health status or treatment preferences

Medical technologies guidance development

- External Assessment Centres
- Critique of manufacturer submission – assessment report
- Summarised and presented to MTAC
- Manufacturer invited to meeting to answer MTAC's Qs
- MTAC make provisional recs for public consultation
- MTAC considers comments and produces final recommendations
- Issued by NICE in guidance

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

Consultation

- **Processes and methods**
 - Open until 10th September 2010
 - <http://www.nice.org.uk/aboutnice/whatwedo/aboutmedicaltechnologies/EPPConsultationProcessAndMethodsGuides.jsp>
- **SeQuent Please balloon catheter for in-stent coronary restenosis**
 - Open until 5th July 2010
 - <http://www.nice.org.uk/guidance/index.jsp?action=folder&o=49620>
- medtech@nice.org.uk

Notify a product to the Evaluation Pathway

- <http://www.nice.org.uk/aboutnice/whatwedo/aboutmedicotechnologies/notifyaproducttoep.jsp>
- Or email medtech@nice.org.uk