NICE National Institute for Health and Care Excellence

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***

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?