HTA174

Analysis of NICE Fast Track Appraisals: What are the key characteristics for success?

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BACKGROUND

Fast track appraisals for NICE submissions

- Fast track appraisals (FTA's) were introduced by NICE in 2017 with the aim of providing quicker appraisal times for the most cost-effective medicines [1].
- The aim was to provide quicker access for patients to the most cost effective new treatments, with FTAs used if:
  - ➢The company's base-case ICER was less than £10,000 per QALY gained.
  - ➢Likely that most plausible ICER is less than £20,000 per QALY and certainty that the ICER would not be above £30,000 per QALY gained.
  - ➢A cost-comparison case could be made to show that the technology provides similar or greater health benefits at similar or lower cost than technologies already recommended for the same indication.
- After 30 days from publication of the recommended technology, NHS England and commissioners committed to funding for the technology.
- In February 2022, NICE introduced new methods for technology appraisals and this included limiting the FTA appraisal to just cost-comparison cases [2].

OBJECTIVE

To identify and characterise NICE FTAs (and cost-comparisons) and analyse how these characteristics relate to time from submission date to published recommendation.

Table 1: Key Characteristics

Key Variable Identified	Found on NICE 2018 FTA Eligibility Criteria	Score applied to suitability for FTA
Certainty of clinical evidence	Yes	0 – Uncertainty shown in committee 1 – Some uncertainty shown in committee 2 – No uncertainty
Number of comparators	No	# Equals number of comparators in decision problem
Cost of medicine	No	1 – >£1000 a month. 2 – >£500 a month. 3 – <£500 a month
Size of the population	Yes*	1 – <100,000 2 – >100,000
Severity of the disease	No	1 – Life-threatening 2 – Severe 3 – Non-life-threatening
Previous FTA in disease area	Yes**	0 – none found 1 – 1 found 2 – 2 found
Other indications for the same medicine	No	# Equals number of NICE recommendations the drug has in other indications

*The 2018 NICE FTA criteria does not quantify the impact of size of population on the FTA scrutiny decision, disease with small populations are given a lower score due to greater possible uncertainty.**FTA criteria scrutinises the consistency of approach to modelling with models accepted in previous appraisals in the same, or similar indications.

METHODS

- Submissions were reviewed by two independent reviewers to identify the key characteristics by analysing each submission for common themes **(Table 1).**
- Characteristics were quantitatively scored based on the NICE FTA criteria and other measures such as level of innovation (number of comparators as proxy) and establishment in clinical practice (other indications as proxy).
- The higher the score the more suitable an appraisal is for the FTA route, with the impact of characteristics on the score also explored.
- The length of appraisal was calculated by subtracting the publication date from the submission date of the dossier by the company.
- The relationship between the eligibility scores and the difference between the submission date to published recommendation was analysed using a ***Pearson's correlation coefficient***.

RESULTS

- From April 2017 to September 2022, only 15 FTAs (or Cost Comparison) had success **(see Table 2).**
- The mean appraisal time is 31.6 weeks (from dossier submission by company to publication date) for the 15 FTAs, including cost-comparisons.
- The slowest appraisal was TA672, brolucizumab, with only two appraisals completed within the prespecified appraisal time by NICE (TA794 – diroximel and TA803 – risankizumab).
  - ➢ NICE's FTA timelines state from submission to appraisal completion, the process should only take 24 weeks (32 weeks from Invitation to Participate (ITP) to final guidance, ITP to dossier submission is 8 weeks and FTA scrutiny decision 6-8 weeks).
- The highest suitability score from any of the TAs was 18, with a range of 11-18.
- There is a moderate negative correlation of -0.45 (95% CI -0.78, 0.08) between the suitability score and the time from appraisal to guidance **(Figure 1)**. This result is not statistically significant.
- Appraisals with the longest timelines generally have uncertain clinical evidence.

KEY MESSAGES

- Medicines that do not fit these specific characteristics are disincentivised to use the FTA (now cost-comparison) route even if a medicine is eligible. There has been no successful FTAs in complex therapy areas like neuroscience, cardiovascular disease, or oncology.
- Furthermore, if rejected from the FTA process, companies face being re-routed to a single technology appraisal (STA), ultimately taking far greater time than initially entering the STA.
- The number of comparators had the most significant impact on the correlation coefficient. Additionally, appraisals that had similar FTAs in the same therapy area and high quality clinical evidence are associated with quicker appraisal times.
- The mean appraisal time from dossier submission to published guidance is over 8 weeks from NICE's predefined timelines.
- The average time from ITP to published guidance is 40 weeks for a FTA, which is the NICE target for the length of STA. Therefore, FTAs are often not faster than STAs.

Figure 1: Association between appraisal length and FTA suitability score.

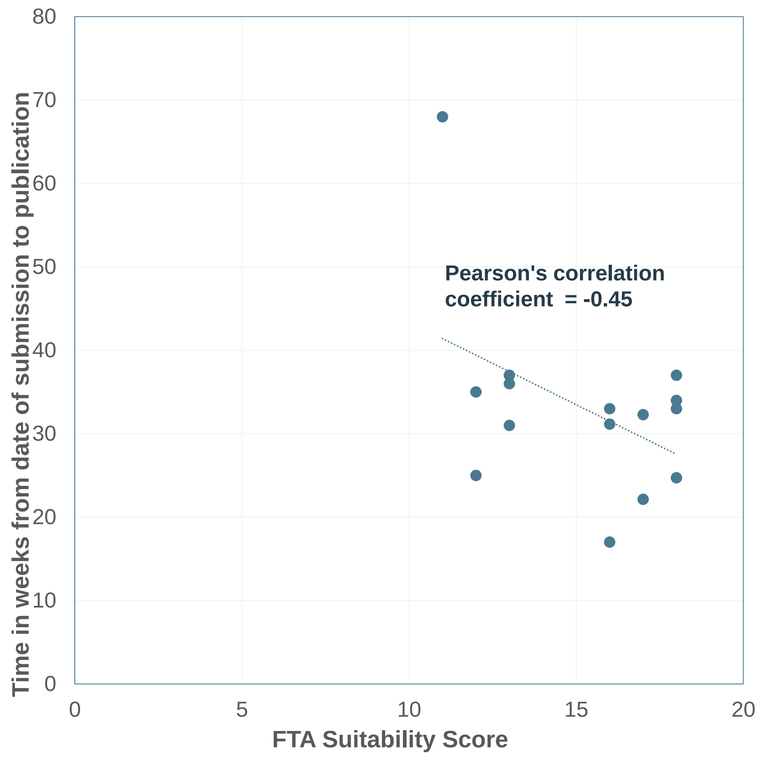

Table 2: Technology Appraisals included in analysis [3-17]

FTA 2017			FTA 2018		
TA & Medicine	**Appraisal time (Weeks)**	**Score**	**TA & Medicine**	**Appraisal time (Weeks)**	**Score**
TA486; Afilbercept	25	12	TA497; Golimumab	31	13
-	-	-	TA521; Guselkumab	33	18

FTA 2019			FTA 2020*		
TA572; Ertugliflozin	36	13	-	-	-
TA596; Risankizumab	37	18	-	-	-

FTA 2021			FTA 2022		
TA671; Mepolizumab	37	13	TA794; Diroximel	17	16
TA672; Brolucizumab*	68	11	TA799; Faricimab	32	17
TA723; Bimekizumab	33	16	TA800; Faricimab	31	16
TA734; Secukinumab	34	18	TA803; Risankizumab	22	17
TA735; Tofacitinib	35	12	TA820; Brolucizumab	25	18

References:

[1] NICE: Guide to processes of technology appraisal. 2018. Available at: Guide to the technology appraisal process (nice.org.uk) Accessed on: 6th October 2022. [2] NICE: Guide to processes of technology appraisal. 2022. Available at: Guide to the processes of technology appraisal (nice.org.uk) Accessed on: 6th October 2022. [3] NICE. Overview: Aflibercept for treating choroidal neovascularisation. TA486 Available at: https://www.nice.org.uk/guidance/ta486 Accessed on: 5th September 2022. [4] NICE. Overview: Golimumab for treating non-radiographic axial spondyloarthritis. TA497. Available at: https://www.nice.org.uk/guidance/ta497 Accessed on: 5th September 2022.. [5] NICE. Overview: Guselkumab for treating moderate to severe plaque psoriasis. TA521. Available at: https://www.nice.org.uk/guidance/ta521 Accessed on 5th September. [6] NICE: Overview. Ertugliflozin as monotherapy or with metformin for treating type 2 diabetes. Available at: https://www.nice.org.uk/guidance/ta572 Accessed on: 5th September 2022. [7] NICE. Overview. Risankizumab for treating moderate to severe plaque psoriasis. TA596. Availabe at: https://www.nice.org.uk/guidance/ta596 Accessed on: 5th September 2022. [8] NICE. Overview: Mepolizumab for treating severe eosinophilic asthma. TA671. Available at: https://www.nice.org.uk/guidance/ta671 Accessed on: 5th September 2022. [9] NICE. Overview: Brolucizumab for treating wet age-related macular degeneration.TA672. Available at: https://www.nice.org.uk/guidance/ta672 Accessed on: 5th September 2022. [10] NICE. Overview: Bimekizumab for treating moderate to severe plaque psoriasis. TA723. Available at: https://www.nice.org.uk/guidance/ta723 Accessed on: 5th September 2022. [11] NICE. Overview: Secukinumab for treating moderate to severe plaque psoriasis in children and young people. TA734. Available at: https://www.nice.org.uk/guidance/ta734 Accessed on: 5th September 2022. [12] NICE. Overview: Tofacitinib for treating juvenile idiopathic arthritis. TA735. Available at: https://www.nice.org.uk/guidance/ta735 Accessed on 5th September 2022. [13] NICE. Overview: Diroximel fumarate for treating relapsing–remitting multiple sclerosis. TA794. Available at: https://www.nice.org.uk/guidance/ta794 Accessed on: 5th September 2022. [14] NICE. Overview: Faricimab for treating diabetic macular oedema. TA799. Available at: https://www.nice.org.uk/guidance/ta799 Accessed on: 5th September 2022. [15] NICE. Overview: Faricimab for treating wet age-related macular degeneration. TA800. Available at: https://www.nice.org.uk/guidance/ta800 Accessed on: 5th September 2022. [16] NICE. Overview: Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs. TA803. Available at: https://www.nice.org.uk/guidance/ta803 Accessed on: 5th September 2022. [17] NICE. Overview: Brolucizumab for treating diabetic macular oedema. TA820. Available at: https://www.nice.org.uk/guidance/ta820 Accessed on: 5th September 2022.

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