The Phantom Menace: How Appeals and Extra Consultations Prolong the HST Pathway

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Background and Methods

The NICE Highly Specialised Technology (HST) pathway aims to streamline decision-making but appeals and consultations can extend timelines.

This study evaluates the impact of appeals and additional consultations on the time and resource efficiency of the HST pathway.

"What is the impact of appeals/extra consultations on time to final decision?"

We collected publicly available data from NICE on HST appraisals from December 2013 to January 2025. The dataset comprised the time from Final Scope (FS) to Final Evaluation Determination (FED) and binary indicators for appeals and additional consultations.[1]

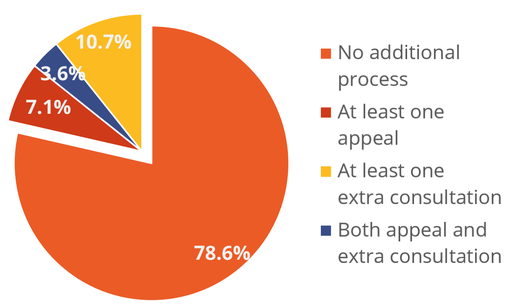
We initially explored these variables using Wilcoxon-Mann-Whitney tests, followed by two robust linear regression models—one treating appeals and consultations as separate variables, and one combining them into a composite indicator.

Findings

Out of 28 HST submissions to NICE with publicly available data, six have undergone either appeals or extra consultations (Figure 1). Three were appealed, while four required additional consultations (one of which incurred both an appeal and extra consultation).

"One in five HST submissions have an appeal or an extra consultation"

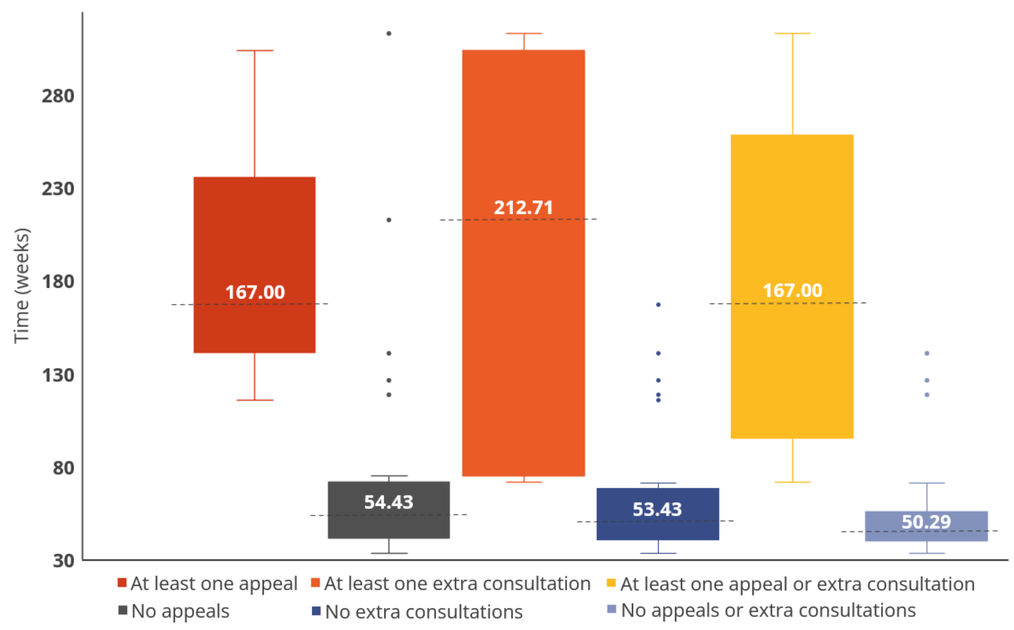
Figure 1. HSTs with additional processes



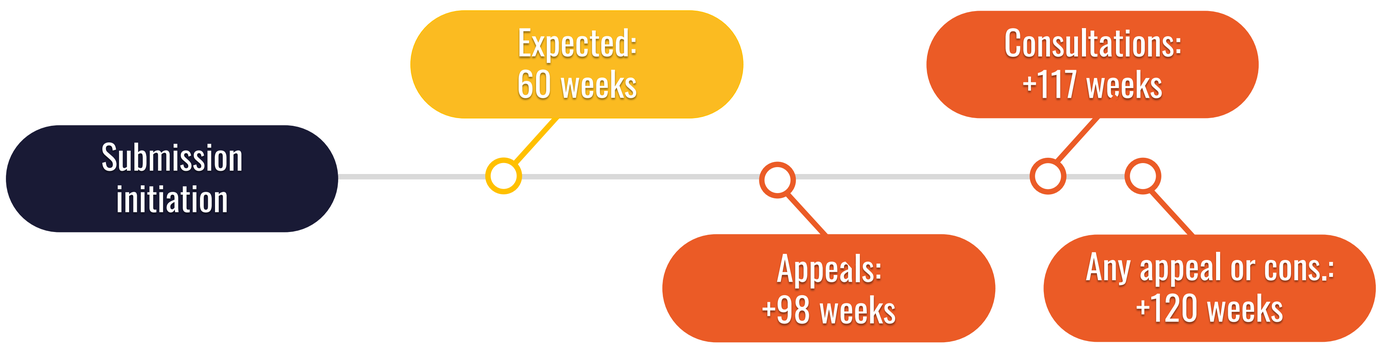
The exploratory, non-parametric tests found a significantly longer time to FED in submissions with at least one appeal (p=0.012) or at least one extra consultation (p=0.001) compared to those without. When both factors were considered together, a significant increase in time to FED was also observed (p<0.001) (Figure 2). These results show that appeals and extra consultations are associated with significantly increased time from FS to FED.

The regression models further confirmed that both appeals and consultations are significant predictors of extended appraisal timelines. The model with individual variables predicted that "clean" submissions have a baseline duration of 58.4 weeks (95% CI: 36.2, 80.5), while an appeal adds 97.9 weeks (95% CI: 34.4, 161.4) and an extra consultation adds 117.3 weeks (95% CI: 66.0, 168.6); notably, the composite model predicted that the presence of either factor increases the pathway duration by 120.0 weeks (95% CI: 70.4, 169.7) compared to a baseline of 59.8 weeks (95% CI: 35.0, 84.6). Given that time is directly linked to financial considerations, these delays not only undermine pathway efficiency but may also have profound economic implications.

Figure 2. Boxplots of time from FS to FED by the presence of appeal, extra consultations, or any appeal or consultation



Conclusion and Implications for Practice



"Having either an appeal or an extra consultation increases the HST pathway duration by 120 weeks"

Delays from appeals and extra consultations in the HST pathway can push back market access by up to 120 weeks. This not only incurs significant financial burdens from lost revenue, increased operational costs, and extended resource use, but also postpones critical treatment access for patients in need.[2] To avoid significant delays, companies should take the following 3 steps:

- **Engage early** with HTA bodies and payers to understand submission requirements and tailor dossiers to each target market.
- Build relationships with patient and physician groups to better **understand the patient journey** and unmet needs.
- Develop a cross-functional **evidence generation plan** to address gaps and support robust economic models with realistic assumptions.

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References

1. National Institute for Health and Care Excellence (2025). *NICE advice and quality standards.* Accessed February 15, 2025. https://bit.ly/NICE_HST
2. Getz. (2024). *Appl. Clin. Trials.* 2024; 33(6):12-13.

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Appendix

Methods

We collected publicly available data from the NICE website on HST appraisals conducted between December 2013 and January 2025. The dataset included the time from Final Scope (FS) to Final Evaluation Determination (FED), the presence or absence of appeals, and the presence or absence of additional consultations.

Descriptive statistics were calculated, and box plots were generated to assess the impact of appeals and additional consultations on HST pathway duration. A preliminary non-parametric analysis of individual variables was performed using Wilcoxon-Mann-Whitney tests. Assumptions for linear regression were evaluated, revealing that residuals were not normally distributed. Although linear regression is generally robust to deviations from normality and heteroscedasticity, models with robust standard errors were used to quantify the impact of appeals and additional consultations on the HST pathway.

Findings

Out of 28 HST submissions to NICE with publicly available data, six have undergone either appeals or extra consultations. Three were appealed, while four required additional consultations (one of which incurred both an appeal and extra consultation).

The exploratory tests found a significantly longer time to FED in submissions with at least one appeal (p=0.012) or at least one extra consultation (p=0.001) compared to those without. When both factors were considered together, a significant increase in time to FED was also observed (p<0.001). These results show that appeals and extra consultations are associated with significantly increased time from FS to FED.

The regression models further confirmed that both appeals and consultations are significant predictors of extended appraisal timelines. The model with individual variables predicted that "clean" submissions have a baseline duration of 58.38 weeks (95% CI: 36.21, 80.54), while an appeal adds 97.94 weeks (95% CI: 34.44, 161.45) and an extra consultation adds 117.32 weeks (95% CI: 66.03, 168.60). This model explained 60% of the variance (R^2_{adj} = 0.565). Notably, the composite model predicted that the presence of either factor increases the pathway duration by 120.05 weeks (95% CI: 70.39, 169.70) compared to a baseline of 59.8 weeks (95% CI: 34.98, 84.64). This model explained 49% of the variance (R^2_{adj} = 0.467).

Regression models	Estimate	SE	t	p	95% CI
Model 1					
Intercept	58.38	7.04	8.29	<0.001	36.21, 80.54
Appeals	97.94	34.74	2.82	0.009	34.44, 161.45
Consultations	117.32	55.25	2.12	0.043	66.03, 168.60
Model 2					
Intercept	59.80	6.80	8.79	<0.001	34.98, 84.64
Any appeal or extra consultation	120.05	41.77	2.87	0.007	70.39, 169.70

Abbreviations: SE = standard error, CI = confidence interval