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Has the New Nice STA Process Addressed Inefficiencies within the Appraisal Process, Resulting in Faster Patient Access?

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Introduction

- Historically, the National Institute of Health and Care Excellence (NICE) appraisal process has been resource intensive, with most drugs requiring two committee meetings prior to receiving a positive NICE outcome.
- In April 2018, NICE began the roll-out of a new single technology appraisal (STA) process incorporating a technical engagement phase to resolve any issues within submissions prior to committee meetings.
- This study aimed to assess whether the new process has resulted in changes to the proportion of drugs receiving a positive decision, or a change in time to final decision.

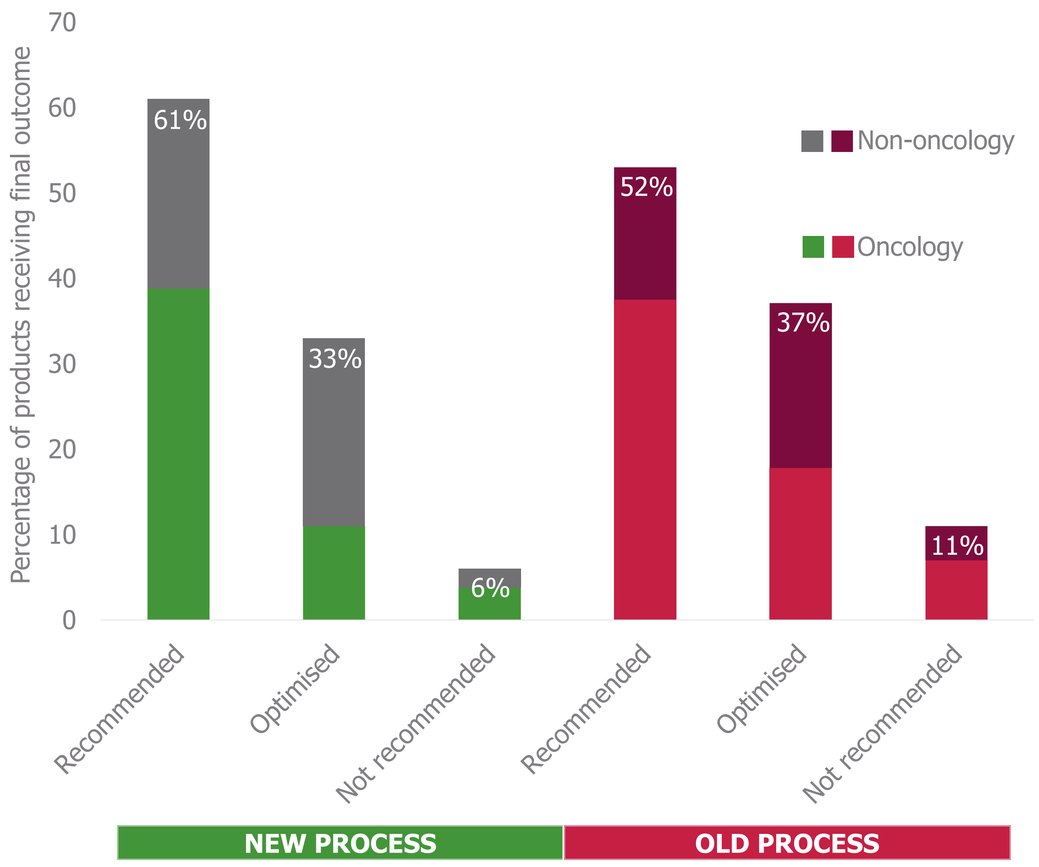
Methods

Analysis period determined: *Jan 2017 – June 2020* → STA reports published within analysis period identified → Outcome data of ACDs (if relevant) and FADs extracted for each appraisal

Results

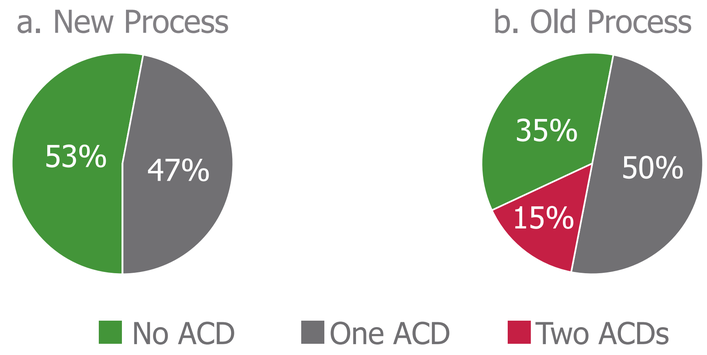
- Of the 148 appraisals identified within the analysis period, 12% (n=18) were assessed by the new STA process, and 88% (n=130) by the old STA process. To further analyse, we split each group into oncology and non-oncology drugs.
- Of the appraisals assessed by the new process, 62% (n=81) were oncology drugs and 38% (n=49) were non-oncology.

Figure 1: A comparison of products receiving a positive decision following assessment by the new or old STA process



- As can be seen in Figure 1, we found that both processes resulted in similar proportions of recommended, optimised and reimbursed outcomes.
- The proportion of processes resulting in a positive (recommended or optimised) decision, was therefore similar with the new process resulting in 94% positive decisions and the old process resulting in 89% positive decisions.

Figure 2: The proportion of products requiring no, one or two ACD meetings before achieving a positive decision from the new or old STA process



- As highlighted in Figure 2, we observed that a greater proportion of drugs undergoing the new assessment process received a positive decision with no ACD meeting (53% vs 35%).
- The remaining drugs assessed by the new process (47%) required just one ACD meeting, whereas 50% of drugs assessed by the old process requires one ACD meeting and 15% required two.
- We also compared the average time to final decision. Time to final decision in the new STA process was on average 34 days quicker from MA to FAD publication, and 39 days quicker from ACD1 to FAD publication.
- A full break down of the decisions made at each meeting can be seen in Table 1.

Table 1: The proportion of products receiving a positive decision at each stage of the new and old STA processes

Stage of Process	New Process % (n)			Old Process % (n)		
	R+O	R	O	R+O	R	O
After first committee meeting (no ACD) *% oncology*	50% (9) *67%*	50% (9) *67%*	0% (0)	32% (41) *46%*	21% (27) *14%*	11% (14) *38%*
After one ACD meeting *% oncology*	44% (8) *38%*	11% (2) *50%*	33% (6) *33%*	45% (58) *69%*	26% (34) *82%*	18% (24) *50%*
After two ACD meetings *% oncology*	n/a	n/a	n/a	13% (17) *77%*	5% (7) *100%*	8% (10) *60%*
Not recommended after two ACD meetings *% oncology*	6% (1) *100%*			9% (12) *67%*		

R: recommended; O: optimised; *% oncology: proportion receiving decision that were oncology products*

Discussion and conclusions

- Introduction of the new process does not appear to have changed the proportion of drugs achieving a recommended, optimized or not recommended NICE outcome, with the trend towards more products receiving a positive outcome not being significant ($p>0.05$). We did not observe any notable changes to the outcomes of STA assessments of oncology products.
- However, the new process has reduced the number of meetings required before achieving a final outcome. This is shown when considering that no product being assessed by the new process has yet needed a second ACD meeting. This aids faster patient access alongside the fall in average time to a final decision.
- Nevertheless, nearly half of appraisals undergoing the new process still require two meetings (including one ACD meeting), suggesting a potential need for further improvement.
- Since our abstract was submitted, additional changes to the NICE STA process have been made, further adapting the technical engagement step by replacing the technical report with a re-framing of the ERG report, presented in an issues-based style. The logic for this was that NICE was not seeing a significant reduction in resource use, which is reflective of our results.
- The aim of the issue style was to improve stakeholder inclusion and provide the NICE technical team with a better opportunity to prepare for the appraisal meeting. The desired outcome is that this will enable more appraisals to only require a single committee meeting, further removing inefficiencies in the STA process and improving patient access.

Abbreviations: ACD: Appraisal Consultation Document; ERG: Evidence Review Group; FAD: Final appraisal determination; MA: Marketing authorization; NICE: National Institute of Health and Care Excellence; STA: Standard Technology Appraisal

ISPOR Virtual European Congress, 16-19 November 2020