The NICE Diagnostics Assessment Programme: Does Assessment Lead to Approval?

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Objective

To better understand the rate of positive recommendations from the NICE Diagnostics Assessment Programme and the economic evidence requirements.

Background

- The National Institute for Health and Care Excellence (NICE) Diagnostics Assessment Programme (DAP) assesses whether evidence for diagnostics is sufficient to support the case for National Health Service (NHS) adoption.
- However, evidence requirements are unspecified, and to our knowledge the frequency of positive recommendations has not been recently investigated.

Methods

- Recommendations, committee discussion and the economic evidence evaluated were analysed from diagnostic guidance (DG) published by NICE between June 2019–June 2024.

Results

Overall Recommendations

- 23 DGs were published during the specified time period; one DG was terminated early (NA, 4.3%) as clinical data were not received (this DG was excluded from subsequent analyses), one DG received full support (FS, 4.3%), 11 received partial support (PS, 47.8%), and 10 were not supported (NS, 43.5%; **Figure 1**).
- 18 DGs assessed multiple technologies and four assessed single technologies.
- Of the DGs receiving PS (n=11), six had positive recommendations restricted to a subset of the technologies assessed, three had conditional positive recommendations requiring further research, one was restricted to specific clinical settings, and one had a positive recommendation for a restricted patient population.

Economic Modelling Results

- *De novo* cost-effectiveness models (CEMs) were developed for 20 DGs, one DG conducted a cost-comparison and one conceptualised a CEM due to lack of data (**Figure 2**).
- Of the DGs with CEMs developed, 1/20 reported technologies were not cost-effective, 8/20 reported at least some of the technologies assessed were likely to be cost-effective, whilst 11/20 reported that cost-effectiveness was uncertain. Of these, 8/11 were NS and 3/11 were PS, with conditional positive recommendations providing further evidence was generated.

Recommendations for Further Research

- NICE provided further research recommendations in 20/22 DGs; of the two that did not have research recommendations, one received FS and the other received PS for restricted use to specific clinical settings.
- Following thematic analysis, the top four research topics recommended were diagnostic performance, impact on treatment decision-making, clinical outcomes following diagnosis, and patient experience or health-related quality of life (**Figure 3**).

Conclusion

- Our analyses highlight a lack of positive recommendations for many of the technologies assessed by the DAP. 10/22 DGs that were completed did not result in positive recommendations for any of the technologies assessed, whilst in a further 11 DGs, positive recommendations were restricted to certain diagnostics or settings, or were conditional to further evidence generation.
- A primary reason for DGs receiving NS was a lack of clinical and diagnostic accuracy data leading to substantial uncertainty regarding cost-effectiveness.
- These analyses suggest the need for comprehensive evidence generation to inform robust cost-effectiveness modelling.
- Manufacturers must collect sufficient data if they are intending to pursue a positive recommendation via NICE, highlighted by the high proportion of DAPs with recommendations for further research.

FIGURE 1

Overall recommendations

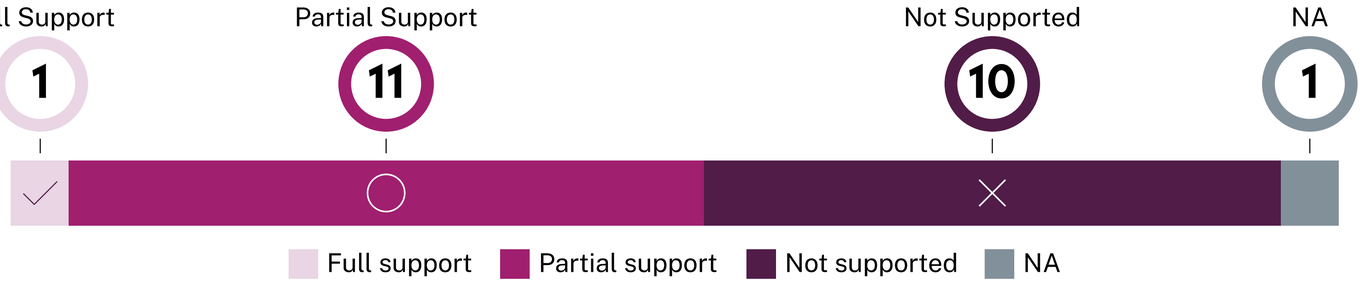


FIGURE 2

Association of cost-effectiveness modelling results with NICE recommendations

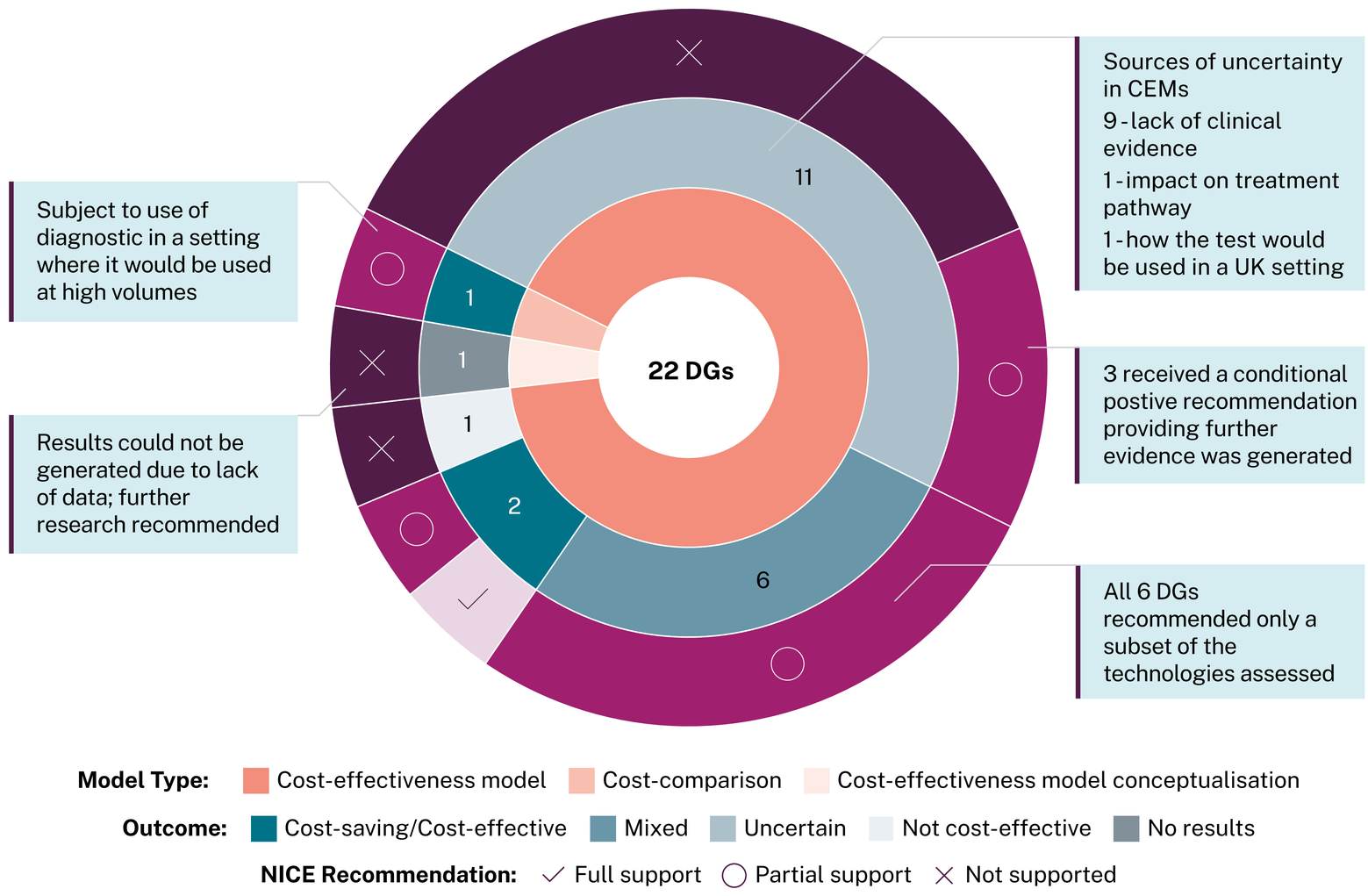
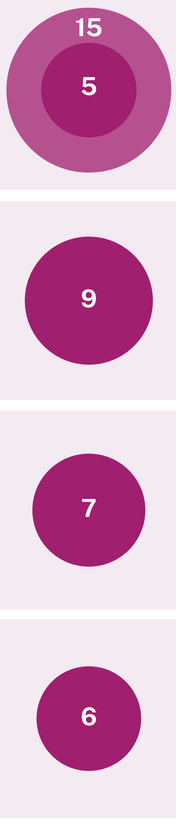


FIGURE 3

NICE recommendations for further research



Further data on diagnostic performance (n=15), within specific subgroups (n=5)

Impact of the diagnostic on treatment decision-making

Clinical outcomes following diagnosis

Patient experience or HRQoL

Our results in the context of the UK HTA landscape for diagnostics

- Greater transparency from NICE on evidence requirements may ensure their limited resources are not spent assessing technologies with little chance of support. NICE is transforming, with the following likely to impact evidence generation for manufacturers:
  - Restructuring of the NICE Advice service, to provide an earlier, tailored opportunity for engagement with NICE including on evidence requirements and study design.
  - Restructure of the HealthTech programme to take a product life cycle approach and streamline the number of programmes. This will comprise:
    - Early value assessment (EVA)
    - Multi-tech medical technologies guidance (MTG)
    - Late-stage assessment (LSA).
  - The introduction of EVA, in particular, could address the issues highlighted by this research. The EVA aims to assess technologies earlier in their lifecycle, publishing an evidence generation plan as part of a conditional positive recommendation, which can be carried out ahead of undergoing a full MTG appraisal.
- The UK healthcare system should review uptake of diagnostics following positive recommendation to ensure patients and healthcare professionals have access to diagnostics that are assessed to be cost-effective.

Abbreviations: CEM: cost-effectiveness model; **DAP:** diagnostics assessment programme; **DG:** diagnostic guidance; **EVA:** early value assessment; **FS:** full support; **HRQoL:** health-related quality of life; **HTA:** health technology assessment; **LSA:** late-stage assessment; **MTG:** multi-tech medical technologies guidance; **NA:** not applicable; **NHS:** National Health Service; **NICE:** National Institute for Health and Care Excellence; **NS:** not supported; **PS:** partial support.

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