

What are the reasons for receiving a negative decision from NICE? - A 5-year review (2019-2023) of NICE decisions

HTA3

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Background

- ▶ After-market authorization, receiving positive recommendations from the respective Health Technology Assessment (HTA) bodies is necessary for achieving access to new drugs.
- ▶ More than 40% of the new drugs approved by European Medicines Agency (EMA) are not recommended by National Institute for Health and Care Excellence (NICE).
- ▶ Understanding the factors influencing NICE's decisions is crucial for ensuring access to innovative and effective treatments.

Objectives

- ▶ To understand the reasons for negative reimbursement decision, we undertook a review of NICE decisions.

Methods

- ▶ Hand searching of NICE website was undertaken to retrieve the HTA submissions receiving negative recommendations in the last 5 years (2019-2023)

Results

- ▶ Search identified a total of 25 technology appraisals [24 Single Technology Appraisal (STA) and 1 Highly Specialized Technologies (HST)] that received negative recommendations from NICE
- ▶ In the last 5 years, among the 25 TAs that received negative recommendations, 9 TAs received negative recommendations in the year 2023, followed by 6 TAs in 2022, 5 TAs in 2021, 4 TAs in 2019 and 1 TA in 2020 (Table 1)
- ▶ Majority of the non-recommendations were in oncology (44%) followed by blood and immune system conditions (16%), 8% each in cardiovascular, respiratory, and neurological conditions and 4% each in infections, metabolic, neurodevelopmental, and digestive tract conditions (Figure 1)
- ▶ There were multiple reasons for receiving a negative decision from NICE (Figure 2). One of the most common reason of rejection was uncertain and higher cost-effectiveness estimates (more than NICE thresholds) reported in all the 25 HTAs. In addition, other reasons of rejections were
 - ▶ Uncertain long-term benefits/efficacy measure
 - ▶ Absence of direct comparison with relevant comparators
 - ▶ Lack of meaningful improvement in health-related quality-of-life assessments
 - ▶ Inadequate sample size
 - ▶ Unclear method used for indirect comparisons (ITC)
 - ▶ Trial results not being generalizable to the National Health Service (NHS)
 - ▶ Failure to meet NICE's criteria for consideration as a life-extending treatment at the end of life

Table 1: Negative recommendations from NICE in last 5 years

Year	Total number of TAs	Negative recommendations
2019	51	4 (7.8%)
2020	50	1 (2%)
2021	92	5 (5.4%)
2022	102	6 (5.9%)
2023	97	9 (9.3%)
Total	392	25 (6.4%)

Figure 1: HTA submission receiving non-recommendations across all therapeutic areas

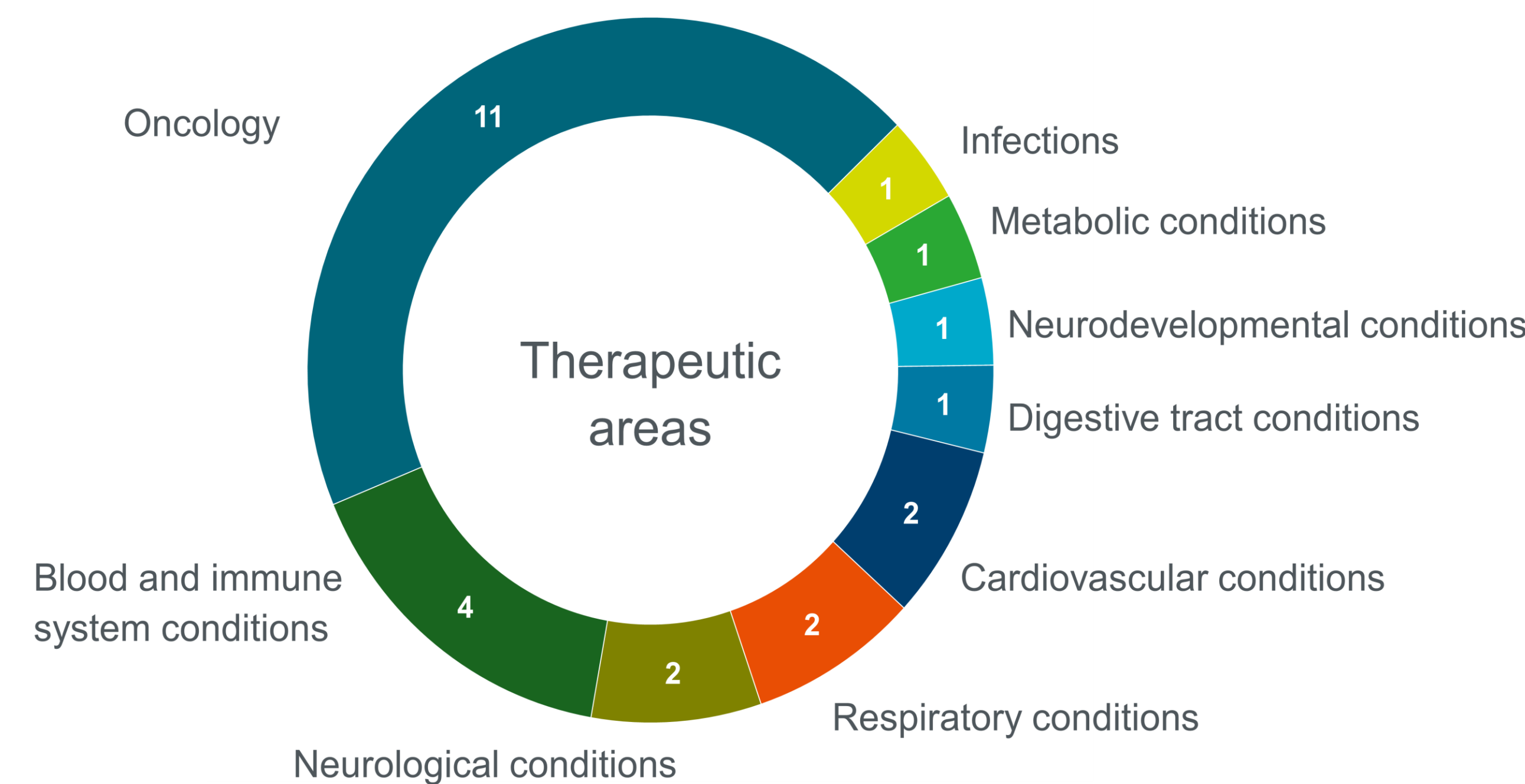
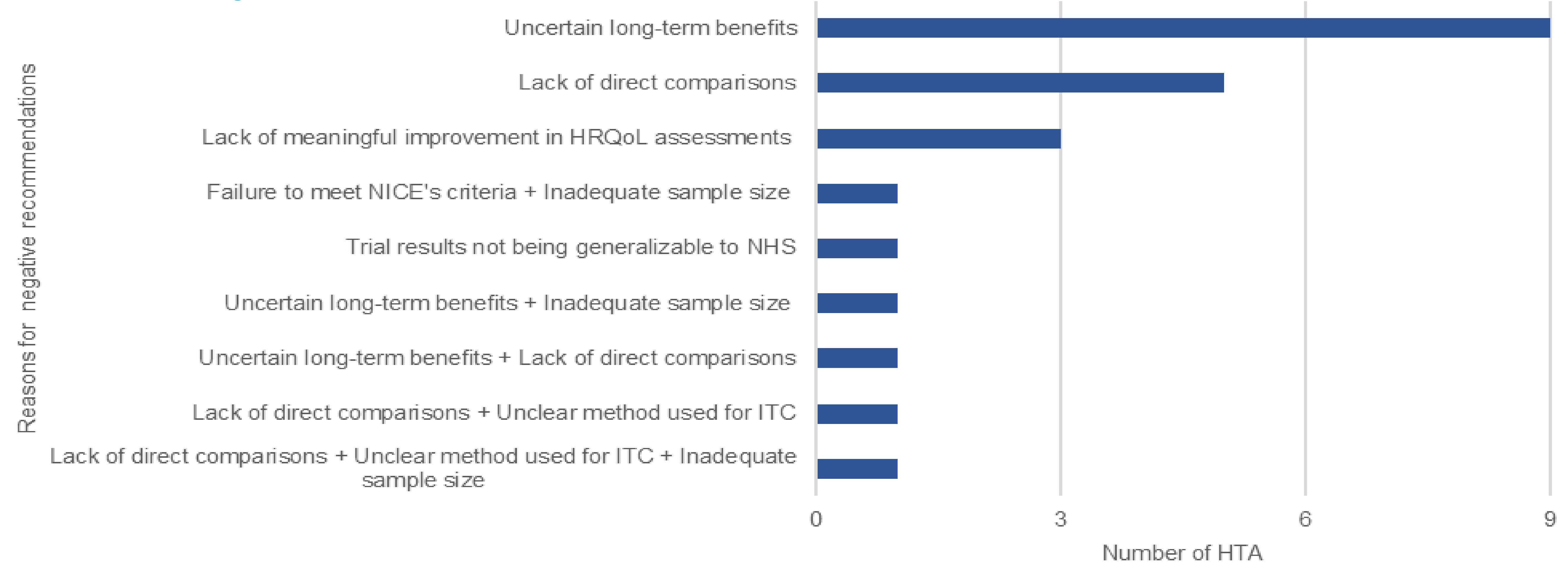


Figure 2: Reasons* for negative recommendations in HTA submission



*All the reasons were in addition to uncertain and higher cost-effectiveness estimates than what NICE normally considers an acceptable use of NHS

Conclusions

- ▶ This research highlighted that uncertain long term-benefit is usually the result of an unfavourable Incremental Cost-Effectiveness Ratio (ICER) analysis. This was the main reason for NICE's decision not to recommend certain drugs or health technologies.
- ▶ Furthermore, the analysis highlights the role of additional reasons in influencing NICE's decision-making process. Factors such as the lack of direct comparisons was the second most cited reason for unfavourable assessment. Considering these additional reasons alongside the ICER threshold is crucial for understanding the rationale behind NICE's negative recommendations.
- ▶ The threshold for the ICER varies depending on several key factors, including the indication, medical need, and other considerations listed in the conclusion above. NICE evaluates the cost-effectiveness of interventions by considering their long-term efficacy, direct comparisons to existing treatments, and overall cost. If the ICER exceeds the threshold set by NICE, it is likely to impact the decision-making process and result in a negative recommendation.
- ▶ By including the ICER as a prominent determining factor, NICE ensures that healthcare resources are used in a cost-effective manner while delivering optimal patient outcomes. The variation in ICER thresholds indicates the agency's recognition of specific medical needs and the importance of tailoring recommendations accordingly.
- ▶ Overall, NICE's consideration of the ICER threshold in relation to specific indications, medical needs, and other influencing factors ensures that the agency maintains a balanced approach towards evaluating cost-effectiveness. Addressing the ICER and other relevant factors will be essential in enhancing patient access to effective treatments, promoting equitable healthcare outcomes, and guiding future research and development efforts.

Reference <https://www.nice.org.uk/>