National Institute for Health and Care Excellence

Report from the Executive Team

This is the second Executive Team report to the Board, replacing the previous separate Chief Executive and Directors’ reports. It covers key priorities and areas of progress since the last Board meeting, structured by the pillars of our new strategy and the business plan, as well as any key emerging risks. It sits alongside the new integrated performance report, which provides data on the status of our key performance indicators and business plan deliverables.

The Board is asked to review the report.

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September 2021

Introduction from the Chief Executive

1. Since the last Board meeting, we have continued to make excellent progress against our seven key priorities for this year, to: support recovery from COVID-19; undertake rapid and responsive technology evaluations; provide living guidelines; enhance NICE's international position; increase our capacity to assess digital technologies; build new channels of engagement; transform our organisation; and create financial sustainability.
2. The majority of this Executive Report focusses on business plan deliverables aligned against pillars of the strategy where we are approaching a delivery milestone or where there are other significant achievements to report. There are three additional areas to highlight upfront: prominent guidance; COVID-19 recovery; and medical revalidation.

Prominent guidance

Inclisiran

1. On 1 September 2021 we published draft final guidance recommending the novel anti-cholesterol drug Inclisiran for people with primary hypercholesterolaemia or mixed dyslipidaemia who have already had a cardiovascular event. The draft guidance attracted significant and positive early media coverage.
2. Inclisiran represents a potential game-changer in preventing thousands of people from dying prematurely from heart attacks and strokes. NICE has therefore been pleased to recommend it as a cost-effective option on the NHS. This recommendation will be supported by a commercial arrangement between NHS England and Improvement (NHSE&I) and the company that could see as many as 300,000 people receive the drug over the next three years.
3. We expect to publish the final guidance on 6 October 2021.

Myalgic encephalomyelitis (or encephalopathy)/ chronic fatigue syndrome/ (ME/CFS)

1. In September 2017, NICE agreed to review and re-consult on the guideline for ME/CFS, following a public consultation with patient and professional groups. A draft updated guideline was published in November 2020, with a plan to publish the final updated guideline on 18 August 2021.
2. Following significant concerns raised about the draft updated guideline by key professional groups, NICE paused the publication of the guideline on 27 August 2021.
3. To further explore concerns raised and determine how we can progress the guideline to ensure effective implementation, we have announced our plan to hold a roundtable event on 17 September 2021. The meeting will have an independent chair and include representatives from patient organisations and charities, relevant professional societies, NHSE&I, NICE and the guideline committee.

Supporting recovery from COVID-19

1. NICE’s work continues to support recovery from the COVID-19 pandemic through updating and developing guidance recommendations. Key recent activity has included: updated guideline recommendations on heparins for venous thromboembolism (VTE) prophylaxis in people with COVID-19, Tocilizumab, Sarilumab and Doxycycline; new recommendations on non-invasive respiratory support; and the publication of a new COVID-19 rapid guideline on vaccine-induced immune thrombocytopenia and thrombosis (VITT).
2. We have also recently developed a COVID-19 ‘generic’ disease model for technologies in the pre-hospitalisation setting, to provide insights to the Therapeutics Taskforce and RAPID-C19 and to potentially be utilised in formal NICE appraisals.

Medical revalidation

1. The final point to highlight is that the Annual Revalidation Report has been submitted to the Department of Health and Social Care (DHSC), covering the appraisal cycle 1 April 2020 – 31 March 2021. NICE is required to provide annual assurance to DHSC that the policies, systems, and processes needed to support the appraisal and revalidation of doctors at NICE are in place and that statutory requirements have been met. In prior years the Board has reviewed the Revalidation Report, but this is no longer a requirement of the process. The report is available to Board members on request.

Key updates aligned to the strategic pillars

Pillar 1 - rapid, robust, and responsive technology evaluation

Publish updated methods and processes for the selection and evaluation of technologies

1. The aim of the new methods and processes is to ensure we can assess new drugs, devices, diagnostics and digital technologies more quickly, where appropriate, and provide fairer access in the NHS. Modified processes aim to improve the way we work with patients, the NHS and the life sciences industry.
2. The public consultation on the proposed changes to topic selection, methods and processes of health technology evaluation launched on 19 August 2021 and will close on 13 October 2021.
3. To be successful, the consultation needs engagement and feedback from our stakeholders. To support this, the communications team has delivered a multi-channel digital campaign to promote the launch of the public consultation. Analysis of initial media coverage, over 5,000 website news story views and [animation](https://www.youtube.com/watch?v=4Tphd-_WHfk) / [pdf ‘explainer’](https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/nice-guidance/chte-methods-and-processes-consultation/ambitions-for-the-future-of-health-technology-evaluation.pdf) downloads, plus subscribers to our methods review podcast, indicated a high level of external engagement. Four additional awareness-raising webinars have been planned during the consultation window, each with over 220 registrations as of 1 September 2021.

Increase our capacity and capability to assess digital technologies

1. A key priority this year is to enhance our capacity and capability to identify and evaluate digital health technologies, particularly those that offer the greatest potential to significantly improve or transform health and wellbeing, improve patient flow through the system, or present a high degree of clinical, organisational, or financial risk to the health and care system.
2. Building on the initial commitment to establish an Office for Digital Health in Q1, several additional workstreams are underway to further develop our capabilities in the evaluation of digital technologies. These include: testing a new model of contingent approval in addition to our existing pipeline of digital health technologies being evaluated; work with NHSX to establish a reimbursement model; work with Medicines and Healthcare Products Regulatory Agency (MHRA) and others to simplify regulatory processes and support industry; and methodological development work on how to assess effectiveness of AI technologies.

Digital evaluation pipeline and contingent approval pilot

1. There are currently eight pieces of guidance in development on digital technologies across NICE’s medical technology programmes; two are health applications and two involve the use of artificial intelligence. Of note, the Diagnostics Assessment Programme is developing guidance on digital hybrid closed loop systems for managing diabetes. Discussions with NHS England have led to access to funded real world data collection that will be used in the NICE evaluation as part of a contingent approval approach. This will be the first pilot of contingent approval. This diagnostics guidance will also be incorporated into the suite of NICE guidelines on diabetes.
2. NICE has already published eight Medtech Innovation Briefings (MIBs) on digital technologies. We expect to complete a further five MIBs on digital technologies by year end.

Reimbursement model

1. We are continuing to work closely with NHSx and NHSE&I to develop the pathway to adoption for digital health technologies and to inform the NICE evaluation approach to tailor NICE outputs to meet the needs of the system. This includes considering the size of the pipeline and resource requirements, as well as the existing infrastructure for adoption and reimbursement of digital health technologies in the NHS. We are working with industry and NHSx to test our hypotheses. In addition, work is ongoing to inform the scope of the modular update in digital technologies, and in developing our strategic approach to topic selection to ensure we match innovative digital solutions with system and patient need.

Multi Agency Advice Service (MAAS)

1. The Multi-Agency Advisory Service (MAAS) for artificial intelligence (AI) and data-driven technologies (AI&DDT) was commissioned by the NHS AI Lab and is a collaboration NICE is leading with other regulatory bodies, specifically the MHRA, Care Quality Commission, and Health Research Authority (HRA). Its aims are to assess the current state of AI regulatory and health technology assessment to develop more effective ways of working among partners, to provide guidance that meet the needs of key users, and to assess the need for an advice service for artificial intelligence (AI) and similar data-driven technologies in health and care.
2. Work on the MAAS has progressed at pace. Extensive engagement on the legislation and guidance for AI products in the health and care system has been completed with key system stakeholders. The digital agency supporting this work, BJSS, has conducted user research with developers and adopters, defined the user archetypes, and started to map out the content of the information platform based on information provided. Meetings have been held with Welsh and Scottish HTA bodies to discuss their potential involvement in the MAAS. A working group has been supporting the independent evaluation partner, RAND Europe, to identify potential sources of baseline data to support the future estimation of the impact of the MAAS. Finally, the advert for the senior scientific adviser in AI, a new role in the MAAS secretariat, is live.

AI methods

1. NICE has established an academic collaboration with Imperial College London, Birmingham University and the Alan Turing Institute to develop evidence of effectiveness standards for AI technologies, which we intend to publish in 2022.

Communications on digital technologies

1. To promote our work in this area we have published regular posts across Twitter and LinkedIn and contributed to an NHSX-authored blog focussed on the MAAS. New externally facing digital health web pages are in development and internally we have promoted the work to all staff through our intranet.

Explore managed access approaches for medical technologies

1. NICE is exploring opportunities to develop existing processes and procedures to enable more systematic and intelligent identification of innovations (devices, diagnostics and digital technologies) for evaluation.
2. We have identified an opportunity to pilot an interim access/contingent approval approach (with data collection) within the multiple technology appraisal (MTA) of hybrid closed loop systems for managing blood glucose levels in type 1 diabetes where NHSE&I has committed funding to data collection that would further inform the MTA.
3. We have also been working with the Association of British HealthTech Industries to develop proposals for a scheme to enhance the adoption of promising HealthTech. These proposals were presented at the Health Technology Partnership meeting in July 2021 and were positively received.
4. NICE will continue to work closely with partners from the Accelerated Access Collaborative, Office for Life Sciences and NHSx to progress the scheme and to develop some concrete options for resourcing interim funded MedTech and conditional reimbursement.

Enhancing NICE’s international position

1. A key strategic ambition for NICE is to grow our influence internationally and in turn learn from our international partners. For the past decade, the European Network for Health Technology Assessment (HTA) (EUnetHTA) has been a major focus for our international work. Following the UK’s departure from the European Union, we have continued to maintain strong links with longstanding European collaborators, including by participating in the design of the EUnetHTA network. However, we have also been exploring new opportunities and priorities for broader international collaboration.
2. A programme of work is underway to strengthen collaboration with national and international health technology assessment partners and regulators that will support NICE and the UK to discover, develop and deploy innovative health technologies. Key developments include a draft collaboration agreement between NICE and Canadian and Australian HTA counterparts.
3. The NICE International team has also been developing proposals to further enhance NICE’s international work, which will be considered by the Board in due course.

Develop processes and procedures for NICE’s role in the Innovative Medicines Fund

1. NICE is closely involved in the Government’s commitment to create a new Innovative Medicines Fund (IMF) to support patient access to promising new licensed medicines.
2. The development of the IMF is being overseen by a joint NICE and NHSE&I advisory group that reviews proposed policy principles and the content of the IMF document as it is developed.
3. The changes that NICE plans to make to our HTA methods and processes will also enable us to support the ambitions of the IMF. The new unified health technology evaluation manual will improve the transparency of our processes concerning managed access and opportunities for companies and other stakeholders to contribute to the development of data collection agreements.

Pillar 2 - dynamic, living guideline recommendations

A consolidated portfolio of integrated guideline topics

1. To enable NICE to focus our efforts to produce dynamic, living guideline recommendations, we are prioritising the guideline portfolio in line with system priorities.
2. An initial classification of NICE guidelines into topic suites has been completed and this work was presented to the Cross Agency Topic Advisory Group in July 2021. We are awaiting feedback on individual guideline classifications from the Cross Agency Topic Prioritisation Panel to finalise the portfolio groupings.

Review our approach to addressing health inequalities

1. Following the update provided to the Board in June 2021, work to review our approach to addressing health inequalities is progressing at pace.
2. The narrative on how NICE currently considers health inequalities and supports the system has been presented to key national partners resulting in positive feedback and a keenness to collaborate.
3. A number of exciting projects are already underway with external collaborators, including a prototype equity impact calculator developed with the University of York. It provides a framework for considering health inequalities both qualitatively and quantitatively from scoping to implementation. The next step is to pilot this with a live case study to identify barriers and resources required for adoption. Other projects looking at weight management and sexually transmitted infections are exploring the potential to use Real World Data to inform consideration of health inequalities in guidance development and implementation. In addition, two NICE Fellows are undertaking projects on health inequalities focusing on learning disabilities and cancer (aligning with priorities identified by NHSE&I).
4. We have also considered how other HTA organisations address health inequalities as part of the recent methods review. Fourteen countries’ programmes were looked at. Eight were found to consider equity in some manner in their HTA decision making, although only the Agency for Health Technology Assessment and Tariff System (AOTMiT) (Poland), Swedish Agency for health technology assessment and assessment of social services (SBU) (Sweden) and Institute for Clinical and Economic Review (USA) provide detail as to how health inequality concerns are considered in decision making. The AOTMiT and SBU focus on ensuring that all patients have equal access to a medicine, while the Institute for Clinical and Economic Review appears to place more importance on addressing wider population inequities. Further detail is available to Board members on request.
5. Other ongoing work includes strengthening our Equality Impact Assessment process across guidance programmes and continuing the field team’s engagement with local systems to understand where NICE can best add value and support action on health inequalities at local level.

Develop new mechanisms to gather feedback and system intelligence from our partners and stakeholders.

1. NICE collects a range of data, insight and intelligence from users of our guidance, partners and stakeholders in various parts of the organisation. But there is more we can do to leverage this intelligence in a consistent manner to inform our guidance development and there are opportunities to establish further mechanisms to gather feedback.
2. We have been strengthening our objectives in this area through new collaboration agreements with strategic partners that set out how we will work together on areas of mutual interest. For example, a new collaboration agreement has recently been signed with the Royal College of Obstetricians and Gynaecologists that highlights priorities for collaboration that include supporting shared decision making for women and addressing health inequalities.
3. We have also launched a new series of roundtable events with external stakeholders and partners to gather ongoing input to our work. The first events this autumn will explore how NICE can support recovery from COVID, innovation and priorities for Integrated Care Systems. A range of stakeholder organisations are participating. NICE is also hosting a separate roundtable in September specifically to develop a joint statement with system partners of how NICE’s work can add value across the health and care system.

Pillar 3 - effective guidance uptake to maximise our impact

Identify data collection sources to routinely monitor the uptake of NICE guidance in an automated way, in conjunction with partners

1. We are exploring whether aspects of NICE’s impact reports can be developed to enable us to track the uptake of NICE guidance recommendations using automated data sources. Initially Long COVID is being considered for automation. This topic provides a good opportunity to demonstrate the feasibility of the proposal due to the availability of new data sources through system partners such as OpenSafely and the cardiovascular disease (CVD)-COVID consortium.
2. The scoping phase of the Long COVID impact report is due to be completed by mid-September 2021. We are in the process of submitting data requests for OpenSafely and will meet with CVD-COVID consortium in early September to discuss data requirements.
3. A paper will be presented to the Board in March 2022 on the lessons learned from this work.

Update the implementation strategy to improve adoption of our recommendations and to refer to the new role of integrated care systems

1. The NICE [Implementation Strategy](https://www.nice.org.uk/Media/Default/About/what-we-do/Into-practice/Help-Implement-NICE-guidance/Implementation-Strategy.pdf) was published in 2017. It sets out a number of objectives to support the effective use of NICE guidance and standards. It is now being refreshed to reflect NICE’s five-year strategic objectives and to focus implementation activities to optimise our impact.
2. An Implementation Strategy Oversight Group has been established to oversee the strategy refresh and we have engaged the North of England Commissioning Support Unit (NECS) to support this work. NECS has conducted a range of interviews with key internal and external stakeholders, and undertaken analysis of comparator external organisations involved in implementing guidance to inform an options appraisal.

Pillar 4 - leadership in data, research, and science

Establish “NICE Listens” as a new mechanism for deliberative public engagement, replacing the Citizens Council

1. NICE Listens is a mechanism for engaging the public to debate complex moral and ethical issues from a societal perspective – a form of ‘deliberative engagement’. It replaces the Citizens Council as a new key pillar of our public engagement work, complimenting activities undertaken through the guidance programmes, Public Involvement Programme and Audience Insights Team.
2. We are planning four workshops during October and November for the engagement, leading to a report in January. An independent research agency, Basis Research, has been appointed to co-run the deliberative public engagement on the first topic – health inequalities.
3. The Board will hear more about NICE Listens at the September Board meeting.

Complete the NICE evaluation stage of the collaborative project with NHS England to develop and test innovative models for the evaluation and purchase of antimicrobials

1. NICE is part of a major collaborative project with NHSE&I and DHSC to develop and test innovative models for the evaluation and purchase of antimicrobials.
2. The project recognises the very weak pipeline of new antimicrobials in development and the major public health need to incentivise increased investment. It aims to demonstrate the feasibility of paying for antimicrobials based on a NICE evaluation of their value to the NHS, as opposed to the volumes used. By recognising the full value of antimicrobials and paying based on that value and not the volumes used, there is also no incentive for over-use, so the model also supports optimal stewardship. Due to antimicrobial resistance, the attributes of value of antimicrobials are broader than for other medicines – including areas such as spectrum, transmission, enablement, diversity and insurance value. Capturing the full value is complex and goes beyond NICE’s current HTA value framework.
3. A procurement exercise resulted in the selection of Cefiderocol and Ceftazidime with avibactam as the products for NICE evaluation. Submissions by the company and consultee submissions have recently been completed. It is expected that the NICE evaluation will be completed in December 2021 and final contracts and payments will be in place by April 2022. NICE’s guidance will inform final discussions between NHSE&I and the companies to agree the payment levels for NHS access to the products, as well as ongoing arrangements for the evaluation and purchase of antimicrobials.

Progress of strategic enablers

Digital workplace programme

1. In May 2021, the Board approved a business case to invest in building an efficient digital workplace at NICE.
2. The procurement of an implementation partner for our digital workplace programme has completed and we have signed contracts with Civica. Work is now ongoing to create a programme roadmap and skeleton programme plan and we will be publishing communications to staff and ‘launching’ the programme in September 2021.
3. Work that was underway to prepare for the programme has also been completed and this has provided good foundations to inform our approach to accessible service design, infrastructure configuration and information/records management that will feed into the full programme once commenced.
4. As with other IT/digital roles, recruitment of internal resources to drive the digital workplace programme is proving challenging. Despite recruitment campaigns, we are yet to appoint a business change manager and a project manager to the team. We will work with our implementation partner to plug critical gaps on an interim basis. Going forward, a joint team approach and collaborative ways of working will underpin delivery of the programme.

Sustainable organisation and transformational change

Implement recommendations of organisational design review

1. To deliver our strategic objectives and operate with agility, pace and excellence, NICE requires an organisational structure with sufficient capacity. At present, there are senior capacity gaps in relation to: the people agenda and organisational transformation; new work on evaluation of medical technologies, digital and devices; ongoing strategic engagement and adoption; and the delivery of new externally facing digital NICE products.
2. In July 2021 the Board agreed to a small number of new senior posts to address these capacity gaps, which are now in recruitment. An interim Chief People Officer was sought as a priority and the successful candidate, Nicole Gee, has taken up the role. She will provide a detailed plan on the key changes required over the next six months.

Future skills and ways of working

1. NICE has appointed Deloitte to independently review research, cutting edge thinking, and best practices from other organisations on the ‘future world of work’. The consultants will test emerging ideas about more flexible, technologically advanced ways of working and the skills we may require in the future with staff across NICE. Deloitte will translate their findings into recommendations to support our future recruitment and organisational transformation.

Key risks

1. As reported to the Audit and Risk Committee in September, the risks of most concern to the Executive Team at the present time are:
   1. Capacity, including senior leadership capacity to deliver the strategy. This risk has emerged as a result of NICE’s growing portfolio of work. In mitigation, a small number of new senior posts are being recruited, as referenced above. In the meantime, we have prioritised business plan objectives and focussed on providing additional support for staff health and wellbeing.
   2. Recruitment to fill vacancies caused by internal movement, and hard to reach specialist roles. In mitigation, we have developed an action plan to address these hard to fill roles through creative recruitment approaches. We are also investing in additional workforce planning and recruitment expertise.
   3. The requirement for ongoing financial resourcing to support the transformation programme and Life Sciences vision beyond the current financial year. These pressures are reflected in our recent CSR bids.

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