National Institute for Health and Care Excellence

Centre for Health Technology Evaluation progress report

1. This report provides an overview of the work and achievements by staff and programmes in the Centre for Health Technology Evaluation, focussing on November and December 2020.

Summary of activity

We published final guidance for Zio XT for detecting cardiac arrhythmias (MTG52) after the topic successfully completed the digital health technology pilot project.

We worked with the MHRA towards the launch of the Innovative Licensing and Access Pathway (ILAP) on 1 January 2021. We provided our expertise and input into the four pilot ILAP topics, and we are working with individual companies and the MHRA to facilitate arrangements for technology appraisals of oncology products using the Project Orbis regulatory process.

We continued work on CHTE 2020 and NICE Connect transformation projects, with a focus on methods, process, topic selection and implementation.

Preparatory work for the 2021 annual conference of HTA international in/from Manchester (<https://htai.eventsair.com/htai-manchester-2021-am/>) continues.

We continued to implement our COVID-19 recovery plans for all health technology evaluation topics paused between March and June 2020.

We worked with NHS Test and Trace on developing medical innovation briefings for diagnostic tests used for COVID-19.

Notable issues and developments

Ongoing response to COVID-19

We started development of the first 'testing MedTech Innovation Briefing (MIB)' focussing on the OptiGene COVID-19\_Direct Plus RT-LAMP KIT-500 for laboratory-based testing. We anticipate the final MIB will publish in January 2021. We held a committee meeting to discuss exploratory economic modelling of SARS-CoV-2 viral detection point of care and serology tests in care and residential home settings, in response to a commission from the Accelerated Access Collaborative (AAC). We are establishing the route for dissemination of this work.

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 services were restoring at different rates and the latest surge may have a further impact on patient treatment and data collection. In response, NICE is working with registry and analytical providers to proactively adjust plans for the delivery of new evidence from these projects.

We further developed the governance and operational arrangements for the multi-agency RAPID-C19 initiative (NHSE/I, MHRA, NIHR and representatives from the devolved nations), establishing closer links with the Therapeutics Taskforce, and with the UK clinical trials forum and UK COVID-19 Therapeutics Advisory Panel (UK-CTAP). This has enabled us to share intelligence between groups that supports the system wide rapid response.

Supporting innovation

We have made significant progress in developing the guiding principles for a new innovative medicines fund (IMF), which include many different policy areas for managed access - to help facilitate robust policy making in this area.

The AAC secretariat continues to coordinate activities to support the rapid adoption of innovation through the early stage workstreams focussing on Histology independent technologies, Advanced Therapeutic Medicinal Products and the NICE methods review.

The Executive Team agreed to expand the AAC team to support the ongoing AAC secretariat, RAPID-C19 and the MHRA/NICE Innovative Licensing and Access Pathway (ILAP). Recruitment is underway.

Scientific advice projects were initiated for 6 different technologies. Several other engagements aimed at supporting innovators took place including a webinar for the Association of British HealthTech Industries (ABHI) on engaging with NICE and an educational session with the Academic Health Science Networks on the META Tool.

Since March 2019 over 1000 innovators have registered to use HealthTech Connect, and 330 technologies have been submitted. 27% of technologies have been selected by NICE for a Medtech Innovation Briefing or NICE guidance. 54% of technologies have been selected for support by a number of different organisations including the AHSN network, NIHR, and Department for International Trade.

Digital technologies

The second diagnostics advisory committee meeting for software packages used to calculate fractional flow reserve during coronary angiography was held in November. This will be the second piece of diagnostics guidance assessing digital technologies to be published this business year.

We continued to work with the AAC team running the AI in Health and Care Awards and will be conducting a META Tool review for an additional health technology from the first round of the competition. We have produced a case study on the work we have done to date and are exploring how we continue to work with the AAC team to support future rounds of the competition and contribute to the overarching aim to establish a globally leading testing infrastructure for innovation in the UK.

As part of the AI Multi-Agency Advice Service project, NICE, MHRA CQC and HRA have initiated the discovery phase for the project by conducting a series of interviews with key stakeholders from both industry and the health and care system.

Patient safety

CHTE representatives Professor Kevin Harris and Dr Hannah Patrick are taking a lead role in the recently established cross-directorate Patient Safety Oversight Group. The group provides oversight of NICE’s response to the Independent Medicines and Medical Devices Safety (IMMDS) Review, facilitating and co-ordinating across directorates the actions presented to and accepted by the Board in September 2020.

The group is also conducting a review of patient safety activity at NICE, which will generate recommendations for a sustainable model for managing patient safety issues in a structured and systematic way across the organisation, as well as the potential resources required to support such changes.

Transformation

The public consultation on the proposals for changes to CHTE methods closed on 18 December 2020. During this time, a virtual consultation webinar was held with over 500 attendees, representing a broad spectrum of key stakeholders. Work is underway to process and review all consultation comments.

A paper outlining the public consultation on the proposals for changes to CHTE processes is in development and is being presented to the Board in January 2021.

International collaboration

NICE International presented their 1st annual review document to the NICE public board in November detailing their progress to date and the future international opportunities that are in the pipeline. A third phase of HTA workshops was delivered virtually for Uruguay and Mexico, supported by the Department of International Trade in Latin America, and a series of virtual HTA seminars for the Department of Health in the Philippines was completed as part of the Prosperity Fund Better Health Programme.

Recruitment

Between November and December, 16 vacancies were created. The result of internal moves and promotions, development of a new 'Life Sciences' team, and 2 staff being seconded to NICE Connect. Recruitment campaigns are underway for all current vacancies and 10 are at the offer stage. We continue to be flexible and creative in recruitment, utilising additional appointable candidates from recent campaigns in 3 vacancies to cut down the recruitment timeline considerably.

Key risk

We are unable to deliver on the COVID-19 adjusted outputs and other commitments for CHTE because of the recent school closures which, coupled with the existing staff vacancy rate, is expected to have a detrimental effect on capacity, of our teams, contractors and stakeholders, potentially leading to impact on patient care, inability to apply income received, and damage to our reputation. The impact on guidance publication will be mostly for topics publishing in next business year (2021-22). We are using our contracts with external organisations and support from other teams in NICE to mitigate some of this risk.

Figure 1 Performance against plan for non-guidance outputs in November and December 2020

The volume of Managed Access Agreements (MAAs) and Patient Access Schemes developed in any period is subject to fluctuation and have been lower than anticipated between November and December 2020. One less MAA was concluded in this period, due to factors beyond NICE's control (i.e. extended commercial negotiations between NHSE&I and the company).

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