

Benefits Not Captured in the Quality-Adjusted Life Year Calculation: What Role Do They Play in the National Institute for Health and Care Excellence Updated Decision-Making Process?



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Objective

Following the 2022 methods updates from the National Institute for Health and Care Excellence, this research aimed to investigate how submitting companies utilise the new explicit opportunity to discuss benefits not captured in the quality-adjusted life year calculation in their submissions, and the extent to which this information is considered in decision-making.

Background

- A February 2022 update to the National Institute for Health and Care Excellence (NICE) single technology appraisal (TA) process allows for more structured discussions of the benefits of technologies not captured in the quality-adjusted life year (QALY) calculation through the addition of a specific section into the template requesting this information.¹ This could facilitate more diverse value elements being reflected in decision-making.

Methods

- TAs that commenced after 1 February 2022 and had final guidance published before 7 September 2023 were reviewed. Where company submissions discussed benefits not captured in the QALY calculation, the evidence presented by the company, alongside External Assessment Group (EAG) and Committee commentary, were systematically extracted for analysis into a predefined extraction grid.

Results

- The first TAs to include a section on benefits not captured in the QALY calculation were published in January 2023; as of 7 September 2023, 51 TAs had been published. Of these, 21 (41.2%) company submissions discussed additional benefits not captured in the QALY calculation (Figure 1).
- Technologies assessed in the relevant TAs were most commonly indicated in cancers (10/21; 47.6%), of which non-small cell lung cancer was the most common disease area (4/10; 40.0%).

Categorisation of the Elements of Value Reported

- In total, 61 additional benefits beyond those captured in the QALY calculation were reported across the relevant TAs.
- In relation to the ISPOR value flower,² the additional benefits discussed were most commonly associated with QALY and cost benefits not captured in the company's cost-effectiveness model (Figure 2).
- Among elements of value in the ISPOR value flower considered to be potentially novel,² severity of disease was the most widely leveraged (28.6%), followed by fear of contagion (14.3%; Figure 2).
- Notably, all three instances of additional benefits relating to fear of contagion focused on the benefits of oral therapies compared with treatments administered in healthcare settings. All arguments focused on the benefit of home administration in avoiding pathogen exposure in healthcare settings in the face of the COVID-19 pandemic.

EAG and Committee Perception of Benefits Not Captured in the QALY Calculation

- The EAG and Committee explicitly acknowledged additional benefits not captured in the QALY calculation in three and ten appraisals, respectively. There was no overlap in the appraisals in which the EAG and Committee noted additional benefits.
- Of the ten TAs in which the Committee acknowledged the additional benefits reported, these impacted the decision making process in less than a quarter of the TAs (2/10; 20%) (Figure 3).

Conclusions

Evidence indicates that companies are increasingly discussing benefits not captured in the QALY calculation in NICE TAs, including those related to potentially novel elements of value. However, there remains limited evidence that these additional benefits are being considered in decision-making, with few examples to date of TAs in which proposed additional benefits have been explicitly noted to have impacted decision-making.

FIGURE 1

Use of the 'benefits not captured in the QALY calculation' section in TAs published in 2023 (N=51)

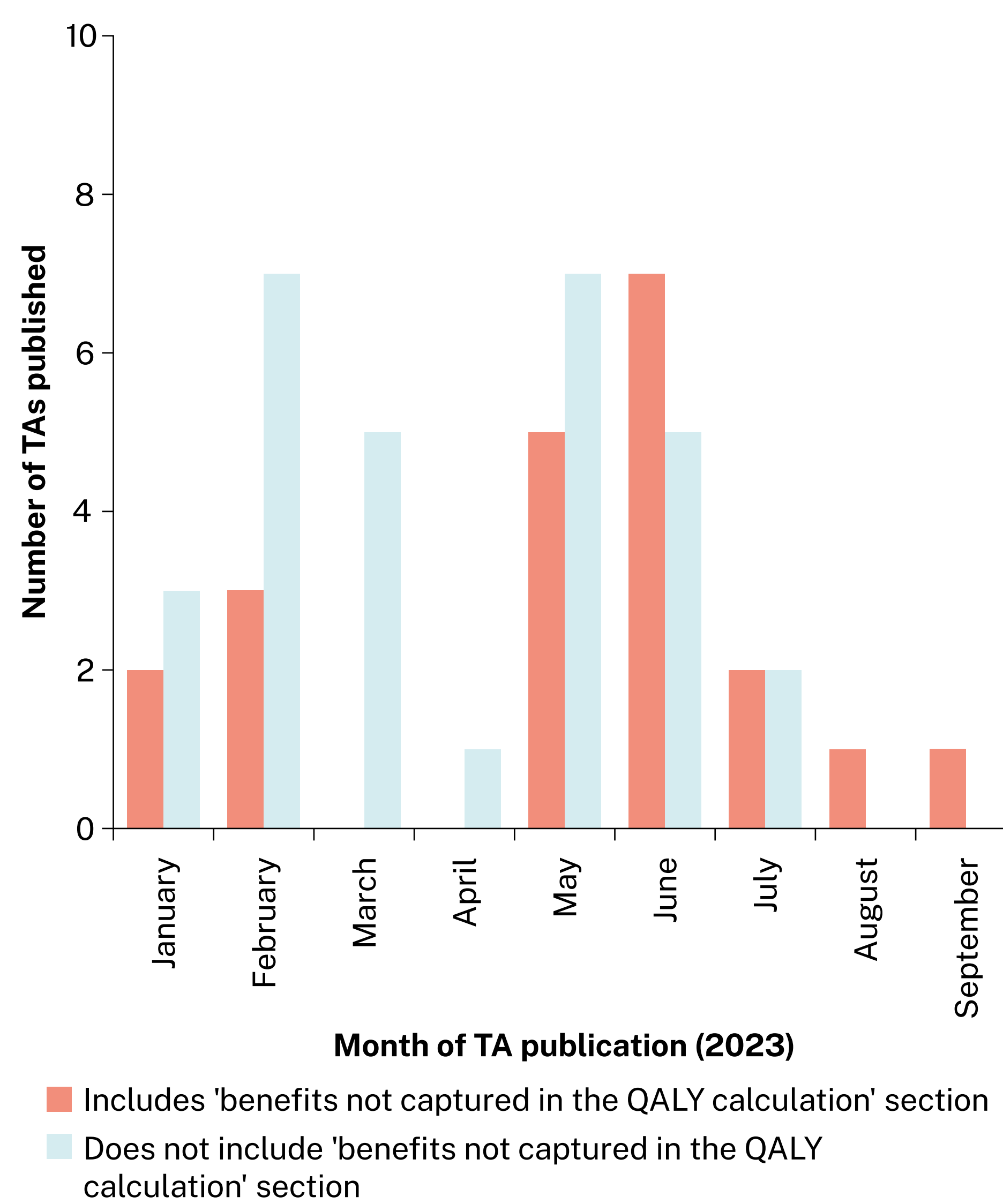


FIGURE 3

Impact of benefits not captured in the QALY calculation on the Committee's final decision

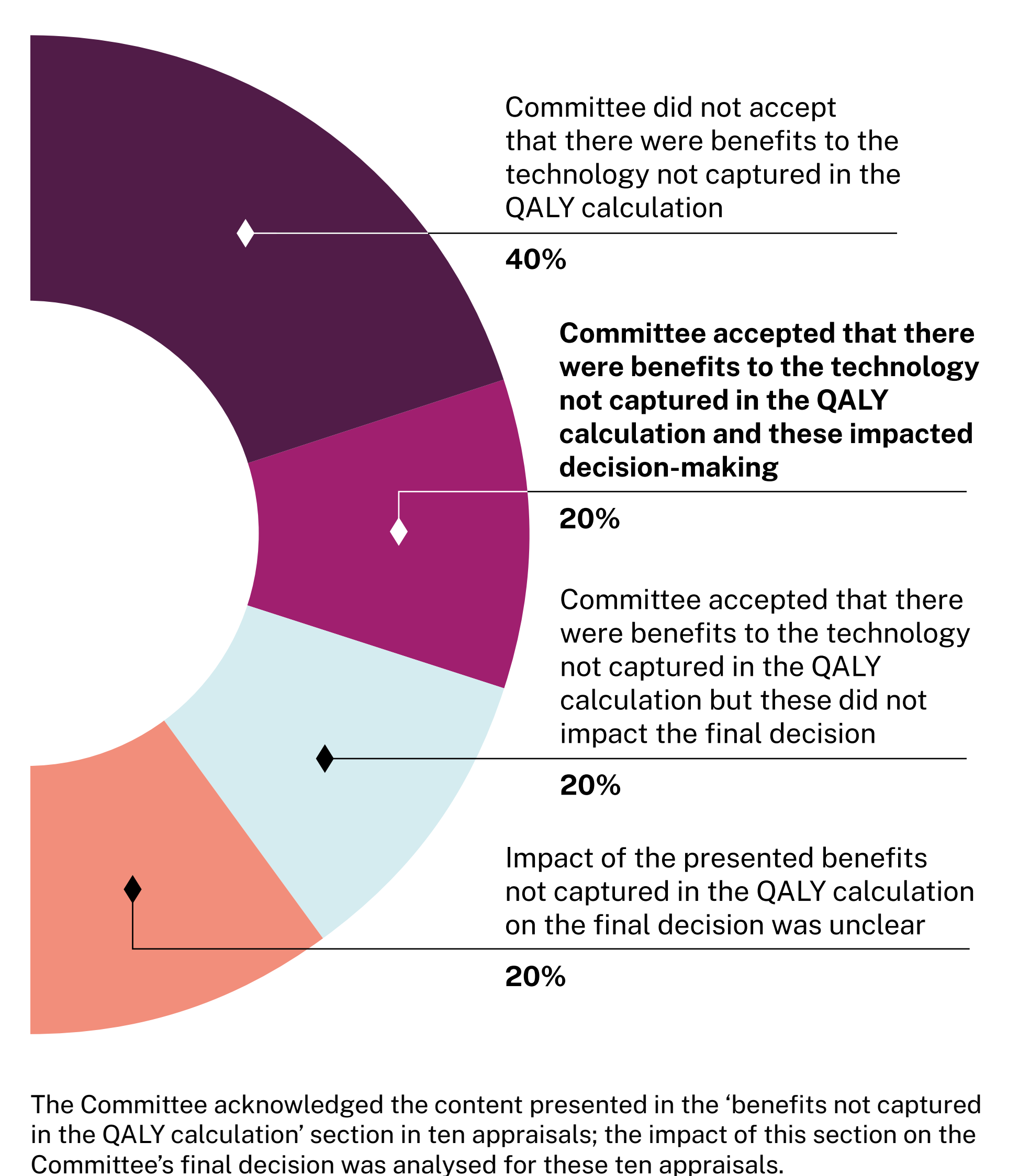
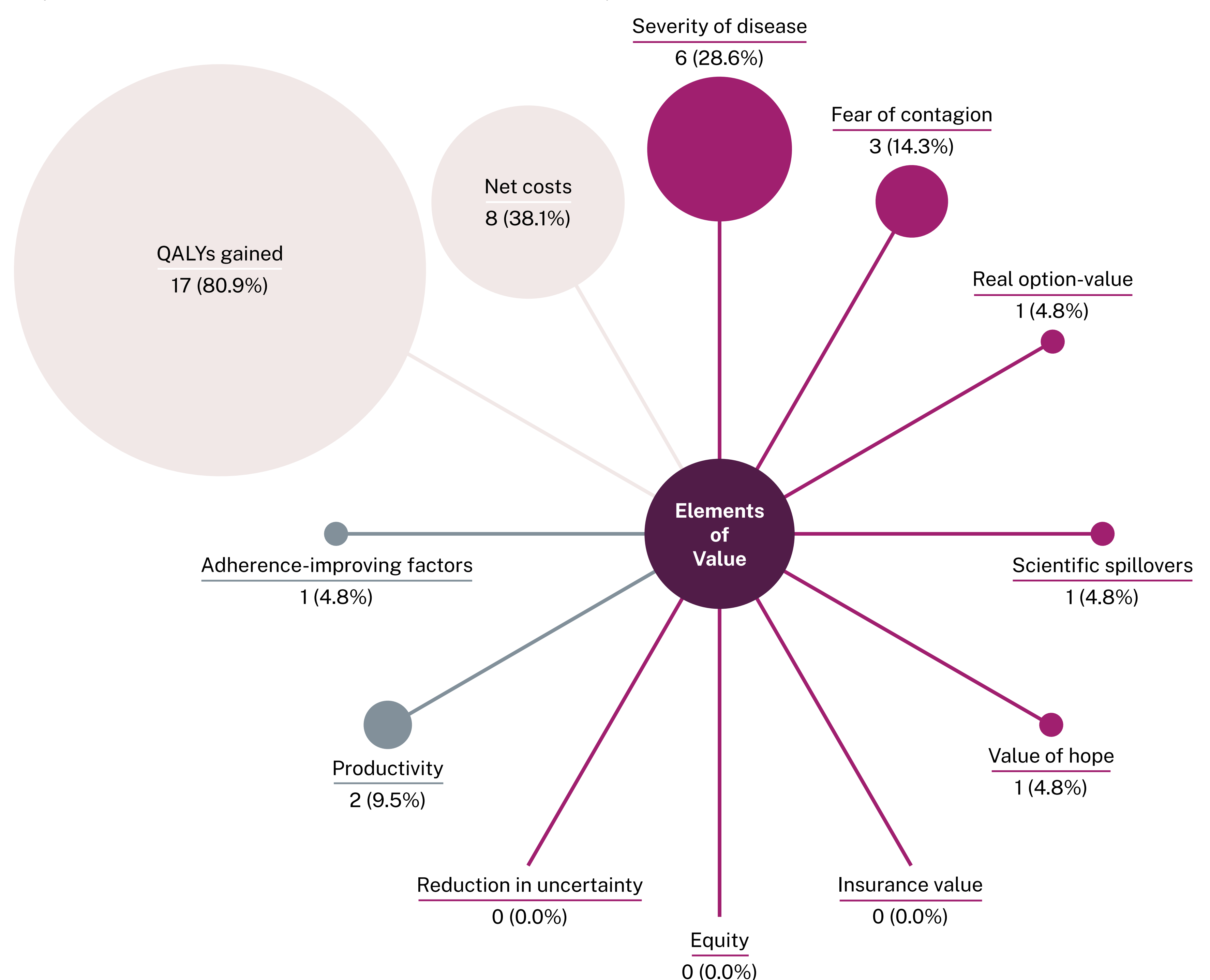


FIGURE 2

Key value drivers discussed in the 'benefits not captured in the QALY calculation' section across 21 TAs



Number of TAs discussing the value element, n (%)

- Core elements of value
- Common but inconsistently used elements of value
- Potentially novel elements of value

Value drivers are categorised based on the ISPOR value flower.² In total, 61 additional benefits beyond those captured in the QALY calculation were discussed across 21 TAs. The figure demonstrates the percentage of TAs including each type of value element.

Abbreviations: COVID-19: coronavirus disease 2019; EAG: External Assessment Group; ISPOR: International Society for Health Economics and Outcomes Research; NICE: National Institute for Health and Care Excellence; QALY: quality-adjusted life year; TA: technology appraisal.

References: ¹National Institute for Health and Care Excellence. Single technology appraisal and highly specialised technologies evaluation: User guide for company evidence submission template. Available at: <https://www.nice.org.uk/process/pmg24/chapter/cost-effectiveness> [Last accessed: 15.09.2023]; ²Lakdawalla DN et al. Value in Health 2018;21(2):131-9. Acknowledgements: The authors thank Emma White, Costello Medical, for graphic design assistance.