Health Technology Assessment of Diagnostics

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NICE – What we do

Improve outcomes for people using the NHS and other public health and social care services.

• **Produce evidence-based guidance** and advice for health, public health and social care practitioners.

• **Develop quality standards and performance metrics** for those providing and commissioning health, public health and social care services.

• **Provide a range of information services** for commissioners, practitioners and managers across the spectrum of health and social care.
Medical Technologies Programmes

• Two new programmes established in 2010 driven by notification of technologies by manufacturers / sponsors
  • representing major increase in capacity for medtech evaluation

• Programmes aim to improve the timeliness and consistency of adoption of technologies with the potential to:
  • Improve patient outcomes
  • Reduce costs
  • Provide system benefits (e.g. facilitate service redesign)

❖ Medical Technologies Evaluation Programme
❖ Diagnostics Assessment Programme
Medical Technologies Programmes

• **Medical Technologies Evaluation Programme (MTEP)** and the **Medical Technologies Advisory Committee (MTAC)**
  - Undertakes **topic selection** and routing for all medtech products, including diagnostics
  - Produces **Medtech Innovation Briefings (MIBs)**
    - Description of technology – no judgement of value
  - Produces **guidance** on topics routed to itself
  - Undertakes **research commissioning** for both medtech programmes
  - Supported by an infrastructure of independent external assessment centres
Medical Technologies Evaluation Programme
Assessment of diagnostics

• Applicable to diagnostic technologies offering:
  • Potential for cost savings and equivalent or superior clinical performance compared to current practice
  • Superior clinical performance compared to current practice at no additional cost

• 38 week process to produce guidance on a single technology

• Evaluates diagnostic accuracy, clinical effectiveness and cost effectiveness of technology – cost consequences analysis

• Evidence submission by the sponsor, including economic model to support the case for adoption
Medical Technologies Evaluation Programme
Evidence considerations

• The evidence should demonstrate:
  • Equivalent or superior clinical performance
  • NHS cost savings

• The evidence includes:
  • Systematic review of the clinical and economic evidence with appropriate meta-analyses
  • De novo cost analysis (where needed)
  • Clinical and technical expert advice

• The submitted evidence is reviewed by an independent external assessment centre
MTEP Example – MTG 3

- Cardio Q Oesophageal Doppler Monitoring for intra-operative fluid management
- Evidence on clinical effectiveness demonstrated:
  - Fewer post-op complications
  - Earlier mobilisation – reduced length of stay
  - No increase in repeat surgery or re-admission
- Economic modelling demonstrated average cost saving of £1,100 per patient
- The Medical Technologies Advisory Committee recommended adoption
Medical Technologies Programmes

- **Diagnostics Assessment Programme (DAP)** and the Diagnostics Advisory Committee (DAC)

  - Specialist programme for complex assessments of diagnostic technologies
  - Produces guidance on topics routed to DAP by MTAC
    - Adoption recommendations
    - Research recommendations
  - Supported by an infrastructure of independent external assessment groups
Diagnostics Assessment Programme Assessment

- Characteristics of diagnostic technology routed to DAP
  - Expensive new technology with the potential to significantly improve patient outcomes
  - Uncertainty in diagnostic and care pathways
  - Significant advantages of assessing other technologies with similar purpose - MTA
  - 62 week process to produce guidance
  - Evaluates diagnostic accuracy, clinical effectiveness and cost effectiveness of technology – cost utility analysis
  - Structured information request but no sponsor submission
Evidence Considerations - DAP

• The evidence includes:
  • Systematic review of the clinical and economic evidence with appropriate meta-analyses
  • Modelling of patient outcomes, costs and cost effectiveness
  • Clinical and technical expert advice

• Patient outcome benefits – length and quality of life are expressed in quality adjusted life years (QALY)
• Cost effectiveness calculated – cost (£) per QALY
• This requires evidence throughout the care pathway

Diagram:

- Diagnostic accuracy → Impact on treatment decisions → Impact on outcomes
Evidence Considerations - DAP

• The ideal evidence would be a good quality ‘end-to-end’ study – follows patients from testing, through treatment, to final outcomes
  • Typically not available for diagnostics
  • Search for data on test accuracy, direct outcomes from the test, indirect health outcomes from the test result, and costs
  • Identified evidence can then be combined through a linked evidence approach
DAP Example – DG 5

• SonoVue (sulphur hexafluoride microbubbles) - contrast agent for contrast-enhanced ultrasound imaging of the liver
  • No end-to-end studies were available
  • High quality diagnostic accuracy data were available for SonoVue compared to CT and MRI (the comparators)
  • Evidence available on care pathways and outcomes
• SonoVue cost-effective and recommended in one population
  • reduced patient anxiety - diagnosis in same appointment
• SonoVue less cost-effective than MRI or CT in others but recommended where MRI and CT not appropriate
• Research recommendations to explore other potential applications
Guidance Recommendations

- The NICE guidance from the DAP or MTEP may include:
  - Adoption recommendations
  - Research recommendations
- Research recommendations expected to be important for DAP and MTEP
- The programmes include capacity for research commissioning to:
  - Clearly capture the key research questions resulting from evidence gaps
  - Facilitate the efficient generation of research data
DAP topics

• Published
  • 11 diagnostics guidance documents published
  • See http://guidance.nice.org.uk/Type/DT/Published

• In progress
  • For diagnostics guidance in development see
    http://guidance.nice.org.uk/DT/InDevelopment

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Workshop

- How will the new IVD regulations impact HTA of diagnostic technologies?

- Will the regulatory requirement to generate utility data help or hinder the development of clinically important diagnostic technologies?

- What are the implications of the IVD Regulations on the in-house exemption?