HTA70

Insights into NICE's approach to Uncertainties in Health Technology Appraisals

Panigrahi S, Edwards H, Large S, Wellington C
Pfizer UK Ltd., Tadworth, United Kingdom

OBJECTIVE

The National Institute for Health and Care Excellence (NICE) conducts health technology assessments (HTAs) in England. The HTA process requires the committee to consider uncertainty in their decision on the cost effectiveness of new technologies.[1] The aim of this study was to understand the types of issues highlighted in the recent technology appraisals, explore potential trends of issues raised by the committees, and understand NICE's approach to account for these.

METHODS

30 recently published NICE appraisals (June 2023-November 2023) were identified and extracted. Key issues for committee consideration and their impact on the Incremental Cost-Effectiveness Ratio (ICER) as reported in the committee slides were extracted and assessed to categorise the raised uncertainties into 2 categories, Clinical & Cost.

The source of all uncertainties were explored further from individual draft guidance and committee papers to sub-categorise the issues/uncertainties into 6 sub-categories. Individual issues raised in the appraisals were assessed to explore the final assumptions accepted by the committee and it was categorised into Evidence Assessment Group (EAG) (If the committee preferred the EAG's assumption/input over the company submission), Company (If the committee preferred the assumption/input in company's original submission over EAG's preferred assumptions) and alternative committee assumptions (If the committee adopted an alternative assumptions/input to the EAG and the company, informed by EAG scenarios, committee opinion or a clinical expert's opinion).

RESULTS

In total, 139 issues were identified from the 30 recently published (June 2023-November 2023) appraisals which had either small, medium or large impact on the Incremental Cost-Effectiveness Ratio (ICER), as defined in committee slides (Figure 1).

The most frequently (86%) raised issues pertain to clinical parameters such as trial data, patient population, treatment pathway.(Figure 2) The majority(~57%) of these uncertainties stemmed from the clinical assumptions and inputs used to demonstrate clinical effectiveness in the cost-effectiveness models. Methodological concerns associated with trial design and the health-related quality of life (HRQoL) estimation were also common (Figure 3). Uncertainties related to the cost inputs and the assumptions/inputs around health care resource use in the cost-effectiveness model was 13.7% of the total uncertainty points raised in the appraisals (Figure 3).

Figure 1: Issues by ICER impact

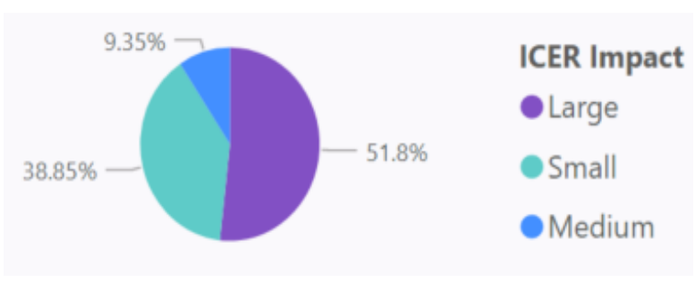


Figure 2: Issues by category

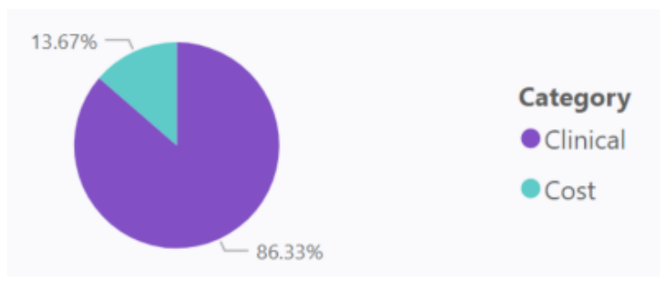
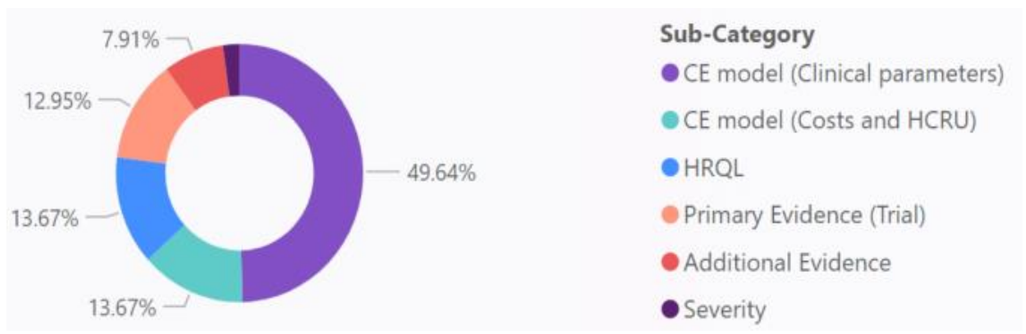
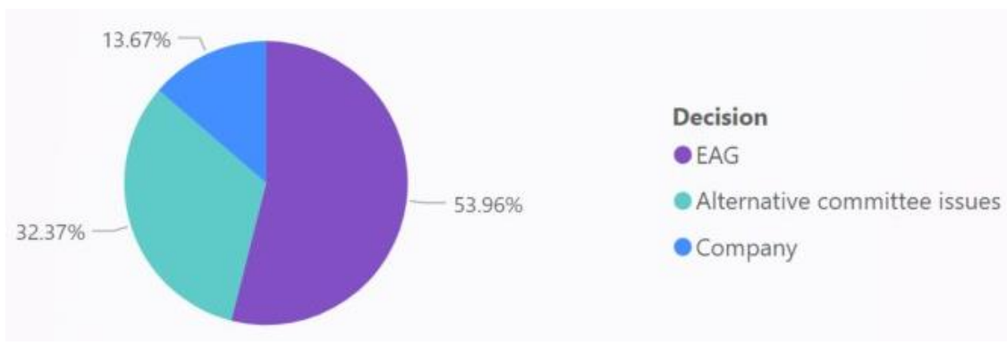


Figure 3: Issues by sub-category



For the majority (54%) of key issues raised, the committee aligned to the Evidence Assessment Group's (EAG) proposed assumption , with remaining assumptions falling between company's original submission and alternative assumptions proposed by the committee (Figure 4).

Figure 4: Issues by decision



Most (19/30) of these appraisals received a positive reimbursement decision with restriction by NICE (Figure 5). Appraisals that received a positive recommendation with restriction has the highest average number of issues, with the majority of the issues having a large impact on the ICER. On the contrary, appraisals that received negative recommendations have the lowest average number of issues with majority of the issues with small impact on ICER (Figure 6).

Figure 5: Recommendation decisions for included appraisals

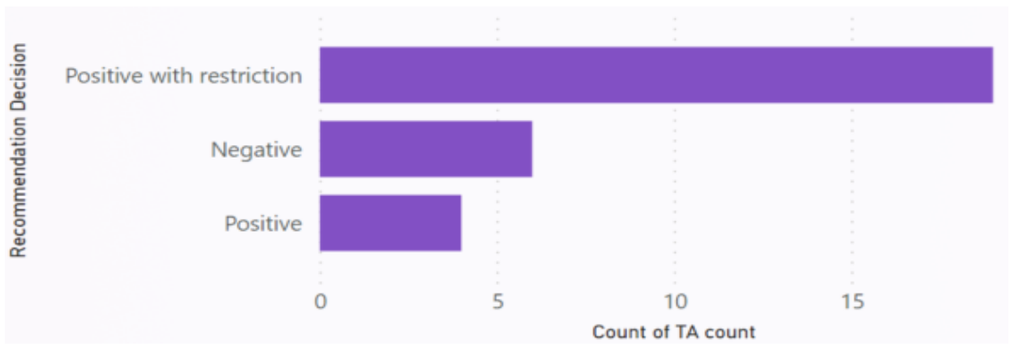


Figure 6: Average issues with ICER impact by recommendation decisions

CONCLUSION

The results demonstrate a close alignment between the committees and the EAG, which brings into question the role of the EAG's and committee's attitude to risk and the utilisation of the flexibility towards uncertainties as per the health technology evaluation (HTE) manual within NICE's decision-making process.[1-2] The findings also highlight an opportunity for future research to examine the plausibility of the issues raised during the appraisal process to further understand the degree of flexibilities that can be explored for various categories of the issues. Although this process is ensuring robust scrutiny of evidence, with lesser flexibility and acceptance to certain uncertainties, the evaluation process is potentially underestimating the value of new medicines and delaying or restricting access to innovative treatments in England.

REFERENCES

1. NICE, 'NICE health technology evaluations: the manual', January 2022, available at Introduction to health technology evaluation | NICE health technology evaluations: the manual | Guidance | NICE
2. NICE, Review of methods for health technology evaluation programmes: proposals for change, August 2021

DISCLOSURES

This study was sponsored by Pfizer Ltd.