

The NICE Diagnostics Assessment Programme

Evaluating the evidence for diagnostic tests - how can we improve bench to bedside process?

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Overview

- Introduction to NICE
- New medical technologies programmes
- Medical Technologies Evaluation Programme (MTEP)
- Diagnostics Assessment Programme (DAP)
- DAP topics
- Evidence considerations

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.

It was established in 1999 as a Special Health Authority and in 2005 it was expanded to include the functions of Health Development Agency.

In 2013 (subject to legislation) it will be re-established as a non departmental public body and will expand to incorporate social care.

The Institute's aims

- Speed the uptake by the National Health Service (NHS) of interventions that are both clinically effective and cost effective
- Encourage more equitable access to healthcare (reduce post-code lottery of care)
- Encourage better and more rational use of available resources by focussing the provision of health care on the most cost-effective interventions
- Encourage the creation of new and innovative technologies.

Medtech evaluation: recent developments at NICE

- New programmes driven by notification of technologies by manufacturers / sponsors
- Two new programmes 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)

The Medtech 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 guidance on topics routed to itself

Note: Some diagnostic technologies will be assessed within the MTEP
- **Diagnostics Assessment Programme (DAP) and the Diagnostics Advisory Committee (DAC)**
 - Specialist programme for complex assessments of diagnostic technologies

Categories of diagnostic technologies

- The NICE Medtech programmes evaluate technologies from all the major classes of diagnostics:
 - Laboratory tests and pathology
 - Imaging
 - Endoscopy
 - Physiological measurement
- Remits include considering diagnostics for:
 - Initial diagnosis
 - Clinical monitoring
 - Treatment triage
 - Assessing disease stage and severity
 - Risk stratification

Assessment of diagnostics technologies within the MTEP

- Programme methodology includes the evaluation of clinical effectiveness and cost impact – *but not cost effectiveness (no evaluation of patient outcome benefits)*
- 38 week process from topic selection to guidance publication
- Assessments limited to the specific technology notified to the programme
- Applicable to diagnostics technologies offering both:
 - Equivalent or superior clinical performance compared to current practice
 - Potential for cost savings or no net increase to NHS costs

Diagnostics Assessment Programme (DAP)

- Specialist programme to undertake complex assessments of diagnostic technologies
- Assessments include cost effectiveness analysis
- Assessments may involve single or multiple related diagnostic technologies
- Detailed scoping undertaken by NICE technical team
- Assessments undertaken by independent external assessment groups (EAGs)
- Recommendations devised by the Diagnostics Advisory Committee (DAC) comprising:
 - Chair (Prof. Adrian Newland)
 - 22 standing members (2 or 3 year term)
 - Specialist members - experts on the specific topic

Characteristics of topics for the DAP

- Cost effectiveness analysis needed to provide a meaningful assessment
 - Expensive new technology with the potential to significantly improve patient outcomes
 - Cost saving technology where cost savings may outweigh reductions in health benefits
- Care pathway(s) not well understood requiring access to highly specialist clinical expertise
- Significant advantages of assessing multiple technologies

DAP topics

1. EOS Ultra Low Dose 2D3D System – biplanar x-ray system for postural assessment
2. Elucigene FH20 and LIPOchip for the diagnosis of familial hypercholesterolaemia
3. High definition computed tomography (CT) scanners for cardiac imaging – Somatom Definition Flash, Aquilion One, Brilliance iCT and Discovery CT750
4. Gene expression profiling and expanded immunohistochemistry tests to guide selection of chemotherapy regimes in breast cancer management
5. Adjunctive colposcopy technologies for examination of the uterine cervix - DySIS, LuViva Advanced Cervical Scan, Niris Imaging System and Zilico APX-100

DAP topics

6. SonoVue (sulphur hexafluoride microbubbles) – contrast agent for contrast enhanced ultrasound)
7. E-ENTROPY (and alternative technologies identified during scoping) for monitoring the depth of anaesthesia
8. SeHCAT (Tauroselcholic [75 Selenium] Acid) and other alternative technologies identified during scoping for the investigation of bile acid malabsorption and measurement of bile acid pool loss
9. Xpert MTB/RIF test (and alternative technologies identified during scoping) for diagnosis of multi-drug resistant tuberculosis.

Evidence considerations

- For regulatory and economic reasons, the evidence base for diagnostic technologies is often limited (e.g. compared to pharmaceutical assessments)
- Technologies may be actively marketed to the NHS without a clear understanding of the potential impact on care pathways and outcomes
 - Challenging to commissioners of diagnostic services and those engaged in the HTA of diagnostic technologies
 - May be impeding the adoption of potentially important technologies

Evidence considerations

- The NICE DAP aims to balance the need for robust, evidence based assessments while supporting the timely adoption of important technologies
- Cost effectiveness analysis requires clinical utility evidence (or at least the evidence to populate models where linked evidence approaches are used)
- Technologies offering real promise but are at an early stage in their life cycles are likely to have limited clinical utility evidence

Evidence considerations

- Divergent views on evidence needs
 - HTA standards should not be compromised , in the absence of robust data formal HTA involving cost effectiveness analysis (CEA) should not be attempted
 - Simpler approaches (not employing CEA and not estimating overall outcomes) should be adopted in order to speed the generation of guidance
 - Important to be able to provide early guidance on potentially important technologies using CEA and that making the best use of available evidence was required

Evidence considerations – moving forward

- Consensus development on evidence requirements for diagnostic technologies
 - NHS commissioners
 - HTA community
 - Diagnostics industry
 - Clinical community