HTA180

Linking Clinical Added Value to Normalized Delta QALY: Insights from Therapeutic Product Analysis

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PASS Patient Access

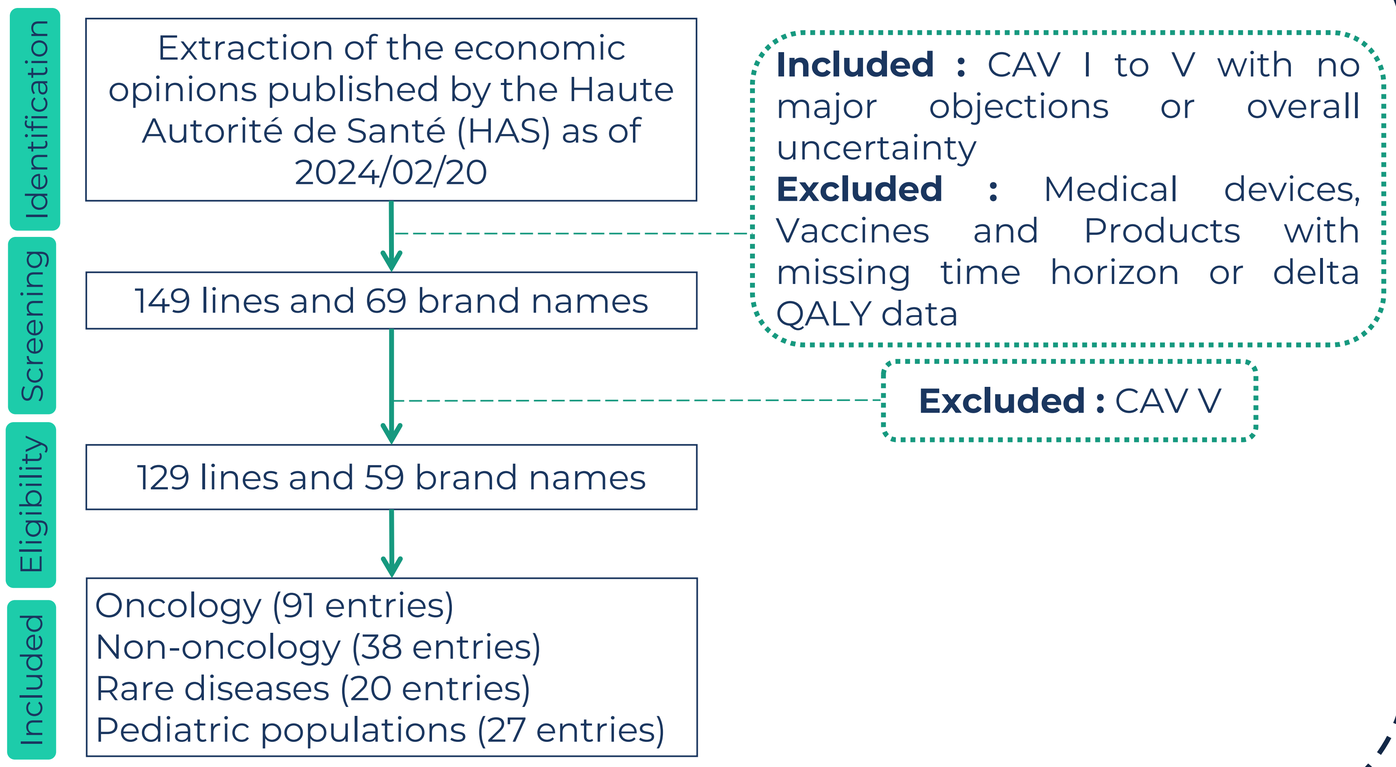
Background and objective

The study aimed to explore and quantify the relationship between the Clinical Added Value (CAV) and the normalized Delta QALY (Quality-Adjusted Life Years). **The time horizon of an intervention significantly influences total QALY gain**: a treatment with a modest effect over a long period can accumulate the same QALY gains as a highly effective treatment with a shorter duration.

Normalizing Delta QALY by time horizon provides a rate of QALY gain per year, allowing for a more equitable comparison of interventions with varying durations. This normalized measure helps to isolate the efficiency of each treatment in delivering health benefits relative to time, offering a clearer basis for comparing products' clinical impact. **By examining the normalized Delta QALY, this study offers insights into how clinical benefits translate into measurable health outcomes over time**, supporting healthcare decision-making and resource allocation..

Method

Figure 1. Flowchart of the opinion selection



Statistical analysis included descriptive statistics and Kruskal-Wallis H-tests to assess significant differences in normalized Delta QALY across different CAV ratings.

Results

The overall analysis revealed a statistically significant difference in normalized Delta QALY between CAV I-III and IV, with the Kruskal-Wallis H-test yielding a **test statistic of 16.766 and a p-value of 0.000042**. This indicates that the CAV are a meaningful discriminator of normalized QALY outcomes, reflecting their link to efficacy in the cost-effectiveness model.

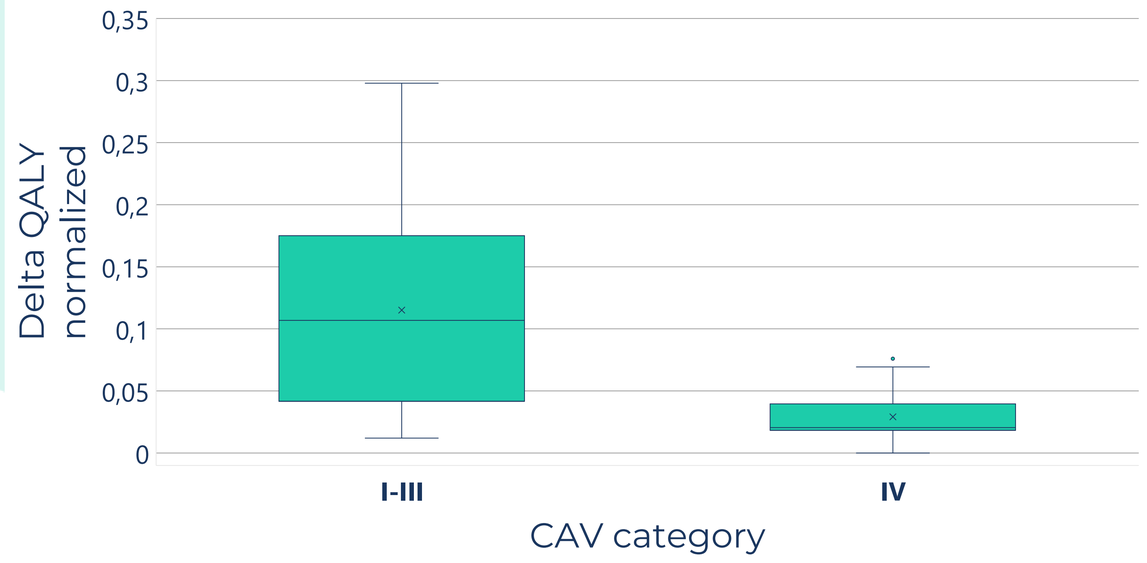
Secondary analyses further confirmed these relationships within specific subgroups, except for rare diseases, likely due to low sample size. The results for the oncology therapeutic area are shown in Figure 2. Concerning the other secondary analyses performed:

- ✓ **Non-oncology (all except oncology): A significant difference** in normalized Delta QALY was noted (n=38, Test Statistic: 15.129, P-value: 0.0001)
- ✓ **Rare diseases: No significant differences** were observed (n=20, Test Statistic: 2.428, P-Value: 0.119), possibly due to small sample size and variability
- ✓ **Pediatric Populations: A significant difference** in normalized Delta QALY was noted (n=27, Test Statistic: 9.453, P-Value: 0.002)

An oncology-specific analysis was conducted. The initial Kruskal-Wallis H-test yielded a result of **2.099 (p=0.147).** With a p-value above the 0.05 threshold, this suggests **no statistically significant difference** in Delta QALY between CAV I to III and CAV IV categories within oncology therapeutic areas. This result appears counterintuitive, as products with CAV ratings I to III are typically more innovative and effective. The likely explanation lies in the varying time horizons across these categories, which may mask differences in effectiveness.

To address this, Delta QALYs were normalized to enhance comparability across treatments, and the Kruskal-Wallis H-test was reapplied. This time, the test result was **4.345 (p=0.037).** With a p-value below 0.05, the finding indicates a **statistically significant difference** in normalized Delta QALY between CAV I to III and CAV IV categories in oncology. This suggests that normalizing Delta QALY values enables detection of distinctions between CAV categories that were not apparent in the raw data, underscoring the **importance of normalization in revealing subtle but meaningful differences in clinical value.**

Figure 2. CAV Category vs normalized Delta QALY box in Oncology Therapeutic Areas



Conclusion and Discussion

The study identified substantial differences in normalized Delta QALY values between CAV I-III and IV, highlighting the link between CAV and treatment efficacy within the cost-effectiveness framework. Significant variations, especially in non-oncology and pediatric areas, suggest that benefits may differ by CAV classification. Normalizing the data minimizes discrepancies from simulations, showing a strong alignment between CAV and Delta QALY.

1. All opinions available on the HAS website since 2014

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