NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Minutes of the Board Strategy Meeting

Wednesday 19 August 2020 via Zoom

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.

## Present

**Non-Executive Directors** Sharmila Nebhrajani

 Elaine Inglesby-Burke

 Dr Rima Makarem

 Tom Wright

**Executive Directors** Professor Gillian Leng

 Meindert Boysen

 Paul Chrisp

 Alexia Tonnel

**Directors in attendance** Jane Gizbert

 Judith Richardson

**In attendance** Dr Amanda Adler

 Dr Peter Jackson

 Dr Mark Kroese

 Professor Alan Maryon-Davis

 Dr Hugh McIntyre

 Norma O’Flynn

 Nick Crabb

 David Coombs (minutes)

 Grace Marguerie

Tracey Barr (for item 6)

Martin Davison (for item 6)

Hilary Baker (for item 7)

Eric Power (for item 8)

Carole Longson (for item 9)

Ian Watson (for item 9)

Dr Colm Leonard (for items 9 and 10)

Rosie Lovett (for item 11)

Alice Murray (for item 11)

Victoria Thomas (for item 11)

Jennifer Howells (for items 1 to 8)

## Apologies (Board and Senior Management Team) (item 1)

1. Apologies were received from Tim Irish and Catherine Wilkinson, with the latter represented by Grace Marguerie.
2. Sharmila Nebhrajani introduced Jennifer Howells to the meeting who will join NICE on 1 September as Director for Finance, Strategy and Transformation.
3. Sharmila noted that Martin Cowie had resigned as a Non-Executive Director to take up a part-time role as Chief Physician Scientist (Heart Failure) at Astra Zeneca, and placed on record NICE’s appreciation for his contribution over a number of years.

## Declarations of interest (item 2)

1. It was confirmed there were no conflicts of interest relevant to the meeting.

## Minutes of June 2020 Board strategy meeting (item 3)

1. The minutes of the Board strategy meeting held on 17 June 2020 were agreed as a correct record.

## Action log (item 4)

1. The Board noted the update on the actions from the meeting held on 17 June and confirmed that those marked ‘completed’ could be closed.
2. Gill Leng updated the Board on the resources available for NICE to respond to the request from NHS England and NHS Improvement (NHSE&I) to integrate and update NICE and NHSE&I’s COVID-19 guidance. As recommended by the Department of Health and Social Care (DHSC), NICE has requested additional funding from NHSE&I and a response is awaited. In the interim, DHSC have verbally indicated they will provide additional funding if required in 2020/21, and a request for further funding for future years has been included in NICE’s initial submission to the Government’s Comprehensive Spending Review (CSR).

## Chairman’s opening remarks (item 5)

1. Sharmila Nebhrajani provided an oral update on recent meetings and other activities of note. These included three speaking engagements; meetings with senior representatives from NHS England, PHE, UCB, Pfizer, GSK, Optum, BIA, as well as meetings with a range of other senior stakeholders. Sharmila summarised the key themes from these meetings and noted that while NICE is held in high esteem and recognised to have an important role in the system, the feedback noted the need for the organisation to reinvent itself for the challenges that lie ahead. The discussions with the life sciences sector highlighted the considerable weight being placed on the methods review, challenges around the adoption of NICE guidance following a positive recommendation, and NICE’s readiness for the future including around the digitisation of healthcare, artificial intelligence and big data. There is an opportunity for NICE to take a leadership position within the already complex health system on key issues including affordability and innovation. Other issues to emerge in the discussions included the need for NICE to have rapidly created and updated ‘living’ guidance, including incorporation of feedback from users. The role of experts and the need for transparency around their selection and input was also highlighted.
2. The Board discussed the feedback and the issues raised, and suggested that these themes should be fed into the strategy formulation process. They also noted that many of these require collaboration with NICE’s partners to address. The Board reflected on the use of experts in the guidance development process both as committee members and witnesses to the committees, and the challenge of ensuring effective committee membership turnover and finding a broad range of expert voices to inform NICE’s work. It was noted that the increasingly early evaluation of technologies can increase the uncertainty in the evidence, which in turn heightens the role of the expert witness at the committee. The Board noted the need to consider the arrangements for ensuring that the committee chairs are comfortable with the witnesses put forward by the sponsoring company and can challenge any perceived conflicts of interest. The Board also discussed the importance of supporting individual committee members, especially those working on contentious topics, in order to encourage people who may not be supported by a stakeholder organisation to put themselves forward.

## Chief Executive’s update (item 6)

1. Gill Leng briefed the Board on a range of recent developments and topical issues. Gill updated the Board on the latest position with the current and potential judicial reviews relating to NICE’s work; the plans for the phased return to the Manchester office; the changes to the new London office; the virtual events that are planned for the autumn following the postponement of the annual conference; and the equality and diversity listening events with staff and the committees that will inform the new equality objectives the Board will consider in November. Due to the ongoing disruption to staff working arrangements, Gill noted that the Senior Management Team (SMT) have agreed not to undertake an annual staff survey in 2020, but instead continue with the regular ‘pulse’ surveys. In response to a request from the Board, Gill agreed that future updates to the Board on the judicial reviews would clarify whether NICE was either a defendant or interested party.

ACTION: Gill Leng

1. Gill updated the Board on the financial position in 2020/21 and the CSR. The forecast year-end position has improved and the aim is to now break-even or better. Gill outlined NICE’s initial submission to the CSR on bids, cost pressures, and potential savings proposals, and noted that a more detailed submission will be required in September. The initial feedback on the funding bids from the Senior Departmental Sponsor at DHSC was positive, apart from the bid for NICE International to support overseas data and analytics capabilities, which it was not felt sufficiently aligned with the CSR priorities. Following further internal discussion, it was therefore agreed not to pursue this proposal as part of the CSR. There may also be an additional request for funding in the CSR to support the implementation of the Independent Medicines and Medical Devices Safety Review. The Board discussed the submission and asked about the extent the bids will support NICE’s work with social care. In response, it was noted that the work on NICE Connect, which was the largest bid for resources, will include looking at how NICE’s guidance could be published in a way that would be most helpful for the social care sector. The Board welcomed this clarification and agreed that it should be made clear as the bid for funding evolves, given social care is a Government priority.

ACTION: Gill Leng

1. Gill updated the Board on the work to develop NICE’s new strategy and introduced Tracey Barr to the meeting who has temporarily joined NICE to support this work. Tracey outlined the approach, process, and timetable for developing the strategy. The aim is to have a draft strategy following the October Board strategy away-day which could then be refined following discussions with staff and external stakeholders. The Board discussed the proposed process and highlighted the importance of ensuring input from a broad range of perspectives, including on how NICE will need to adapt to meet future challenges. It was noted that the work should also consider the implications of the Government’s recent announcement about the future of Public Health England, and also the challenge of integrating health and care services. Sharmila Nebhrajani noted the level of uncertainty about the future and highlighted the importance of a strategy, organisational culture, and risk appetite that enables NICE to respond flexibly. Sharmila asked Tracey to incorporate the Board’s feedback into the next steps and asked about the arrangements for involving the Board prior to the October meeting. In response, Tracey stated that the aim is to share the updated SWOT and PESTLE analyses with the Board in September and stated that she would also arrange individual meetings with Board members to provide opportunity to comment on the emerging proposals and the feedback from the stakeholder interviews.

ACTION: Tracey Barr

## NICE Connect (item 7)

1. Gill Leng presented the progress update on the NICE Connect transformation programme and highlighted the impact of COVID-19 and NICE’s response to it, on this work. Gill noted the complexity of the transformation programme and stated that as part of the strategy work, the scope for a partnership with a third party with expertise in creating digital output will be explored. Gill welcomed Hilary Baker to the meeting who has stepped up to be Acting Transformation Programme Director.
2. The Board confirmed the importance of the transformation and asked about the options for resourcing this if the CSR bid is unsuccessful. Gill stated that if insufficient additional funds are provided, there will be a need to prioritise the Connect activities and also consider whether resources can be released from other programmes in the context of the outcome of the new strategy. Board members discussed the importance of engaging staff in the transformation and welcomed the positive work to date and the further planned engagement activities.

## Planning for the end of the EU transition period and future trade (item 8)

1. Eric Power presented the report that outlined the plans for managing the impact of the end of the EU exit transition period on NICE. Eric noted that while the future relationship with the EU could have a range of impacts across the organisation, the main implications are around medicines and medical devices licensing. NICE is engaged with the MHRA and DHSC on both this issue and EU exit planning more generally, and the internal EU exit oversight group has reconvened. Meindert Boysen referred to the risk register provided to the Board and stated that he would review and update risk 6, which related to the impact of new licensing arrangements on the timescales for producing technology appraisal (TA) guidance.

ACTION: Meindert Boysen

1. Board members asked about NICE’s support for staff and there was a suggestion NICE considers providing legal support for EU staff who are affected by immigration changes. Gill Leng and Grace Marguerie highlighted the support provided to staff to date. They advised that this has not included individual legal support, but agreed to explore the extent this is feasible or permissible under NICE’s spending controls.

ACTION: Grace Marguerie

1. The Board discussed the future licensing arrangements and welcomed NICE’s involvement in the MHRA and Office for Life Sciences future of regulation project. It was noted that while the EU exit risk register is focused on the impact on NICE, it is important to consider the risks for the health system more widely and NICE’s role in mitigating these. It was agreed these system-wide risks should be discussed further at a future Board meeting.

ACTION: Gill Leng and Meindert Boysen

1. In addition, it was agreed that it would be helpful to update the information on NICE’s website about EU exit and the implications of any new licensing arrangements for NICE’s work.

ACTION: Jane Gizbert

## Centre for Health Technology Evaluation (CHTE) methods review (item 9)

1. Meindert Boysen introduced the item and welcomed Carole Longson to the meeting who has rejoined NICE as Life Sciences Adviser. Meindert reminded the Board of the proposals around discounting and modifiers that were previously discussed with the Board, and outlined proposed changes to the timetable for the methods review following discussions with internal and external colleagues. The revised timeline preserves as closely as possible the timescale for the first consultation, but allows additional time for key policy discussions and increases the time available to prepare for the second consultation. It also provides the opportunity to take account of the development of the innovative medicines fund and the ongoing work with the MHRA on future licensing arrangements.
2. Ian Watson then briefed the Board on two further aspects of the methods review: uncertainty and costs. Ian explained that uncertainty is a long-standing challenge, which is increasing due to earlier licensing and the changing nature of technologies under review in particular those that target rare and advanced treatments. The proposal is to allow committees to be less risk averse with evidence uncertainty in certain circumstances, for example orphan conditions, technologies with curative intent or those considered breakthrough/innovative.
3. Ian explained that although calculating costs in economic analyses is primarily a technical challenge, it can raise a number of policy-related issues. There are 3 key areas of challenge: whether to take account of future unrelated healthcare costs; the approach to apportioning costs; and how to evaluate technologies that are not cost effective at zero cost – for example a new drug that extends life is given in combination with supportive care. Ian outlined the proposals for the methods review and the rationale.
4. The Board discussed the proposals and raised a number of questions and comments, including about the impact of the proposed changes on the TA process, the decisions taken by the TA committees, and the NHS budget. It was noted that capturing the total benefit of a new curative technology could increase the likelihood of it being considered cost effective. In response to questions from the Board, Meindert confirmed that NICE is in discussions with NHSE and the competition authorities to explore how information on revenue and pricing could be shared to facilitate evaluation of combination drugs and address the issue of technologies that are not cost effective at zero cost. He confirmed that the proposed changes put forward for modifiers apply to the Technology Appraisal, Medical Technologies Evaluation and the Diagnostics Assessment programmes, but not the Highly Specialised Technologies (HST) programme and should not be seen as undermining the role of the HST programme that has a specific purpose. Meindert confirmed that the cost effectiveness threshold in the TA programme will remain unchanged in line with the commitments in the 2019 voluntary scheme. Therefore any changes to the qualitative measures would need to be within the existing threshold.
5. The Board supported the amended timeline and the proposals set on uncertainty and costs. An update on these, together with the proposals on discounting and modifiers, will come back to the Board in September, followed by presentation to the Board in October for agreement for consultation with stakeholders on the case for change. It was agreed that it would be helpful to model the impact of the proposed changes on the TA committees’ decisions and consider the impact on the TA process, including for example whether this would increase efficiency.

ACTION: Meindert Boysen

## Antimicrobial resistance: developing and testing innovative models for the evaluation and purchase of antimicrobials (item 10)

1. Nick Crabb presented the update on progress with the collaborative project with NHSE&I to develop and test a new model for the evaluation and purchase of antimicrobials. He reminded the Board of the project’s aims and confirmed that the work overall remains on track. Nick highlighted that the resource requirements for NICE’s input will increase considerably in the build up to, and during, the NICE-led HTA stage scheduled for 2021. Resourcing options are currently being explored: these include a bid to the CSR, seeking additional funds from NHSE&I, and considering the scope to reallocate resources from other NICE work.
2. The Board broadly supported the work to date but noted the need to resolve the resourcing for the next phase of work. Board members discussed the challenges of assessing the value of a product that may not be used, and the need for international collaboration including to encourage the life sciences sector to invest in this area.

## NICE Listens: policy development through an interactive conversation with the public (item 11)

1. Gill Leng presented the proposals for a new and flexible process for deliberative public engagement on moral, ethical, and social value issues. The process would be used infrequently to ensure that NICE's policies on complex and controversial issues reflect the values of informed members of the public and would replace the Citizens Council.

1. Board members discussed the proposals and there was broad support for deliberative public engagement. However, Board members queried whether the proposals were sufficiently innovative, flexible, and utilised the opportunities from modern technology. The requirement for a permanent band 8a post to support this work was also queried, given the current resource challenges facing NICE.
2. In response, Rosie Lovett explained the rationale for the new post that was due to the level of work that is required to review proposed topics and consider whether they are appropriate for deliberative public engagement, and then take forward the outcome of the engagement. She also highlighted the flexibility in the process which would take account of the nature of the topic.
3. Gill Leng asked the Board to consider whether health and social care workers should be excluded from participation in the engagement exercises, as they were with the Citizens Council. Given the proposed flexibility in the process, it was agreed that the eligibility for participation and whether it would be helpful to include health and care workers should be considered on a case by case basis in light of the topic.
4. The Board agreed this was an important initiative but asked Gill Leng to consider further whether it could be undertaken in a more cost-effective manner, utilising the most innovative approach that avoided the pitfalls of traditional engagement and gave flexibility over partnership working. It was agreed that in the interim, the decision to stand down the Citizens Council should be communicated sensitively to both the most recent members and wider public and stakeholders. This should highlight the importance NICE places on engagement with the public and patients, clearly stating this was not a retreat from public engagement and set out the many other engagement methods NICE had and was planning to use.

ACTION: Gill Leng/Rosie Lovett

## Any other business (item 12)

1. None.

## Date of the next meeting

1. The next Board strategy meeting will be Board strategy away day on Wednesday 21 October 2020, via Zoom.