

Executive update to the Board

July 2023

Executive Summary

Since the last Board meeting, the government's life sciences 'pro-innovation regulation of technologies review' has reported with implications for NICE's work. We are also closely engaged in the ongoing negotiations between industry and government on the new Voluntary Scheme for Branded Medicines, Pricing and Access (VPAS) (slide 3)

Over the next few year, NICE will transform. Our principles, and the fundamental priorities remain the same. But we will evolve, to make sure we're meeting the changing needs of the health and care system. Our transformation plan will ensure we 1. focus on what matters most 2. create useful and useable advice 3. constantly learn from data and implementation (slide 4)

We are already making progress against these aims, as illustrated by recent guidance and programmes of work:

1. **Focussing on what matters** most by helping reduce pressures on the NHS and make the best use of NHS resources through new guidance to avoid unnecessary colonoscopies, reduce the use of radiotherapy, and supporting implementation of virtual wards to care for people outside of hospitals (slides 5-7)
2. **Creating useful and useable advice** through implementation of our new methods which are enabling increased use of real-world-evidence, additional flexibilities, and showing early promise in applying severity modifiers; consulting on modular updates to make our medicines evaluations even faster; and supporting the NHS to adopt AI technologies through our new advice hub (slides 8-10)
3. **Constantly learning from data and implementation** through recommending the use of digitally enabled therapies for anxiety disorders or depression, enabling access to treatments while further data are gathered to enable a full appraisal (slide 11)

The next update to the Board will be presented in September, covering the period from July.

Our external context is evolving; we are working closely with our partners to deliver government priorities

Regulatory review

The life sciences pro-innovation regulation of technologies review reported in May 2023, building on the international recognition scheme announced in the 2023 Budget.

This includes recommendations about routes to market for therapeutics and devices relating to the MHRA's activity. MHRA has announced 7 trusted partner countries whose regulatory decisions can be recognised by MHRA.

This has implications for NICE's pipeline, and NICE is working closely with the MHRA to confirm the process and implications of these international recognition routes, to ensure the medicines access pathway continues to operate smoothly and a timely NICE appraisal is supported.

The regulatory review also made recommendations about improving the Innovative Licensing and Access Pathway (ILAP) for medicines and establishing a similar pathway for devices; we are working with MHRA on both areas.

VPAS

Negotiations are ongoing for the new Voluntary Scheme for Branded Medicines, Pricing and Access (VPAS), aiming to agree heads of terms in Autumn 2023.

NICE is not a formal partner in negotiations but is closely engaged with NHSE and the Department of Health and Social Care, given NICE's critical role in medicines access.

NICE

NICE's transformation plan

- Over the next few years, NICE will transform. Our principles, and the fundamental priorities remain the same. We will continue to support practitioners and commissioners to get the best care to patients fast, while delivering value for the taxpayer. But we will evolve, to make sure we're meeting the changing needs of the health and care system
- We'll maintain our independence, transparency and rigour. But we will now also focus on:
 - relevance
 - timeliness
 - usability
 - demonstrable impact



Our transformation plan – that we've now embarked on - sets out how we plan to evolve as an organisation. We will transform by targeting 3 key areas:

- 1) focusing on what matters most
- 2) creating advice that's useful and useable
- 3) continually learning from data and implementation

A new online transformation page sets out more about how we will deliver this, and examples of what we have achieved so far

A successful launch webinar on July 10th attracted more than 1360 registrations from 29 countries. A [recording of the session](#) is available to hear more

1. Focussing on what matters most

Helping reduce unnecessary colonoscopies and improving waiting times



- NICE is helping the NHS deliver the best care at the best value for money for people with symptoms suggestive of colorectal cancer to determine if further investigation is required
- In new draft guidance, NICE has recommended extending the use of an at home bowel cancer test, faecal immunochemical tests (FIT), and confirmed the threshold for further investigation
- As well as providing better care for individuals, these FIT tests will help reduce the pressure on the NHS. They can decrease the number of unnecessary colonoscopies and reduce GP referrals for urgent colonoscopies by 50%

1. Focussing on what matters most

Reducing unnecessary healthcare use in our updated breast cancer guideline



- NICE has updated breast cancer guidelines in line with the latest evidence that showed no difference in breast cancer-related mortality or disease recurrence between higher dose and longer intensity radiotherapy, compared with lower dose shorter intensity treatment, for people with early and locally advanced breast cancer.
- Shorter intensity and duration of radiotherapy means that for every 1,000 people receiving the lower number of fractions, 10,000 NHS radiotherapy appointments have been freed up in England every year, reducing pressure on services
- The new guidance also offers a better experience to patients with reduced appointments, but affecting safety or outcomes

1. Focussing on what matters most

Making best use of NHS resources by supporting the health and care system to implement virtual wards



Virtual wards have the potential to expand NHS capacity by managing patients remotely in their homes, creating staffing efficiencies, and providing safe and more convenient care for patients

We are listening to the health and care system to find out what matters most to them and what they need from NICE to implement virtual wards. Based on this insight, this year we are developing the following resources:

- **a new clinical guideline** on acute respiratory infection in over 16s: initial assessment and management (including patient selection and referrals to virtual wards),
- **technology assessment advice** on drivers of value for technologies that enable virtual wards,
- **reviewing the economic evidence** and working with selected NHS sites to extract real world data and produce case studies that illustrate the costs and activity changes among trusts in order to inform activity forecasts and help **commissioners and providers** to implement virtual ward models

2. Creating useful and useable advice

Monitoring implementation of NICE's new methods



- NICE is evolving its methods to better reflect what society values most, to take account of all available evidence, and to enable patients to access promising treatments while evidence is being generated. To understand the impact of this NICE is tracking key data regarding implementation of new and changed methods components
- Up to March 2023, there are **34 topics using the new manual** for technology evaluation, of which 11 are at final guidance stage (all 11 of which are positive):
 - 6 have seen companies apply for a severity modifier, 3 of which have been accepted by committee, using all levels of available modifier (up to 1.7).
 - **Real world evidence has been used in 15 company submissions.** In 6 of these cases, the committee accepted the RWE as primary evidence.
 - **Additional flexibilities have been granted in 5 topics, leading to increased acceptable Incremental Cost Effectiveness Ratio (ICER) thresholds based on difficulties in evidence generation, impact on health inequalities, and uncaptured benefits**

2. Creating useful and useable advice

Consulting on modular updates to NICE's technology appraisal methods to produce guidance more quickly



- NICE is consulting on updates to the health technology evaluations manual to embed improvements identified last year. The consultation addresses our first modular methods updates, seeking views on two changes:
 - Incorporating NICE's proportionate approach to technology appraisals into the manual, allowing us to produce rapid guidance for simpler, risk treatments, and spend more time on complex areas that need tailored support
 - A revised approach to updating technology appraisal recommendations for COVID-19 medicines, reflecting stakeholder comments and changes to the data landscape since our earlier work in this area
- These changes will enable NICE to produce guidance more quickly than under the current methods manual

2. Creating useful and useable advice

Supporting the NHS to adopt AI technologies through our new one stop shop for AI guidance



- NICE, working with our partners, have launched the AI and Digital Regulations Service to help the NHS and wider care system adopt and make use of new digital and artificial intelligence (AI) technologies. The service offers:
 - a website providing centralised, curated and up-to-date regulatory content for both developers and adopters of AI and data-driven technologies; and
 - access to specialist support for both developers and adopters from the service partners.
- The service is a multi-agency collaboration between the National Institute for Health and Care Excellence, the Care Quality Commission, the Health Research Authority and the Medicines and Healthcare products Regulatory Agency and is funded by the NHS AI Lab.
- By collating information from all 4 organisations in one place, the site provides comprehensive guidance at each stage of the adoption pathway to ensure that the NHS can benefit from new technologies, while ensuring that are safe and efficacious

3. Constantly learning from data and implementation

Recommending digital technologies addressing unmet need while further data is gathered



- One in six people report experiencing a common mental health problem such as anxiety and depression in any given week in England, and there were more than half a million referrals to NHS talking therapies for depression and anxiety in 21/22.
- NICE has recommended the use of six digitally enabled therapies for adults with anxiety disorders and three for adults with depression while further data is gathered to enable a full assessment of their clinical and cost effectiveness
- The new digital treatment options use cognitive behavioural therapy (CBT) techniques via an app or website and include the support and involvement of an NHS Talking Therapies clinician or psychological wellbeing practitioner.
- Digitally enabled therapies require less time with therapists and can be more convenient for people accessing services. NICE guidance helps to ensure NHS recommended therapies are evidence based and cost effective.
- Recommending these digitally enabled therapies while collecting further evidence means that people can access these promising therapies at the same time as further evidence is gathered to enable a full appraisal.