Questions from the public: December 2023 Board meeting

# On the methods update, can the Board expand on the guideline recommendations item from the report and the process it will undertake to withdraw individual technology appraisal guidance when a technology is "unlikely to be cost-effective"?

If a technology subject of a positive technology appraisal (TA) recommendation is no longer recommended at any point in the pathway following integration into the guideline then NICE would withdraw the TA recommendation. This would only be after a consultation and the decision would be subject to appeal. There would also be the opportunity for a commercial dialogue. It should also be noted that these are interim methods and processes for 2 pilots, which will be subject to consultation. Following the pilots it is envisaged there will be a further consultation on the substantive methods and process for incorporating and integrating TAs into guidelines.

# Thank you for the introduction to a critical next step in developing NICE methods and processes. Taking a modular approach is clearly the best way forward to adopting new developments. I fully support the focus on integrating HTAs in guidelines, especially in the context of a lifecycle approach to consideration of value, and to ensure patients get access to the best and most appropriate care. I am surprised, though, that the paper makes no mention of the processes required to align NICE's work with the move by the MHRA to recognise licensing activities by other (international) regulators. Surely that is the most pressing concern for the organisation, as this is starting in January. I also note that Helen Lovell did not mention this in her update. Is there more the Executive Team and Board can say about NICE preparedness for this development, in process and methods terms?

NICE is working closely with the MHRA to prepare for the introduction of international recognition, including putting the required foundations in place, such as information sharing and considering what process changes are required to ensure NICE is able to publish timely guidance.

# NICE never formally presented its data on the societal preference that society values severity higher than end of life. Will this ever be published/expanded on in future updates?

The proposal was carefully considered as part of the update of the health technology evaluation manual in 2022. The rationale for the modifier and NICE’s response to the consultation is available on the [NICE website](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation) including the key evidence for the modifier and the case for the change.

# What are the timelines for inputting into the consultation/consideration of the severity modifier?

A timescale for this work is likely to be developed in the middle of 2024.

# I would hope the Executive Team and Board can say something about the use of (generative) artificial intelligence in the development process for HTA and guidelines. This was a key topic at the recent ISPOR conference in Europe, with super helpful contributions from the NICE team. I understand there are concerns about how developers might be using AI to develop submissions and economic models. What assurances has the Board received to feel satisfied that the quality of the NICE outputs remain high?

NICE is currently looking at this issue and the intention is to develop a framework around the use of AI for evidence submission in 2024/25.

# Is the challenge with the severity modifier that too many technology appraisals (TAs) are achieving the 1.7 and the forecast was that more of these would be achieving the 1.2? Or is the problem that not enough TAs are achieving the 1.2 which do not go on to achieve any form of the severity modifier?

Since the modifier was introduced not as many companies are applying for and achieving the 1.2 modifier as was anticipated when it was introduced. The reasons for this will be explored further in the planned review next year.

# Could we have more clarity on interim reviews/potential updates on the severity modifier? It is not clear from the conversation what the action was on this topic

As noted in earlier answers, the next step is to undertake further exploratory work in the first part of 2024 to understand why the 1.2 modifier has not been used as much as anticipated. Following which, the aim is to consider the next steps in the summer of 2024, including whether a review of the manual is required.

# What is on NICE's wishlist for the funding provided by Investment Facility?

In principle, it has been agreed to use the funding provided by the investment facility in the Voluntary Scheme for Branded Medicines, Pricing, Access and Growth (VPAG) for work on NICE’s methods and process for clinically disruptive technologies; a rebuild of UKPharmscan to support horizon scanning; integration and incorporation of technology appraisal recommendations into guidelines; and to support implementation of NICE guidance.