NICE: A Multiprogramme HTA Organisation to Suit All?

Abigail Stevenson,[1] Kimberley Carter,[2] Liesl Millar,[2] Caroline Ling[1]

[1]RTI Health Solutions, Manchester, United Kingdom; [2]National Institute for Health and Care Excellence, Manchester, United Kingdom

OBJECTIVE

- NICE evaluates medicines, medical devices, and diagnostics using different health technology assessment (HTA) methodologies in four specialised programmes: technology appraisal (TA), highly specialised technologies (HST), the medical technologies evaluation programme (MTEP), and the diagnostics assessment programme (DAP).
- This study explores differences between programmes in terms of HTA processes and requirements, and analyses output to date.

METHODS

- Published NICE processes and guidance up to April 2018 were reviewed on the NICE website and verified by consultation with NICE technical staff.
- The processes and HTA requirements of each programme were compared.

RESULTS

Four NICE HTA Programmes: TA, HST, MTEP, and DAP

- HTA methodologies used by the four NICE HTA programmes are compared in Table 1.
- Cost-effectiveness analysis (CEA) is used for decision making by TA, HST, and DAP, whereas MTEP assesses cost neutrality or cost-saving potential using cost-consequences analysis.
- Published estimated timescales ranged from 25 weeks (HST without need for consultation) to 63 weeks (DAP).

NICE Recommendations by HTA Programme

- Recommendations published by each NICE HTA programme up to April 2018 (excluding withdrawn guidance) are shown in Figure 1.
- Recommendations varied between programmes, with MTEP publishing the highest number of positive recommendations (83%) and DAP publishing the highest number of research recommendations (40%).

Disease Areas Covered by NICE HTA Guidance

- NICE has published HTA guidance assessing pharmaceuticals, devices, and diagnostics across a broad range of disease areas (Figure 2).
- More than one-third of TA guidance (42%) assessed treatments for cancer as expected because all cancer medicines are referred to NICE.
- The types of technologies assessed by MTEP and DAP are likely to reflect the type of companies that have notified their products to NICE. HST assesses technologies only for rare diseases, and only 7 HSTs have been published since 2015.

Recent Changes to NICE HTA Processes

- NICE introduced an FTA process in 2017 (Table 1).[1]
  - Three medicines have been recommended via FTA: TA486, aflibercept for choroidal neovascularisation; TA497, golimumab for non-radiographic axial spondyloarthritis; and TA521, guselkumab for plaque psoriasis).
  - These drugs were deemed highly cost-effective and received a funding mandate within 30 days of publication.[5-8]
- In April 2017, a budget-impact test was introduced for TA and HST to assess financial impact. If the budget impact exceeds £20 million in any of the first 3 years, NHS England will have further commercial discussions with the company, including requesting a longer time to implement funding.[1]
- Other changes to TA include a new technical consultation prior to the first committee meeting, aiming to enhance dialogue between the company and NICE, allowing for more informed decision making.

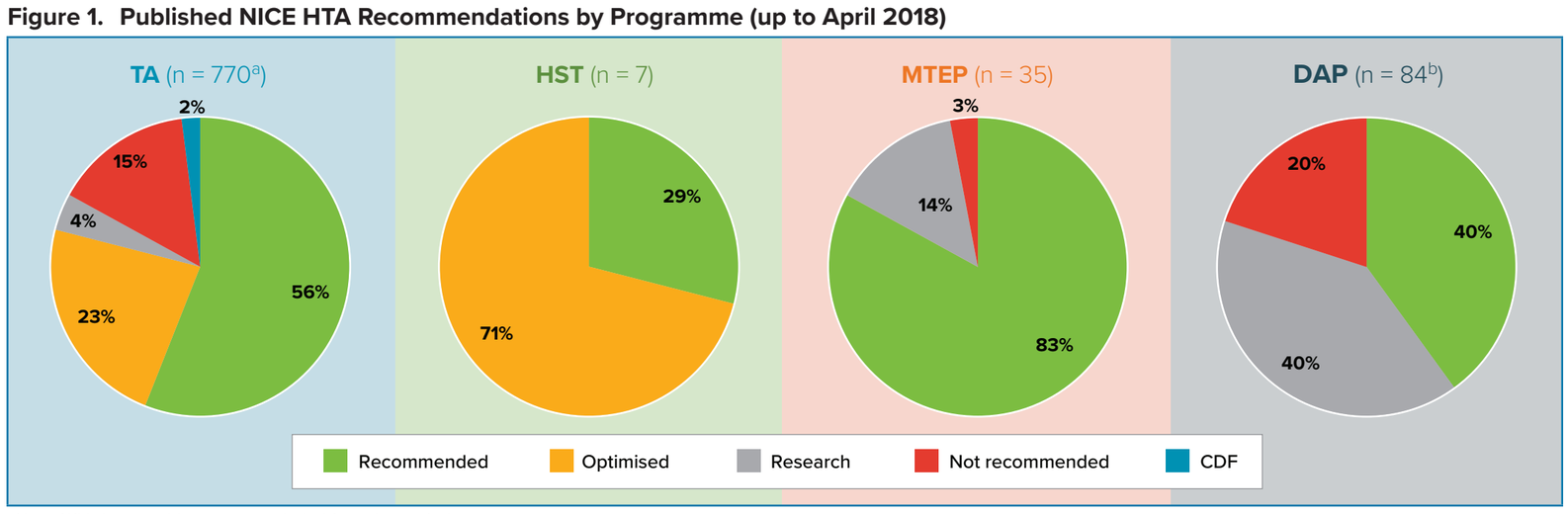
Table 1. Overview of NICE HTA Programmes

	TA[1]	HST[2]	MTEP[3]	DAP[4]
Topic selection	Identified by NIHRIO; selection by NICE, DoHSC and NHSE; referral by DoHSC or routed via MTEP process (devices/ diagnostics only)	As TA	Company can notify NICE directly to be considered for selection for guidance or advice	Selected via MTEP process
Type of technology(s) assessed	Single **(STA)** or multiple **(MTA)** technologies, including: • Pharmaceutical products • Medical devices • Diagnostics • Surgical procedures • Health promotion activities or a single technology for multiple indications **(MTA)**	Single technology for a single indication for very rare conditions. All of the following must apply: • Small target patient group treated in very few NHS centres • Clinically distinct patient group • Chronic and severely disabling condition • Expected use exclusively in highly specialised services • Very high acquisition cost • Potential for lifelong use • A significant need for national commissioning	Single medical device, diagnostic or digital technology, compared with standard care	Class of diagnostic technologies
HTA method(s) used and thresholds	**MTA/STA: CEA; ICER < £20-30K/QALY** (additional weighting for EOL up to £50K) **Fast track (FTA): CEA; ICER < £10K/QALY or cost comparison** shows similar or greater health benefits at similar or lower cost	**CEA: < £100K/QALY:** Above threshold, additional QALY weighting may apply: between 1 and 3, using equal increments, for a range between 10 and 30 QALYs gained	**Cost-consequence:** Technology must be cost saving or cost neutral; HRQOL not considered in model	**CEA: < £20-30K/ QALY**
Evidence submission	**FTA/STA:** by company, critiqued by ERG **MTA:** by companies and ERG	Company evidence submission, critiqued by ERG	Company evidence submission, critiqued by EAC	Evidence submission by EAG
Recommendations	5 options: • Recommended • Optimised • Only in research • Not recommended • Recommended in the CDF (full/optimised)	4 options: • Recommended • Optimised • Only in research • Not recommended	3 options: • Case supported/partially supported • Only in research • Case not supported	3 options: • Recommended • Only in research • Not recommended
Approximate timeline[a] (published)	**MTA:** 47-60 weeks **STA:** 41-50 weeks **FTA:** 32 weeks	25-35 weeks	38 weeks	63 weeks
Funding mandate for positive guidance	Yes: For **MTA/STA** after 3 months (or 9 months if budget impact exceeds £20 million/year); for **FTA** after 30 days	Yes: As MTA/STA	No	No

CDF = Cancer Drugs Fund; DoHSC = Department of Health and Social Care; EAC = external assessment centre; EAG = external assessment group; EOL = end of life; ERG = evidence review group; FTA = fast track appraisal; HRQOL = health-related quality of life; ICER = incremental cost-effectiveness ratio; NIHRIO = National Institute for Health Research Innovation Observatory; MTA = multiple technology appraisal; NHSE = NHS England; QALY = quality-adjusted life-year; STA = single technology appraisal.

[a]Timings are approximate from preparation of draft scope (week 0) to final guidance publication and are subject to change.

Figure 1. Published NICE HTA Recommendations by Programme (up to April 2018)

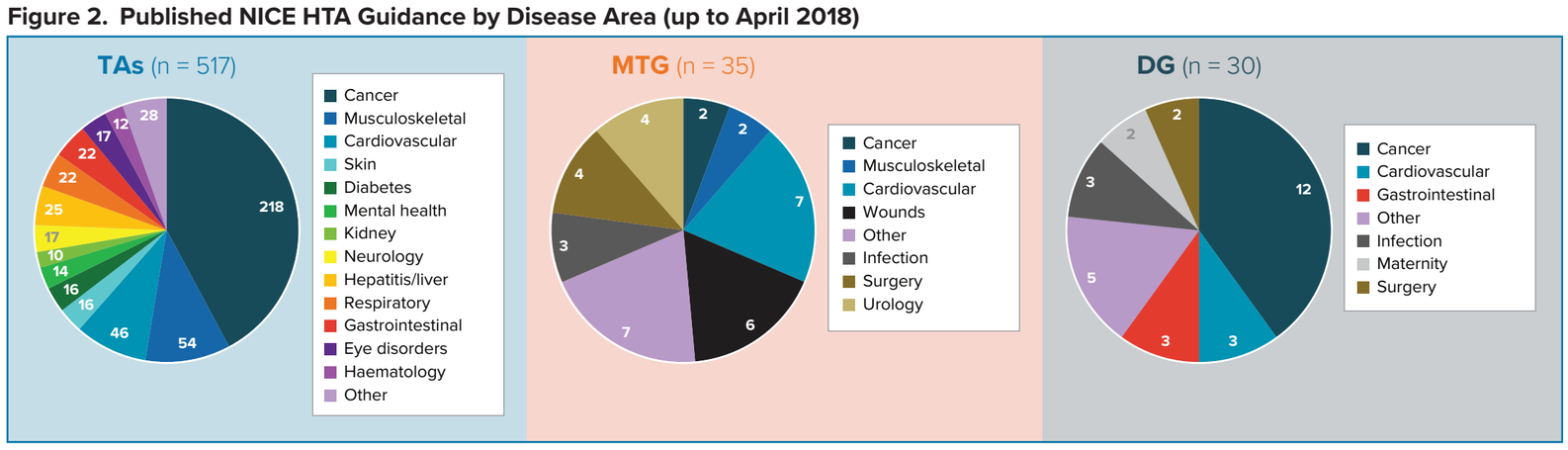


Note: Withdrawn guidance was excluded from the analysis.

[a]517 TAs published, providing 770 recommendations due to some MTAs providing multiple recommendations.

[b]30 Diagnostics Guidances published, providing 84 recommendations involving 87 technologies (there were fewer recommendations than technologies because a single recommendation may apply to a class of devices involving more than one assessed technology).

Figure 2. Published NICE HTA Guidance by Disease Area (up to April 2018)



Note: Categories with ≤ 5 TAs or ≤ 1 DGs or MTGs were classed as "Other." HST was not included as only very rare diseases are assessed.

DG = Diagnostics Guidance; MTG = Medical Technologies Guidance.

CONCLUSIONS

- NICE uses a range of HTA methods to assess technologies in different programmes: cost-consequence analysis in place of CEA for cost-saving devices, and higher thresholds for orphan drugs and those that meet end-of-life criteria.
- New developments include a budget-impact test and a new FTA process for technologies that are likely to be highly cost-effective.

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CONTACT INFORMATION

Abigail Stevenson, DPhil
Senior Research Associate, Market Access and Outcomes Strategy

RTI Health Solutions
Manchester, UK

E mail: alstevenson@rti.org

Kimberley Carter and Liesl Millar
Technical Analysts, Medical Technologies Evaluation Programme

National Institute for Health and Care Excellence
Manchester, UK

E-mail: liesl.millar@nice.org.uk; kimberley.carter@nice.org.uk