Risks and rewards in medtech evaluation

NHS Innovations East -Opening Doors to the NHS

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Mark Campbell

Associate Director – Evaluation Pathway

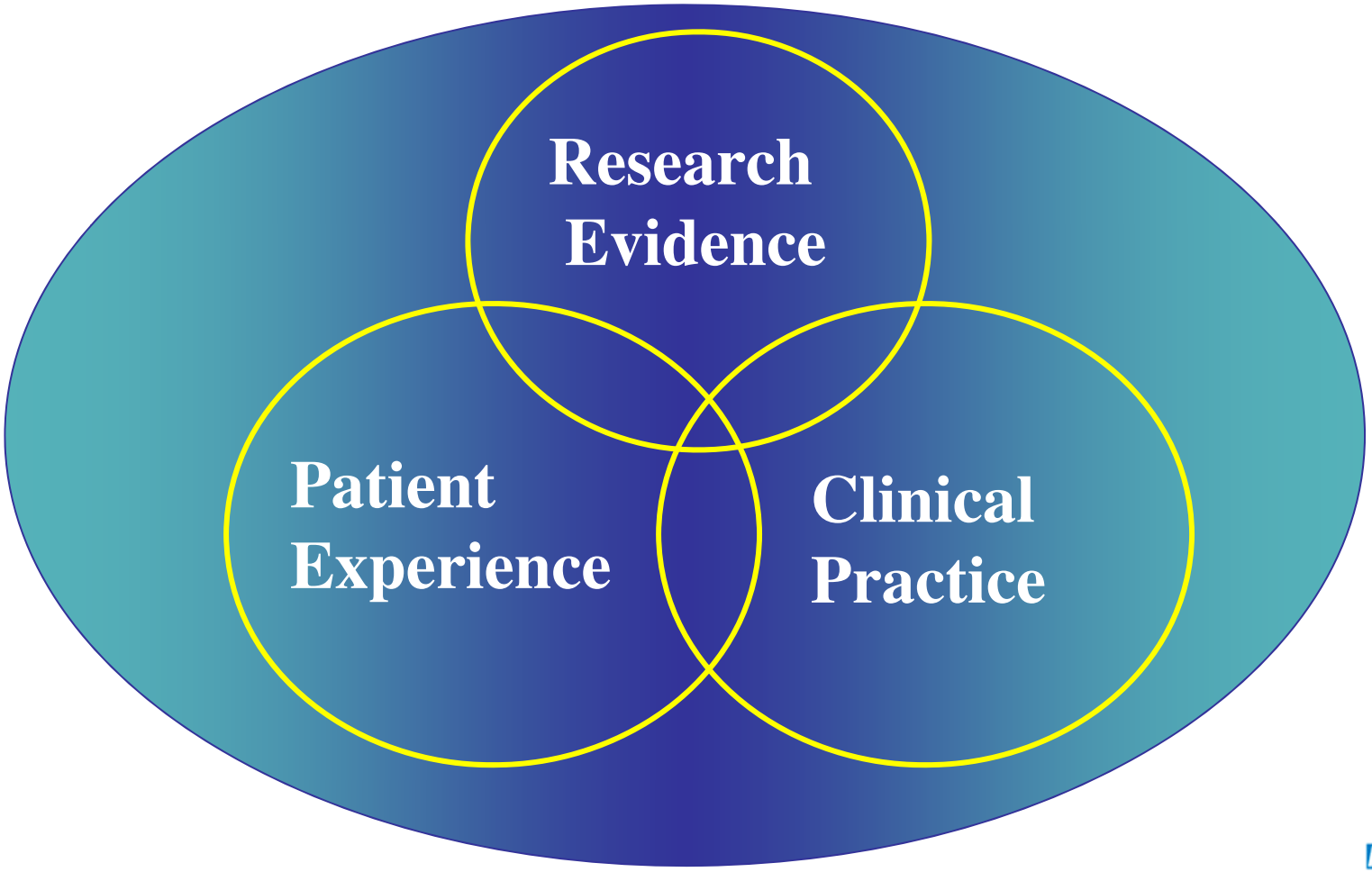
Agenda

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

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

Medtech evaluation in NICE's current programmes (Devices)

Technology Appraisals Guidance	Interventional Procedures Guidance	Clinical Guidelines
• Drug eluting stents • ICDs	• 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	• technologies are established and appear in the pathway of care

Medtech evaluation in NICE's current programmes (Diagnostics)

Technology Appraisals Guidance	Interventional Procedures Guidance	Clinical Guidelines
• Liquid-based cytology • Myocardial perfusion scintigraphy	• Catheterless oesophageal pH monitoring • Lumbar infusion test for the investigation of normal pressure hydrocephalus • Falloposcopy with coaxial catheter	• 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

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

- Single product notification received by NICE from Manufacturer
- Eligibility criteria

- Briefing note prepared for MTAC
- Expert and patient advice
- Selection criteria

- Evaluation worthwhile ?
- Which programme ?

Which programme at NICE?

Technology Appraisals Guidance	Interventional Procedures Guidance	Medical Technologies Guidance	Diagnostics Guidance
• new treatments with potential significant impact on NHS, or policy priorities (cancer, heart disease, stroke) • clinical and cost-effectiveness • 3-month funding direction	• safety and efficacy of novel procedures • New device in a novel procedure where safety and efficacy are still unknown	• Single product • **Innovative devices and diagnostics** (early stage evidence) • **More benefit/same cost** • **Same benefit/less cost**	• More cost/more benefit • Complex care pathways • Multiple or single products

Other evaluation routes

- Advisory Group on National Specialised Services
  - technology is indicated for <500 people in England AGNSS will undertake review and commission pathway
- National Screening Committee
  - If diagnostic test indicated primarily for screening asymptomatic individuals
- Others

Medical technologies guidance development

- Manufacturer submission
- Critical appraisal by External Assessment Centre to produce Assessment Report
- Summarised and presented to MTAC
- Manufacturer invited to meeting to answer questions
- MTAC make provisional recommendations for public consultation
- MTAC considers consultation responses and produces final recommendations
- Issued by NICE in guidance

Stages – guidance development

Scope and submission

- Scope developed (population, indication, comparator, outcome)
- Mfr submits clinical evidence and cost impact

Evidence assessment

- External Assessment Centre critiques submission
- Prepares assessment report for MTAC

Guidance

- MTAC consider assessment report
- Develop draft recs
- Public consultation
- MTAC consider comments and develop final recs

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 in development

Title	Anticipated publication date
SeQuent Please balloon catheter for in-stent coronary restenosis	Nov 2010
CardioQ-ODM (oesophageal Doppler monitor) to guide intravenous fluid management in patients undergoing surgery, or in critical care	Dec 2010
Ambulight photodynamic therapy for the treatment of non-melanoma skin cancer	Mar 2011
Inditherm Mattress for the prevention of inadvertent perioperative hypothermia	Mar 2011
MoorLDI2 Burns Imager a laser Doppler blood flow imager for the assessment of burn wounds	Mar 2011
Evita Open Plus	June 2011
BRAHMS Copeptin test	June 2011
Pipeline Embolisation Device	TBC
SILK artery reconstruction device	TBC

Risks and rewards

Risks

- Technology doesn't meet eligibility criteria (NICE technical team)
- Resources required for submission
- Technology doesn't meet selection criteria (MTAC)
- Technology not recommended in guidance (MTAC)

Rewards

- Thorough assessment process involving NICE technical and, if selected, External Assessment Centre – developmental
- Respected National guidance for NHS in England
- Research recommendations (if topic selected for guidance)

Notify a product to the Evaluation Pathway or contact us

- http://www.nice.org.uk/MT
- Or email medtech@nice.org.uk