

Clinical and Economic Factors Underlying QALY Weights and Severity Modifiers in NICE Health Technology Evaluations: An Analysis of Recent Appraisals

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OBJECTIVE

To identify factors underlying the application of decision modifiers in National Institute for Health and Care Excellence (NICE) evaluations.

BACKGROUND

- Acknowledging that strict adherence to a cost-effectiveness threshold may not capture the full value of health technologies, NICE committees are given the ability to apply decision modifiers:¹
 - For highly specialised technologies (HSTs), which by definition are appraisals of interventions for severe conditions, committees may apply a greater weight to quality-adjusted life years (QALYs) when technologies offer significant health gains [referred to as QALY weights; method since 2017].
 - For single technology appraisals (STAs), committees may instead apply a greater weight to QALYs for technologies for severe conditions [referred to as severity modifiers; method since 2022].
- However, for additional weighting to be assigned to QALY benefits, there must be compelling evidence to convince committees.

METHODS

- The NICE website was searched to identify the 30 most recently published HSTs and 30 most recently published STAs in May and June 2025, respectively.
- For each appraisal, the following was extracted: bibliographic details, disease area, intervention and comparator, information on the calculation and application of the decision modifiers, and clinical and economic factors which may influence the application of decision modifiers.
- Data were extracted into a pre-specified, structured grid; during extraction, if no information was reported in the final draft guidance for a specific category, it was assumed that the committee was satisfied with the company's base case.

RESULTS

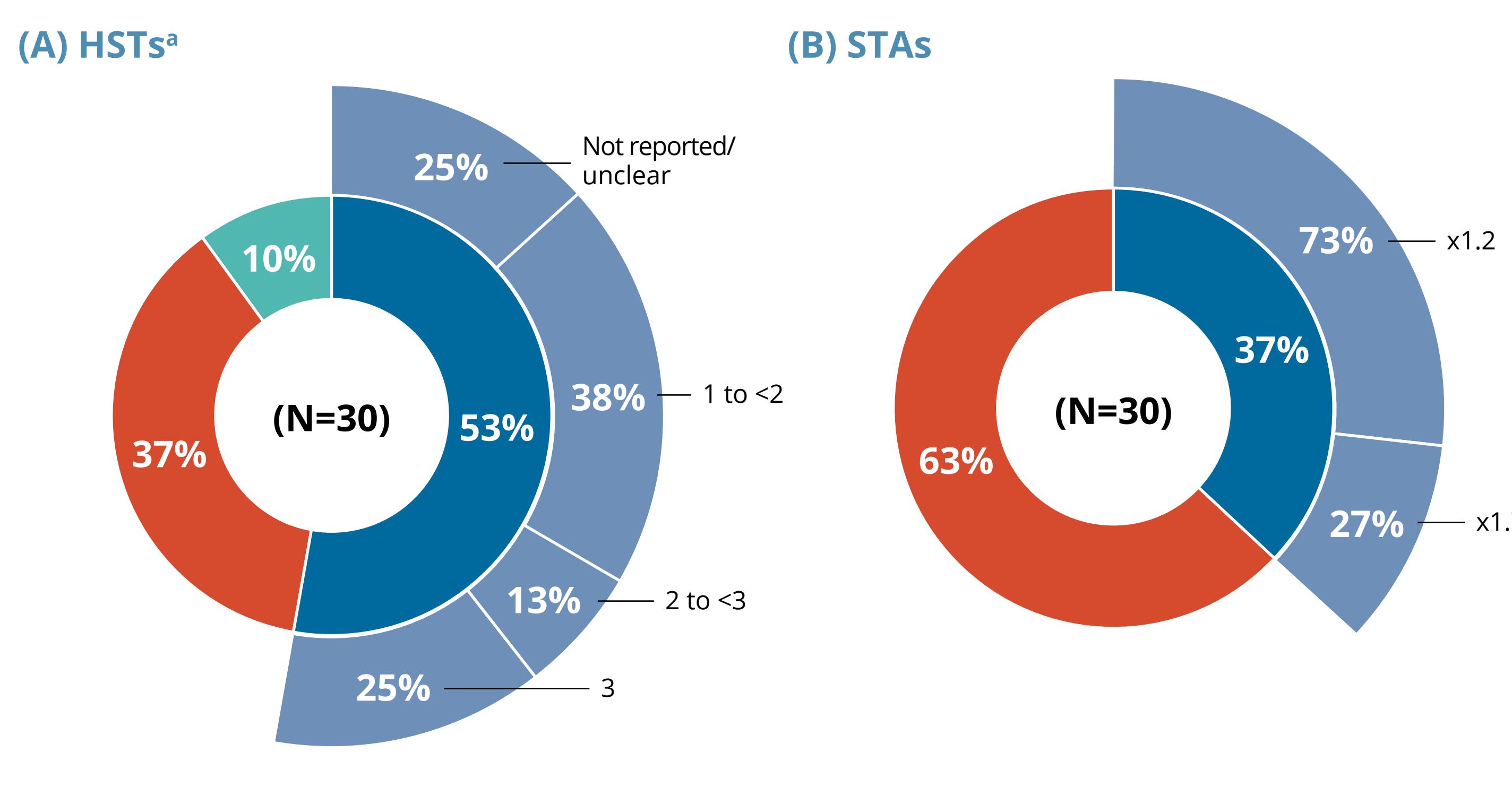
Factors driving QALY weights (HSTs)

- QALY weights were applied by committees in 16/30 (53%) HSTs, including five enzyme replacement therapies and five gene therapies. QALY weights were not applied and not reported in 11/30 (37%) and 3/30 (10%) HSTs, respectively (Figure 1A).
 - The majority of appraisals where weights were applied were in metabolic disorders; 7/10 (70%) HSTs in metabolic disorders had QALY weights applied (Figure 2A).
 - QALY weights were applied in 2/2 (100%) HSTs in immunology (Figure 2A).
- High QALY weights (≥ 2) were applied in 6/16 (38%) HSTs, of which four reported on metabolic disorders (Figure 1A).
 - QALY weights applied by committees usually differed from those proposed in company submissions and were reduced by committees in 2/16 (13%) HSTs specifically due to uncertainty in QALY gains.
- Potential factors influencing the application of QALY weights in HSTs are summarised in Figure 3.
- A positive impact of the treatment on survival appeared to be a key driver of the application of QALY weights, with a positive survival benefit modelled in 8/16 (50%) HSTs with QALY weights, versus 3/11 (27%) HSTs without (Figure 3).

Factors driving severity modifiers (STAs)

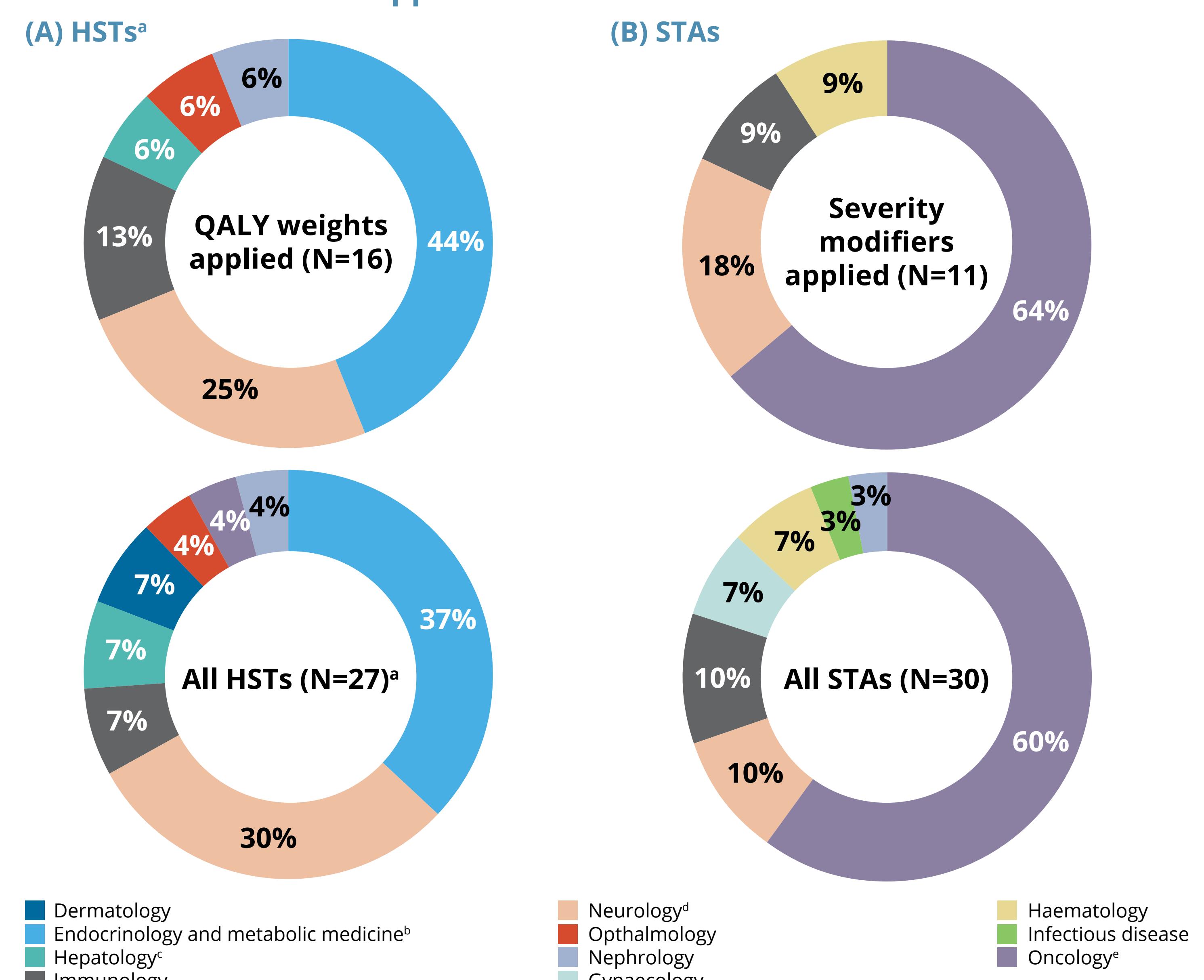
- Severity modifiers were applied in 11/30 (37%) STAs (Figure 1B).
 - The majority of appraisals where severity modifiers were applied were in oncology (7/11; 64%); in 5/11 (45%), supportive care was the modelled comparator.
 - 2/3 (67%) appraisals in neurology had severity modifiers applied (Figure 2B).
- In 3/11 (27%) STAs, the highest severity weight of x1.7 was applied; all three appraisals were in oncology or neurology (Figure 1B).
- Clinical and economic factors did not differ substantially between STAs that received a severity modification and those that did not.

FIGURE 1: Proportion and distribution of (A) QALY weights in HSTs and (B) severity modifiers in STAs



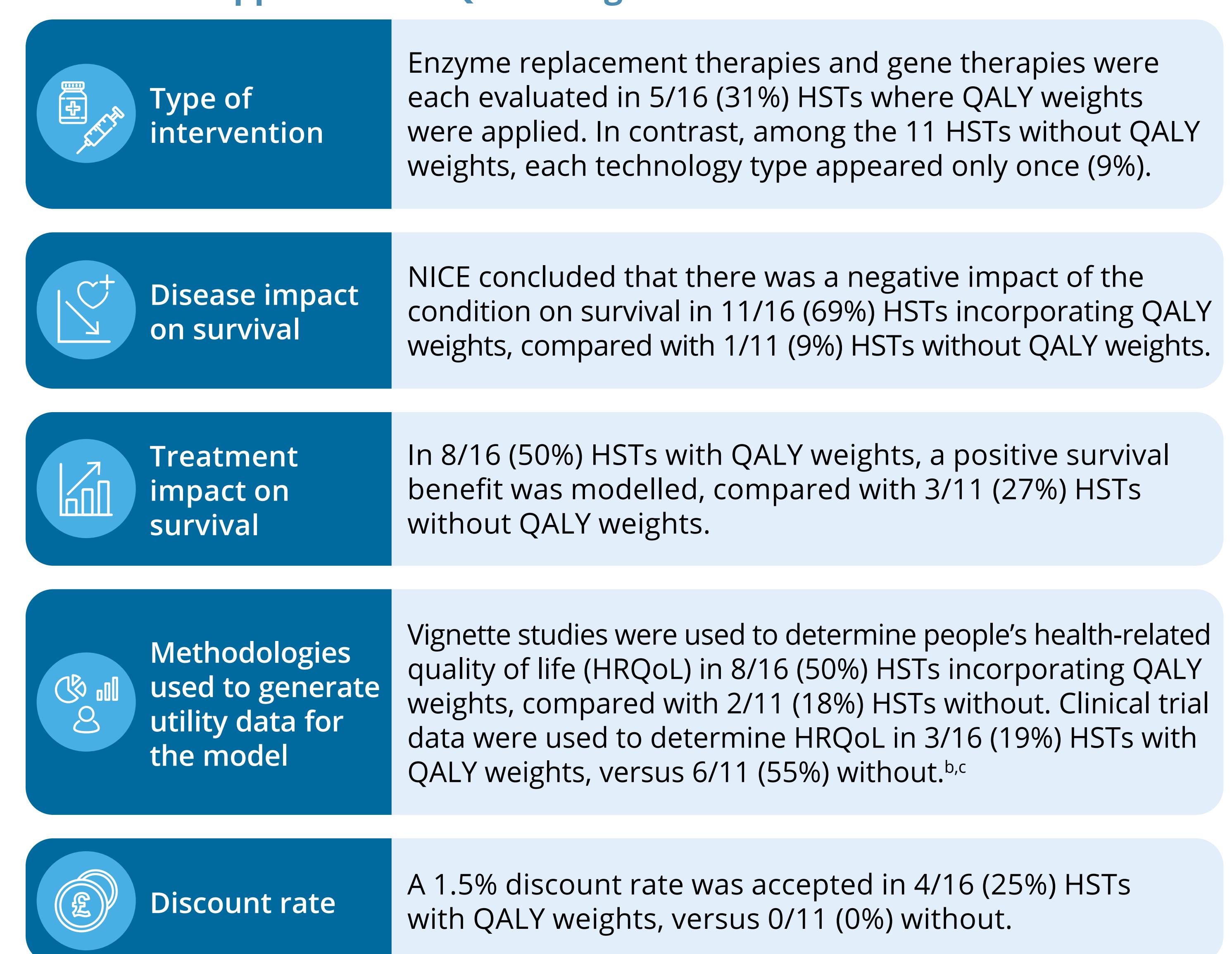
Percentages for each decision modifier category are based on the total number of HSTs/STAs where a decision modifier was applied.
[a] If base case incremental QALY gains were below 10, it was assumed that no QALY weight was applied, in line with the NICE methods.

FIGURE 2: Medical specialties for (A) HSTs with QALY weights applied versus all included HSTs; and for (B) STAs with severity modifiers applied versus all included STAs



[a] Three HSTs did not report whether QALY weights were applied and were therefore excluded. [b] 'Endocrinology and metabolic medicine' also included paediatric metabolic medicine and 'metabolic medicine and genetics'. [c] 'Hepatology' also included 'hepatology and genetics'. [d] 'Neurology' also included paediatric neurology, 'neurology and genetics' and 'neurology and cardiology'. [e] 'Oncology' also included paediatric oncology.

FIGURE 3: Summary infographic of potential influences on the application of QALY weights for HSTs^a



[a] Three HSTs did not report whether QALY weights were applied. [b] Of the HSTs with QALY weights that used vignette studies to generate utility data, 2/6 also used published literature and 1/6 also used clinical trial data. Of the HSTs with QALY weights that used clinical trial data to inform utilities, 1/3 also used data from proxy conditions and 1/3 also used vignette studies. [c] Of the HSTs without QALY weights that used clinical trial data to inform utilities, 1/5 also used published literature and 2/5 also used a quality of life survey.

CONCLUSIONS

Decision modifiers were applied in similar proportions of HSTs and STAs, with highly variable factors influencing these weights. Consistent drivers of QALY weight application in HST appraisals included the negative impact of the disease on survival and the positive impact of the treatment on survival. Improved transparency and methodological standardisation could facilitate more predictable QALY weighting outcomes for companies.

References: 1. NICE (2022). NICE health technology evaluations: the manual. Available at: <https://www.nice.org.uk/process/pmg36> [Last accessed 12 Sep 25].

HSTs Included: HST1, HST4, HST5, HST7, HST8, HST9, HST10, HST11, HST12, HST13, HST14, HST15, HST16, HST17, HST18, HST19, HST20, HST21, HST22, HST23, HST24, HST25, HST26, HST27, HST28, HST29, HST30, HST31, HST32, HST33.

STAs Included: TA1033, TA1034, TA1035, TA1036, TA1037, TA1038, TA1039, TA1041, TA1042, TA1043, TA1044, TA1045, TA1046, TA1048, TA1049, TA1050, TA1051, TA1053, TA1054, TA1055, TA1056, TA1057, TA1059, TA1060, TA1062, TA1063, TA1064, TA1065, TA1067, TA1069.

Abbreviations: HRQoL: health-related quality of life; HST: highly specialised technology; NICE: National Institute for Health and Care Excellence; QALY: quality-adjusted life year; STA: single technology appraisal.

Acknowledgements: The authors thank Peter Lang, Costello Medical, Manchester, UK for graphic design assistance. We also thank Louisa Burton, Costello Medical, London, UK for their contributions and Isabelle Newell, Costello Medical, London, UK for their review and editorial assistance in the preparation of this poster.

Disclosures: GS, AM, KH: Employees of Costello Medical Consulting; JW, JTN: Employees of Pharming Group N.V.