Utility Data in Health Technology Assessments in England by the National Institute for Health and Care Excellence

HTA70

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SUMMARY

OBJECTIVES

- Utility values are an important input in cost-effectiveness models (CEMs) used by the National Institute for Health and Care Excellence (NICE) in England. These values can strongly influence whether a treatment is considered cost-effective
- This study aimed to examine which types and sources of utility data were used in successful health technology assessments (HTAs) in 2025, and to identify how often NICE raised concerns about utility data, in submissions with a positive or negative recommendation

METHODS

- Publicly available committee papers and public committee slides from the NICE website were examined for HTA submissions recommended between January and December 2025
- For each submission, information was collected on disease area, trial design, source and type of utility data, and whether NICE identified any issues related to utilities
- Issues were also categorised by their reported impact on the CEM

FINDINGS

- Eighty-four HTAs were identified; 55 of them received a positive NICE recommendation
- Most of these positive decisions relied on utility data collected in clinical trials, which often used generic utility measures rather than disease-specific measures
- NICE raised at least one utility-related concern in nearly two-thirds of successful HTA submissions. These concerns were raised across all types of utility data sources, including clinical trials, published literature, real-world evidence, vignette studies, and previous NICE submissions
- In some cases, utility issues were considered a major contributor to CEM uncertainty: 7% had major issues that were a main driver of uncertainty, 11% had moderate issues, and 4% had moderate-to-large issues.
  - An additional 13% of successful HTA submissions had major utility issues that were not considered main drivers of CEM uncertainty

CONCLUSIONS

- Review of successful NICE submissions shows that utility data are frequently criticised irrespective of source, including when derived from pivotal clinical trials. This suggests that avoiding criticism is unrealistic and that NICE decision-making is not contingent on 'perfect' utility evidence.
- Instead, positive recommendations appear to depend on how uncertainty is framed, justified, and explored within the CEM. Methodological coherence, transparent handling of limitations, and clear rationale for assumptions were more influential than the specific utility source selected.
- These findings highlight the importance of early, strategic planning of utility data collection and CEM structure, focusing on decision relevance rather than avoidance of uncertainty, to support future NICE submissions.

BACKGROUND & AIMS

- Utility data are a critical component of HTA, particularly in CEMs, s they translate clinical outcomes to quality-adjusted life years (QALYs) and directly influence uncertainty in cost-effectiveness results, including incremental cost-effectiveness ratios (ICERs)
- Recent analysis of 2024 HTAs conducted by Ireland's National Centre for Pharmacoeconomics (NCPE) found inconsistency in the utility measures used in CEMs, often requiring the HTA body to impose base-case adjustments[1]. These findings suggest that variation in utility selection may represent an important source of decision uncertainty
- This study aimed to review the utility data used in NICE submissions in England to assess the consistency of utility values used in CEMs[2]

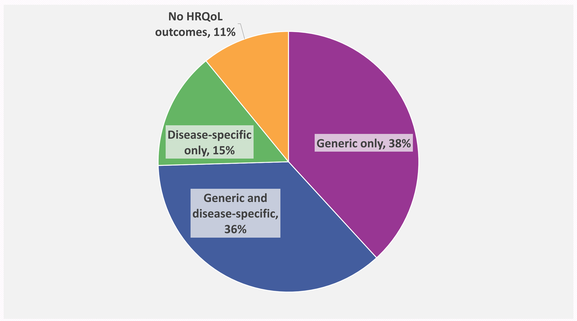
METHODS

- On 5 and 6 January 2026, committee papers and public committee slides from the NICE website were reviewed for HTA submissions from January through December 2025
- Data was extracted about each submission's disease area, trial phase, control, blinding, utility type and source, inclusion of caregiver utility, inclusion of a managed access agreement, and any other key issues related to utilities

RESULTS

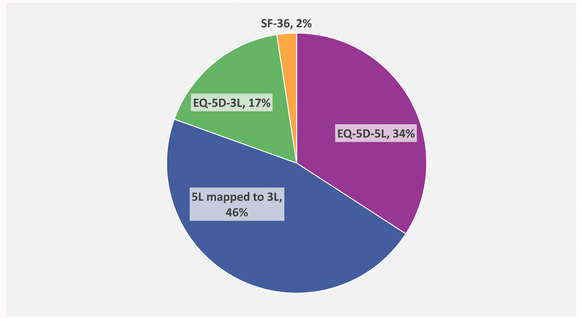
- Of 84 HTAs identified, 55 (64%) led to positive NICE recommendations: 30 (55%) positive outcomes were in oncology, 7 (13%) were orphan drugs, and 27 (49%) were in other areas
- Forty-five positive HTAs (82%) used data from phase 3 trials, followed by 4 (7%) from phase 1/2 trials, 2 (4%) each from phase 2 or 2/3 trials, 1 (2%) from a phase 2b trial, and 1 (2%) from a multiphase trial
- Thirty-one of the positive HTAs (56%) were double blind and the remaining 24 (44%) were open label
- Twenty-three of the studies (42%) were placebo controlled, 21 (38%) were active controlled, and the reminder had a combination of active and placebo controls (4 [7%]) or were single-arm studies (7 [13%])
- Among the 55 HTAs with positive decisions, most used only generic utility measures (21 [38%]) or a combination of generic and disease-specific (20 [36%]) utility measures, and 6 (11%) did not include health-related quality of life outcomes. Only 8 (15%) HTAs used solely disease-specific utility measures (Figure 1)

Figure 1. Types of utilities collected in trials



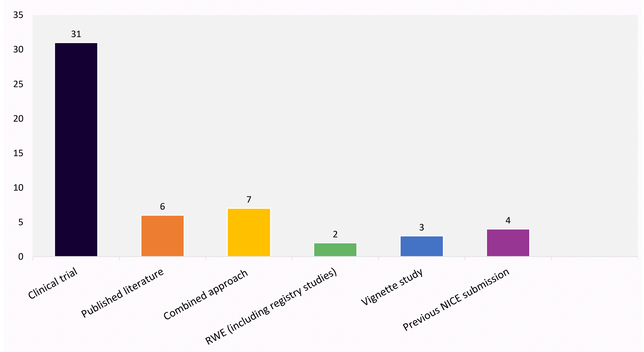
- Among the studies that used generic utility measures, 14 (34%) used the Euroqol-5D-5L (EQ-5D-5L), and 7 (17%) used the Euroqol-5D-3L (EQ-5D-3L); 19 (46%) used 5L data mapped to 3L. Only 1 study (2%) used the SF-36 (Figure 2)

Figure 2. Utility instruments used in NICE submissions



- In the 55 successful submissions, most utilities came from clinical trials (31 [56%]), whereas 6 (11%) used published literature and 7 (13%) used both original clinical trial data and published literature (Figure 3)
  - Another 4 applications (7%) took utilities from a previous NICE submission, and 3 (5%) took their utilities from vignette studies
  - The remainder had utilities from real-world evidence, including registry studies or burden of illness studies (2 [4%] and 1 [2%], respectively)

Figure 3. Sources of utility data in modelling



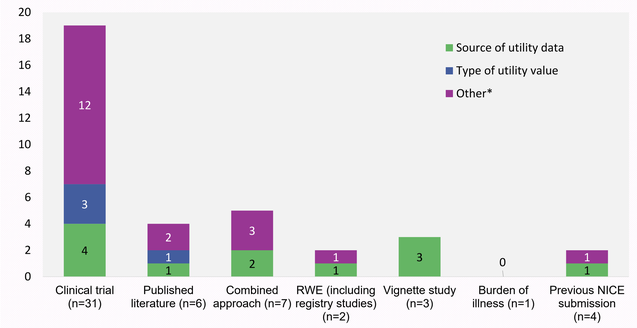
- Among the 55 successful submissions, 35 (64%) had a key issue in the utility data, and 5 (9%) had more than one issue related to utilities, with the remaining 20 (36%) having no issues related to utility data
- Issues related to utilities most often had a small or minor impact on uncertainty in the model (25%), but nearly as many had a major impact on uncertainty (20%) (Table 1)

Table 1. Severity of utility issues

Level of uncertainty	Number (%) N=55
Major: main driver	4 (7%)
Major: not main driver	7 (13%)
Moderate	6 (11%)
Moderate-to-large	2 (4%)
Small-to-minor	14 (25%)
Unknown	2 (4%)

- Utility-related concerns were frequently raised by NICE across all evidence sources, affecting between 50% and 100% of submissions. Clinical trial–based utilities, while most commonly used, were still associated with issues in 61% of cases.
- Utility-related issues were raised by NICE across all data sources, with the majority relating to broader methodological or modelling considerations rather than utility sources or measure type, suggesting that effective handling of utility uncertainty is more important than the choice of data source alone (Figure 4).

Figure 4. Utility issues raised in NICE submissions, by type of data



**Other* was typically related to the size of the utility estimate

- Across all data sources, the predominant driver of concern was the magnitude and plausibility of the utility estimates themselves. This pattern was particularly evident in trial-based and combined approaches, where over 60% of issues were related to the size of utility gains or decrements (Table 2).
- In contrast, vignette studies and previous NICE submissions were primarily challenged on their data source. Overall, these findings suggest that uncertainty in cost-effectiveness models is driven less by methodological choices around utility measurement, and more by how utility values translate into clinically and economically plausible estimates.

Table 2. Utility issues by source

Data source	Source of utility data	Type of instrument	Other*
Clinical trial (n=19)	4 (21%)	3 (16%)	12 (63%)
Published literature (n=4)	1 (25%)	1 (25%)	2 (50%)
Combined approach (n=5)	2 (40%)	0	3 (60%)
RWE, including registry studies (n=2)	1 (50%)	0	1 (50%)
Vignette studies (n=3)	3 (100%)	0	0
Previous NICE submissions (n=2)	2 (100%)	0	0

*A designation of *Other* was typically related to the size of the utility estimate

CONCLUSIONS

- Utility data remain a consistent source of uncertainty in NICE decision-making, regardless of their source. Importantly, concerns are predominantly driven by the magnitude and plausibility of utility estimates rather than their source or measurement instrument.
- This indicates that investment in utility data generation should be accompanied by equal emphasis on how these data are analysed, validated, and presented within the cost-effectiveness framework.
- Embedding utility strategy early in clinical development and aligning assumptions with NICE expectations may reduce uncertainty and improve the robustness of future submissions.

References

1. Looby A. Utility Data in Health Technology Assessments Completed by the National Centre for Pharmacoeconomics. Pharmacoeconomics Annual Symposium. Dublin, Ireland: National Centre for Pharmacoeconomics; 2025.
2. NICE. Technology appraisal committees. National Institute for Health and Care Excellence. https://www.nice.org.uk/get-involved/our-committees/nice-committee-meetings/technology-appraisal-committees. Accessed January 6, 2026.

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