

The NICE Diagnostics Assessment Programme

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Overview

- Introduction to NICE and the Diagnostics Assessment Programme (DAP)
- Methodology challenges
- Companion diagnostics 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.

Diagnostics Assessment Programme (DAP)

- New 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 specific topic

Diagnostics Methodology Challenges

- **Challenge**
 - Typically thin evidence base (compared to pharmaceutical assessments)

- **Potential Solutions**
 - Design programme methodology to make maximal use of available evidence
 - Encourage the generation of robust data

Diagnostics Methodology Challenges

- **Challenge**
 - Lack of studies linking diagnostic test results to final patient outcomes (clinical utility)
- **Potential Solutions**
 - Economic modelling to link intermediate outcomes (e.g. diagnostic test accuracy) to patient outcomes (length and quality of life)
 - Requires significant care pathway research and expert clinician input
 - Clinical utility studies!

Diagnostics Methodology Challenges

- **Challenge**
 - Working with weak or absent data in estimating economic model parameters (e.g. data available but from a different population)
- **Potential Solutions**
 - Application of advanced statistical techniques to combine data, account for biases etc
 - Generating missing information
 - Expert elicitation (within the assessment where appropriate)
 - Through research recommendations (post assessment)

Companion Diagnostics (CDx)

- Companion diagnostics may be used to identify sub-populations of patients where treatment is likely to be more effective
- The term “companion diagnostics” covers a broad range of potential scenarios
- The evaluation issues are likely to vary significantly on a case by case basis
- Anticipated companion diagnostics scenarios for drug treatments and associated evaluation issues are considered in the following slides

Scenario 1

- ***CDx and drug co-developed, drug marketing authorisation requires the use of CDx***
- Features:
 - Co-dependency of drug and CDx
 - Likely that the specific co-developed CDx is the only option (i.e. no alternative CDx options)
 - Likely to be a strong evidence base including outcomes from the drug treatment informed by CDx
 - Strong case for considering the drug and CDx as a “package” and for evaluating together

Scenario 1 – Evaluation Considerations

- Cost effectiveness determination needs to account for the cost of the drug and CDx
- CDx cost considerations should include all patients tested in selecting the group for treatment with the drug

Scenario 2

- ***CDx and drug co-developed, drug marketing authorisation does not require the use of CDx***
- Features:
 - Likely that the specific co-developed CDx is the only option (i.e. no alternative CDx options) if CDx to be used
 - Likely to be a strong evidence base including outcomes from the drug treatment informed by CDx

Scenario 2 – Evaluation Considerations

- Cost effectiveness determinations for the drug with and without CDx could be performed
- Cost effectiveness with CDx should follow the principles in Scenario 1
- Sensitivity analysis on the CDx cost and diagnostic accuracy may be appropriate, especially where cost effectiveness of the drug alone and with CDx appear to be similar

Scenario 3

- ***CDx and drug independently developed, CDx applied in drug clinical development, drug marketing authorisation requires the use of a CDx***
- Features:
 - Co-dependency of drug and CDx
 - May be alternative CDx options
 - Likely to be a strong evidence base including outcomes from the drug treatment informed by CDx
 - Strong case for considering the drug and CDx as a “package” and for evaluating together
 - May need to take account of alternative CDx options

Scenario 3 – Evaluation Considerations

- Considerations of Scenario 1 apply
- If there are alternative CDx that would meet the requirements of the drug marketing authorisation (e.g. test for same marker from a different manufacturer), these should be accounted for e.g.:
 - Sensitivity analysis on diagnostic accuracy and cost to understand the importance of CDx attributes to the outcome benefits
 - Separate cost effectiveness determination for each drug / alternative CDx combination

Scenario 4

- ***CDx and drug independently developed, CDx applied in drug clinical development, drug marketing authorisation does not require the use of CDx***
- Features:
 - May be alternative CDx options
 - Likely to be a strong evidence base including outcomes from the drug treatment informed by CDx

Scenario 4 – Evaluation Considerations

- Considerations of Scenarios 2 and 3 apply
- The potential need to undertake cost effectiveness determinations on the drug alone and with a range of alternative CDx could make evaluations large, resource intensive undertakings

Scenario 5

- ***CDx developed independently and offers the potential to improve targeting of existing drug(s)***
- Features:
 - May be alternative CDx options
 - Thin evidence base likely (compared to pharmaceutical assessments)
 - Lack of studies linking diagnostic test results to final patient outcomes (clinical utility) likely

Scenario 5 – Evaluation Considerations

- Robust diagnostic accuracy studies essential for any meaningful evaluation
- In the absence of clinical utility evidence, modelling to link diagnostic accuracy to outcome benefits from the CDx targeted drug treatment may be undertaken
- Extant models of drug cost effectiveness may provide an important starting point for evaluation