NICE National Institute for Health and Care Excellence

HTA166: How Successful has the Technical Engagement Phase of NICE Appraisals Been in Resolving Issues?

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Background

In the past decade, there has been an increase in demand for technology appraisals. This has been driven by trends such as earlier marketing authorisations (MA), developments in 'personalised medicine' resulting in multiple indications for new technologies and NICE's remit expanding to evaluations of all new active substances and significant extensions to MAs.[1] The National Institute of Health and Care Excellence (NICE) has regularly reviewed ways in which to accommodate this increase in demand and in April 2018, introduced the technical engagement phase. This was introduced as a 20-day engagement period, during which stakeholders are provided with the opportunity to comment on key technical issues. The technical engagement (TE) phase was introduced with the aim of resolving important issues with stakeholders before the appraisal committee meeting (ACM). The expectation was that this would enable the committee to meet only once for most appraisals.[1] This research reviews how successful technical engagement has been in resolving issues before ACMs.

What we did and why

NICE technology appraisals published from January 2019 to December 2021 were identified from the NICE website. A total of 201 appraisals were identified. Of these, 40 (20%) were terminated appraisals and so excluded from further analysis. An additional 13 appraisals were excluded because of publication before January 2019, as they were likely to be initiated before implementation of TE. Of the 148 appraisals remaining, 50 did not have a TE step and so were excluded from analysis. This left 98 appraisals for inclusion within the analysis.

For each of these appraisals, the number of issues before and outstanding after TE were extracted using publicly available information. Details on the nature of the issues were also collected to explore whether there were trends in the types of issues being resolved during TE.

In addition, details on the number of ACMs required for the topic were also collected.

Outcomes and impact

On average there were 8 issues at TE and 25% of these were resolved during TE. In 27% of the appraisals no issues were successfully resolved during TE.

The most frequently reported issues were those relating to utilities, survival modelling and indirect treatment comparisons.

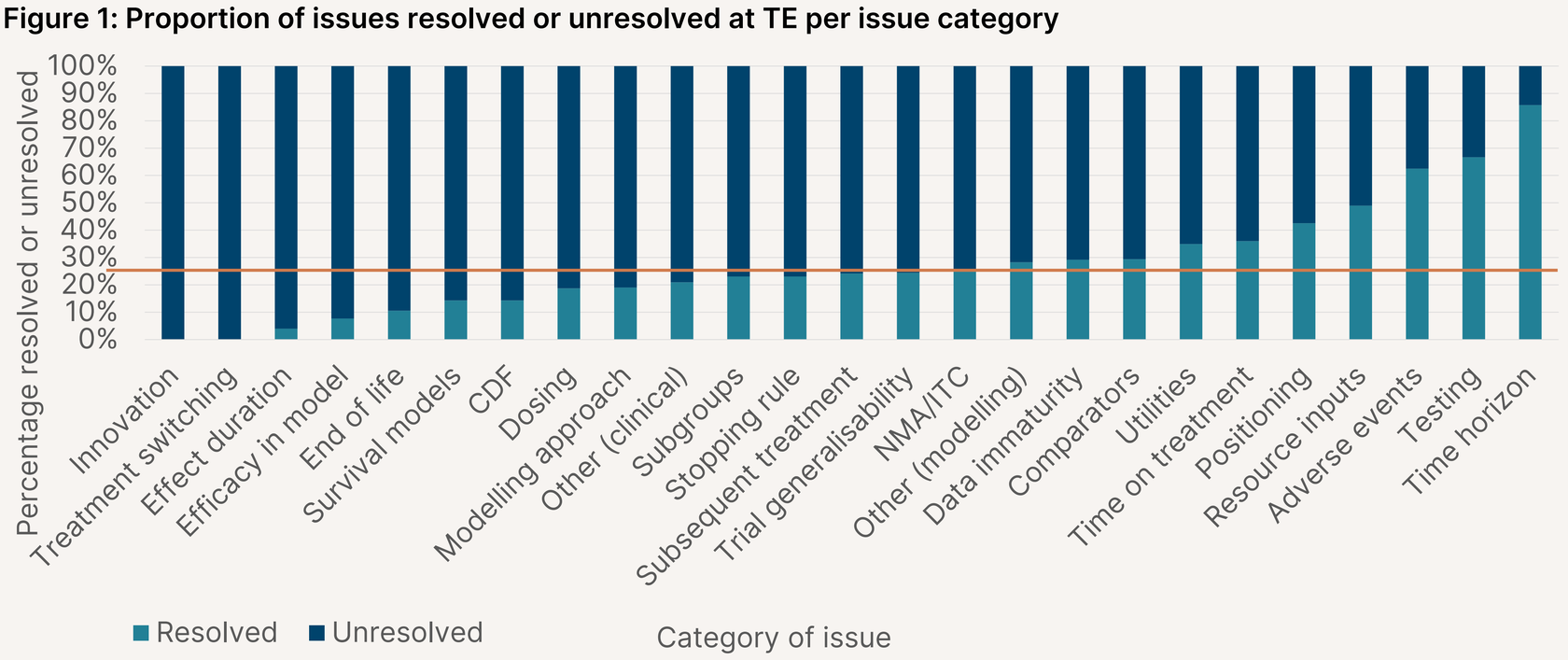
Figure 1 illustrates that issues relating to innovation, end of life and modelling approaches mostly remained unresolved during TE. In contrast, most issues relating to time horizons, diagnostic testing and adverse events, can be resolved during TE.

Overall, 42% of appraisals required 1 ACM, 50% of appraisals required 2 ACMs and 8% required more than 2 meetings. Topics with 1 and 2 meetings had on average 29% and 23% of issues resolved at TE, respectively. In contrast, topics with more than 2 meetings had only 10% of issues resolved on average during TE.

Cancer vs. non-cancer appraisals: 62% of technology appraisals included in the analyses were for cancer drugs. For both cancer and non-cancer drugs, there were on average 8 issues at TE. A similar proportion of issues were resolved on average for both cancer and non-cancer drugs (25% vs. 24%, respectively).

Trends over time: There was a statistically significant trend towards fewer issues being resolved during technical engagement over time.

Figure 1: Proportion of issues resolved or unresolved at TE per issue category



What we learnt

TE has been successful in resolving some issues before ACMs, saving committees discussion time. In particular, issues around time horizon are frequently resolved. However, progressively fewer issues are being resolved over time. Current analysis has not investigated potential reasons for this trend. TE has also not resolved any issues for several topics.

Utilities play a fundamental role in cost-utility analyses and so unsurprisingly are the most common issues in appraisals. Issues relating to modelling approach, survival modelling, treatment efficacy and duration are all likely to be important drivers of cost-effectiveness and remain mostly unresolved during TE. Issues relating to end of life can have an important impact on the cost-effectiveness threshold and are mostly unresolved during TE. Other issues which are likely to be an important source of uncertainty also generally remain unresolved (including issues relating to indirect treatment comparisons which are likely to be seen in topics where there is a lack of randomised controlled trials compared with the main comparator of interest).

Appraisals which required 1 ACM appear to have had a greater proportion of issues resolved at TE. This may reflect TE enabling earlier resolution of some issues but may also suggest topics requiring further meetings often have complex issues, relating to areas of high uncertainty, which would not be able to be resolved at an early stage. Further analysis comparing the types of issues remaining for topics which required 1 ACM versus those that required further meetings may be beneficial.

Previous research[2] suggested that the introduction of TE reduced the number of ACMs required compared with appraisals undergoing the pre-TE NICE process. However, both this research and previous research suggest a large percentage of appraisals are still requiring more than one committee meeting. Overall, this highlights that whilst TE can be helpful in some instances, there are frequently important issues which cannot be resolved. The more issues that can be resolved at TE may facilitate committee discussions and decision making. As of April 2022, TE is not a mandatory stage of the evaluation process. This will enable the NICE technical team to proactively make decisions on the potential benefit of having TE for a given topic.

References

1. NICE (2018) 'Proposals for increasing capacity with NICE's technology appraisal programme'
2. F Chunara et al. (2020). 'Has the new NICE STA process addressed inefficiencies within the appraisal process, resulting in faster patient access?' Value in Health, Volume 23 (2)

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