**National Institute for Health and Care Excellence**

**Board meeting**

**22 July 2022**

**Title**

Report from the executive team

**Purpose of paper**

For discussion

**Board action required**

The Board is asked to review the report.

**Brief summary**

This is the Executive Team (ET) report to the Board. It updates the Board on the key priorities and areas of progress since the last Board meeting. It sits alongside the integrated performance report, which provides data on the status of our key performance indicators and business plan deliverables.

**Board sponsor**

Sam Roberts, Chief Executive

Paul Chrisp, Director, Centre for Guidelines

Jane Gizbert, Director, Communications

Jennifer Howells, Director, Finance, Strategy and Transformation

Felix Greaves, Director, Science, Evidence and Analytics

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Alexia Tonnel, Director, Digital, Information and Technology

Nicole Gee, Interim Chief People Officer

Helen Knight, Acting Interim Director, Medicines

Mark Chapman, Interim Director, Medtech

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Introduction from the Chief Executive

1. Since my last report, we have continued to make good strides in the delivery of our 4 organisational priorities for 22/23, as shown in the Integrated Performance Report, which accompanies this document. Our governance structures are now in place and the first round of our monthly steering board meetings for each priority have recently occurred. Each priority has a non-executive sponsor who attends every other steering board, which will enable greater integration between the non-executives and the rest of the organisation.
2. At Board level, our focus has been on:
   1. Substantively recruiting to our 3 interim Executive Team positions: Chief Medical Officer, Chief People Officer and Director of Partnerships and Implementation (formerly Dir. Health & Social Care). Shortlisting has already begun, and I am confident we have a strong pool of candidates. Final interviews will take place at the end of July, with a view to appointing as soon as possible after then.
   2. Refining Board and Exec-level governance with a clearer distinction between minuted formal meetings and informal-co-design seminars.
   3. Developing the overall change story which will guide our operational focus and activity over the next 5 to 10 years. We have discussed this as part of recent ET workshops as well as at our strategic board seminar in June. Taking the 5-year strategy and culture workshops as a jumping-off point, we have begun to articulate what NICE would look like if we were an organisation that was as brilliant as our people: creating useful and useable advice focused on the most important improvements in care that form a core part of the learning health system of the future. This is not something we can develop on our own and over the coming months we will seek both internal and external views to further refine our change story. The final product needs to be a co-production with the whole organisation, and we will be using our existing change champion network as a basis for facilitating organisation wide-engagement.
   4. As part of our ongoing transformation journey, we are also finalising changes in working practices which were begun last year. We are currently agreeing our approach to home working with those that have current home working contracts. Through a combination of individual and group meetings, working closely with our Unison colleagues, we will agree a set of principles for home working that seeks to balance differences between teams, the needs of individuals, HMRC tax rules and equity across the organisation.
3. Lastly, we cannot ignore the changing external environment within which we are operating. The previous few weeks have seen some political upheaval with more to come when the new Prime Minister is selected. Our sponsor minister in DHSC, Lord Kamall, has remained in post which provides welcome continuity, and we are not expecting radical changes from the new Health Secretary, Steve Barclay, while the leadership contest is ongoing. Our team here will monitor the proposals from all the candidates to ensure NICE is well placed to respond to whoever takes over from Boris Johnson in the autumn.
4. We also continue to monitor our performance relative to our international peers. As part of this, we regularly review reports comparing medicines access internationally. These reports show that NICE is a world leader in rapid access to medicines and remains among the top performing HTA agencies globally, something confirming my anecdotal experiences at recent international conferences. A summary of the findings of these reports is presented as a separate agenda item. Having a clear picture of where we sit globally will be important especially as we consider upcoming VPAS negotiations in 2023 as well in the development of our long-term vision as we seek to maintain and enhance our leading position.

NICE highlights

Launch of NICE’s real-world evidence framework

1. On 23 June, NICE hosted a public launch event for the new real-world evidence framework. NICE staff were joined by 10 international experts and opinion leaders in the field of data and evidence who discussed the role of real-world evidence in healthcare decision making. The event was very well attended and attracted 2200 live views, and the publicly available recording of the event has had around 800 views to date.
2. External stakeholders were able to provide valuable feedback on the framework, during its development in a series of workshops, and through a public consultation in June. Consultation comments were largely positive, for instance 88% (N=62) of stakeholders agreed that the framework would help highlight uses for real-world evidence in NICE guidance.
3. Following consultation, minor presentation changes were made to the framework, including a clarification on the scope of the framework. The framework is intended to complement NICE’s methods manuals and signal the need for quality and transparency of real-world evidence studies with the aim of supporting critical appraisal and build trust in high-quality real-world evidence. It does not set minimum standards for evidence required in the context of decision making across different programmes of NICE.
4. Further development of the framework will be considered in the context of external feedback and through engagement with Centre for Health Technology Evaluation and Centre for Guidelines colleagues. Training and awareness events have already taken place, for example through internal staff lunch-and-learn events, the standing committee chair forum, and externally through training hosted by NICE Scientific Advice.  Further training programmes are being planned for NICE staff, committees, external assessment groups and evidence developers.

Supporting the UK’s efforts to tackle antimicrobial resistance

1. The previous report updated on the new subscription-style payment model that has been designed to try and address the poor commercial incentives to develop new antimicrobials, as a result of strict controls to restrict their usage, and the growing threat posed by antimicrobial resistance. NICE has been closely involved in this work, publishing draft guidance estimating the value for two antimicrobial drugs - cefiderocol and ceftazidime–avibactam to the NHS on the 12April.
2. Following the draft guidance, innovative subscription-style payment contracts were implemented on 1 July 2022 for the two antimicrobial drugs after final commercial discussions between the companies (Shionogi and Pfizer) and NHS England. Announcing the deal at NHS ConfedExpo, NHS Chief Executive Amanda Pritchard called the revolutionary subscription deal a game-changer and the latest NHS success in using its commercial power to benefit NHS patients in line with the NHS Long Term Plan.

Launch of the ‘refactored’ British National Formulary and British National Formulary for Children websites

1. At the end of May 2022, we launched a ‘refactored’ version of our British National Formulary (BNF) and British National Formulary for Children (BNFc) websites. The project was needed to simplify the structure of the site and further automate processing of regular updates from our partner, Pharma press. Because the sites are extremely popular, we also wanted to make sure that they were 100% accessible and could deliver content on all devices very rapidly.
2. Given the ever-increasing traffic to these sites (see graphs below), with the BNF touching nearly 4million user sessions in March, the improved performance and reduced administrative burden will bring significant benefits to both users and NICE teams.

Guidance highlights

100% NICE breast cancer drug approvals since 2018

1. Further price cuts agreed with the makers of 2 breast cancer treatments, alpelisib (also known as Piqray) and sacituzumab govitecan (also known as Trodelvy), have paved the way for NICE to be able to make them routinely available immediately to around 1,250 people on the NHS.
2. In final draft guidance published on Thursday 14 July 2022 NICE has recommended alpelisib, used with the hormonal therapy fulvestrant, for treating hormone receptor-positive, HER2-negative, PIK3CA-mutated locally advanced or metastatic breast cancer that has grown after treatment with combined hormonal therapy and a cancer growth inhibitor (an aromatase inhibitor plus a CDK4/6 inhibitor).
3. NICE has also recommended sacituzumab govitecan for treating locally advanced or metastatic triple negative breast cancer which can’t be removed surgically. It is used after people have had 2 or more lines of systemic therapies, at least one of them for locally advanced or metastatic disease which can’t be removed surgically.
4. NICE has now made positive recommendations in all 15 of its appraisals of breast cancer medicines since March 2018, driving innovation into the hands of clinicians to give better outcomes for thousands of NHS patients. The decision also means that alpelisib and sacituzumab govitecan become the 99th and 100th NICE-approved cancer treatments respectively to be made available immediately at the point that NICE issues positive final draft guidance under the Cancer Drugs Fund (CDF) interim funding arrangements.

Hundreds of thousands set to benefit as NICE recommends new treatment to prevent heart attacks and strokes

1. NICE has published final draft guidance which recommends icosapent ethyl for reducing the risk of cardiovascular events such as heart attacks and strokes in adults who have raised levels of a type of blood fat called triglycerides.
2. It means that around 425,000 people could now benefit from the first licensed treatment shown to reduce the risk of heart attacks and strokes in people with controlled low-density lipoprotein cholesterol (LDL-C – sometimes called “bad” cholesterol) who are taking a statin and who have raised levels of triglycerides.
3. NHS England estimates that between 25% and 35% of people having statin therapy have elevated triglycerides. Until now there have been no medicines for people at risk of cardiovascular events who have raised levels of triglycerides despite having statins with or without ezetimibe (another type of anti-cholesterol medicine).

NICE sets out further details on menopause guideline update

1. NICE has outlined what aspects of menopause care will be updated in upcoming guidance, including areas where more research is needed. The ‘scope’ of the menopause guideline, published on Friday 27 May, sets out new areas of evidence which NICE will look at and consider either making new recommendations or updating existing ones.
2. The following areas have been identified for inclusion in the scope:
   1. Managing menopausal symptoms.
      1. Cognitive behavioural therapy to manage symptoms associated with the menopause.
      2. Interventions to manage genitourinary symptoms associated with the menopause.
   2. Effects of hormone replacement therapy on overall health outcomes.
3. The surveillance and scoping process did not identify any substantive new evidence on using testosterone beyond the current recommendations in the NICE guideline for using testosterone for altered sexual function. NICE discussed the need for evidence in this area with the National Institute for Health and Care Research (NIHR) who have agreed to scope new research.

Requested programme updates

Managed access arrangements for advance therapy medicinal products (ATMPs) and treatment for rare diseases

1. The board asked for an update on how managed access arrangements are facilitating patient access to ATMPs and treatments for rare diseases. This is in light of the newly launched Innovative Medicines Fund (IMF).
2. The managed access approach is typically best suited for treatments where there is 1) a high unmet need, 2) potential for significant clinical benefit and/or 3) a step change in treatments available for a disease or cohort of patients. These filtering considerations enable NICE to proactively reach out to companies about the potential for managed access, via the Cancer Drugs Fund (CDF) or the IMF, to better understand the uncertainties that will need to be addressed during an evaluation. This early engagement also enables NICE to reach out to system partners about real-world data needs and to prompt NHS England to ensure services are ready to start when NICE guidance is published.
3. The managed access approach can support timely patient access to both ATMPs and treatments for rare diseases. Experience to date shows:
   1. ATMPs
      1. 4 x CAR T treatments have been recommended with managed access via the CDF – England was among the first countries in Europe to offer patients access to these innovative treatments
      2. 4 x further ATMPs within the CHTE workplan are being monitored by NICE for the potential to be recommended with managed access
      3. 1 x non-cancer ATMP – onasemnogene for pre-symptomatic patients with spinal muscular atrophy was recommended with managed access (this could have been recommended via the IMF, but the decision was announced prior to the IMF)
   2. Rare diseases
      1. 8 x treatments for rare diseases have been recommended with managed access since 2015
      2. 1 x managed access review has been completed using real-world data collected on NHS patients who received treatment during the MAA
      3. 2 x managed access reviews are underway
      4. Every HST topic is being reviewed to assess the feasibility of managed access to support patient access to treatments for rare disease

COVID-19 – the next stage

1. We have agreed an approach to COVID-19 for the upcoming winter, which will move us from a reactive footing to more standard engagement and resourcing. However, we will constantly monitor the system needs and be responsive to any changing requirements and, if the need arises, will step up more resource as required.
2. For our RAPID C-19 programme we will continue our active monitoring of priority treatments in trials for COVID-19. Through our continued surveillance and horizon scanning activity we will be well positioned to enable increased activity should the pandemic context or current treatment availability change. We will also maintain our Oversight Group so that we are able to stand this up quickly when emerging evidence indicates a need to do so, to formulate advice to CMO to support consistent system messaging and equitable access across the UK. This will be coupled with ad hoc support for system partners to enable information provision and rapid evidence synthesis when required.
3. On COVID-19 guidelines we have been consolidating our portfolio over the last few months as well as reviewing the NICE RAPID COVID-19 Guidelines and NHSE speciality guides. The outcome of this work has been to step down out-of-date content and move relevant recommendations into our living Managing COVID-19 guideline. We maintain our constant surveillance and development approach for our living COVID-19 guidelines and work closely with RAPID C-19 to support rapid access to new therapeutics. Over the next 6 months we will slowly step down our resource in the COVID guideline team, with the intention of treating these guidelines as part of our portfolio from March 23.
4. The Technology Appraisal programme has initiated a Multiple Technology Appraisal (MTA) to inform the transition back to usual commissioning arrangements for therapeutics for treating COVID-19. This will provide recommendations on the clinical and cost-effectiveness of treatments currently commissioned on an interim basis for use in hospital for people with severe COVID-19 and in the community to prevent people at high risk of severe disease needing hospital treatment.
5. An independent academic group has developed a model and report which is being consulted on with stakeholders until the end of July. A committee meeting to discuss the MTA is expected to be held in October 2022. It is anticipated that any new COVID-19 therapeutics will be assessed by the Technology Appraisal programme before commissioning decisions are made. In order to do this efficiently, we are exploring how we can maintain and update the MTA model so it can form the basis of these future assessments.

Launch of the COVID-19 inquiry TOR

1. The Covid-19 inquiry terms of reference have been confirmed. The inquiry will examine, consider and report on preparations and the response to the pandemic in England, Wales, Scotland and Northern Ireland, up to and including the Inquiry’s formal setting-up date, 28 June 2022. The final terms of reference were in line with all Baroness Hallett’s recommendations to the prime minister following the consultation exercise. It confirmed that inequalities and the voice of the bereaved will underpin all the inquiry’s work and focus. There we no surprises and they were in line with NICE’s planning to date.
2. The aims of the inquiry are to:
   1. Examine the COVID-19 response and the impact of the pandemic in England, Wales, Scotland and Northern Ireland, and produce a factual narrative account, including:
      1. The public health response across the whole of the UK
      2. The response of the health and care sector across the UK,
      3. The economic response to the pandemic and its impact
   2. Identify the lessons to be learned from the above, to inform preparations for future pandemics across the UK
3. NICE’s preparations continue in line with the programme plan. We have held an introductory meeting with the inquiry and our current focus is to work with our legal advisers to ensure we are ready to respond to the first information requests from the inquiry. We await further information from the inquiry on how it will operate. Further updates will be provided to the board in due course.

Working with NHSE to tackle health inequalities

1. In response to a direct request from NHSE, we have progressed with scoping a practical health inequalities resource for Integrated Care Systems (ICSs). The resource will collate NICE recommended, evidenced approaches to address health inequalities, set in the context of ICS priorities and aligned to recognised health inequalities frameworks including Labonte and Marmot. The web-based resource will provide a ‘go to’ place on the NICE website, raising the profile of our offer and the fit of our guidance with system needs. The work will be guided by an external reference group made up of key partners working across the health and care system (e.g., from NHSE, Local Government Association, Care Quality Commission and ICSs).
2. We have mapped NICE quality standard statements aligned with the 7 principles in NHSE’s [Health Inequalities Improvement Planning Matrix](https://www.england.nhs.uk/about/equality/equality-hub/national-healthcare-inequalities-improvement-programme/contacts-and-resources/healthcare-inequalities-improvement-planning-matrix/). The matrix outlines key areas for consideration when services are designed, implemented, and evaluated. The matrix is being used by national NHS programme and workstreams leads, and service leads at a regional, system and provider level. It helps to ensure that programmes do not widen healthcare inequalities and covers areas including equitable access and co-production. The quality standard statements provide the evidence base and will be made available alongside the matrix. NICE field team will also use the resource to support work with ICSs as part of their planned engagement campaign.
3. We are also collaborating with NHSE and HQIP (Healthcare Quality Improvement Partnership) on a ‘closing the loop seminar’ aiming to raise awareness of the role of clinical audit in reducing health inequalities through contributing to guidance development and quality improvement work. The idea for this virtual event arose from a series of round table workshops with national clinical audit providers and a presentation provided by NICE health inequalities programme lead outlining the potential for national clinical audit to inform the development of recommendations aimed at reducing inequalities for example in uptake of continuous glucose monitoring.

Key risks

NICE continues to monitor and manage key risks in a number of areas:

1. **Strategic relevance** – the health and life sciences sector remain extremely fluid, experiencing rapid rates of change particularly in terms of emerging technology and patient need. NICE needs to continually evolve to meet the needs of users, national system partners and the life science sector. Ensuring our continued strategic relevance is one of the key drivers behind the business priorities we have outlined for 22/23, which are designed to help maintain our world leading position. In considering our 5 to 10 year positioning as part of our change story we aim to manage and get ahead of the longer-term trends.
2. **Financial sustainability** - The economic challenges post-COVID have meant there is a need for ongoing restraint in public spending, to ensure the government finances are placed on a sustainable footing. While NICE has not been included in the first round of ALB reviews kicked off by the Cabinet Office, we need to ensure we are able to continue to meet the requirement for efficiency savings across the public sector at the same time as securing the financial resources to invest in our long-term development in key areas. Alongside our rigorous financial planning processes, we continue to maintain a programme of continuous improvement to identify potential efficiency savings as well as continuing to raise the commercial awareness of the organisation as a whole.
3. **Organisational transformation** – As a result of NICE’s ambitious organisation wide transformation programme, we may not have enough experienced and capable people with capacity to focus on transformation alongside continued BAU work. As well as continuing to establish an organisational-wide transformation effort we are looking at how to secure wider staff buy-in and engagement to our overall transformation. In order to be successful our transformation needs to be driven at all levels in the organisation and we will be working with a group of identified ‘change makers’ to help lead this work.

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