NICE and the External Assessment Centres

CEDAR Open Day
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Agenda

• Introduction to NICE
• Background to NICE’s role in evaluating medtech
• What NICE values in its External Assessment Centres
What is NICE?

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
This is what we do

Evidence assessment and interpretation

Economic evaluation and resource impact assessment

NICE and NHS Evidence
Evidence – guidance – shared learning

Pathways, guidance and standards

Web access for decision support and e-learning
This is how we add value

- Better outcomes for patients
- Knowledge for professionals and patients
- Effective use of NHS resources
- Access to the NHS market

Our purpose is to improve the quality and productivity of clinical practice, public health and social care.

Independence, objectivity and transparency.
A short history of NICE
Core principles of all NICE guidance

- Based on the best evidence available
- Expert input
- Patient and carer involvement
- Independent advisory committees
- Genuine consultation
- Regular review
- Open and transparent process
What evidence does NICE use?

- Research evidence
- Patient experience
- Clinical practice
“…..the most important initiative to date between Government and the healthcare products industry……”

“The domestic and global business environment is evolving rapidly, and both Government and the industry need to be able to keep pace with new technological advances so that we can provide a modern health service.”

“HITF was established to explore issues of common interest and identify opportunities for co-operation that would bring benefits for patients and service users, health and social care services, and industry.”
HITF November 2004 report recommendations

- **Centre for Evidence-based Purchasing:** “to better inform purchasing decisions”, assess value of new technologies
- **Innovation Centre:** “to spread best practice in promoting and supporting development of new healthcare technologies”
- **Build R&D capacity:** Healthcare Technology Co-operatives
- Maximise UK influence in regulatory matters in the EU and other international forums
Centre for Evidence-based Purchasing

• Hosted by NHS Purchasing and Supply Agency (PASA)
• Range of products
• Framework of 18 contracts (7 core, 11 cost-per-case)
• Contract framework transferred to NICE 1 April 2010
Next Stage Review ("Darzi Report")
June 2008

• New treatments are constantly redefining what high quality care looks like. We must support innovation to foster a pioneering NHS

• For new medical technologies, we will simplify the pathway by which they pass from development into wider use, and develop ways to benchmark and monitor uptake.
New NICE Programmes – bespoke for medtech

• Medical Technologies Evaluation Programme
  – Selecting medtech topics for NICE
  – Evaluating topics
    • Non-inferior, resource releasing value proposition
    • Cost consequences approach
    • Devices and diagnostics
  – Facilitating research on medtech topics

• Diagnostics Assessment Programme
  – Increased cost and benefit
  – Cost-effectiveness approach
  – Diagnostics with complex care pathway
Service items

• Assessment reports
• Facilitating collaborative research into clinical utility and cost utility
• Specification, compilation and analysis of datasets, data linkage and validation
• Systematic reviews and meta-analysis
• Technical evaluation to advise on effective use
Assessment reports

• Key document considered by MTAC when developing medical technologies guidance
• EAC prepares a critical appraisal of submission of evidence in the form of an assessment report
• Additional work may be required in specific cases and could include evidence synthesis and modelling of indirect and intermediate clinical and system outcomes
• Sponsor carries out factual check which is processed by EAC who respond to all sponsor comments
Research Facilitation role

• Committee may recommend a technology be used in a research context
• Uncertainties may relate to clinical outcomes, service impact, or organisational factors
• NICE specifies research questions and important outcome measures, and may also make suggestions about study design
• For controlled and comparative studies, EACs will be required to
  – develop detailed research questions based on the NICE recommendations
  – identify suitable research partners in the NHS
• EACs may be requested to act as the coordinating centre
• EACs become involved as required in research ethics and governance applications, and general following of IRAS
• EACs responsible for monitoring timelines for research outputs
Observational studies using registers or databases

- Register data or similar may be used
  - to see whether a particular recommendation has been put into practice
  - to provide follow-up data for guidance reviews
  - to follow up significant adverse events or safety outcomes.
Dedicated databases or registers for specific procedures or technologies

- engagement with specialists etc to agree appropriate datasets
- consideration of whether appropriate governance arrangements and independent oversight are in place
- setting up and managing databases or registers
- arranging and undertaking data linkage with routine information (eg HES)
- delivering and presenting appropriately analysed data to NICE advisory committees in a timely manner.
- EACs will be responsible for collecting and collating data to present appropriately analysed data to NICE advisory committees.
Established national registers

- engagement with specialists, and register supervisors to agree appropriate datasets
- collaboration to monitor numbers of patients and amount of data accrued; timely reporting
- arranging and undertaking data linkage with routine information systems (eg HES) in order to
  - assess coverage of specialist datasets
  - check for extra safety and efficacy information
- being involved as required in analysis and presentation of data to NICE advisory committees.
Systematic review and meta-analysis

• Interventional Procedures Programme develops guidance on safety and efficacy of new interventional procedures
• Evidence is assessed and presented internally, with the occasional requirement for systematic review
• Eg where the body of evidence is too great for rapid review, or there are questions that cannot be resolved without meta-analysis
Technical evaluation

- Medical technologies may have features that mean
  - that usability or technical factors will affect the product’s performance, or
  - its ability to deliver the potential benefits claimed for it
- EAC may identify such issues during the period of guidance development to determine what advice should contain, and what technical evaluation might be required to achieve this
- Potential academic publication
## Services for NICE programmes

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<th>Medical Technologies Prog</th>
<th>Diagnostics Prog</th>
<th>Interventional Procedures Prog</th>
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<tr>
<td>Assessment report</td>
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<td>Research facilitation</td>
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Thank you

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