When the Price Is Right: When, in Practice, Are Confidential Discounts Introduced in the NICE Process?

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Objectives

 To investigate the extent to which manufacturers offer a nationally available discount when submitting to NICE technology appraisals, and explore any patterns in the timing of when in the process a nationally available discount is introduced.

Background

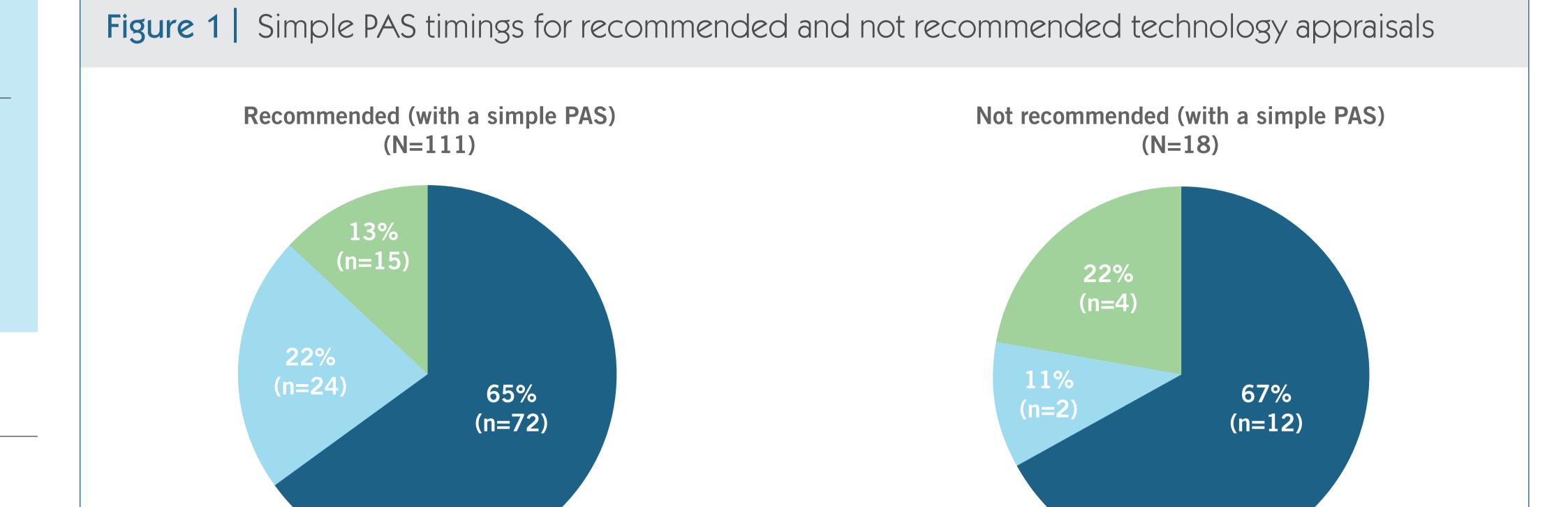
- Manufacturers often submit a patient access scheme (PAS), or other type of nationally available discount, to increase their cost effectiveness during technology appraisals (TAs) undertaken by the National Institute for Health and Care Excellence (NICE).
- There are two types of PAS that can be submitted by manufacturers for NICE TAs. A simple PAS is a commercially confidential simple discount on the list price of a treatment, which may be changed during the appraisal process. Alternatively, the manufacturer may submit a complex PAS, which may vary considerably in construction, but is not a simple discount. A complex PAS is not generally changed once initially submitted. Other types of nationally available discounts are also submitted by manufacturers, including commercial access agreements (CAAs), which may also be changed during the appraisal process.
- This study reviewed all TAs from October 2007 to determine whether a nationally available discount was submitted, and explore the timings of when these discounts were introduced.

Methods

- Using the NICE website, all TAs between October 2007 and August 2017 were reviewed, including those with a "not recommended" decision from NICE.1
- Each TA was allocated to one of four discount categories: initially submitted, initially submitted but changed during process, introduced after submission, no submission of a nationally available discount. This was dependent on the timing of the nationally available discount introduction.
- Where there was no mention of a PAS, simple discount, CAA, managed access arrangement or similar terminology found in NICE TA documents, it was assumed that the manufacturer had not submitted a nationally available discount for appraisal.
- A separate analysis was conducted to examine whether there was a temporal pattern in the introduction of nationally available discounts before and after January 2014, when the current Pharmaceutical Price Regulation Scheme (PPRS) came into effect.²

Results

- Between October 2007 and August 2017, 460 technologies were appraised by NICE, with 368/460 (80%) recommended. Of those recommended, 147/368 (40%) were contingent on a nationally available discount.
- Of the 169 recommended and not recommended TAs in which a nationally available discount was introduced, the form of the discount was a simple PAS in 129/169 (76%) and a complex PAS in 31/169 (18%). Other discounts, such as CAAs, were present in 9/169 (5%) of appraisals.
- The proportion of technologies with positive recommendations was not notably different for those

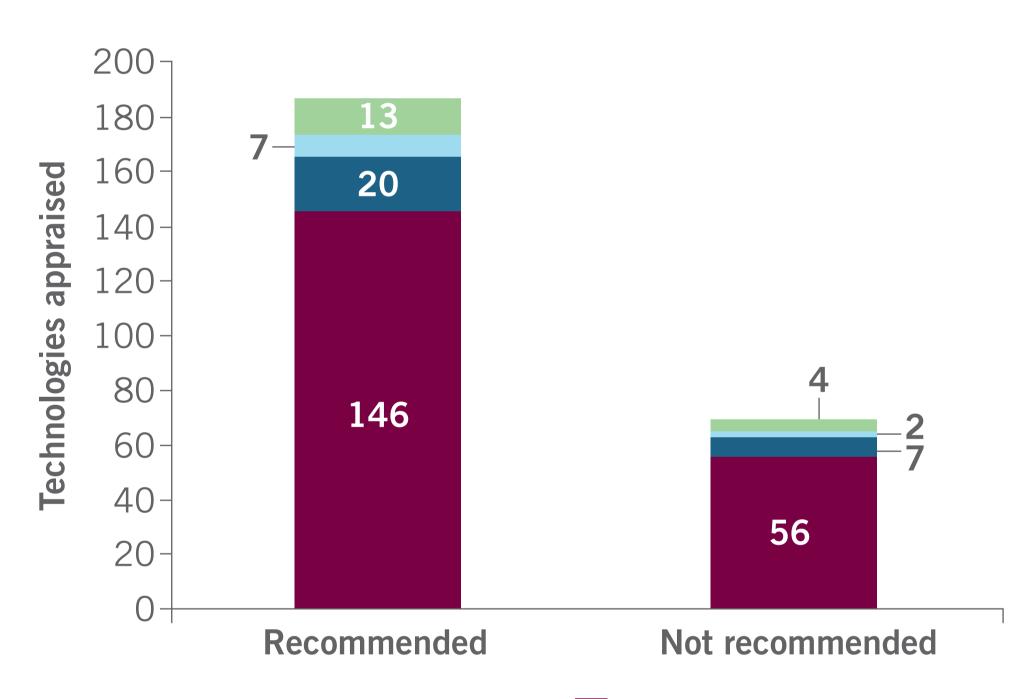


Nationally available discount timings for recommended and not recommended technology appraisals (A) before and (B) after the introduction of the current PPRS

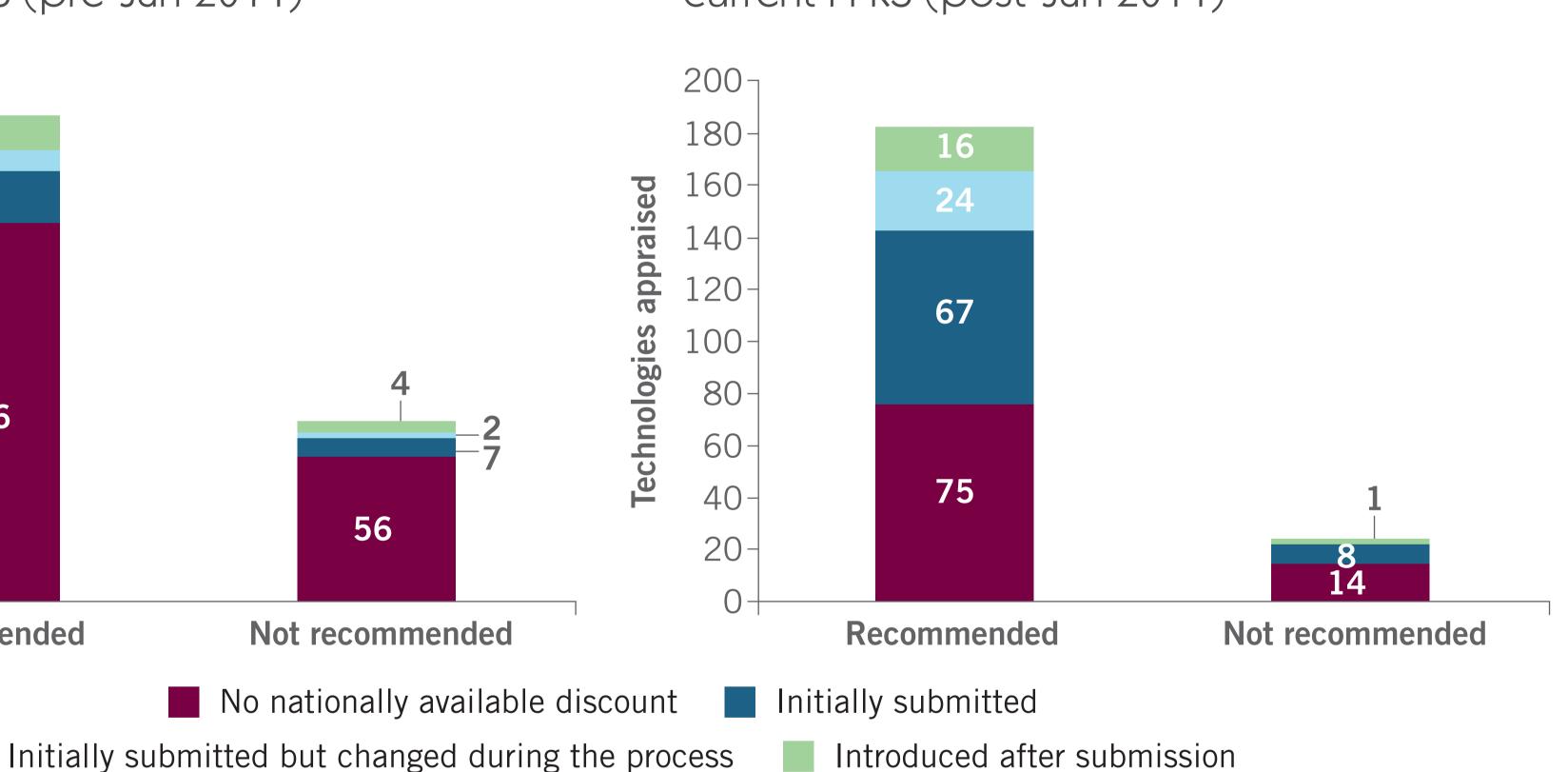
Initially submitted but changed during the process

A) Timings before implementation of the current PPRS (pre-Jan 2014)

Initially submitted



B) Timings after implementation of the current PPRS (post-Jan 2014)



Introduced after submission

offering a simple versus a complex PAS (86% vs 87%, respectively), whilst all technologies which included a CAA in their submission were recommended.

- The timing of the introduction of simple PASs is presented in Figure 1; of the simple PASs submitted, implicit price flexibility (i.e. changes to the offered price) during the appraisal was evident in 35% of technologies with a positive recommendation compared to 33% of technologies with a negative recommendation (Figure 1).
- Before 1 January 2014 (Figure 2A), a nationally available discount was only used in the minority of cases across both recommended (22% of cases) and not recommended (19%) technologies. In the period since 1 January 2014 (Figure 2B), use of a nationally available discount increased overall but to a greater degree in technologies ultimately receiving a positive recommendation from NICE (not recommended: 19% to 39%; recommended: 22% to 59%).
- In particular, there appears to have been a large increase in the proportion of manufacturers who initially submitted a nationally available discount (Figures 2A and 2B).
- In the period since 1 January 2014 (Figure 2B), the proportion of technologies with a positive recommendation where implicit price flexibility during the appraisal was revealed increased (from 20/186) to 40/182.

Conclusions

- Since the introduction of the current PPRS, the majority of technologies have offered a nationally available discount. The most common offer is a simple PAS at the time of submission; however, there is increasing evidence of implicit price flexibility during the appraisal process to achieve a positive recommendation.
- It may be preferable for a manufacturer to submit a simple PAS or other nationally available discount upfront. Once the submission has been appraised, there is more certainty of the likely outcome, and the PAS or discount can be adjusted if necessary.

References

1. National Institute for Health and Care Excellence (2017). Full list of recommendations. Available at: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/ NICE-technology-appraisal-guidance/summary-of-decisions/ta-decision-summary-sep-17. doc [Last accessed 14.09.17]; 2. Association of British Pharmaceutical Industry (2017). Understanding the Pharmaceutical Price Regulation Scheme. Available at: http://www. abpi.org.uk/our-work/commercial/pprs/Pages/default.aspx [Last accessed 25.09.17].

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