Is the new NICE appraisal process for oncology indications too positive in its assessment of cancer drugs in England?

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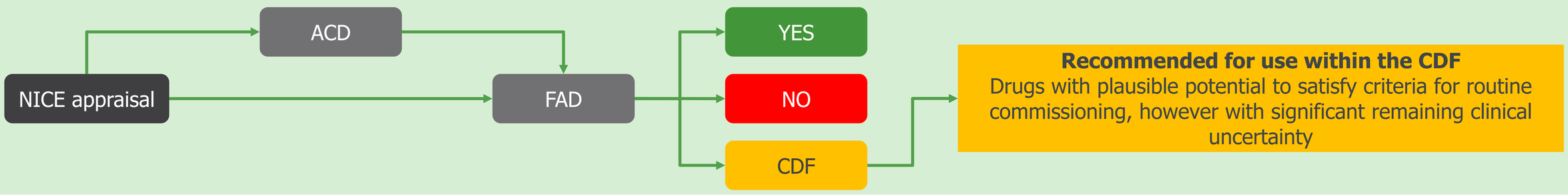
Introduction/objective

- Since 29 July 2016, the appraisal process for oncology indications in England has been modified to allow one of three outcomes; recommended for routine use, not recommended, or recommended within the Cancer Drugs Fund (CDF) managed access scheme.
- Draft and final outcomes of NICE appraisals are published in Appraisal Consultation Documents (ACDs) and Final Appraisal Determinations (FADs), respectively (Figure 1). ACDs are only produced if the preliminary assessment is negative or substantially more restrictive than market authorisation.
- The objective of this study was to understand the trends in NICE appraisal outcomes following the introduction of the new appraisal process.

Methods

- NICE cancer appraisals conducted via the new oncology assessment process between 29 July 2016 and 24 April 2018 were identified from the NHS England CDF list and NICE website.
- The following information was collected for each drug:
  - Draft recommendations published within ACDs
  - Final NICE guidance published within Final Appraisal Determinations (FADs)
  - Details of patient access schemes (PAS), if applicable
  - ACDs and FADs were also analysed in order to understand end-of-life status of the drug and reasons for NICE decision-making.
- Drugs transitioning from the old CDF were excluded from analysis.

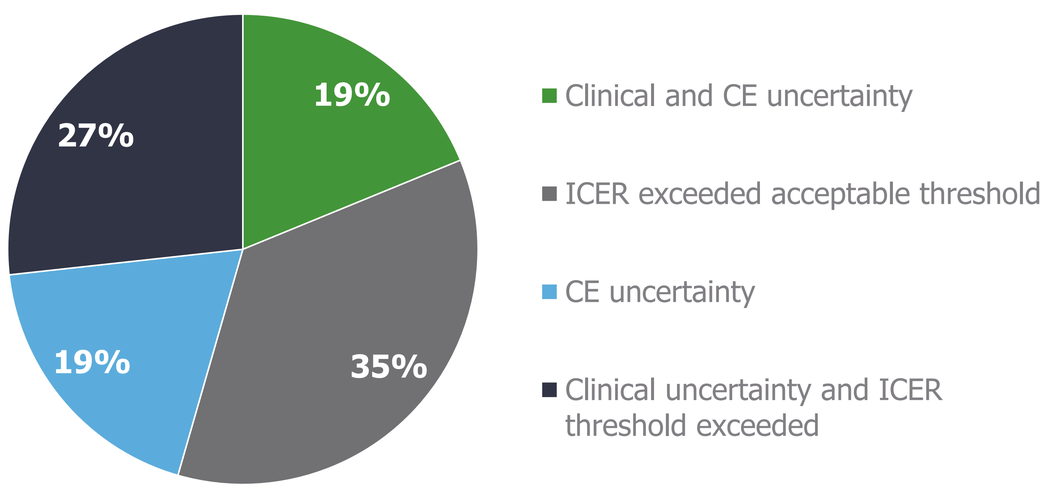
Figure 1: Flow diagram of the modified CDF appraisal process NICE implemented from July 2016



Results

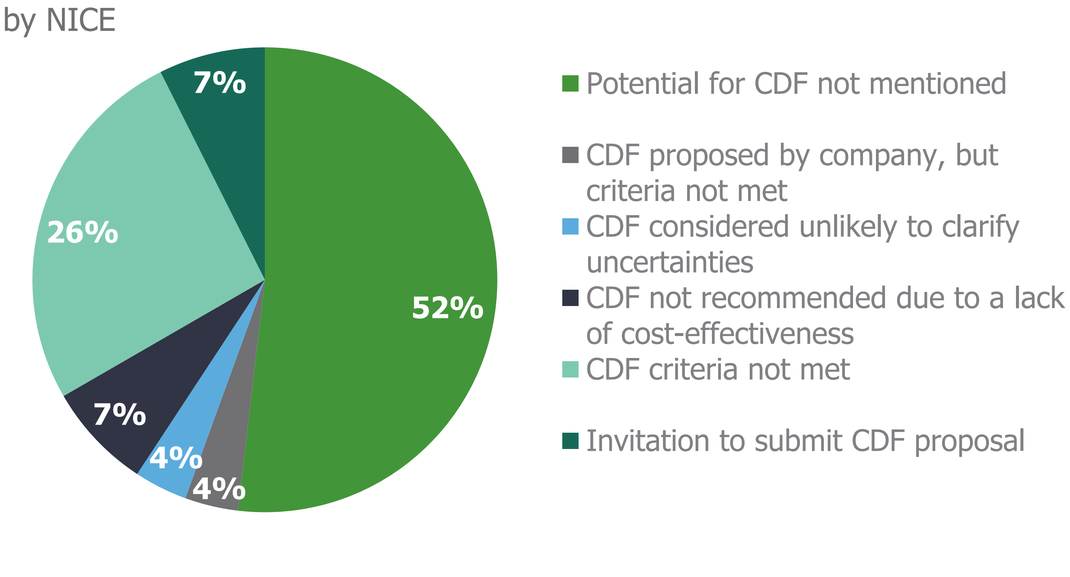
- A total of 39 oncology appraisals met inclusion criteria and underwent the NICE appraisal process described in Figure 1. Of these, 95% of appraised drugs received positive final recommendations for either routine use (59%) or for use within the CDF (36%). ACDs were produced for 74% of all drugs appraised.
- For the 29 ACDs issued, all ACDs (100%) did not recommend the drug for use. The primary reason for this was the ICER exceeding acceptable thresholds (Figure 2).

Figure 2: Reasons for negative ACD recommendations for oncology products assessed by NICE



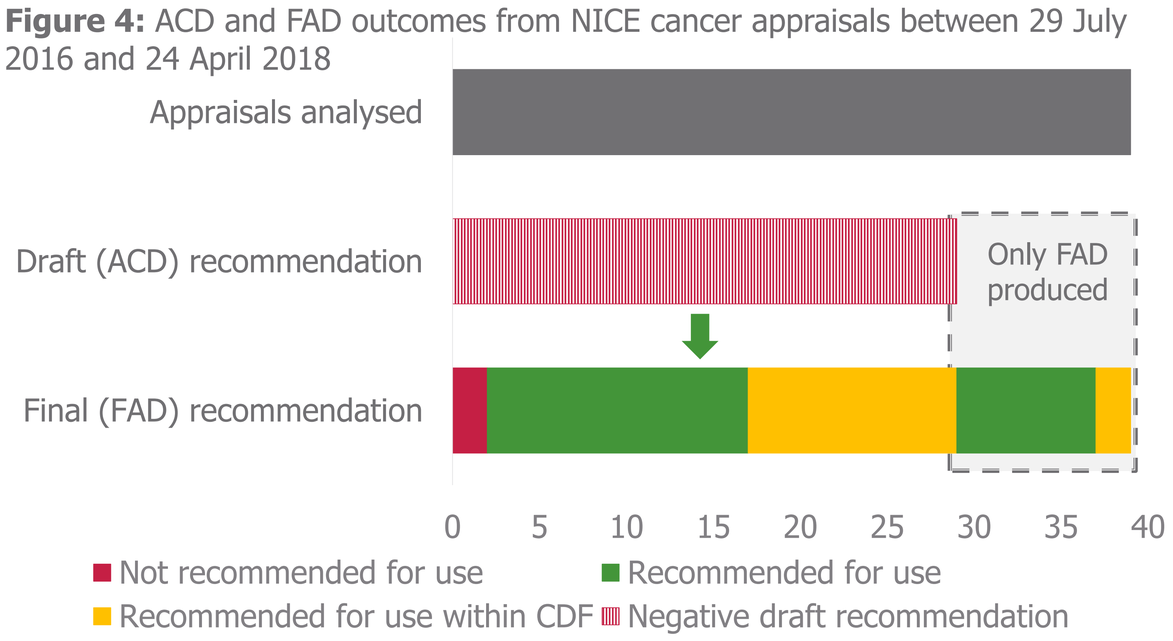
- The majority of ACDs (52%) did not discuss the eligibility of the drug for the CDF (Figure 3). In addition, in only 7% of ACDs did NICE suggest that a manufacturer submit a CDF proposal.

Figure 3: Eligibility consideration for CDF at the ACD stage for oncology products assessed by NICE



- For five appraisals, a second ACD was published prior to FAD publication. All second ACDs were negative. However in three cases, manufacturers were invited to submit CDF proposals for specific sub-populations, in which NICE believed further data collection could be valuable.
- From the 29 ACDs issued, 27 (93%) subsequently received positive FAD recommendations (Figure 4).

Figure 4: ACD and FAD outcomes from NICE cancer appraisals between 29 July 2016 and 24 April 2018



- All drugs recommended for routine use were subject to PAS, involving simple discounts. The majority of drugs recommended for routine use were considered to meet NICE end-of-life criteria (58%). In contrast, only 45% of drugs recommended for use within the CDF were considered to meet end-of-life criteria.
- Of the two drugs not recommended for use by NICE, only one met end-of-life criteria. Both drugs had PAS agreed with the Department of Health, however had ICERs which significantly exceeded thresholds considered acceptable by NICE.

Discussion and conclusion

- Whilst 95% of NICE cancer appraisals eventually received positive recommendations, 74% drugs initially receive one (and in some cases two) negative draft recommendations. The high discrepancy between draft and final recommendations suggests an inefficient use of NICE and manufacturer resources and may delay patient access. This is not restricted to only oncology appraisals: overall, 60% of all NICE draft guidance is negative, whereas 80% of final guidance is positive.[1]
- The majority of negative draft recommendations are due to ICERs exceeding acceptable thresholds and clinical uncertainty. This implies that pharmaceutical companies are submitting to NICE with insufficient clinical trial data or unrealistic price expectations, which is supported by the fact that all FAD positive recommendations utilise either a PAS or use within the CDF.
- The high level of uncertainty in initial submissions and inefficiencies of the STA process have been recognised by NICE.[1] In April 2018, a new appraisal process was announced for all drugs, which will enable manufacturers to respond to NICE uncertainties through technical engagement earlier in the appraisal process.
- In conclusion, NICE appraisals have historically been inefficient with significant discrepancies between draft and final recommendations. This may be addressed by NICE's new STA process and future investigations into whether the new process has increased efficiencies are likely to be interesting.

ACD=Appraisal Consultation Document; CE=Cost-effectiveness; CDF=Cancer Drugs Fund; ICER=Incremental cost-effectiveness ratio; FAD=Final Appraisal Determination; NICE=National Institute For Health and Care Excellence; PAS=Patient Access Scheme; STA=Single Technology Assessment

1. Prescott J. Roadmap for the life sciences: a new approach to NICE technology appraisals. Presented at NICE Annual Conference, 2018

ISPOR 21st Annual European Congress, 10-14 November 2018, Barcelona, Spain