National Institute for Health and Care Excellence

Health Technology Evaluation

Process, Methods and Topic Selection Review

Conclusions and final update

In 2019, NICE embarked on a large-scale programme of work to update the methods and processes, and topic selection approaches for its health technology evaluation programmes.

This report provides the Board with details of the launch of the final topic selection manual and health technology evaluation guidance development manual (including processes and methods). This follows a public consultation on the draft manuals and proposals for change that took place from August to October 2021.

This report addresses 3 distinct aspects of the health technology evaluation programmes: topic selection, processes and methods. The report describes the key responses to the proposals from stakeholders and members of the public, and the rationale and judgements NICE has made to come to final conclusions.

The key conclusions for each aspect reviewed are highlighted below. We ask the Board to consider these specifically when reading through document.

Topic selection

* A clear vision and accompanying routing criteria have been set out for the Highly Specialised Technologies Programme
* More explanation has been provided on how briefings for devices, diagnostics, and digital technologies are developed and used in the topic selection process
* We have clarified which types of guidance may be developed for the different technologies and their different value propositions

Processes

* By considering all our health technology evaluation programmes together, we have aligned our processes to ensure those stakeholders who work with us have a consistent and predictable experience. We have also been clearer on processes that we use in our commercial and managed access functions to help streamline and simplify patient access to new innovative health technologies.
* We present a package which allows flexibility in the application of different steps and stages to provide a faster process while, at the same time, remaining robust and efficient in our approach. We have removed some older processes that were not working efficiently and have established new processes that will better meet the needs of patients and the NHS and respond to the evolving challenges in health technology evaluation.
* We have increased the opportunity for stakeholder involvement at different stages in the work programmes to provide more transparency and increase input, understanding and satisfaction of the people that we work with.

Methods

* We will give additional weight to health benefits in the most severe conditions (a ‘severity modifier’), using the approach proposed in the consultation and using weights of 1.2 and 1.7 as the lower and higher weights (‘option 1’ in the consultation). The additional considerations for life-extending treatments at the end of life (the ‘end of life criteria’) have been removed.
* No changes have been made to how we consider health inequalities in health technology evaluations. This is an important and complicated area to include in our methods, and more work is needed.
* We have clarified how we will handle ‘uncertainty’, particularly in circumstances when evidence from research trials or elsewhere is especially difficult to generate.
* No change to the discount rate has been made. We will collect evidence on the effect of discounting in future health technology evaluations, to help us contribute to further discussions on this issue.
* The draft manual has been updated, to make sure it is clear, robust and appropriate for different types of evaluation. This includes: better information about how we will use real-world evidence; clearer descriptions of how to measure health-related quality of life when our preferred tool (the EQ-5D) is unsuitable, and on the correct prices to use for medicines; other updates that are particularly relevant for medical devices and diagnostics.

The conclusions within the report inform the content of 2 final unified manuals: the topic selection manual and the health technology evaluation guidance development manual. Subject to Board approval of this report, it is anticipated that the final manuals will be published on 31 January 2022.

We have developed a detailed implementation plan to support smooth and efficient uptake of the updated methods and processes. A communication plan has been developed for the launch of the final manuals with a range of multi-channel, multi-stakeholder activities planned for February, including a news story on the website, comprehensive press and enquiry handling plans, social media, and targeted engagement events to key audiences.

Future updates of the methods and processes of health technology evaluation will use a more modular and iterative approach, moving away from a cycle of updating every 4 to 6 years. We have already identified further areas of methods and processes to prioritise in future modular updates, and have included additional information in the report to explain our next steps and describe how we will establish our modular update approach.

Issues for decision

The Board is asked to:

* Note the progress made to date.
* Support the final conclusions for topic selection, processes and methods detailed in the report, focussing on the key issues listed above.
* Approve publication of the final topic selection and health technology evaluation guidance development manuals and support implementation from 01 February 2022.

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