National Institute for Health and Care Excellence

Centre for Health Technology Evaluation progress report

This report provides an insight in the activities of staff and programmes in the Centre for Health Technology Evaluation, focussing on March and April 2021. The report also contains a chart detailing all non-guidance outputs produced by the Centre during the 2020-21 business year.

Summary of activity

We continue to develop the Innovative Licensing and Access Pathway through membership of its Steering Group and work packages, and are putting in place operational arrangements to support products going through the pathway.

We are working on the second phase of the process and methods review for our health technology evaluation programmes, including engagement with external stakeholders through the task and finish groups, working party and steering group.

The RAPID-C19 Oversight Group celebrated its anniversary having held 52 meetings, reviewing 66 topics, supporting patient access for 5 drugs and continue to monitor a further 64.

In addition to the final guidance publication stated in the Chief Executive's report, across the Technology Appraisal, Highly Specialised Technologies, Diagnostics Assessment and Medical Technologies Evaluation programmes we have started the guidance development process for 33 new topics. The Technology Appraisal and Highly Specialised Technologies programmes also issued 11 draft pieces of guidance for public consultation, and released 11 final documents for appeal.

Notable issues and developments

Ongoing response to COVID-19

RAPID-C19 continues to play an important part in the contribution we make to the COVID response. Apart from informing activities within the participating organisations, including NIHR, MHRA and NHSE, and the health technology assessment agencies of the devolved nations, the programme has extended its work for the Therapeutics Task Force to support future procurement of COVID therapeutics. Funding for RAPID-C19 has been secured for the coming year. The RAPID-C19 team came second in the first ever NICE team awards.

We provided scientific advice for one technology through the free COVID-19 advisory service, established at the start of the pandemic and we continue to monitor the impact of COVID-19 on data collection for existing managed access agreements and commissioning through evaluation projects, with an awareness that NHS services are restoring at different rates.

Rapid robust and responsive technology evaluation

Guidance outputs

The Chief Executive's report presents performance against plan for guidance and advice outputs developed in CHTE since April 2020. These past two months of March and April have seen a strong level of guidance production with 26 publications. Many of these publications are for topics that were subject to delay due the re-prioritisation exercise undertaken in March 2020 in response to the emerging pandemic.

Non-guidance outputs

Figure 1 presents non-guidance outputs of programmes of work within the centre during the 2020-21 business year.

Figure 1 Performance against plan for non-guidance outputs during 2020-21

Methods and process review

The methods and process review has entered the second stage of development where we describe how we propose to implement the various cases for change. Consultation responses are being reviewed and we continue to engage with stakeholders on the proposals, including a webinar on the HST Topic Selection criteria vision and principles with over 300 participants. Timelines for development of the draft unified manual have been amended, recognising the continued COVID constraints on the ability for our stakeholders to participate effectively in earlier consultation. We expect to consult on the draft manual in August and September 2021, with publication in January 2022.

Supporting innovation

Managed access provides for an important opportunity to support patient access while further data is collected. Over the reporting period, final guidance was developed for 5 technologies following a period of managed access in the Cancer Drugs Fund. The evidence considered in these reviews was underpinned by further clinical trial data supplemented with real world evidence generated during the managed access period. We are jointly working with NHS England and NHS Improvement on developing guiding principles for managed access, which along with input from key stakeholders have informed an early draft of the innovative medicines fund (IMF) engagement document. A formal public consultation exercise will follow later in the year.

We are both a partner in the Accelerated Access Collaborative and a provider of technical services to support the delivery of several activities of the collaborative. Our work is summarised in an MOU, signed in April, detailing the work on horizon scanning, early-stage products, rapid uptake products, the medtech funding mandate and COVID (RAPID-C19). The MOU covers a substantial amount of non-GIA income for NICE.

Over the past months, colleagues across government and the health service have launched several initiatives to support the life sciences, innovation and regulation to which we have extensively contributed. We are tapping into a significant desire from across the arms-length bodies to collaborate on developing an attractive and innovative regulatory and access pathway. Our joint work with the MHRA and the Scottish Medicine Consortium on the Innovative Licensing and Access Pathway is progressing at pace, with 10 Innovation Passports having been awarded since the programme started earlier this year.

Digital technologies and genomics

Multi-disciplinary work across the CHTE and SEA directorates on the arrangements to support identification and evaluation of digital health technologies has kicked off in earnest. The SEA report contains an overview from the perspective of NICE's Office for Digital Health. At the CHTE end, work is ongoing to explore how to best align horizon scanning and topic selection to the demands for advice and guidance on digital health technologies, and to consider what 'products' we use to disseminate information, evidence and recommendations on digital health technologies. This includes aligning with developing ideas about reimbursement, commissioning and funding of digital health technologies, including consideration of models for 'contingent approval'.

In support of a 'test and learn' approach, the assessment of hybrid closed loop systems for managing blood glucose levels in type 1 diabetes has been converted from diagnostics guidance to a multiple technology appraisal (MTA). Hybrid closed loop systems use a combination of real-time glucose monitoring from a continuous glucose monitoring device and a control algorithm to direct insulin delivery through an insulin pump. Some of these systems are built by combining interoperable devices from different manufacturers. This approach to guidance development allows us to test alignment of evaluation processes, the application of the funding mandate to a complex technology, including a digital component, and learn from the experience.

Following selection by the AI in Health and Care Award, the first of several AI technologies has entered the diagnostic assessment programme. The programme will assess the clinical and cost-effectiveness of artificial intelligence software for automated detection of suspected brain abnormalities in CT scans from people with a suspected acute stroke with the aim of developing recommendations on their use in the NHS. In partnership with the Accelerated Access Collaborative, META Tool gap analyses were initiated for 7 of the winners of the second round of the AI in Health and Care Award. This will inform evidence generation plans prior to HTA assessments and scale up of the technologies across the NHS.

NICE Scientific Advice had a very successful year, initiating over 70 advice projects, the highest number of advice projects in its history so far. Scientific Advice recovered all costs and made a full contribution to overheads, as well as being able to offer 12 free of charge advice projects for technologies for COVID-19 and contributing to the methods and process review. A key area of growth was in advice to digital health technology developers. We performed 8 META tool gap analyses for phase 4 winners of the first round of the AI Award in Health and Care and supported companies within the Innovate UK digital health technology catalyst round 4 competition.

Discussions with NHSE&I about collaborative working to embed genomics in NICE's ongoing activities and outputs, are positive and ongoing. There are also opportunities to strengthen NICE's managed access arrangements for medical technologies because the new infrastructure provided by the new Genomic Medicine Service and Genomics England will facilitate data collection on genomic tests and allow the use of these tests in the NHS to be monitored. Historically, NICE has had to rely on companies for this information on genomic tests which are not a companion diagnostic test to a drug.

The National Genomic Research Library (collates genomic data from Genomic Medicine Service and Genomics England testing services) also provides a repository of genomic data and real world evidence which may identify new genomic risk factors and scores, and pharmacogenomic markers, as well as providing further evidence on companion diagnostic and existing genomic tests. Optimising the use of this evidence to inform NICE health technology guidance and clinical guidelines will require a review of NICE methodologies and quality assurance frameworks to consider genomic profiles and data. This will be catered for through a modular update to the methods of health technology evaluation.

The Genomic Medicine Service has also introduced, on a national scale, whole genomic sequencing and in-house panel tests for cancer-associated genomic markers. The aim is that cancer patients will be provided with multiple genomic test results at the point of diagnosis to inform and tailor their individual treatment and care. Further details on this new approach are being gathered so that NICE can understand potential changes in clinical decision making and lines of treatment, and any implications for regulatory licensing, managed access arrangements, NICE guidance and advice products.

International collaboration

NICE International continued its long-term collaboration with Denmark by providing a peer-to-peer seminar on committee decision making to its HTA council members. The team also facilitated the support for UK Department for International Trade-organised missions in Brazil and Thailand with a focus on genomics, and a prosperity fund event in China focused on medical devices.

HTAi 2021

We continue to work closely with Health Technology Assessment international (HTAi) on the arrangements for the virtual 2021 HTAi annual meeting in June 2021. We have moved forwards with logistical arrangements for the virtual setting, and have also identified a cohort of NICE staff who will attend the conference to showcase their work and network with national and international colleagues in this sector.

Key risk

High vacancy rates continue to risk our ability to deliver on the outputs for CHTE. We are using our contracts with external organisations and support from other teams in NICE to mitigate some of this risk and considering alternative approaches to the evaluation of technologies to create capacity. Specific recruitment initiatives are also being put in place with a virtual careers event planned to be held in early May. And we are exploring ways of managing topics differently, on a case-by-case basis, with a focus on applying staff and committee resources flexibly.

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