HTA8

Changes in NICE Guidance Following Surveillance Review: When, How and Why?

Odunlami B,[1] Jameson K,[1] Rafia R,[1] Porteous A[2]

[1]Novartis Pharmaceuticals UK Limited, London, UK; [2]Costello Medical, London, UK

Objective

To investigate triggers for NICE surveillance reviews and the characteristics of re-appraisals.

Background

- NICE monitor technology appraisal (TA) guidance via their 'surveillance' process to ensure it remains current and accurate, amending and updating guidance wording to reflect changes in evidence, regulatory status, care pathways, safety recommendations and costs.[1]
- Surveillance information that reveals recommendations may be unsafe, invalid or inaccurate may trigger re-appraisals in the form of partial or full reviews of published TAs. Rapid reviews requested by manufacturers can also lead to revision in TA guidance (**Figure 1**).
- The timing and process for surveillance reviews are more flexible than reviews following managed access (e.g. through the Cancer Drugs Fund [CDF]), where a review is scheduled at the end of the data collection period.

Methods

- The NICE database was searched for TAs with changes in guidance between 1 January 2014 and 24 April 2024 (excluding CDF reviews), as shown in **Figure 2**.
- Analysis sets were pre-defined as follows:
  1. **'Guidance updates':** TAs reporting any change in guidance wording since initial publication.
  2. **'Re-appraisals':** The subset of TAs that included a re-appraisal with accompanying committee papers.
- Supplementary manual searches of all published TAs since 24 April 2022 were conducted to identify re-appraisals not captured by database searches.

Results

Search Results

- Database searches identified 610 TAs; 41 (6.7%) reported guidance changes, of which five were re-appraisals. Supplementary hand searches identified an additional six re-appraisals (**Figure 2**).

Guidance Updates

- TAs with guidance changes spanned a wide range of disease areas and had a mean time between publication and latest update of 5.7 years (range: 0.2–17.1 years) (**Figure 3**).
- Common triggers for guidance changes (not mutually exclusive) are shown in **Figure 4**.
- Mean time to latest guidance update was shorter for TAs citing a change in commercial arrangement (3.9 years) than TAs citing a change in related NICE guidance or guidelines changes (~8–10 years).

Re-appraisals

- Re-appraisals included rapid (n=4), partial (n=5) and full (n=2) reviews and could be requested by NICE or manufacturers. One identified re-appraisal (TA921) was a full review of a prior terminated appraisal and thus was considered a new TA and excluded from all analyses.
  - Evidence informing partial/full reviews varied dramatically, including longer follow-up from existing trials, new clinical trials, real-world evidence and updated indirect treatment comparisons to include additional comparators (**Figure 5**).
  - Rapid reviews had short timelines (median 2.6 months) and typically a single committee meeting (mean 1.0); larger variation in timelines was observed for partial (median 9.0 months) and full reviews (median 12.8 months).
  - Rapid reviews typically included amended economic models and, in some cases, limited clinical evidence (**Figure 5**).
- Re-appraisals led to expansions in the recommended population (n=5), changes from negative to positive recommendations (n=5) or new and revised recommendations (n=1).

Conclusion

Changes in NICE guidance are rare but occur across wide-ranging disease areas and for varied reasons.

Re-appraisals appear to be diverse, varying in both process and format, and their characteristics depend on the re-appraisal type. In cases of initial restricted or optimised recommendations, additional evidence assessed through re-appraisal facilitated wider reimbursement without changes to commercial arrangements.

Surveillance remains an important process to ensure guidance is up-to-date and maximise patient access to innovative health technologies, conditional on new evidence.

FIGURE 1

Re-appraisal formats[1]

Triggered by surveillance	**Partial reviews**	♦ Typically focus on a subgroup of the population specified in the original TA or additional patient populations not previously captured
	Full reviews	♦ Typically consider the full population specified in the original TA
Not triggered by surveillance	**Rapid reviews**	♦ Can be requested by manufacturers within 16 weeks of publication of final guidance ♦ Typically, only a new approved PAS or commercial access agreement will be considered ♦ Can include submission of additional new evidence, but this may trigger a full review proposal

FIGURE 2

NICE database and post-hoc supplementary searches

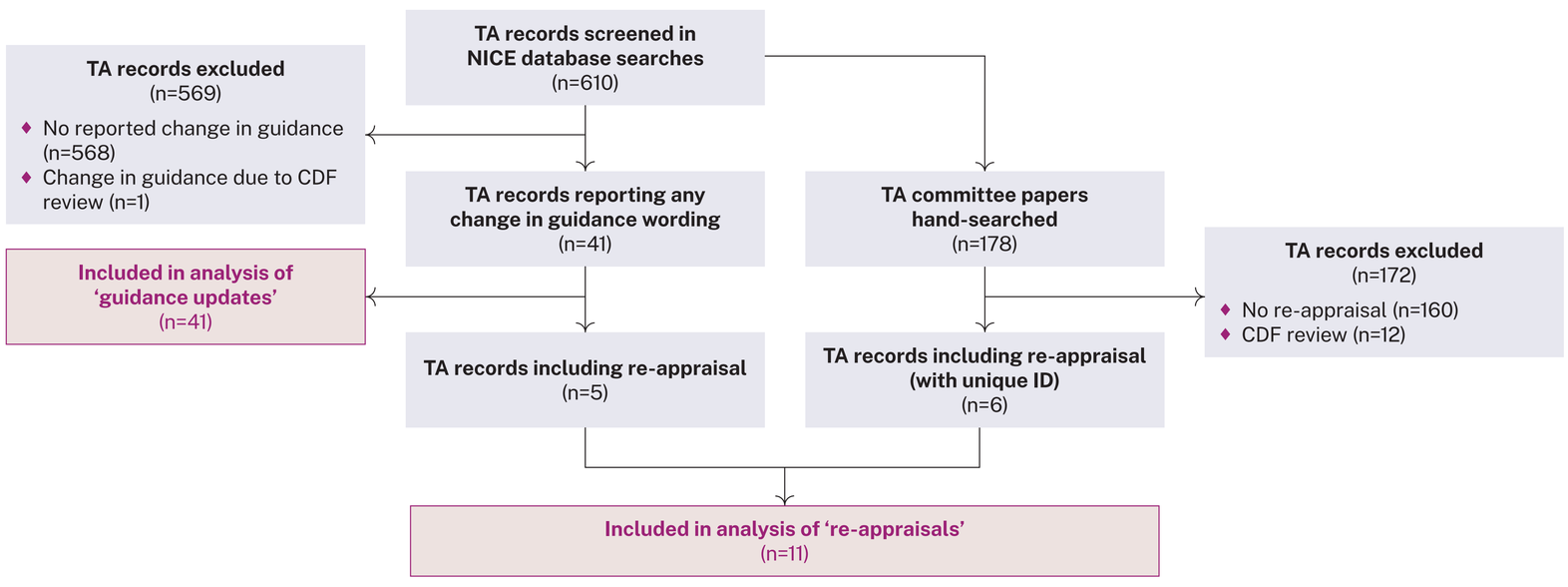


FIGURE 3

Guidance updates: Distribution of disease areas

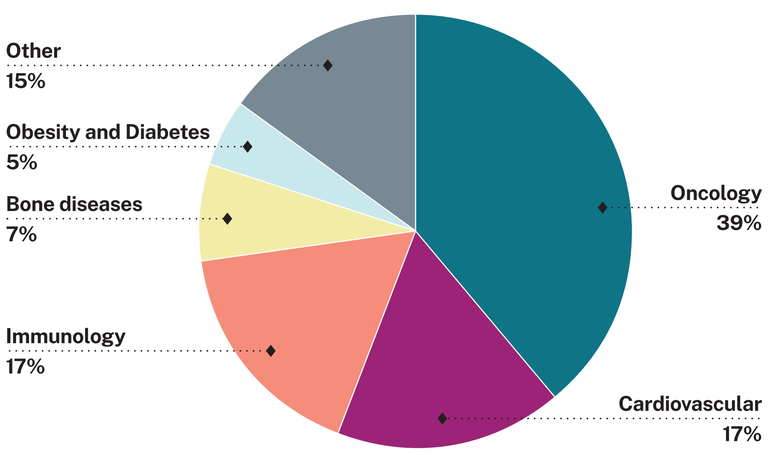


FIGURE 4

Guidance updates: Reasons for changes in guidance

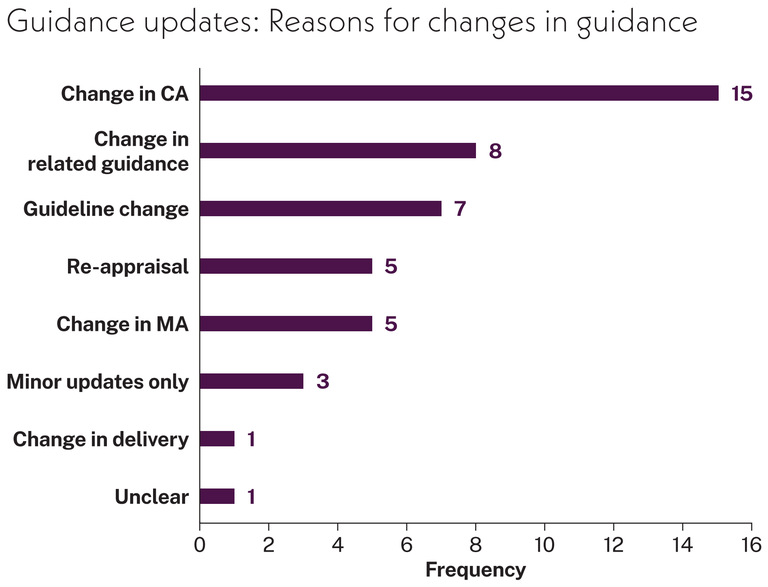
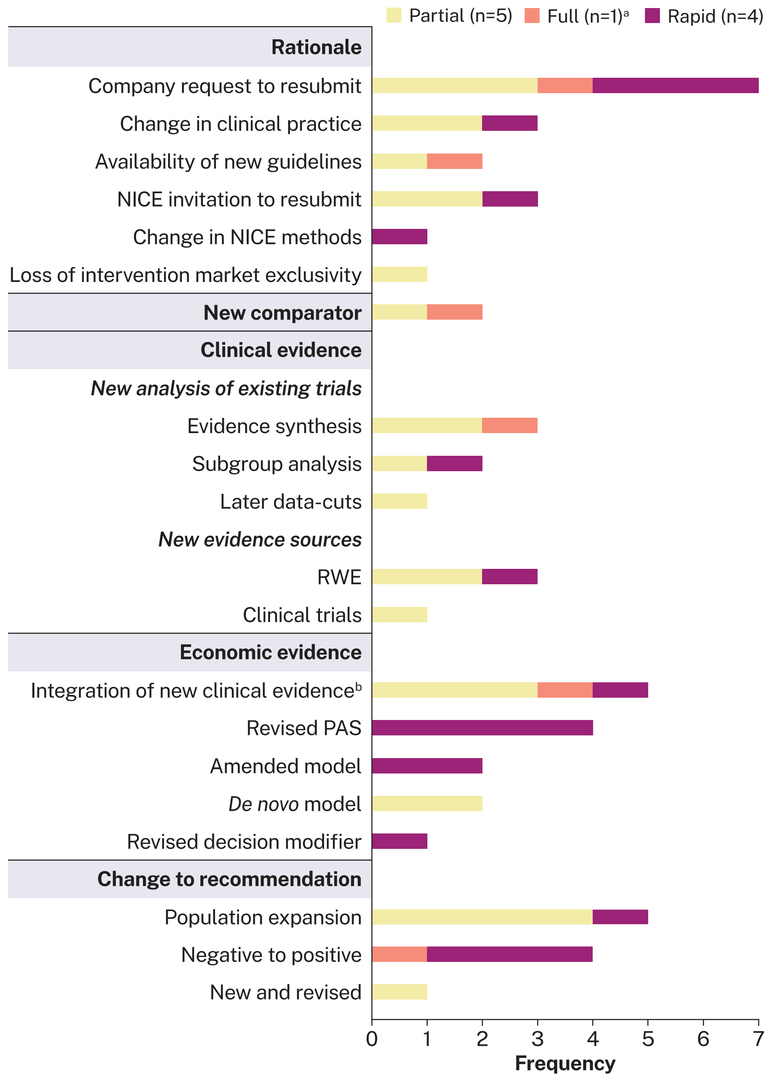


FIGURE 5

Re-appraisal characteristics



[a]One of the re-appraisals identified as a full review (TA921) was a review following a prior terminated appraisal and, thus, is considered a new STA. As such, this re-appraisal has been excluded from all analyses. [b]Integration of new clinical evidence into existing economic model.

Abbreviations: CA: commercial arrangement; **CDF:** Cancer Drugs Fund; **MA:** marketing authorisation; **NICE:** National Institute for Health and Care Excellence; **PAS:** patient access scheme; **RWE:** real-world evidence; **STA:** single technology appraisal; **TA:** technology appraisal.

References: [1]National Institute for Health and Care Excellence (NICE) (2023). NICE health technology evaluations: the manual. Available at: https://www.nice.org.uk/process/pmg36/resources/nice-health-technology-evaluations-the-manual-pdf-72286779244741 [Last accessed 4 October 2024]. **Acknowledgements:** The authors thank Amie Ennew, Costello Medical, for graphic design assistance. We also thank Abigail Lampkin and Joshua Gahan for their contributions in the preparation of this poster. **Disclosures:** BO, KJ and RR are employees of Novartis Pharmaceuticals UK Limited, London, UK. AP is an employee of Costello Medical Limited, a company that received funding from Novartis Pharmaceuticals UK Limited to conduct this study.

Presented at ISPOR Europe 2024 | Barcelona, Spain | 17–20 November