Health Policy OPEN 10 (2026) 100156

Contents lists available at ScienceDirect

Health Policy OPEN

journal homepage: www.elsevier.com/locate/hpopen

The NICE experience of designing and utilising severity weights

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ARTICLE INFO

Keywords:
NICE
Severity
End of life
Absolute shortfall
Proportional shortfall

ABSTRACT

Background: In January 2022, NICE changed from "End of Life" (EoL) to "severity" weights, whereby additional value is applied within cost effectiveness analysis to health benefits arising from health technologies deemed to qualify This study examines the relationship between these concepts, how they relate to patient age, and whether the new system is cost-neutral as intended.
Methods: Data was extracted from 555 NICE Technology Appraisal decisions from 2009 to 2024. Absolute (AS) and proportional shortfall (PS) severity indicators were estimated for pre 2022 decisions. Post 2022 decisions were judged against EoL criteria.
We describe the relationship between severity weights, including the constituent AS and PS elements, age and EoL. Comparisons are made between the distribution of AS, PS and overall severity categories using descriptive statistics and significance tests.
Results: AS and PS have different relationships with patient age. In NICE appraisals, AS reduces with age but the relationship is flat between 40 and 60 years. All decisions in the highest AS category (AS > 18 QALYs) have a starting age below 20 years. PS peaks around 60 years. EoL applies almost exclusively where age exceeds 40 years. 91 % of appraisal decisions meeting EoL would receive a severity weight above 1.
There is no difference in the mean severity weight between pre and post 2022 appraisal decisions (1.116 vs 1.125). Mean AS is lower in post 2022 appraisals.
Conclusions: Severity weights do not correlate precisely with EoL. They have been applied as often as expected. The change from EoL to severity weights has been approximately cost-neutral.

1. Background

The National Institute for Health and Care Excellence (NICE) issues mandatory guidance to the UK National Health Service in England and Wales on the use of medicines and other treatments. NICE published the latest version of its guidance on the methods to be used in its technology appraisals programme in January 2022 [1]. One of the most substantial changes made in the manual was the introduction of a "severity modifier" replacing the "End of Life modifier" (EoL) that was itself first used in 2008.

EoL applied a greater weight (around 1.7 times) to health gains from health technologies for patients with a short life expectancy (less than 24 months) and that extend length of life (by at least 3 months).

The change to severity allocates a greater weight (up to 1.7 times more) to health benefits generated by technologies for health conditions deemed to be more severe.

Severity of a condition is defined as the future health lost by people living with the condition with standard care in the NHS. It is measured in terms of Absolute and Proportional Shortfall (AS and PS). Both measure the difference between the number of discounted Quality Adjusted Life Years (QALYs) patients would be expected to experience over the remainder of their lives under current care compared to the general population of the same age and sex. AS expresses this in terms of the number of QALYs lost. PS is a ratio of the number of QALYs lost compared to the total number of QALYs expected [2,3].

Weights are applied to the health benefits (incremental QALYs) estimated in the cost-effectiveness assessment according to Supplementary Table 1.

There are three categories of AS and PS attracting weights of 1, 1.2 and 1.7. The definition that provides the highest weight for severity is

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https://doi.org/10.1016/j.hpopen.2025.100156
Received 6 December 2024; Received in revised form 27 November 2025; Accepted 29 November 2025
Available online 4 December 2025

the one that should be used. There is therefore an "overall" categorisation that considers both AS and PS and is used for decision making.

The cutoffs used to define the three categories of AS and PS, as well as the weights to be applied, were based on analysis of previous NICE appraisals. Specifically, they were designed to ensure that the change from using the EoL modifier to severity modifiers was broadly "opportunity cost neutral" [4] by matching the average quality-adjusted life year (QALY) weight per decision for the severity modifier to that under EoL. This was a pragmatic simplification on the part of NICE, effectively treating each appraisal decision as equally cost incurring.

There are claims that the severity modifier has been used less frequently than expected (see for example The Association of the British Pharmaceutical Industry (ABPI) [5], Njoroge et al. [6]) and concerns about the impact of the severity modifier on specific technology decisions (see for example Health and Social Care Committee [7], Coughlan et al. [8]). If these claims are correct, there could be grounds to redesign the cutoffs used to define severity categories and/or the weight applied for assessments for health technologies deemed to be for more severe patient populations.

Interest in extending the range of factors considered in HTA, including severity, have gained considerable traction in recent years. ISPOR's "Value flower" is one high profile example [9]. NICE is one of the leading HTA agencies globally and, therefore, its experience with severity provides potentially important lessons for decision makers beyond England and Wales.

This study uses evidence extracted from 555 NICE Technology Appraisals, including the underlying confidential information. The objective is to demonstrate how the severity modifier is designed, how it impacts assessments for particular patient groups, expected changes from the system it replaced, and whether the application of severity weights in practice has worked as expected. We demonstrate how the different components of the severity modifier (AS and PS) are individually and jointly related to age and the now replaced EoL modifier. HTA agencies such as NICE need to be aware of the potential differential impact of their methods on people of different ages, including for reasons of equality. Severity using shortfall has an intrinsic link with age since life expectancy is a component of the calculations. We compare the set of appraisals used to design the severity modifier (2009–2021) with appraisals from 2022 onwards where severity was implemented, to test claims that it has been underutilised.

2. Methods

2.1. Data

Data was extracted from NICE Technology appraisals (TAs). The unit of analysis here is each decision, of which there may be multiple in any appraisal. Appraisals can comprise multiple decisions where there are different patient subgroups considered separately, including those subgroups defined by the comparator that would be considered relevant (e.g. patients intolerant to the comparator in widespread use), or where there are multiple technologies under consideration including those cases where a technology is considered either in combination with other agents or as monotherapy.

For each decision within a TA, we aimed to extract data on comparator QALYs, baseline patient age and whether the condition met EoL.

Collection of the data took place in three stages. The primary collection took place prior to the development of the NICE 2022 Methods Manual. This covered TAs with guidance published during the period from April 2011 to November 2019 and is described in the results section as the primary calculation sample. This information was used to inform the AS and PS cut-off points stated in the NICE 2022 Methods Manual. Additional data was collected in response to consultation on the methods manual, which extended the period covered from Jan 2009 to March 2021. This is referred to as the primary plus sample. Further data was collected following the implementation of the methods manual, covering the appraisals conducted using the severity modifier until August 1st 2024.

2.2. Data analysis

Absolute and proportional shortfall was calculated for pre 2022 appraisal decisions and extracted from post 2022 appraisal documentation. EoL was assessed for post 2022 appraisals and extracted from appraisal documentation in the pre 2022 appraisals.

We describe the relationship between severity weights (as described in Supplementary Table 1), including the constituent AS and PS elements, age and EoL. Comparisons are made between the distribution of AS, PS and overall severity categories using simple descriptive statistics and significance tests between the distributions by categories (chi-squared and z-tests of proportions) and the mean weight for health benefits. It is the mean weight which aligns to the definition of cost neutrality adopted by NICE.

3. Results

3.1. Primary calculation sample

AS and PS cut-offs in the NICE 2022 Methods Manual were based on information extracted from 364 decisions from 218 technology appraisals where the guidance was issued between April 2011 and November 2019 in which AS/PS could be calculated. A total of 570 decisions from 323 appraisals were reviewed for the period meaning that 36 % decisions could not have AS/PS calculated. 20 decisions (3.5 %) were not classified as cost-utility analyses. The primary subsample (n = 364) refers to those appraisal decisions where severity has been calculated.

3.2. Additional calculation sample

Following consultation on the proposed changes to NICE methods, an additional 100 decisions were added from 51 appraisals that covered the period Jan 2009 to April 2011 and from Feb 2020 to March 2021 where AS and PS could be calculated. These were drawn from 175 decisions (83 appraisals) in total conducted during that time period. 43 % of decisions did not have AS/PS calculated. 9 appraisal decisions (5.1 %) were not classified as cost utility analyses. When these data are added to the primary subsample, this forms the primary + subsample (n = 464), and this is the focus for several of the analyses presented.

3.3. Implementation sample

Appraisals conducted using the severity modifier up to August 1st2024 were included. 82 appraisals covering 112 decisions were included. 18 decisions (16 %) were from appraisals conducted using cost-comparison methods.

After excluding a further 3 appraisal decisions for which AS/PS could not be calculated, a total of 91 decisions from 62 appraisals were included. This is referred to as the implementation subsample (n = 91).

3.4. Comparison of pre and post 2022 appraisals

There is no statistically significant difference (at the 5 % level) between the mean age of the Primary+ (52.8 years) and Implementation (55.3 years) samples (p = 0.129). Nor is there a discernible difference in the distribution of ages between the same two appraisal samples.

Table 1 compares pre 2022 appraisal decisions (both the primary and primary samples) to post 2022 appraisal experience.

The implementation sample shows a slightly higher percentage of appraisal decisions are in severity categories 1 (64.8 % vs 62.5 %) and 1.7 (11.0 vs 8.2 %) in the primary sample, but there is no statistically

Table 1
The distribution of AS/PS and combined severity categories in NICE appraisals.

		Primary	Primary+	Implementation
	n	**364**	**464**	**91**
Absolute shortfall				
	Mean	9.39	9.31	8.62
Cat 1 (AS < 12)		269	342	77 (84.6)
	n (%)	(73.9)	(73.7)	
Cat 1.2 12 ≤ AS < 18)		89 (24.5)	113 (24.4)	11 (12.1)
Cat 1.7 (AS ≥ 18)		6 (1.7)	9 (1.9)	3 (3.3)
Proportional shortfall				
	Mean	0.62	0.61	0.64
Cat 1 (PS < 0.85)		261	332	66 (72.5)
	n (%)	(71.7)	(71.6)	
Cat 1.2 (0.85 ≤ PS < 0.95)		78 (21.4)	100 (21.6)	18 (19.8)
Cat 1.7 (PS ≥ 0.95)		25 (6.9)	32 (6.9)	7 (7.7)
Overall				
	Mean weight	1.119*	1.116*	1.125
Cat 1		223	290	59 (64.8)
	n (%)	(61.3)	(62.5)	
Cat 1.2		111 (30.5)	136 (29.3)	22 (24.2)
Cat 1.7		30 (8.2)	38 (8.2)	10 (11.0)

*These figures (including sample sizes) precisely align with those reported by NICE in Table 2 of the document "Review of methods, processes and topic selection for health technology evaluation programmes: conclusions and final update Appendix: Further discussion and rationale for conclusions – methods".

significant difference between the distribution of decisions across severity categories. The overall mean weight is higher in the implementation sample (1.125), but this is not a statistically significant difference compared to either the primary (1.119, p = 0.413) or primary+ (1.116, p = 0.482) samples.

Mean AS is lower in the implementation sample than the primary or primary samples (p < 0.05 for both). The most substantial difference is that there are more appraisal decisions in category 1 and less in category 1.2. There are no significant differences in the distribution of appraisal decision to the PS categories between the three samples.

3.5. Age and severity

Fig. 1 illustrates how the AS and PS NICE categories are related conceptually to age. Fig. 1a plots the maximum number of QALYs patients can obtain under current care, at each age, and generate AS = 12 QALYs. Above the line indicates those combinations of age and comparator QALYs that would generate less than 12 QALYs for AS (i.e. be considered less severe using this definition alone). Below the line are combinations of age and comparator QALYs that generate more than 12 QALYs i.e. are more severe using this definition. Similarly, the line for PS indicates those combinations of age and comparator QALYs which generate PS = 0.85. Above this line, PS is lower than 0.85 and below the line PS is higher. The frontier of the AS and PS functions therefore delineates the combinations of age and comparator QALYs required for a technology to meet the criteria for the overall severity modifier category 1.2 (or above).

There is a stronger relationship between age and comparator QALYs for AS than there is for PS. At young ages, the number of QALYs that patients can receive can be relatively high and still generate category 1.2 severity weight via AS. For example, at age 5 years, patients could still expect to receive over 12.5 discounted QALYs under current care and be assessed as category 1.2 severity because AS > 12. Current care is required to far less effective for patients at these ages to have PS ≥ 0.85. Up to the age of 55 years, any patient group assessed as meeting category 1.2 for PS would, by definition, also qualify for category 1.2 AS. Because there is a much weaker relationship between PS and age than AS and age, this switches at age 55 years.

Also note that at approximately 62 years, remaining discounted quality adjusted life expectancy falls below 12. At this point it is not feasible for AS to be above category 1 (there are some theoretical exceptions to this).

Fig. 1b is similar but shows the combinations of age and comparator QALYs that generate AS = 18 and PS = 0.95. As age increases, the maximum number of QALYs expected for current care rapidly falls for AS but the relationship is shallower for PS. The AS and PS lines intersect at age 48 years approximately.

This complex relationship between AS, PS and age is evident in appraisal decisions, illustrated in Fig. 2 for the Primary sample.

Fig. 2a is a scatterplot of AS by age for the primary+ subsample, with a best fit line (using Locally Estimated Scatterplot Smoothing – LOESS). Values for AS = 12 and 18 are also plotted. It demonstrates that there is a trend for AS to reduce with age, but that the relationship is flat, on average, between the ages of 40 and 60. All decisions where AS exceeds 18 are in those appraisals with a starting age below 20 years. For AS over 12, there are a large number of appraisals where the mean age lies between 40 and 60 years.

For PS, the relationship is more complex. On average, PS is broadly flat at around 0.55 where patient starting ages are below 40 years. There is then an increase in average PS that peaks soon after 60 years. PS above 0.85 and 0.95 occurs across the age distribution but the greatest frequency occurs between 40–65 years.

The relationship between EoL and age is more straightforward than for severity. In the Primary sample, appraisal decisions deemed to meet the EoL criteria had a mean patient age of 59.4 years, and the minimum was 37 years except in one case (TA588 Nusinersen for treating spinal muscular atrophy for young children and babies). This is higher than for appraisal decisions that did not meet EoL (51.4 years, p < 0.001).

3.6. EoL and severity

Severity weights were designed to reflect but not precisely mirror EoL. Of 81 (17.5 %) appraisal decisions that met the EoL criteria in the primary sample, 91 % would have been allocated a severity weight exceeding 1. And 25.9 % of those that did not meet EoL would have received a severity weight greater than 1, mainly in the 1.2 category. Therefore, the mean severity weight for these appraisal decisions (1.281) is higher than the mean for the 382 appraisal decisions that did not meet the EoL criteria (1.081, p < 0.001). Mean AS (12.2 vs 8.7 QALYs, p < 0.001) and mean PS (0.91 vs 0.54, p < 0.001) are both higher in those appraisal decisions that met EoL compared to those that did not. EoL is more strongly associated with higher PS (correlation 0.51) than higher AS (0.31).

There were proportionally more EoL topics in the implementation sample but the difference is not statistically significant at the 5 % level (24.8 % vs 17.5 %, p = 0.103), see Table 2.

Of these EoL appraisal decisions, there were fewer in the 1.2 severity weight category (63.6 % vs 71.6 %) but more in the 1.7 category (31.8 % vs 19.8 %). However, these are relatively small subsamples and the difference in the distributions is not statistically significant (p = 0.436). The mean weight for severity in appraisals classed as meeting the EoL criteria is higher in the implementation subsample compared to the primary + subsample (1.35 vs 1.28, p = 0.205). The table reinforces the finding that EoL is more closely correlated to PS than AS, in both appraisal samples.

4. Discussion

EoL weights were used in NICE's Technology Appraisals for over 13 years, so the move to severity as a replacement had to balance several competing considerations, key of which was the requirement for the change to be approximately cost neutral for the health system. The pragmatic weights NICE implemented, based on three categories of AS and PS, correlate with EoL but are not identical. Whilst EoL was only

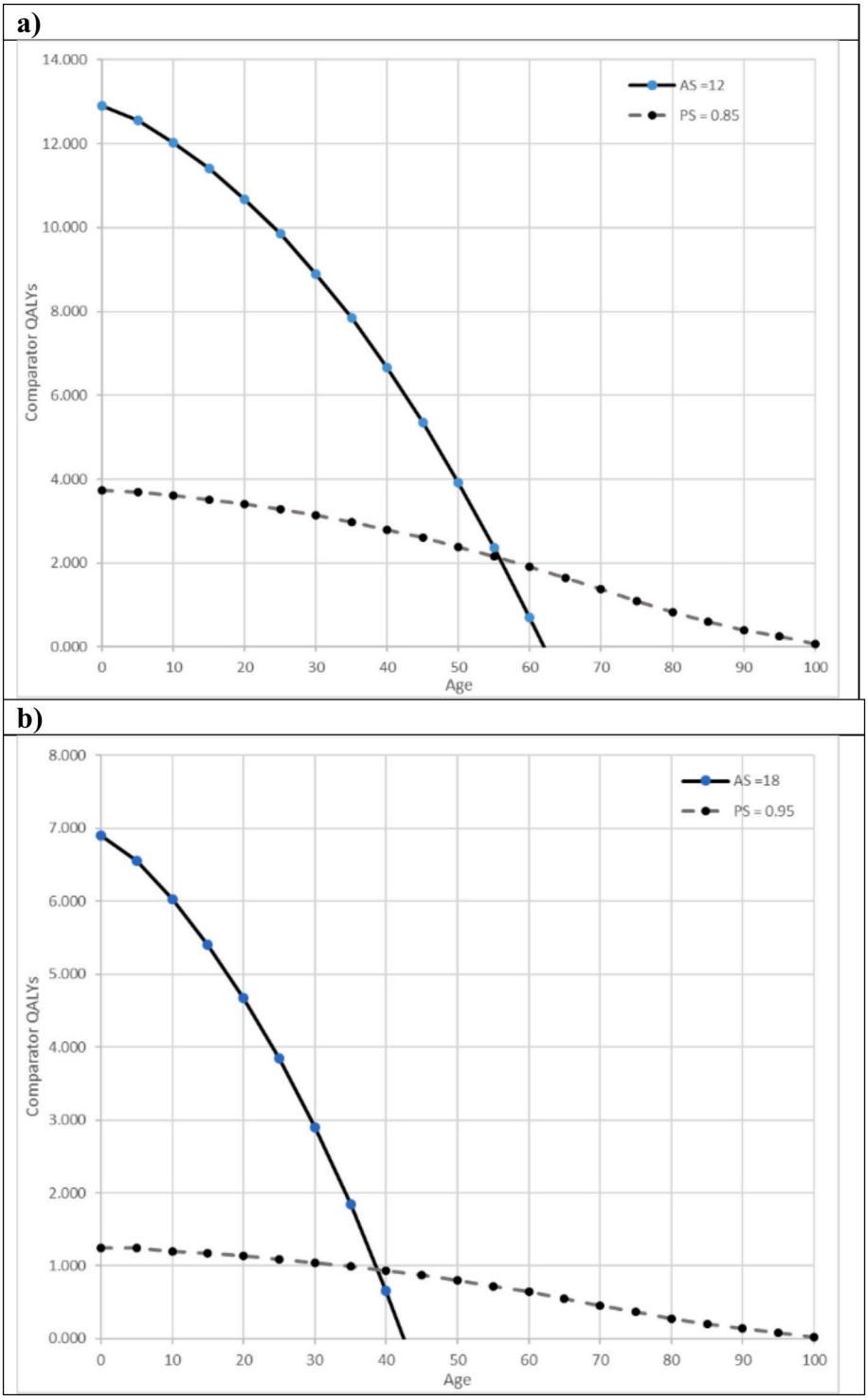

Fig. 1. The maximum number of comparator QALYs compatible with achieving a) severity level 2 and b) severity level 3.

exceptionally relevant for younger patient groups, AS allocates the highest weights almost exclusively to those aged below 20yrs. Yet the relationship between age and qualification for severity weights is complicated by the dual criteria in play (AS and PS). Samples of appraisal decisions therefore need to be compared in terms of their overall distribution of patients ages across appraisals. The nature of the relationship between severity and age in real NICE appraisals is also a factor of relevance for those that may seek to design societal preference elicitation studies.

Most technologies that would have qualified for additional weighting from the EoL criteria would also qualify for additional weight under the severity based approach. This is true both of the primary+ data where the severity weights were designed (8.6 % of EoL decisions would be in category 1 for severity) and in the implementation appraisals where severity has been used (4.6 %, representing 1 decision). It is also the case that many of these cases would not receive the same degree of weight (1.7) under EoL as under severity. The one decision in the post 2022 sample that would likely have qualified for additional weight under EoL criteria but did not qualify for any additional weight under severity was "Dabrafenib plus trametinib for treating BRAF V600 mutation-positive

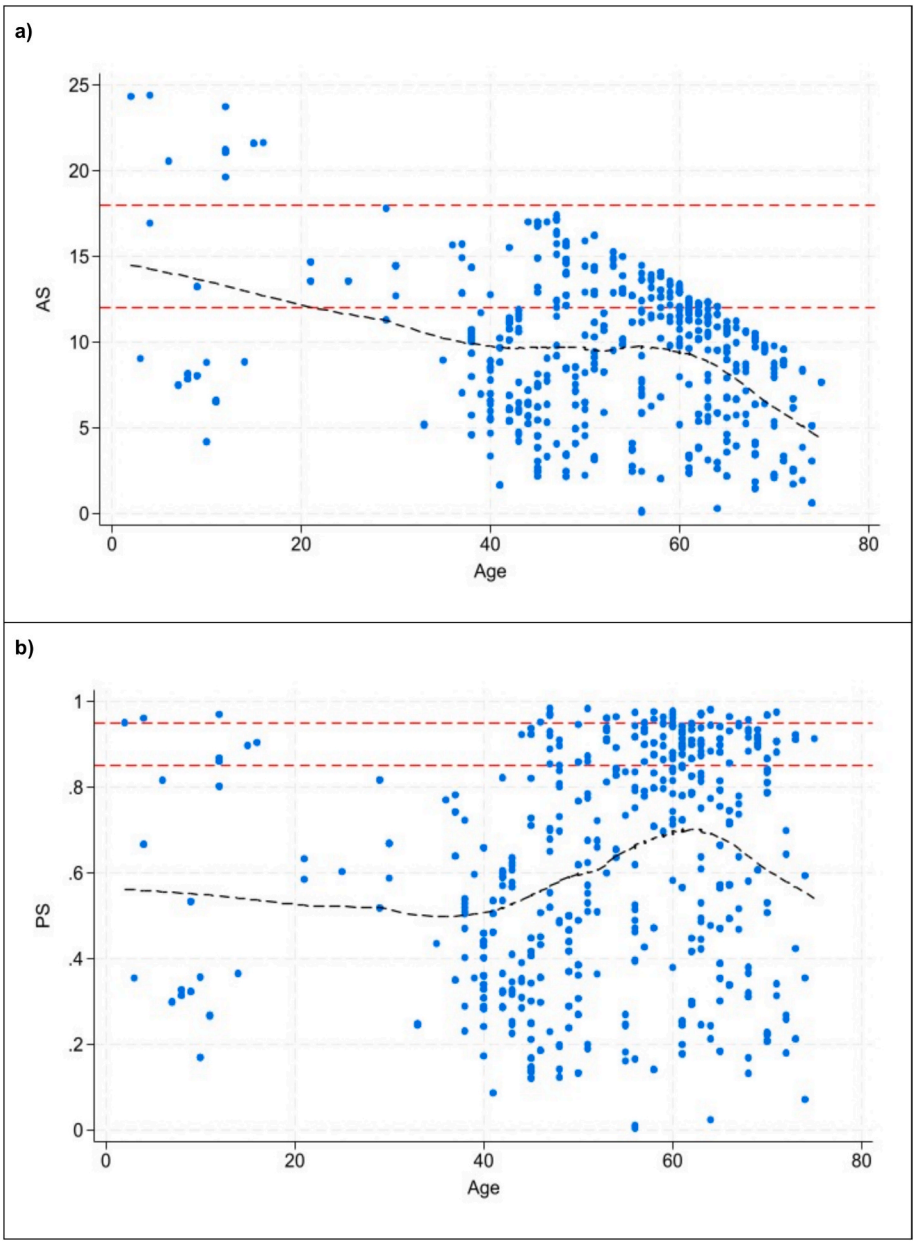

Fig. 2. Severity shortfalls by age (years) in the primary+ subsample with LOESS smoother for a) AS and b) PS.

advanced non-small-cell lung cancer"[10]. (cite guidance), though PS was only marginally below the 0.85 category cutoff.

The evidence presented here is possible only because we were able to access the confidential information underpinning NICE appraisals. It suggests severity weights are working as intended. There is no statistically significant difference between mean overall severity weights in the post 2022 implementation sample compared to the appraisal decisions in which the severity weights were designed. This is a key finding in relation to the goal of achieving approximate cost-neutrality. The number of appraisal decisions in any given year is relatively small (48 in 2023 for example) and variability across appraisals over time is high. Claims that severity weights were being used less than expected may have been premature. Of course, conclusions outlined here could also change as the size of the appraisal evidence base expands.

There are statistically significant differences observed between the implementation and primary+ subsamples in terms of the distribution across AS categories. Whilst of interest, it should be noted that severity weights and cutoffs were designed to achieve a broadly similar overall weighting as under EoL, not for the AS and PS components to remain similar across appraisal samples. It is also worth noting that AS and PS are highly correlated. Of the 11 appraisal decisions in the PS 1.2 category that were also in the AS 1 category, the mean AS was 10.4 QALYs (sd 0.34). Appraisal decisions that were close to the boundary of the AS 1.2 (12 QALYs) category were largely already assigned a weight of 1.2 or higher for the purposes of decision making because they qualified on the basis of PS.

There are several limitations.

The extent of missing data should be noted. In the original primary and primary samples, it was not possible to calculate severity shortfalls in approximately one third of cases. Where AS and PS were not calculated, this was often because we could not identify reporting of the number of QALYs that were estimated for current care, a necessary component for the AS/PS calculations. We attempted to record data that aligned to the stated preferred committee case, but this was often not possible either because no such scenario was given by the committee or we could not identify baseline age or comparator QALYs for the relevant

Table 2
Severity category for appraisals meeting end of life criteria.

	Primary+ (n = 464*)				Implementation (n = 91)			
	EoL Yes		EoL No		EoL Yes		EoL No	
n	N	%	N	%	N	%	N	%
Total	81	17.5	382	82.3	22	24.8	69	74.4
Absolute shortfall								
Cat 1 (AS < 12)	43	53.1	299	78.3	17	77.3	60	87.0
Cat 1.2 (12 ≤ AS < 18)	37	45.7	75	19.6	5	22.7	6	8.7
Cat 1.7 (AS ≥ 18)	1	1.2	8	2.1	0	0.0	3	4.4
Proportional shortfall								
Cat 1 (PS < 0.85)	11	13.6	321	84.0	2	9.1	64	92.8
Cat 1.2 (0.85 ≤ PS < 0.95)	54	66.7	45	11.8	13	59.1	5	7.3
Cat 1.7 (PS > 0.95)	16	19.8	16	4.2	7	31.8	0	0.0
Overall								
Mean weight	1.281		1.081		1.350		1.054	
Cat 1	7	8.6	283	74.1	1	4.6	58	84.1
Cat 1.2	58	71.6	77	20.2	14	63.6	8	11.6
Cat 1.7	16	19.8	22	5.8	7	31.8	3	4.4

* For one decision, the appraisal committee did not consider EoL (TA192).

scenario. Appraisals that were not conducted using cost utility analyses would not have these calculations, for example. This is an important limitation to note when making comparisons between severity weights in appraisals undertaken in this period versus more recent appraisals where missing data for these reasons is much less frequent. However, it is important to note that the severity cutoffs and weights were designed only in those appraisals that had complete AS/PS data.

Comparisons of data that categorise appraisal decisions to severity categories and EoL rely on data calculated from different processes. In the case of EoL, appraisal decisions in the implementation sample were classified according to the life expectancy reported in the appraisal and the addition to life expectancy from the technology in question. This is not the same as the primary sample, where this categorisation was undertaken as part of the appraisal process, scrutinised by academic groups and decision making committees. When first introduced, eligibility for EoL additionally required the appraisal to be for small patient groups and there are appraisals included in the primary sample that were deemed not to meet the EoL criteria because of this criterion (e.g. TA242 [11]). Similarly, the categorisation of severity, both AS and PS, in the implementation sample will be subject to intense scrutiny given the impact on decision making. In the historical primary samples, these categorisations have been made retrospectively and no such scrutiny applied. For these reasons, different appraisal samples may be incommensurable.

5. Conclusion

Severity weights introduced by NICE for Technology Appraisals that commenced from 2022 onwards do not mirror the EoL weights they replaced. The use of both AS and PS to define severity means that health technologies for children and young adults are more likely to receive additional weight.

Evidence from 62 appraisals conducted using the new severity weights suggests they are being implemented as frequently as expected. Therefore, the requirement for the change from EoL to severity weights to be approximately cost-neutral has been achieved.

CRediT authorship contribution statement

Allan Wailoo: Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Helen Bell Gorrod:** Writing – review & editing, Investigation, Formal analysis. **Lorna Dunning:** Writing – review & editing, Writing – original draft, Methodology, Data curation, Conceptualization. **Juliet Kenny:** Writing – review & editing, Writing – original draft, Methodology, Data curation. **Emily Leckenby:** Writing – review & editing, Writing – original draft, Formal analysis. **Koonal Shah:** Writing – review & editing, Writing – original draft, Formal analysis.

Funding

This work was funded by the National Institute for Health and Care Excellence (NICE) via its Decision Support Unit based at the University of Sheffield.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Allan Wailoo reports financial support was provided by National Institute for Health and Care Excellence. LD, JK, El and KS are employees of NICE. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

Several people provided information and comments that contributed to this work. Matt Stevenson, Nick Latimer, Mónica Hernández Alava and Donna Davis. Several colleagues at NICE assisted this work by providing documentation for analysis. The views, and any errors or omissions, expressed in this manuscript are of the authors only.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.hpopen.2025.100156.

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