NICE diagnostics assessment programme

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Background

The National Institute for Health and Clinical Excellence (NICE) has long evaluated the clinical and cost-effectiveness of medicines and other health technologies. It aims to support doctors working in the NHS to deliver healthcare that is high quality, safe and based on the best available evidence. In 2009–2010 NICE established its diagnostics assessment programme (DAP), after discussions with the British In Vitro Diagnostics Association. The new programme provides a further opportunity for NICE to evaluate innovative health technologies to inform best practice.

The programme mainly concentrates on pathological tests, imaging, endoscopy, algorithms or test combinations and physiological measurement because these represent most of the investigations performed on patients. As well as initial diagnosis, these technologies may be used for a variety of purposes, including clinical monitoring, screening, treatment triage, assessing stages of disease progression and risk stratification. All of these fall within the remit of the programme. The programme does not evaluate the effectiveness of tests based on clinical signs elicitation (ie as part of a 'bedside' clinical examination not involving use of instruments or devices) or tests that involve questionnaire-based assessments of a patient's symptoms.

The diagnostics evaluated are intended for use within the NHS in England and are ones that are defined in EU directives 93/42/EEC (concerning medical devices), 98/79/EC (concerning in vitro diagnostic medical devices) and 90/385/EEC (concerning active implantable medical devices), as amended. Genetic tests are covered by the programme provided they have a medical purpose.

Aims of programme

The aims of the programme are to:

- > Promote the rapid and consistent adoption of clinically innovative and cost-effective diagnostic technologies across the NHS.
- > Improve treatment choice or the length and quality of life by evaluating diagnostic technologies that have the potential to improve key clinical decisions.
- > Promote the efficient use of NHS resources by evaluating diagnostic technologies that have the potential to improve systems and processes for the delivery of health and social care.

Key activities of programme

The key activities of the DAP are:

- > undertaking evaluations of diagnostic technologies that require complex analysis because of the involvement of multiple technologies or indications; or because cost-effectiveness analysis (requiring the evaluation of patient outcome benefits) is required for meaningful evaluation;
- > developing and publishing diagnostics guidance on selected diagnostic technologies to the NHS in England and its social care partners;
- > recommending research into the clinical utility and/or healthcare system benefits of diagnostic technologies; and
- > reviewing and updating diagnostics guidance when required.

Key audiences

The diagnostics assessment programme has several audiences that are expected to take note of its guidance:

- > NHS commissioners – for example, when specifying services that incorporate the use of diagnostic technologies
- > Practitioners who use diagnostic technologies in clinical or research settings
- > Healthcare operational managers in primary and secondary care settings, particularly when planning services or facilities in which diagnostic technologies are used

Purchasing and procurement organisations, when planning procurement of these products, constitute an additional audience. Patients and carers of people who may be affected by the technologies are also an important audience for the programme because diagnostics guidance can help them make informed decisions about their treatment, in consultation with their clinicians.

Methodology

The assessment of diagnostic technologies is complex, as the potential benefits for patients need to be modelled through the post-diagnosis care pathways. These benefits are determined by what happens after the diagnostic technology is used – ie the treatments that may then be offered and how these affect the patients' quality of life and the progression of their condition.

Where there is a nationally agreed clinical guideline, decisions about what to include in the assessment of the post-

diagnosis care pathway are more straightforward. When no clinical guideline exists, additional expert input is needed and a number of options for post-diagnosis care pathways may need to be modelled. Similarly, expert input is required when the diagnostics advisory committee (DAC) formulates its recommendations. The DAC is made up of standing members as well as specialist members recruited for their expertise in the specific topic under evaluation. The committee's structure has been specifically designed to reflect the complexity of diagnostics assessments.

The evidence base for diagnostic technologies is typically much thinner than that for pharmaceuticals. This is due in large part to the less onerous regulatory framework, which is a further source of complexity in assessing these technologies.

Due to the complexity of diagnostics assessment and the lack of generally accepted methodologies, it was identified at a very early stage that receiving expert input and building expert consensus was key to the success of the programme. A methods working group (MWG) comprising highly respected academics in the field of health technology assessment, representatives from the diagnostics industry, the Department of Health and NICE staff was set up to provide this expertise. The MWG met seven times over an 18-month period to January 2011 and has made a major contribution to the programme methodology.

Programme status and guidance in development

In 2010, work was completed on a pilot project to test and further develop the methods and processes for the programme. In parallel with the pilot, work was initiated on early 'live' topics. To date, four topics have been initiated:

1. EOS Ultra Low Dose 2D/3D system – biplanar x-ray system for postural assessment (EOS low dose)
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

A programme manual covering both methods and process is at an advanced stage of development and public consultation is scheduled to commence in summer 2011. The first guidance – on EOS Ultra Low Dose 2D/3D system – is scheduled for publication in October 2011.

For further information about the programme and how you can contribute to the development of its guidance, visit: <http://www.nice.org.uk/aboutnice/whatwedo/aboutdiagnosticsassessment/diagnosticsassessmentprogramme.jsp>.