HPR203

Terminated NICE Appraisals – A Hidden Driver Behind the UK's Access Challenges?

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Objectives

The NICE methods review has proposed ways to provide faster, fairer access [1] to medicines in the UK. This research aimed to establish the current status quo to monitor the impact of these changes moving forward. Particularly, given the differing published positive recommendation rates (EFPIA report [2]: 67%; NICE's website[3]: 83%).

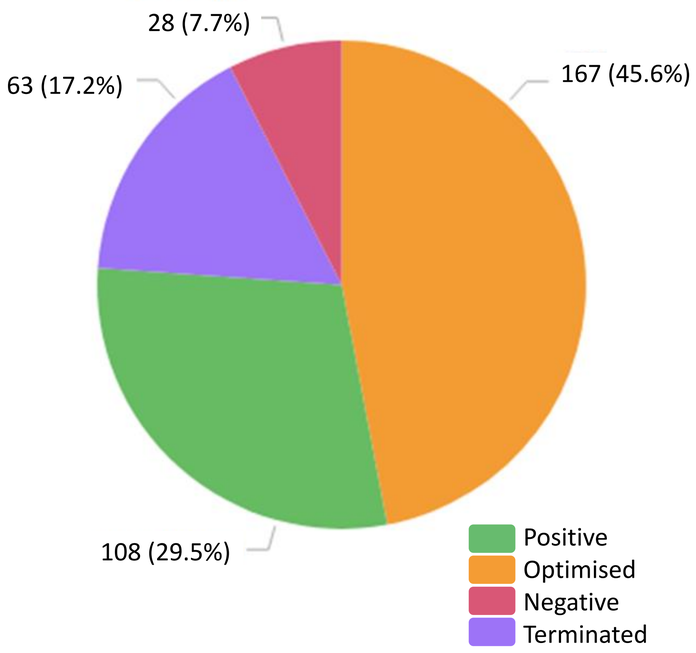
Methods

Data was collected from 366 appraisals between July 2016 and May 2022 to enable calculation of an overall recommendation rate, observe how this has changed over time and identify any trends across variables extracted. Acknowledging there are potential confounding factors that are not included in the analyses.

Results

The analysis identified a positive recommendation rate of 75.1% (275/366) (Figure 1) which was between that of the EFPIA and NICE figures (acknowledging these analyses were conducted over different time periods).

Figure 1: NICE recommendations Jul 2016 – May 2022

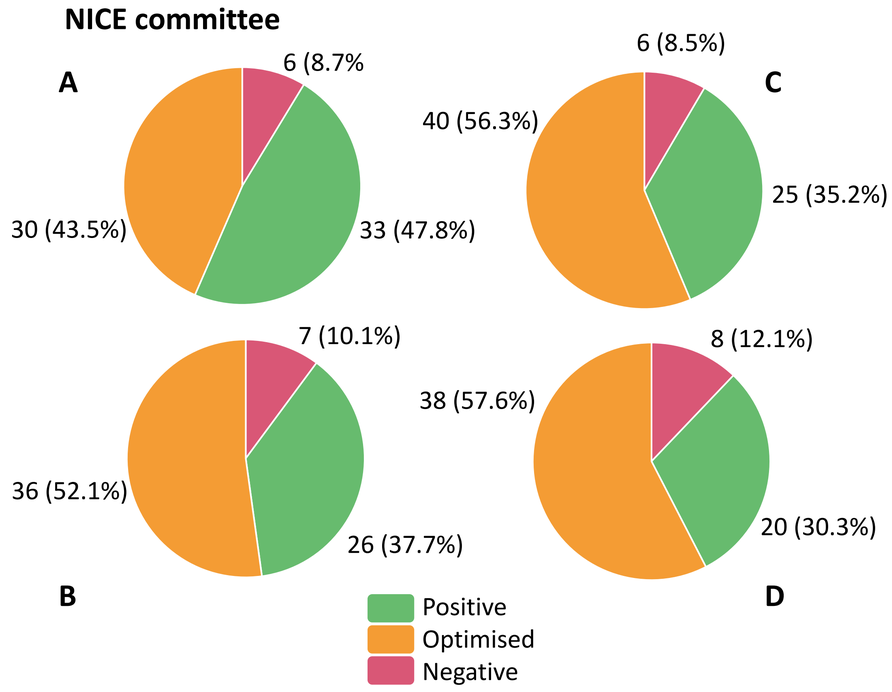


Of note, we observed the number of terminated appraisals (which were not included in NICE's analysis), have been increasing, from 4% (2/54) in 2018 to 25% (20/81) in 2021. Of the 31 appraisals terminated in 2020/21, >63% of these received marketing authorisation within 12 months of termination, indicating these cannot be attributed to NICE clearing outdated appraisals.

Additionally, we observed 28.26% (13/46) of all combination therapies appraisals have been terminated, highlighting such appraisals have increasingly led to companies not submitting.

NICE's recommendation rates for each committee was also analysed individually. Whilst it is accepted that the therapy area each committee tends to appraise and other confounding factors may impact the findings, there are notable differences between NICE committees, ranging from 8.5% to 12.1% negative recommendations and 30.3% to 47.8% positive without optimisation.

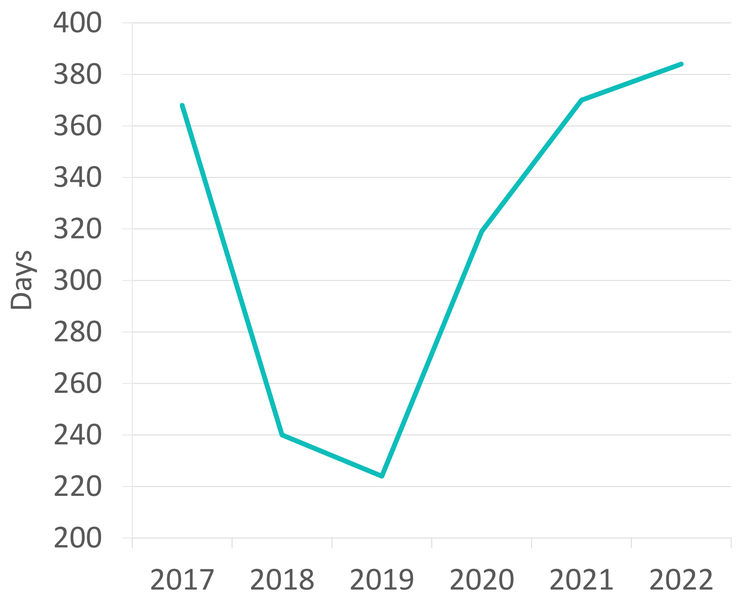
Figure 2: Recommendations July 2016 – May 2022 by NICE committee



In addition to recommendations, we considered the time to reimbursement (T2R) of each appraisal, defined as the time from marketing authorisation to the publication of guidance.

We found the median T2R to be 321 days, similar to that found in the EFPIA report, 340 days. However, when breaking this down by year (Figure 3) we found this to have been increasing since 2019.

Figure 3: Median time from marketing authorisation to published guidance by publication year



Inconsistencies were observed in time to guidance by NICE committees (Figure 4), but more so by evidence assessment groups (EAGs) (Figure 5), with the median time from marketing authorisation to published guidance ranging from 324-414 days and 245-495 days, respectively.

Figure 4: Comparing median time from marketing authorisation to reimbursement across NICE committee's

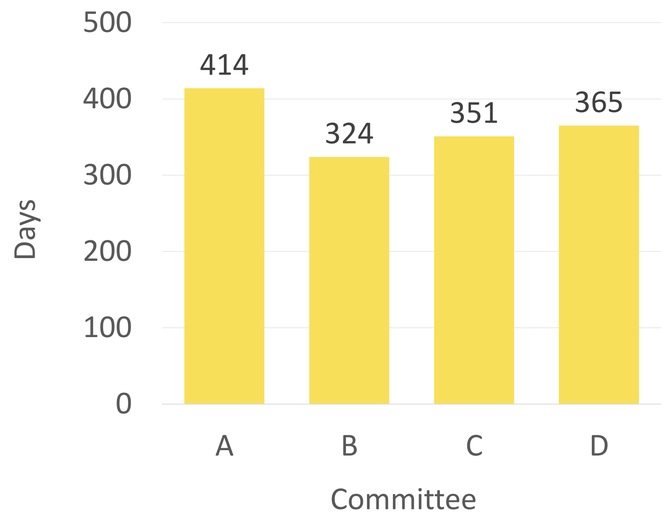
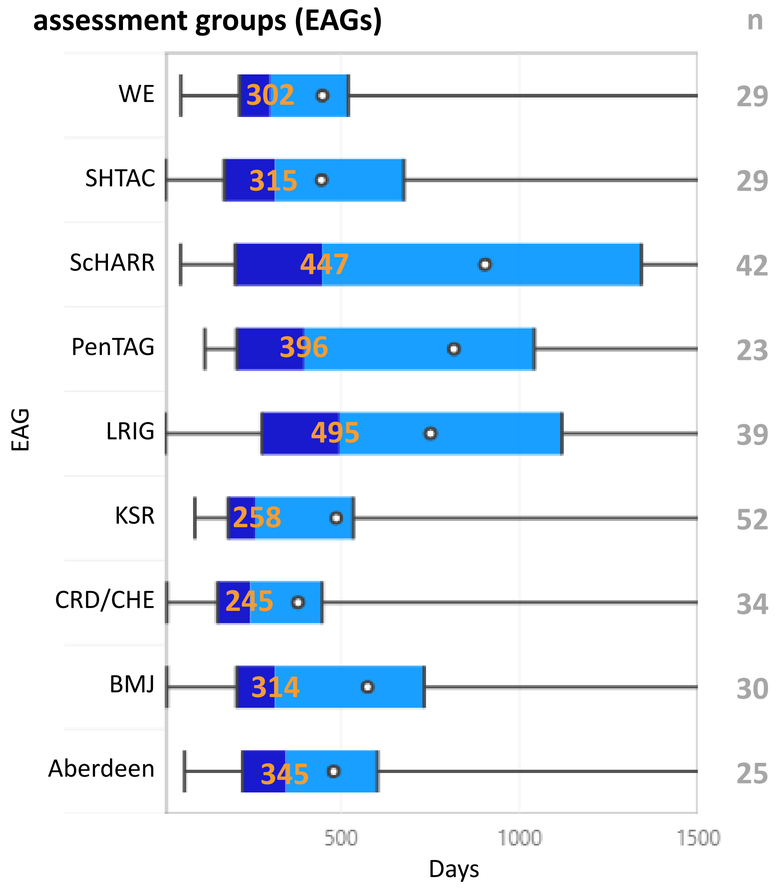


Figure 5: Comparing median time from marketing authorisation to published guidance across evidence assessment groups (EAGs)



Min, Q1, Median, Dot – mean, Q3, Max

Abbreviations - BMJ: BMJ Technology Assessment Group; CRD/CHE: Centre for Reviews and Dissemination/Centre for Health Economics - University of York ; KSR: Kleijnen Systematic Reviews Ltd; LRiG: Liverpool Reviews and Implementation Group; PenTAG: University of Exeter; ScHARR: School of Health and Related Research- Sheffield; SHTAC: Southampton Health Technology Assessments Centre; Warwick: Warwick Evidence

Conclusion

This analysis has provided a baseline to allow monitoring of the impact of new access initiatives in the UK. However, it has also demonstrated the importance within metrics of incorporating all appraisal outcomes, including terminated appraisals. With the UK currently ranked 7th in Europe for total availability of approved medicine (2017-2020) in the most recent EFPIA 'Waiting to Access Innovative Therapies' (WAIT) report [2], holistically monitoring future trends is imperative.

References

1. NICE (2022) *NICE changes to provide faster, fairer access to new drugs and devices*. Available at: https://indepth.nice.org.uk/methods-review/index.html
2. EFPIA (2022) *EFPIA Patients W.A.I.T. Indicator 2021 Survey.* Available at: <https://efpia.eu/media/636821/efpia-patients-wait-indicator-final.pdf>
3. NICE (2022) Technology appraisal data: appraisal recommendations. Available at: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/data/appraisal-recommendations