**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

Public Board Meeting
held on 15 May 2024 at City Tower, Manchester and via Zoom

# Unconfirmed

These notes are a summary record of the main points discussed at the meeting and the decisions made. They are not intended to provide a verbatim record of the Board’s discussion. The agenda and the full documents considered are available in accordance with the NICE Publication Scheme.

## Board members present

Sharmila Nebhrajani Chairman

Mark Chakravarty Non-Executive Director

Jackie Fielding Non-Executive Director

Alina Lourie Non-Executive Director

Bee Wee Non-Executive Director

Justin Whatling Non-Executive Director

Sam Roberts Chief Executive

Jonathan Benger Chief Medical Officer and Interim Director of the Centre for Guidelines

Helen Knight Director, Medicines Evaluation

Boryana Stambolova Interim Director, Finance

## Directors in **attendance**

Helen Brown Chief People Officer

Nick Crabb Interim Science, Evidence and Analytics Director

Jane Gizbert Director, Communications

Clare Morgan Director, Impact and Partnerships

Raghu Vydyanath Chief Information Officer

## In attendance

David Coombs Associate Director, Corporate Office (minutes)

Jeanette Kusel Director, NICE Advice

Danielle Mason Associate Director, Strategic Communications and Marketing

Swapna Mistry Chief of Staff, Clinical Directorate (item 8)

Claire Mulrenan National Medical Director's Clinical Fellow, Clinical Directorate (item 8)

Kay Nolan Associate Director, Guidelines Surveillance Team (item 8)

Sinead Peare Pharmacy Clinical Fellow (item 8)

Emily Robinson Public Health StR (item 8)

Laura Flight Scientific Advisor (item 9)

Koonal Shah Associate Director, Science Policy and Research (item 9)

Lizzie Walker Health Technology Assessment Adviser (item 9)

Anastasia Chalkidou Associate Director, Medical Technology Evaluation (item 10)

Helen Lovell Deputy Director, Medicine Regulation and Prescribing, Department of Health and Social Care (items 1 to 6)

## Apologies for absence (item 1)

1. Apologies were received from Michael Borowitz, Gary Ford and Mark Chapman, with the latter represented by Jeanette Kusel.

## Declarations of interest (item 2)

1. No new interests were declared, and the previously declared interests recorded in the register of interests were noted and it was confirmed there were no conflicts of interest relevant to the meeting.

## Minutes of the last meeting (item 3)

1. The minutes of the Board meeting held on 20 March 2024 were agreed as a correct record.

## Action log (item 4)

1. The Board noted the progress with the actions arising from the public Board meeting on 20 March 2024 and those open from preceding meetings as set out in the action log. The actions marked closed on the log were confirmed as complete.

## Update from the Department of Health and Social Care (item 5)

1. Helen Lovell provided an update from the Department of Health and Social Care (DHSC) and highlighted 3 current areas of work at the Department relevant to NICE. Firstly, the announcement of the Government’s new national action plan on antimicrobial resistance to prevent drug resistant infections, which NICE will help deliver through its role in the subscription model for new antimicrobials. Secondly, the publication of the Cass report on gender identity services, which notes the lack of high quality evidence to underpin service delivery. Thirdly, the current consultation on updates to the NHS Constitution, in which a limited set of specific changes are proposed to improve the current content, reflect important changes to government policy, and to keep both the NHS Constitution and the handbook legally up to date. No changes are proposed to the right to technologies recommended through NICE’s technology appraisal and highly specialised technologies programme, but the consultation provides an opportunity to feed into an important document that defines and enshrines the values of the NHS.

## Business plan 2024/25 (item 6)

1. Sam Roberts presented the 2024/25 business plan for the Board’s approval and highlighted how the plan builds on the achievements in 2023/24, which included publishing over 180 pieces of guidance, while developing and implementing improvements to NICE’s methods such as increased use of real-world evidence; improving the usability and timeliness of NICE’s guidance; improving the relevance of guidance through the new prioritisation framework; and developing the way NICE measures the impact of its guidance. The 2024/25 business plan continues the work to ensure NICE provides high quality, timely advice that is relevant, useable and impactful through 7 aims:
* Improving the timeliness of NICE guidance through simplified, aligned guidance production.
* Improving the assessment of value through expanding the HTA Lab, updating methods for health inequalities and reviewing NICE’s approach to severity.
* Ensuring NICE guidance focuses on what matters most through integrated horizon scanning, topic selection, and prioritisation.
* Improving access to and experience of people using NICE’s guidance by simplifying the product portfolio, improving the presentation of guidance, and making guidance easier to find.
* Increasing the uptake of NICE’s guidance by working with partners and delivering support based on insight, and expanding the ways in which people and communities can contribute.
* Improving user experience and impact by including medicine and HealthTech recommendations in guidelines.
* Embedding NICE’s values in daily work.
1. Helen Lovell highlighted the importance of recognising the business plan may need to adapt in light of potential changes in the strategic context, particularly in the year of a general election. In addition, NICE will also need to be mindful of the requirement in Managing Public Money to seek HM Treasury approval for any changes arising from the modular updates of NICE’s methods and processes that could be seen as novel and contentious, such as new modifiers.
2. Board members reflected on the achievements in 2023/24 and congratulated the executive team and staff for progress in delivering the 2023/24 business plan. In particular, the average time to medicines access following regulatory approval for ‘optimal’ technology appraisals (36 days) was highlighted as an exceptional achievement, which gives confidence on how the process can deliver timely guidance and also NICE’s ability to work closely with the MHRA.
3. Board members discussed the proposed priorities for 2024/25 and noted the importance of working in partnership with other organisations to increase the uptake of NICE guidance. It was suggested that it would be helpful for the Board to understand the proportion of positive technology appraisal (TA) guidance that contains ‘optimised’ recommendations as it reviews performance in 2024/25, and also to understand how NICE compares internationally in terms of the use of real-world evidence in guidance development. It was noted that the proposed business plan activity on the integration of technology appraisals into guidelines will need to be reviewed once NICE has confirmed how it intends to take forward this work after the recent public consultation.
4. Subject the above potential amendment regarding integration of technology appraisals into guidelines, the Board approved the business plan and delegated approval of any final amendments following review by the Board and the Department of Health and Social Care to the Chief Executive.

Action: Sam Roberts

## Integrated performance report (item 7)

1. Sam Roberts introduced the integrated performance report that presented the year-end outturn against the objectives and targets in the 2023/24 business plan. Sam paid tribute to the executive team and staff for delivering such positive performance in the context of the widespread management of change exercises that took place over the year.
2. Helen Knight explained that 93 pieces of technology appraisal (TA) and highly specialised technologies (HST) guidance were published against a business plan target of 110; this was primarily due to topics that were due to publish in the final quarter of 2023/24 slipping into 2024/25. Helen highlighted that there was a 57% increase in number of ‘optimal’ TA topics and these topics published 50% quicker on average compared to 2022/23. However, the timeliness targets for ‘divergent’ and all topics were not met. There is extensive work underway to understand the process and what the target time should be when a topic is ‘divergent’ given it will not be possible to publish the guidance within 90 days of GB marketing authorisation. Board members noted that the two main causes of topics becoming ‘divergent’ were late notification of the topic and companies negotiating delayed evidence submissions. It was suggested that it would be helpful for the Board to have an insight into the impact of the delays caused by late notification of a topic, and to understand the extent NICE meets the revised timeline following agreement to delayed evidence submission. Board members noted the average timelines for the HST guidance were significantly longer than for TA and therefore suggested separating reporting of TA and HST timeliness.

Action: Helen Knight

1. Jeanette Kusel updated the Board on the health technology indicators that did not achieve the year-end target. In terms of the proportion of NICE Advice services provided for diagnostics, devices and digital technologies, it was noted that the team have held a number of discussions with the health technology sector, and it is hoped these will lead to a higher proportion of early engagement services being provided to these companies. If they do not, NICE Advice will review whether their services meet these companies’ needs. No early value assessments (EVAs) were completed within the target 6 month timeframe, with the average 8 months in 2023/24. Work is therefore underway to explore how to reduce the timeline to be closer to the target timeframe of 6 months. In relation to the standard health technology evaluations, Sam Roberts explained that a new process has been developed to deliver a 17% reduction in line with the business plan target. However, no topics have yet completed the new timeline, which meant the chart for this indicator in the report did not include out-turn data.
2. Helen Brown highlighted that sickness, turnover and appraisal targets were not met, and the management of change exercises were a likely factor. While the targets to increase the proportion of ethnic minority staff were also not met, Helen confirmed this was, and remains, a huge focus and she was confident the proportion will continue to increase. Sam Roberts noted the scope to improve the target setting and reporting for the people indicators, including sickness and turnover, and welcomed any feedback from the Non-Executive Directors on good practice they have seen in other organisations.
3. Raghu Vydyanath updated the Board on progress with the objective to provide useful and usable advice and stated that NICE has not procured content management technology as originally envisaged at the start of the year. Following feedback from the market engagement on how NICE could digitise its guidance process, the focus is to build a sematic database that will sit behind a content management system. Raghu also noted that improvements to the NICE website will shortly go live, which should further increase traffic, and the team are looking at better ways of tracking usage.
4. Boryana Stambolova noted that the provisional year-end financial position is a £300k underspend, which is positive given the overspend forecast earlier in the year. Capital funds were £0.2m underspent due to timing of receipt of additional budget related to cyber security which meant NICE was only able to partially utilise it within the year-end deadline.
5. Board members asked about the impact of NICE exceeding its notional Annually Managed Expenditure (AME) limit due to the year-end movement in provisions. Boryana Stambolova explained this is due to the current estimation of the dilapidations arising from the Manchester office move being higher than originally estimated. The level of NICE’s liability for dilapidations remains under negotiation with the landlord; DHSC are aware of this issue and that it arises from the move to a smaller office that will offer better use for public funds.
6. Board members discussed the level of confidence in the pipeline of TA and NICE Advice income given this had been lower than plan in 2023/24. In response, Boryana Stambolova highlighted the improved tracking of future income through lead indicators and assured the Board that the level of deferred income for the TA programme is much higher than last year. In response to questions from the Board about the potential trends in income, Sam Roberts explained that the analysis of TA activity indicates the shortfall in 2023/24 income was due to a reduced number of TA topics starting between December 2022 and July 2023. There is now a strong pipeline of topics already in the TA process and a number of topics are in the regulatory pipeline which will then be subject to a future NICE evaluation. Boryana also highlighted the financial planning for 2024/25 which includes contingency for reduced income, a strategic investment reserve, and improved forecasting, which will all help effectively manage the financial position. Board members welcomed these strengthened arrangements for forecasting TA and NICE Advice income. The benefit of NICE considering other opportunities for increasing income was highlighted and the Board agreed to hold a session on NICE’s commercial strategy once this has been further developed.

Action: Boryana Stambolova

## Review of the proposed approach to NICE-wide topic prioritisation and the strategic principles (item 8)

1. Jonathan Benger presented the paper that summarised the themes in the feedback from the public consultation on the proposed approach to NICE-wide topic prioritisation and the strategic principles for public health, social care and rare diseases. The proposals are central to ensuring NICE focuses on what matters for the health and care system and provide clarity on the principles NICE will adopt when prioritising topics relevant to public health, social care and rare disease topics.
2. Jonathan Benger noted that overall, the feedback was positive with no major areas of contention. Jonathan highlighted the feedback on the composition of the prioritisation board and stated that the board will build on the positive patient involvement in the topic selection oversight panel that it replaces. To maintain NICE’s independence the prioritisation board will not include NHS England or the DHSC, however NICE will share information with both organisations, plus the Welsh Government, for comment ahead of each meeting.
3. Jonathan Benger highlighted that some of the respondents felt the proposed new clarification process may not be appropriate for Highly Specialised Technologies (HST) routing as there is no opportunity to appeal, and also that the timeframe for organisations to seek clarification is insufficient given the complexity of the subject matter. Jonathan explained that in response to the feedback, the period for seeking clarification after the publication of the prioritisation decision will be extended to 20 working days. Having considered the feedback about the suitability of the clarification process for HST, the proposed approach is felt to be proportionate and has not changed, however it was noted there have been concerns about the application of the HST criteria in the past and NICE is committing to review and consult on the criteria later this year.
4. The Board:
	* Approved the consultation themes and responses arising from the public consultation on the proposed approach to NICE-wide topic prioritisation, and the strategic principles for public health, social care and rare diseases.
	* Delegated to Guidance Executive approval of any subsequent changes to the associated topic prioritisation manual and strategic principles.
	* Requested an update on the experience of the first formal prioritisation board meetings.

Action: Jonathan Benger

## Development of a framework for a modular approach to updating NICE manuals (item 9)

1. Nick Crabb and Lizzie Walker presented the proposed framework for how NICE will identify and prioritise modular updates to the guidance development methods and process manuals and then undertake these updates in a streamlined manner. It was noted that the framework applies across NICE and supports efforts to harmonise methods and processes across the Centre for Guidelines and Centre for Health Technology Evaluation.
2. The Board discussed the role and membership of the Modular updates Selection and Oversight Panel (MSOP) and the Board’s role in the modular updates process. In response, it was noted that the MSOP will include representatives from across NICE with sufficient seniority to ensure decisions reflect organisational priorities, alongside technical expertise. Sam Roberts explained that the Guidance Executive (GE) will review proposed modular updates prior to consultation, with the highest profile changes also presented to the Board for review. Sharmila Nebhrajani highlighted the importance of ensuring alignment between the Board, GE and the MSOP on the priorities for modular updates and also the risk appetite.
3. Mark Chakravarty, lead NED for the TA and HST appeals, highlighted the need for clarity on the implementation date of any modular updates so all parties are clear on the methods and process used for a particular evaluation, especially if the guidance is subject of appeal.
4. The Board approved the framework.

## Review of the themed responses to the Late Stage Assessment Interim Methods and Process Statement (item 10)

1. Jeanette Kusel presented the paper on the outcomes of the public consultation on the Late-Stage Assessment Interim Methods and Process statement and noted that the high level of responses received in the consultation demonstrated how valuable the new arrangements will be for the system. Jeanette noted that the new arrangements sit alongside the early value assessments to ensure NICE has an evaluation process for the whole life cycle of health technologies.
2. Anastasia Chalkidou summarised the themes in the consultation feedback and stated that clarifications have been provided in response to the feedback on the interrelation between late-stage assessment and the DHSC Medtech Strategy; the relationship with and deviation from the process and methods set out in the NICE health technologies evaluations: the manual; user preference and use of Multi-criteria Decision Analysis (MCDA); and the variability of technology categories selected for evaluation. Anastasia noted that the methods and process statement has been amended in relation to the use of benchmarked pricing and its impact on NICE’s reference case in response to the feedback.
3. The Board:
	* Supported the proposed approach to Late-stage assessment.
	* Approved the consultation themes and responses arising from the public consultation on the Late-stage Assessment Interim Methods and Process statement.
	* Delegated to Guidance Executive approval of any subsequent changes to the manual and principles.

## Audit and risk committee annual report and terms of reference (item 11)

1. Alina Lourie presented the annual report from the audit and risk committee and highlighted the committee’s work across the 2023/24 year. Alina explained the background to the 2 internal audits that received a limited assurance opinion – on training and the control framework – and the management action to address the findings. Alina also noted the committee’s work on risk management over the year and highlighted the planned focus on the risk appetite and tolerance in 2024/25. The committee also propose minor amendments to its terms of reference including a change in name to the audit and risk assurance committee to reflect its matured role in risk management and examination of the assurance that risks are being effectively managed.
2. The Board received the annual report and approved the updated terms of reference and amended committee name.
3. Sharmila Nebhrajani noted the committee were planning a training session on the use of artificial intelligence in evidence submissions to NICE and suggested this would be of interest and relevance to the full Board.

Action: David Coombs

## Any other business (item 12)

1. There was no further business to discuss.
2. The Board then passed the following resolution to move to a part 2 meeting to discuss confidential matters:

*"That representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest".*

## Next meeting

1. The next meeting of the Board will be held on 19 June 2024 (private meeting to approve the annual report and accounts).