What's my age again? Exploring the importance of patient age assumptions in calculating severity modifiers

Snell, T.[1]; Stainer, L.[1]; Tolley, K.[1]

[1] Tolley Health Economics Ltd., Buxton (UK)

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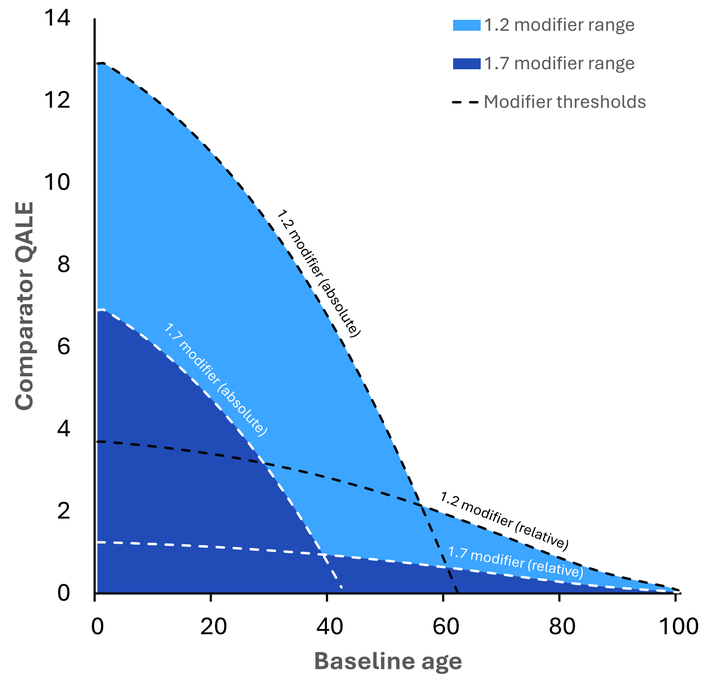
Background

- Severity modifiers were introduced by NICE in 2022 as a means of weighting QALYs in technology appraisals in which patients receiving currently-available treatments are expected to have a large shortfall in quality-adjusted life expectancy (QALE) relative to the general population. Modifiers are calculated based on an absolute reduction of 18 QALYs or relative reduction of 95% compared to the general population estimate (1.7 modifier) or an absolute reduction of 12 years or relative reduction of 85% (1.2 modifier). [1]
- Compared to the end-of-life criteria used previously as a mechanism for severity weighting by NICE, baseline patient age can have a direct influence on whether or not modifier criteria are met.
- **Figure 1** illustrates the maximum baseline age thresholds from which absolute or relative modifiers apply according to comparator QALE. Notably, modifier criteria can only be met on the basis of relative rather than absolute shortfall in patient populations with a baseline age above 43 years (1.2 modifier) or 61 years (1.7 modifier), even if comparator QALE is assumed to be zero.

Objectives

- To examine the sensitivity of modifier decisions to baseline age assumptions, drawing on evidence from NICE technology appraisals published since 2022.

Figure 1: Absolute and relative modifier thresholds by comparator QALE and baseline age (50% female population)



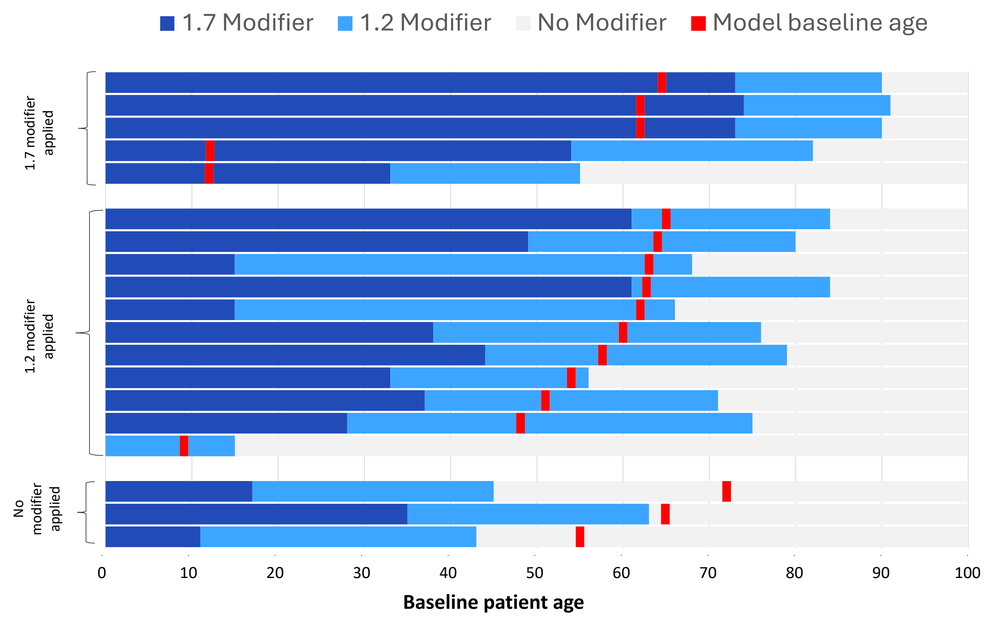
Methods

- As a first stage, a list of all non-terminated NICE technology appraisals (TAs) published since the introduction of severity modifiers in 2022 was compiled from the NICE website. [2] A bespoke script was developed using the *R* software package to scrape the contents of all NICE TA guidance documents published between June 2022 and June 2024 to identify those that made reference to severity modifiers. Identified records were cross-checked against selected published summaries of early NICE severity modifier decisions to validate screening sensitivity. [3]
- From the list of TAs identified, committee papers were examined to data extract input data used for modifier calculations (including baseline age and gender, total discounted comparator QALY estimates and general population QALE) where available. Where fields were not directly reported but could be calculated using unredacted data (for example, general population QALE was not reported but absolute shortfall values were available), calculated estimates were used. TAs in which the minimum level of data was not reported or was not easily calculable due to redaction were excluded from further analysis.
- Using the baseline age and gender values and comparator QALE estimates extracted from each included TA, modifier calculations were replicated using the approach and recommended data sources described in NICE TSD 23. [4] Where discrepancies between the calculated values and those reported in TA documentation existed and were found to be due to alternative general population input assumptions being used by submitting companies, the shortfall estimates derived using the methods outlined in NICE TSD 23 were used for further analysis.
- Having reproduced or recalculated absolute and relative shortfall calculations, a sensitivity analysis was conducted for each TA to identify the baseline age ranges at which each modifier level (1.7, 1.2 or 1.0; the latter denoting no modifier) would apply, and thereby approximate the robustness of modifier decisions to alternative baseline age assumptions.

Results

- A total of 144 TAs published between June 2022 and June 2024 were included for searching. This included both single and multiple technology appraisals, but excluding those appraised under NICE's Highly-Specialised Technology programme in which severity modifiers are not considered.
- Of the appraisals carried forward for document scraping using *R*, references to severity modifiers were identified in the guidance documents of 25 single or multiple appraisals. From these, unredacted data sufficient for reproducing modifier calculations was identified for 19 individual modifier decisions.
- Severity modifiers were found to be particularly sensitive to adjustments to baseline age in older populations: among appraisals with a baseline model age ≥ 50 years and which a severity modifier or 1.2 or 1.7 had been applied (n=13), the minimum increase in baseline age that would result in a lower modifier being applied was 2 years (mean 14.0 years, range 2.0 to 26.9 years). Among those with a baseline model age < 50 years (n=3), the minimum increase in baseline age that resulted in a lower modifier was 6.0 years (mean 22.9 years, range 5.9 to 41.9 years).

Figure 2: Summary of estimated modifiers ranges consistent with alternative baseline age assumptions



Conclusion

- The generalisability of study populations to real-world settings is a longstanding consideration for HTA. As baseline age was not a direct determinant of end-of-life criteria, however, discussions around the appropriateness of baseline age assumptions have focused mainly on potential biases in efficacy outcomes and in terms of its influence on age-related mortality and utility estimates.
- The analyses demonstrate that since the introduction of severity modifier criteria, adjustments to baseline age may also have a pronounced effect on cost-effectiveness results by influencing modifier decisions, suggesting that the validity of baseline population characteristics used for cost-effectiveness modelling requires scrutiny when identified as a potential driver of shortfalls. Additional research is warranted to provide a more refined analysis of modifier calculations using cost-effectiveness model data directly.

Abbreviations: NICE, National Institute for Health and Care Excellence; QALE, quality-adjusted life expectancy; QALY, quality-adjusted life year; TA, technology appraisal

References:

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4. Wailoo, A. A guide to calculating burden of illness for NICE Evaluations: Technical Support Document 23, 2024. https://www.sheffield.ac.uk/nice-dsu/tsds/severity-shortfall-tsd