NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

PUBLIC BOARD MEETING – MEETING AS THE BOARD COMMITTEE

Wednesday 20 May 2020 at 1:30pm via Zoom

AGENDA

20/040 Apologies for absence **(Oral)**
To receive apologies for absence

20/041 Declarations of interests **(Item 1)**
To declare any new interests and consider any conflicts of interest specific to the meeting

20/042 Minutes of the last Board meeting **(Item 2)**
To approve the minutes of the Board meeting held on 25 March 2020

20/043 Chief Executive's report **(Item 3)**
To receive the report
Professor Gillian Leng, Chief Executive

20/044 Resources report **(Item 4)**
To review the report
Catherine Wilkinson, Acting Director, Business Planning and Resources

20/045 Business plan 2020/21 **(Item 5)**
To approve the business plan
Professor Gillian Leng, Chief Executive

20/046 Collaboration with the Medicines & Healthcare products Regulatory Agency (MHRA) **(Item 6)**
To receive an update
Dr Nick Crabb, Programme Director, Science Advice and Research

20/047 Audit and Risk Committee **(Item 7)**
To receive the unconfirmed minutes of the meeting held on 22 April 2020
Dr Rima Makarem, Chair, Audit and Risk Committee

20/048 Audit and Risk Committee annual report and terms of Reference **(Item 8)**
To receive the annual report
Dr Rima Makarem, Chair, Audit and Risk Committee

20/049 Risk management policy **(Item 9)**
To approve the updated policy
Catherine Wilkinson, Acting Director, Business Planning and Resources

20/050 Director's report for consideration **(Item 10)**
Evidence Resources Directorate

Directors' reports for information

20/051 Centre for Guidelines (Item 11)

20/052 Centre for Health Technology Evaluation (Item 12)

20/053 Communications Directorate (Item 13)

20/054 Health and Social Care Directorate (Item 14)

20/055 Any other business **(Oral)**
To consider any other business of an urgent nature

Date of the next meeting
To note the next public Board meeting will be held on 15 July 2020 at 1.30pm via Zoom.

NICE National Institute for Health and Care Excellence

Interests Register - Board and Senior Management Team

Name	Role with NICE	Description of interest	Interest arose	Interest ceased
Prof Tim Irish	Interim Chair	Life science assets held in a blind trust and managed by an independent trustee.	2015	
		Professor of Practice, King's College London's School of Management / Business and a paid consultant to King's Commercialisation Institute.	2017	
		Non-Executive Director, Life Sciences Hub Wales Ltd.	2017	2019
		Chairman and Non-Executive Director, Quirem Medical BV Supervisory Board.	2015	
		Non-Executive Director, Fiagon AG.	2017	2020
		Non-Executive Director, eZono AG.	2018	
		Non-Executive Director, Feedback plc.	2017	
		Non-Executive Director, Styrene Systems Ltd.	2017	2019
		Board Member, Pistoia Alliance Advisory Board.	2017	2019
		Non-Executive Director, Pembrokeshire Retreats Ltd.	2006	
		Non-Executive Director, ImaginA b Inc.	2019	
		Non-Executive Director, Rutherford Health Plc	2019	
Prof Martin R Cowie	Non-Executive Director	Consultancy payments for the membership of Steering committee/DSMBs/Endpoint committees related to Global Clinical Trials or Registries: XATOA, COMPASS, COMMANDER-HF (Bayer); SHIFT, QUALIFY, OPTIMIZE (Servier); RELAX-Region Europe, PARALLAX, VERIFY (Novartis); COAST (Abbott); COAST-AHF (Neurotronik); FIRE1 system (FIRE1); SERVE-HF (ResMed).	2016	

		Associate Editor honoraria from Heart (BMJ Publications) and Journal of the American College of Cardiology.	2016	
		Research grants to Imperial College London to support investigator-led research projects (ResMed; Bayer; Abbott; Boston Scientific; NIHR; British Heart Foundation).	2016	
		Fellowships of the Royal College of Physicians of London and Edinburgh, and of the European Society of Cardiology, the Heart Failure Association of the European Society of Cardiology, and the American College of Cardiology.	2016	
		Chair of the Digital Committee of the European Society of Cardiology, and Member of the Digital Committee of the British Cardiovascular Society.	2016	
		Member of the Advocacy Committee of the European Society of Cardiology.	2016	2020
		Member of the Medical Advisory Board of the patient charity: the Pumping Marvellous Foundation.	2016	
		Trustee of the Atrial Fibrillation Association (patient charity).	2019	
		Adviser, BMJ Best Practice	2019	
Elaine Inglesby-Burke CBE	Non-Executive Director	Chief Nursing Officer, Northern Care Alliance NHS Group (Salford Royal NHS Foundation Trust and Pennine Acute NHS Trust).	2004	
		Board Member – AQuA (Advancing Quality Alliance).	2012	
		Professional Advisor (Secondary Care) Governing Body – St Helens CCG.	2014	2019
		Trustee – Willowbrook Hospice, Merseyside.	2007	

Dr Rima Makarem	Interim Vice Chair and Senior Independent Director	Audit Chair & Non-Executive Director, University College London Hospitals NHS Foundation Trust (UCLH).	2012	2019
		Chair, National Travel Health Network & Centre (NaTHNaC).	2015	2019
		Trustee at UCLH Charity.	2013	2019
		Independent Council Member at St George's University of London.	2016	2019
		Non-Executive Director and Audit Committee Chair, House of Commons Commission.	2018	
		Non-Executive Director, The Hillingdon Hospitals NHS Foundation Trust.	2019	2019
		Lay Member, General Pharmaceutical Council.	2019	
Tom Wright CBE	Non-Executive Director	Chief Executive, Guide Dogs.	2017	
		Trustee, Doteveryone charity.	2017	2019
		Chairman, Leeds Castle Enterprises and Trustee, Leeds Castle Foundation.	2019	

		Chairman, Imperial War Museum Development Trust.	2019	
Prof Gill Leng	Chief Executive	Honorary Librarian and Trustee at the Royal Society of Medicine.	2013	2020
		Editor of the Cochrane EPOC Group.	2012	2020
		Visiting Professor at the King's College London.	2012	
		Association Member BUPA.	2013	2019
		Chair - Guidelines International Network (GIN).	2016	
		Spouse is an Executive Director at Public Health England.	2013	
Ben Bennett	Director Business Planning & Resources	None.		
Meindert Boysen	Deputy Chief Executive and Director Centre for Health Technology Evaluation	Member of the Board of Directors for the International Society for Pharmacoeconomics and Outcomes Research.	2017	
		Member of the International Advisory Panel for the Agency for Care Effectiveness (ACE) in Singapore.	2019	
Paul Chrisp	Director Centre for Guidelines	Spouse works in medical communications offering services to a range of pharmaceutical companies.	2009	
Jane Gizbert	Director	Non-Executive Director Tavistock and Portman NHS Mental Health Trust.	2014	2019

	Communications			
Judith Richardson	Acting Director Health & Social Care	Mentor for supported return to training (SuppoRTT) in the North West.	2019	
		Faculty of Public Health, Part B (OSPHE) Examiner.	2016	
		Educational supervisor for public health training.	2007	
Alexia Tonnel	Director Evidence Resources	None.		
Catherine Wilkinson	Acting Director Business Planning & Resources	Trustee, Age UK, Lancashire.	2018	

NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Public Board Meeting held on 25 March 2020
Via Zoom

Unconfirmed

These notes are a summary record of the main points discussed at the meeting and the decisions made. They are not intended to provide a verbatim record of the Board's discussion. The agenda and the full documents considered are available in accordance with the NICE Publication Scheme.

Board members present

Professor Tim Irish	Interim Chair
Professor Sheena Asthana	Non-Executive Director
Professor Martin Cowie	Non-Executive Director
Dr Rima Makarem	Non-Executive Director
Tom Wright	Non-Executive Director
Sir Andrew Dillon	Chief Executive
Professor Gillian Leng	Health and Social Care Director and Deputy Chief Executive
Alexia Tonnel	Evidence Resources Director

Directors in attendance

Meindert Boysen	Centre for Health Technology Evaluation Director
Paul Chrisp	Centre for Guidelines Director
Jane Gizbert	Communications Director
Catherine Wilkinson	Acting Business Planning and Resources Director

In attendance

David Coombs	Associate Director – Corporate Office (minutes)
Leighton Coombs	Senior Programme Analyst – Health and Social Care (for 20/029)
Fiona Glen	Programme Director – Centre for Guidelines (for 20/030)
Adrian Jonas	Associate Director – Data and Analytics (for 20/028)
Grace Marguerie	Associate Director – Human Resources (for 20/030)
Mark Salmon	Programme Director – Information Resources (for 20/028)

20/019 APOLOGIES FOR ABSENCE

1. Apologies were received from Elaine Inglesby-Burke.

20/020 EXCLUSION OF THE PRESS AND PUBLIC

2. Tim Irish welcomed the Board to the meeting which for the first time was taking place through Zoom web-conferencing. Due to the rapidly evolving situation with coronavirus it had not been possible to provide the opportunity for the public to observe the meeting.

3. The Board noted the unprecedented circumstances and challenges, and agreed to proceed with the meeting without the press and public present.

20/021 DECLARATIONS OF INTEREST

4. The previously declared interests recorded on the register were noted, and it was confirmed there were no conflicts of interest relevant to the meeting.

20/022 MINUTES OF THE LAST MEETING

5. The minutes of the Board meeting held on 29 January 2020 were agreed as a correct record.

20/023 MATTERS ARISING

6. The Board reviewed the actions arising from the public Board meeting held on 29 January 2020 and noted that:

   - Feedback on the Field Team's activities in Wales will be brought to the Board as requested, but later than the timescale suggested at the last meeting due to coronavirus.
   - The colour scheme in the impact report has been amended in line with the Board's feedback.
   - The Principles have been published.
   - The approach to engaging with stakeholders about the proposed changes to the prioritisation of the guidelines programme is outlined in a report to be discussed later in the meeting.
   - Following testing of different models, the Senior Management Team (SMT) decided to buy two models of laptop for staff. The standard model, for the majority of staff, has a range of features to support collaborative working, while a more powerful model will be purchased for a small number of staff who require a machine with greater processing power. Once there is greater clarity on the delivery timescale the arrangements for storing and building the laptops during the office closure will be considered.

20/024 CHIEF EXECUTIVE'S REPORT

7. Andrew Dillon presented his final Chief Executive's report which provided an update on the main programme activities and a summary of the financial position at the end of February 2020. Andrew offered his congratulations to Gill Leng and Sharmila Nebhrajani on their appointments as Chief Executive and Chair respectively.

8. Andrew briefed the Board on the actions that the Senior Management Team (SMT) were taking in response to the coronavirus (COVID-19) pandemic. The Institute had moved to home working with effect from 20 March and the two offices had been closed until further notice. A decision had been taken to focus activity on therapeutically critical topics, including cancer and on new commissions from NHS England/Improvement on the management of patients suspected of having or who have been diagnosed with COVID-19 in inpatient settings. The first of this guidance had been published on 21 March and would be followed by a further 3 topics each week, until further notice. In addition, evidence reviews were being conducted on COVID-19 related treatments. He noted that as a result of the disruption to current and planned activities caused by coronavirus, it was not possible to submit the 2020/21 business plan to this meeting as planned. It will be necessary to review the key business objectives and programme outputs and bring a revised plan to the Board.

9. Catherine Wilkinson updated the Board on the production of the annual report and accounts. If the planned tasks can be completed in the next 3 weeks, then the accounts could potentially be produced to the usual deadline. However, it is likely that the laying of annual reports and accounts before Parliament will be deferred until after the summer recess.

10. The Board received the report.

20/025 RESOURCES REPORT

11. Catherine Wilkinson presented the report which outlined the financial position at February 2020, provided an update on workforce developments, and included the statutory reporting on the gender pay gap. At the time of writing the report there was a £1.7m underspend which was forecast to reduce to £1.3m at the year-end. However, as a result of the disruption from coronavirus the underspend is now likely to be nearer £2m due to lower than planned spend on the laptops in 2019/20 and reduced travel and subsistence. The budgets for 2020/21 will be reviewed in light of the disruption from coronavirus and it is likely to be a challenging year financially due to under-recovery of technology appraisal income and potential cost pressures arising from a delay to the London office move. Catherine highlighted the workforce update, including the statutory reporting on the gender pay gap.

12. It was noted that the median gender pay gap had reduced to 1.5% at 31 March 2019, but the mean pay gap increased to 7.9%. Catherine stated that the finance and HR teams have explored this issue but have been unable to conclusively identify the reason for the divergent trends.

13. The Board received the report.

20/026 CENTRE FOR HEALTH TECHNOLOGY EVALUATION TOPIC SELECTION

14. Meindert Boysen presented the paper that set out proposed changes to the topic selection processes for guidance produced by the Centre for Health Technology Evaluation (CHTE). In summary, the proposals seek to consolidate existing eligibility, selection, and routing criteria to improve clarity; align decision making and stakeholder engagement processes to improve efficiency; and better describe governance arrangements to improve accountability and transparency. Meindert noted that the Board may wish to consider deferring the planned consultation on the proposals in line with the decision to limit NICE's outputs during the coronavirus pandemic.

15. Meindert highlighted that the criteria used to decide whether a technology should be routed to either the highly specialised technologies programme or technology appraisals programme are still under review and will be subject to consultation at a later date.

16. The Board discussed and supported the proposals. Given topic selection is a sensitive issue, it was agreed that the proposals would benefit from a robust consultation and engagement with stakeholders. As such, it was agreed that the planned initial 6 week consultation should be delayed. In the interim it was agreed that the topic selection oversight panel (TSOP) should be established and start work in line with the terms of reference in the paper. Prior to the consultation, it was agreed that planning for the changes should continue, so these could be implemented in a timely manner if the feedback from the consultation is positive. In addition, it was agreed that it would be helpful to test the proposed new topic selection criteria on a range of technologies to see whether this would lead to different outcomes to the current criteria.

ACTION: Meindert Boysen

20/027 NICE GUIDELINES PROGRAMME: PRIORITISATION OF ACTIVITIES

17. Paul Chrisp presented the paper that provided an update on the initial engagement on the proposed approach to prioritisation of activities in the guidelines programme. He noted the significant change in context due to coronavirus since the paper was produced, which has highlighted the importance of prioritising NICE's work programme. The pandemic will also delay the engagement with key national stakeholders.

18. The Board discussed the proposed principles for assessing the priority areas for new guideline development and updates to existing guidelines. It was suggested that the principles for prioritisation could be too broad and may need to be refined in order to enable sufficient prioritisation between topics. It was agreed that the need for a quality standard should be removed from the prioritisation principles, and the approach for prioritising areas for quality standards should be considered separately. It was noted that this work would de-prioritise some topics and so the proposals should be tested through consultation.

19. Subject to these comments, the Board broadly supported the proposals. It was agreed that Paul Chrisp should reflect on the timescale for this work and the approach to consultation on the proposals.

ACTION: Paul Chrisp

20/028 WIDENING THE EVIDENCE BASE: THE USE OF BROADER DATA AND APPLIED ANALYTICS IN NICE'S WORK

20. Gill Leng presented the paper that set out the next steps to implement the aims of the statement of intent regarding the appropriate use of data analytics across NICE including development of a data and analytics standards framework.

21. The Board reviewed the report and welcomed the activities undertaken. It was suggested that it would be helpful to acknowledge the risks of using data that had not been generated from randomised control trials, and to look back and evaluate decisions made using such data in order to identify any learning for future analytics.

22. The Board supported the planned next steps for the data and analytics transformation programme including the development of a standards framework setting out best practice in conducting analyses as the first output from the planned data and analytics methods and standards programme.

20/029 IMPACT REPORT: CHILDREN AND YOUNG PEOPLE'S HEALTHCARE

23. Gill Leng presented the impact report on how NICE's evidence-based guidance contributes to improvements in children and young people's healthcare. As usual with these reports, there is a mixed picture in terms of successes and areas for further improvement. Positive trends include the reduction in antibiotic prescribing to children, young people and adults in primary care; and fewer children and young people with asthma, diabetes or epilepsy admitted to hospital in an emergency. Areas for improvement include further increasing the proportion of children and young people with a learning disability who have a health check, and completing sepsis risk assessments in emergency departments.

24. The Board noted and welcomed the report.

20/030 EQUALITY OBJECTIVES

25. Catherine Wilkinson presented the paper that set out proposed equality objectives for 2020 to 2024. There has been some positive progress with the current objectives, which seek to increase the proportion of applicants for committee roles from people from Black, Asian and minority ethnic groups, and to increase the proportion of staff in senior roles from these groups. The SMT propose retaining these as objectives but with refocused language, alongside a new objective around the way equality issues are identified and considered in guidance development.

26. Board members supported these objectives but expressed concerns about the way they were presented in the report, which could inadvertently indicate the objectives arise from an external requirement rather than a commitment from the organisation. In addition, it was felt that the objectives were too narrowly focused and should take account of other protected characteristics.

27. It was therefore agreed that the SMT should consider further areas for equality objectives and bring these back to the Board alongside the annual equality report. This would provide the opportunity to present the objectives in the context of the wider activities at NICE on equality and diversity outside of the formal equality objectives. In addition to the 3 objectives already proposed, there should be objectives that relate to other protected characteristics. This would mean objectives would be set slightly longer than the maximum 4 yearly interval, but it was agreed this short delay was justifiable to ensure the right approach to setting objectives.

ACTION: Catherine Wilkinson

20/031 APPOINTMENT OF A COMMITTEE OF A BOARD

28. Andrew Dillon presented the paper that set out a proposal to establish a committee of the Board, comprising all of the Board members, to exercise the Board's powers once the number of Non-Executive Directors (NEDs) falls below the statutory minimum on 1 April 2020. The committee would for all practical purposes operate in the same way as the Board, including meeting in public. It would cease to exist once the new chair is in place and the legally required minimum number of NEDs are in place. The proposal had been developed on the advice of NICE's legal advisers who had reviewed the paper and the committee's terms of reference.

29. The Board agreed to establish the time-limited committee of the Board in line with the terms of reference set out in the Board paper.

ACTION: David Coombs

20/032 AUDIT AND RISK COMMITTEE MINUTES

30. Dr Rima Makarem, chair of the Audit and Risk Committee, presented the unconfirmed minutes of the committee's meeting on 22 January 2020. She noted that since the meeting was held, implementation of IFRS 16 has been deferred.

31. Catherine Wilkinson advised the Board that contingency arrangements for the likely delay to the London office move are being considered, and the need to include provisions in the 2019/20 accounts for these cost pressures will be discussed with the external auditors shortly. Gill Leng confirmed that NICE's risk register will be substantially reviewed in light of coronavirus.

32. The Board received the unconfirmed minutes.

20/033 DIRECTOR'S REPORT FOR CONSIDERATION

33. Meindert Boysen presented the update from the Centre for Health Technology Evaluation. He noted that the report was produced prior to the coronavirus pandemic and stated that the resulting prioritisation of NICE's guidance activities will help mitigate the capacity issues in the technology appraisals programme in the short term. There remains a need however to look at the actions required to ensure the Centre can deliver the commitments for technology appraisals in the 2019 voluntary scheme for branded medicines pricing and access in the medium to long term. Meindert highlighted a range of other activities underway across the Centre, including the work on commercial and managed access and the pilot evaluation of digital health technologies. He noted that the timetable for the methods review will be reconsidered in light of the coronavirus pandemic.

34. The Board noted the report and thanked Meindert for the centre's work.

20/034 – 20/037 DIRECTORS' REPORTS FOR INFORMATION

35. The Board discussed the increased number of HM Coroner's regulation 28 reports sent to NICE, as referenced in the Communications Directorate report. It was noted that NICE's patient safety lead, Professor Kevin Harris, is involved in preparing NICE's response to each report and it was agreed that the Chief Executive's report to the Board would in future highlight any significant action for NICE arising from these reports.

ACTION: Gill Leng

36. Gill Leng highlighted the changes in the Health and Social Care Directorate from 1 April 2020, when Judith Richardson will become Acting Health and Social Care Director and Interim Responsible Officer for Revalidation.

37. The Board received the Directors' Reports.

20/038 A SHORT STATEMENT FROM THE CHIEF EXECUTIVE

38. Tim Irish repeated his comments at Andrew Dillon's leaving event in February and paid tribute to Andrew's character which has defined NICE. On behalf of SMT, Gill paid tribute to Andrew and stated he will be greatly missed.

39. Andrew responded by stating how it has been privilege and pleasure to work at NICE. He thanked Board colleagues for their advice, support and friendship over the years and in particular thanked Gill Leng for her support.

20/039 ANY OTHER BUSINESS

40. Tim Irish noted this was Sheena Asthana's last Board meeting, and on behalf of the Board, thanked Sheena for her contribution to NICE.

NEXT MEETING

41. The next public meeting of the Board will be held on 20 May 2020 at 1.30pm. The meeting arrangements are to be confirmed in light of the coronavirus pandemic.

National Institute for Health and Care Excellence

Chief Executive's report

This report provides information on the outputs from our main programmes for the 12 months to the end of March 2020 together with comment on other matters of interest to the Board.

The Board is asked to note the report, in particular unprecedented context related to the COVID-19 pandemic.

Professor Gill Leng
Chief Executive
May 2020

Introduction

1. This report sets out the performance of the Institute against our business plan objectives and other priorities for the 12 months to the end of March 2020. The report notes the guidance published since the last public Board meeting in March and refers to business issues not covered elsewhere on the Board agenda.

Impact of COVID-19

2. As reported to the Board at its last meeting, the organisation moved to full home-working on March 20th in line with Government guidance. We are expecting this to continue for at least another 3 months, and we will keep this under review. I am really pleased at how well the staff have adapted to this new way of working, although it is clearly not ideal and can be very challenging when compounded by caring responsibilities.

3. As the pandemic began to impact on the health and care system in March, we took a decision to only publish therapeutically critical topics and COVID-related outputs. The resultant publication of a series of rapid guidelines in COVID-19 related topic areas was extremely well received, and the teams involved are to be commended for their flexible and adaptable working. We are also supporting the development and implementation of the Research to Access Pathway for Investigational Drugs in COVID-19 (RAPID-C19), a multi-agency initiative to ensure safe and timely patient access to medicines useful in treating patients with COVID-19 infection, as well as testing implementation activities for NHSE/I.

4. As the pressure on the system lessens, we will begin to increase our output and restart committees that have paused. We are planning for all committees to be held virtually, and are prioritising guideline topics to consider which will best support the system. We're also looking at whether new processes will help move the work forward more quickly in the context of ongoing capacity constraints. We will take the opportunity to promote already published guidance that will be useful as the healthcare system starts to build up capacity in non-COVID services, such as in mental health and in vulnerable populations.

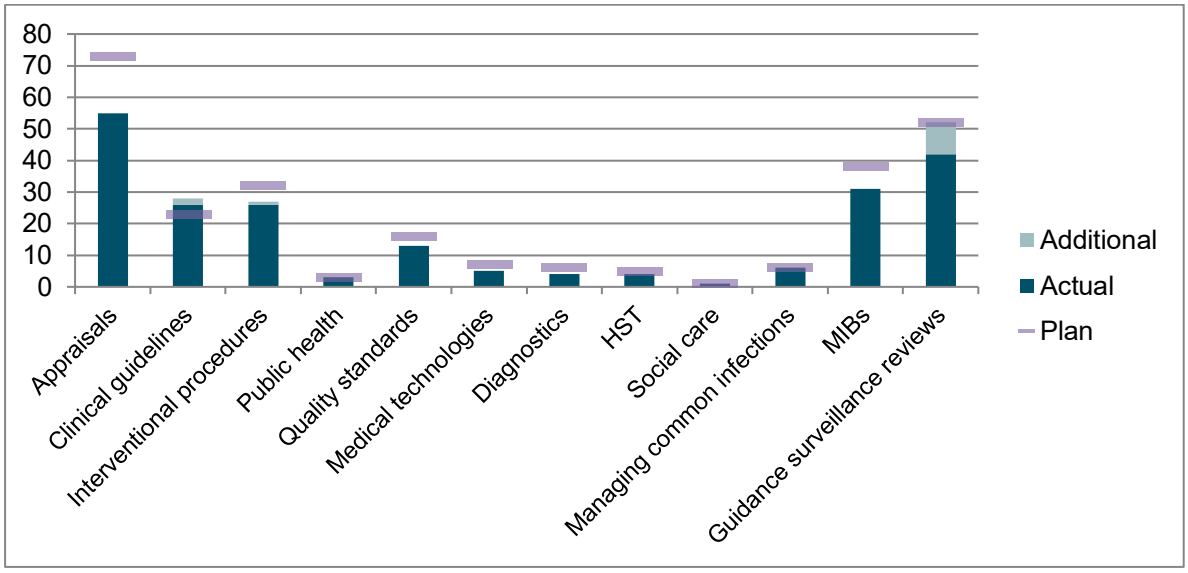
5. Further detail on NICE's response to COVID-19 is given in the Directors' progress reports.

Performance

6. The current position against the objectives in our 2019/20 business plan is set out in Appendix 1.

7. Extracts from the Directors' reports, which refer to particular issues of interest, are set out at Appendix 2. The performance of the main programmes between April 2019 and March 2020 is set out in Chart 1.

Chart 1: Main programme outputs: April 2019 to March 2020



download the data set for this chart

Notes to Chart 1:

a) HST refers to the highly specialised technologies programme (drugs for very rare conditions)
b) MIBs (medtech innovation briefings) are reviews of new medical devices
c) Guidance surveillance reviews provide the basis for decisions about whether to update current NICE guidance
d) The variance is the difference between the target output for the reporting period, as set out in the business plan and the actual performance
e) 'Additional' topics are either those which should have published in the previous financial year, or that have been added since the publication of the business plan

8. Details of the variance against plan are set out at Appendix 3. Guidance, quality standards and other advice published since the last Board meeting in March is set out Appendix 4.

Notable issues and developments

Financial Performance

9. NICE's total operating expenditure was £68.7m for the financial year ending 31 March 2020. Our total funding for the year was £69.1m, received from the Department of Health and Social Care and other income sources, including fees for technology appraisals and from the devolved administrations.

10. The net variance was £0.4m underspend against budget. This satisfies our statutory duty to breakeven or better. Further details on the financial position for 2019/20 are provided in the resources report.

Response to coroners' reports

11. Since the last Board meeting, NICE has responded to one Coroner's report. The report stated that publication of NICE guidance on acute behavioural disturbance (ABD) would be of vital benefit in preventing future deaths. There is no current NICE guidance dealing specifically with ABD, and the number of deaths from ABD is rising.

12. In response, we have noted these concerns for the forthcoming update of the guideline on short-term management of violence and aggression in a range of settings (NG10). We will consider whether issues related to ABD can be included in an expanded scope.

NICE Connect programme

13. We have reprioritised our Connect core deliverables for 2020/21 as a result of the disruption caused by COVID-19, and these are presented in the updated NICE 2020/21 business plan. Because the COVID-19 work has prompted changes to our internal processes and a drive to use new technologies, the priorities for 2020/21 now reflect internal efficiencies rather than an external presentation.

14. A new project manager joined the transformation unit in April, from within NICE. Recruitment is also underway for an Associate Director - Transformation to support the NICE Connect programme director in driving forward the programme. This is expected to be filled by the end of the month.

NICE Scientific Advice & NICE International

15. 2019/20 was a successful year for NICE Scientific Advice & NICE International, with the team exceeding its financial targets and making a full contribution to the NICE overheads. There were several notable achievements including: the design and launch of a new concurrent advice procedure in April to allow companies to seek advice from NICE alongside existing routes with the EMA and EUnetHTA; the commencement of the NICE DataLab support offer for the winners of the latest round of Innovate UK's Digital Health Technology Catalyst in September; and the re-launch of NICE International in November.

16. The team also co-developed the new LSE-NICE Executive MSc in the Evaluation of Health Care Interventions and Outcomes due to launch later in 2020, played a key role in the on-going antimicrobial resistance work being done in collaboration

with system partners and has recently launched a free protocol review service for developers of therapeutics and diagnostics for combating COVID-19.

17. NICE International delivered a total of 60 international engagements, including 32 that were fee-based and 28 that were delivered for business development or strategic purposes. In October 2019 and March 2020, NICE International delivered workshops on Health Technology Assessment to government health authorities and relevant healthcare stakeholders in 7 different countries in Latin America (Uruguay, Brazil, Colombia, Mexico, Panama, Costa Rica and the Dominican Republic). The NICE International team is listed as a Strategic Partner for the Prosperity Fund Better Health Programme led by the Foreign and Commonwealth Office (FCO) where NICE is providing support to the programme at both a strategic and technical level.

Science Policy and Research

18. To keep improving how NICE works and to anticipate and adapt to changes in health and social care delivery, the Science Policy & Research (SP&R) team has continued to build on their portfolio of grant-funded projects in 2019/20 to enable NICE to undertake methods research. They have secured a further two new projects, funded by the Innovative Medicines Initiative (IMI). These are:

    - ERA4TB (European Accelerator of Tuberculosis Regime) – a 6-year project in which NICE will act as an interface with key stakeholders, mainly HTAs, regulatory authorities and patients, to maximise uptake and impact of ERA4TB's results. The project activity will complement NICE's ongoing work in the area of antimicrobial resistance.
    - HARMONY PLUS – a 3-year project will run concurrently with the existing HARMONY (Healthcare Alliance for Resourceful Medicine Offensive against Neoplasms in Haematology) project. NICE's role will be to develop guidance and decision tools to identify appropriate procedures and resources for Regulatory/HTA/Payers engagement.

19. So that NICE's research needs are recognised, and to ensure relevant research is prioritised, the team has advised funding panels at the Medical Research Council (MRC) and the Department for Health and Social Care R&D Committee. We also liaised with the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC), who actively review all NICE research recommendations as a key source of relevant research topics and, where appropriate, commission research to answer the research recommendations within the remit of its funding programmes. In 2019/20, NETSCC awarded funding to 3 projects as a result of the NICE key priority arrangement.

EUnetHTA project

20. May 2019-May 2020 was going to be the final year for the EUnetHTA JA3. However, in 2019 the joint action was extended for 1 year to claim unspent funds. During the extension NICE will continue its commitment to EUnetHTA activities.

21. The team continues their work supporting the development of a future model of HTA cooperation. In the last year the work has included an audit of existing elements of a model of HTA cooperation and identification of gaps and areas for improvement in existing ways of working. The team facilitated in-depth discussion groups to prioritise the areas for improvement and define next steps for addressing these.

Appendix 1: Business objectives for 2019/20 - progress update

The table below provides an update on the delivery of the business objectives in the 2019/20 business plan.

Deliver and support the adoption of accessible, up to date and adaptable advice, fully aligned to the needs of our users	Delivery date	Progress update
• Deliver guidance, standards, indicators and evidence products and services, in accordance with the schedule set out in the business plan and the balanced scorecard, including the planned increases in the technology evaluation programmes	• Ongoing	• Details of the main programmes' performance against plan, including explanations for any variances are set out elsewhere in this report.
• Subject to evaluation of the NICE Connect project pilot, develop a business case and programme plans for the next phase of the project	• End of Q3	• Prioritising guidelines activities continues, having been impacted by the re-prioritisation of activities to support rapid COVID guideline development and maintenance. There is support from guideline commissioners (DHSC, NHS England) and Public Health England to have a portfolio more focused on system priorities.
• Subject to evaluation of the NICE Connect project pilot, develop a business case and programme plans for the next phase of the project	• End of Q3	• A NICE Connect business plan has been developed for 2020/21. The focus of the plan is on operational productivity and internal efficiency improvements.
• Undertake a review of the topic selection arrangements for the HST programme and methods guides for the technology evaluation programmes	• End of Q4	• In progress.
• Undertake a review of the topic selection arrangements for the HST programme and methods guides for the technology evaluation programmes	• End of Q4	• Work on the review of processes and methods for the technology evaluation programmes has progressed well in 2019/20. COVID-19 has resulted in a change to the development timelines for

		2020/21. Stakeholders have been informed of the change. No objections have been received to date and some are welcoming the opportunity for increased time for input.
• Review and update the guidelines methods and process manual to determine the optimal development path and timeline for guideline development in the context of the NICE Connect project	• End of Q4	• Work is ongoing with other NICE teams and external guideline developers to identify priority areas for update to the methods and process manual. This will be reflected in the Connect methods, process and analytics expert group.
• Review and update the guidelines methods and process manual to determine the optimal development path and timeline for guideline development in the context of the NICE Connect project	• End of Q4	• The expert group includes workstreams on prescribing pathways, surveillance and wording of recommendations.
• Maintain and monitor performance of NICE Evidence Services (CKS, HDAS, BNF microsites, Evidence Search, Medicines Awareness Service), with investment in new features on a strictly needed basis	• Ongoing	• Negotiations were successfully concluded for a new three-year England-wide licence to access the Cochrane library when the current licence ends in April 2020.
• Maintain and monitor performance of NICE Evidence Services (CKS, HDAS, BNF microsites, Evidence Search, Medicines Awareness Service), with investment in new features on a strictly needed basis	• Ongoing	• In recent months the team has worked to ensure our commissioned evidence services such as Clinical Knowledge Summaries, our daily and weekly Medicines Awareness Services and NICE Evidence Search fully reflect NICE guidance on COVID-19 and we have used relationships with publishers and key partners, such as Health Education England, to ensure NICE guidance on COVID-19 is made as widely available to the system as possible.
• Enable access to the new national core content and procure any additional content in line with Health Education England's (HEE) commissioning decisions	• Q1	• Complete.

• Enable access to the new national core content and procure any additional content in line with Health Education England's (HEE) commissioning decisions	• Q1	• We have agreed a 2-year contract extension for the Identity Provider and Access Management Federation (OpenAthens) contract until May 2022.
• Support shared decision making within NICE through delivery of commitments in the action plan of the Shared Decision-Making Collaborative	• Ongoing	• We will be updating the NICE shared decision-making webpages and resources to take account of current work.
• Deliver a range of tools and support for the uptake of NICE guidance and standards, including adoption support products, endorsement statements, and shared learning examples	• Ongoing	• Tools and support have been delivered as planned.
• Deliver a range of tools and support for the uptake of NICE guidance and standards, including adoption support products, endorsement statements, and shared learning examples	• Ongoing	• Adoption support products have been refreshed as part of the ongoing offering to the Accelerated Access Collaborative.
• Evaluate the most effective social and multimedia channels currently used to promote NICE's work	• Ongoing	• This work was paused because of re-prioritisation of our work during COVID-19. It will resume and report in Q3 2020/21.
• Evaluate the scope to improve the recruitment and retention of advisory committee members	• End of Q2	• New digital platforms have been used to promote opportunities for committee members, and ways of being more proactive about recruitment are being explored in CHTE.

Play an active, influential role in the national stewardship of the health and care system	**Delivery date**	**Progress update**
• Work with NHS England and other health and care system partners to support the implementation of the NHS long term plan	• Ongoing	• We have mapped areas of NICE's work to the implementation arrangements for the Long-Term Plan (LTP) and are working with NHS England to ensure NICE guidance is appropriately reflected. However the

		national LTP implementation plan has been delayed until autumn.
• Explore with NHS England the options for a digital health technology evaluation workstream, building on the Evidence for Effectiveness standards	• End of Q2	• In progress.
• Explore with NHS England the options for a digital health technology evaluation workstream, building on the Evidence for Effectiveness standards	• End of Q2	• One of the four apps identified as pilot topic, Zio ® XT, a continuously recording, wire-free heart monitor, was considered by the Medical Technologies Advisory Committee in February.
• Explore with NHS England the options for a digital health technology evaluation workstream, building on the Evidence for Effectiveness standards	• End of Q2	• Two of the other pilot technologies were identified as suitable for Medtech Innovation Briefings relevant to the COVID-19 pandemic because they support social distancing in healthcare delivery.
• Explore with NHS England the options for a digital health technology evaluation workstream, building on the Evidence for Effectiveness standards	• End of Q2	• A report describing the learning from the pilot will be considered by the steering group chaired by NICE, with NHSX as a key sponsor.
• Subject to the UK's EU exit arrangements, design and put in place changes to our current technology appraisal process in order to secure consistency with UK regulatory arrangements	• End of Q2	• In progress.
• Subject to the UK's EU exit arrangements, design and put in place changes to our current technology appraisal process in order to secure consistency with UK regulatory arrangements	• End of Q2	• Joint development work on aligning publication timelines for NICE guidance with options for the Medicines and Healthcare products Regulatory Agency (MHRA)'s regulatory timelines to maintain timely patient access to effective new medicines and technologies, has progressed well.

• Subject to the UK's EU exit arrangements, design and put in place changes to our current technology appraisal process in order to secure consistency with UK regulatory arrangements	• End of Q2	• The combined impact of exiting the EU and impending changes to European device regulations on NICE's guidance recommendations for medical devices and diagnostics is being closely monitored.
• Commission a bi-annual NICE reputation research project to assess our key stakeholders' views of NICE and our work, and conduct specific and targeted audience research on key issues that contribute to meeting corporate business objectives and implementation of NICE guidance	• End of Q2	• The reputation research project is complete.
• Commission a bi-annual NICE reputation research project to assess our key stakeholders' views of NICE and our work, and conduct specific and targeted audience research on key issues that contribute to meeting corporate business objectives and implementation of NICE guidance	• End of Q2	• The first stage of our implementation study to explore stakeholder expectations of our implementation offer is nearing completion. We have carried out strategic interviews with key internal stakeholders and external partners at national organisations and are currently identifying the emerging themes. We have paused the next phase which requires face to face work with stakeholders but hope to continue the project later in the year.
• Commission a bi-annual NICE reputation research project to assess our key stakeholders' views of NICE and our work, and conduct specific and targeted audience research on key issues that contribute to meeting corporate business objectives and implementation of NICE guidance	• End of Q2	• A survey has been designed to capture feedback on our rapid guidelines to inform future ways of working and NICE Connect. It is anticipated that this will be part of a wider research project to evaluate the rapid guidelines and our future approach once we resume routine guidance development
• Deliver a suite of activities to mark NICE's 20th anniversary	• End of Q1	• Complete.

Take advantage of new data sources and digital technologies in developing and delivering our advice	Delivery date	Progress update
• Develop and establish a long term data analytics strategy for NICE together with a framework for the appropriate use of data analytics across NICE's programmes, and facilitating a national leadership in the field	• End of Q3	• Over the last two months, the work of the team has focused on supporting the COVID effort. The team is accelerating work to develop a (simplified) standards and methods framework for broader use of data in the development of rapid COVID-19 guidance to ensure the evidence base and analysis fully utilises the wide range of emerging coronavirus data sources and is fit-for purpose.
• Develop and establish a long term data analytics strategy for NICE together with a framework for the appropriate use of data analytics across NICE's programmes, and facilitating a national leadership in the field	• End of Q3	• The team also developed an extension to NICE's existing data catalogue to cover COVID-19 and now has oversight of the monitoring of external COVID-19 data and analytic initiatives.
• Identify digital investment priorities, and their sequencing, to align with the NICE Connect project transformation work, reviewing the roadmap quarterly	• Ongoing	• We have completed work with a strategic partner to support the development of digital workplace strategy enabled by the roll out of Office 365 including an information and records management strategy. The pace of delivery has mostly been maintained despite the remote working arrangements under COVID-19.
• Identify digital investment priorities, and their sequencing, to align with the NICE Connect project transformation work, reviewing the roadmap quarterly	• Ongoing	• Components of the digital workplace strategy have been brought forward by the coronavirus context. A pared down roll-out of MS Teams and training was initiated early to facilitate remote working across NICE. Office 365 applications are being trialled and tested where appropriate to support

		initiatives such as the 'Skills marketplace' to enable capacity and skills available and required due to remote working to be matched. Alongside Office 365, the DS and Information Governance teams supported the rapid roll-out of Zoom across NICE.
• Identify digital investment priorities, and their sequencing, to align with the NICE Connect project transformation work, reviewing the roadmap quarterly	• Ongoing	• Planning for a transition from our current managed IT service provider continues but the contract end date has been moved to end March 2021.
• Identify digital investment priorities, and their sequencing, to align with the NICE Connect project transformation work, reviewing the roadmap quarterly	• Ongoing	• Progress has continued on a range of digital services projects including work on our evidence management platform, our identify management solution, our existing pathways site.
• Manage and maintain the live digital services of NICE utilising user insight and strategic service goals to prioritise use of resource	• Ongoing	• Usual activity of defect resolution and responding to change requests continues.

Generate and manage effectively the resources needed to maintain our offer to the health and care system	**Delivery date**	**Progress update**
• Deliver performance against plan for all budgets and achieve or exceed on non-Grant-in-Aid income targets	• End of March 2020	• We will deliver a grant-in-aid underspend which means that we expect to remain within the tolerance agreed with DHSC for the transition year to the full cost recovery for technology appraisal and highly specialised technologies.
• Deliver performance against plan for all budgets and achieve or exceed on non-Grant-in-Aid income targets	• End of March 2020	• Both NICE Scientific Advice (NSA) & NICE International (NI) exceeded their financial targets and made a full contribution to the NICE overheads, delivering 73 and 32 paid engagements respectively. The NSA/NI

		team has had several other notable achievements including: the design and launch of a new concurrent advice procedure and the commencement of the NICE DataLab support offer for the winners of Innovate UK's Digital Health Technology Catalyst. The team has also co-developed the new LSE-NICE Executive MSc in the Evaluation of Health Care Interventions and Outcomes due to launch later in 2020, played a key role in the ongoing antimicrobial resistance work being done in collaboration with system partners and has recently launched a free protocol review service for developers of therapeutics and diagnostics for combating COVID-19.
• Introduce charging for technology appraisal and highly specialised technologies and recover the target income for 2019/20	• From 1 April 2019	• As above: charging systems are now fully operational. Income is below budget at the end of the financial year, primarily as a result of the current COVID-19 situation and a review of accounting treatment.
• Deliver existing grant funded research projects to plan and timetable and secure a pipeline of new projects for 2020/21	• End of March 2020	• Science Policy and Research income achieved target in 2019/20. Several projects extend to future years (some to 2023), with funding for the next 2 years secured at comparable levels to 2019/20. Existing projects are being delivered to plan.
• Promote our capacity for knowledge sharing with international organisations interested in NICE's expertise and experience, including the re-use of NICE's published content outside of the UK	• Ongoing	• Of the fee-based engagements delivered by the NICE International team, 20 involved delivering bespoke educational seminars/workshops with international

		stakeholders and 8 involved providing consultancy services.
• Promote our capacity for knowledge sharing with international organisations interested in NICE's expertise and experience, including the re-use of NICE's published content outside of the UK	• Ongoing	• For the whole of 2019/20, the team responded to 303 domestic and international requests to re-use NICE content. Forty-nine content licences and five syndication licences were signed. The total income invoiced in the year was £117,618 against an income target of £75,000.

Support the UK's ambition to enhance its position as a global life sciences destination	**Delivery date**	**Progress update**
• Make preparations to implement the commitments of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access related to NICE so that (i) all new active substances and drugs with significant licence extensions will be appraised, except where there is a clear rationale not to do so, by April 2020; (ii) NICE is able to publish recommendations on non-cancer drugs within 90 days of licensing to match the timescales for cancer drugs (ongoing)	• End of Q4/on-going	• Preparations were made to expand the technology appraisal programme in response to increase in demand resulting from the 2019 Voluntary Scheme, including a recruitment drive for technical and project management staff.
• Make preparations to implement the commitments of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access related to NICE so that (i) all new active substances and drugs with significant licence extensions will be appraised, except where there is a clear rationale not to do so, by April 2020; (ii) NICE is able to publish recommendations on non-cancer drugs within 90 days of licensing to match the timescales for cancer drugs (ongoing)	• End of Q4/on-going	• Capacity constraints in the technology appraisal programme as a result of lower than expected adoption of the opportunities provided in the new 'technical engagement process', challenges in aligning the appraisal process with arrangements for commercial and managed access, and a high vacancy rate have meant that for a number of topics NICE cannot guarantee a second or subsequent committee meeting within a timeframe that might otherwise

		have been expected, impacting the ability to publish timely guidance.
• Deliver the actions set out for NICE in the Government's Life Sciences Sector Deals and significantly increase the number of evaluations of these health tech products conducted, giving greater scope for considering different types of innovation, including digital products.	• Ongoing	• Confirmation has been received from the DHSC that the expansion of the Medical Technologies and Diagnostics programmes will be funded. Recruitment to the newly created posts has started.
• Deliver the actions set out for NICE in the Government's Life Sciences Sector Deals and significantly increase the number of evaluations of these health tech products conducted, giving greater scope for considering different types of innovation, including digital products.	• Ongoing	• Work on the development of the Innovator Portal has started, with NICE as a key partner to ensure that the HealthTech Connect offer continues to align with overall ambitions of the Accelerated Access Collaborative.
• Prepare a final case for establishing a not for profit organisation delivering fee for service advisory and educational programmes, aligned to NICE's public task	• End of Q3	• The Board agreed in June 2019 that the original proposal was not viable and to stand down planning for the proposed entity.

Maintain a motivated, well-led and adaptable workforce	**Delivery date**	**Progress update**
• Ensure that all staff have clear objectives supported by personal development plans	• End of Q1	• Each directorate has an individual business plan and that is cascaded into individual objectives which links to the annual appraisal and informs personal development plans.
• Actively manage staff engagement and morale with the objective of ensuring that the global job satisfaction index in the annual staff survey is maintained or improved from its 2018 level	• End of Q1	• The annual staff survey achieved our highest-ever completion rate of 85%. The proportion of staff who consider NICE is a good, very good or excellent place to work remained consistent with the previous year's result at 94%. The results and organisational action plan were presented to the Board at its September meeting. The

		next staff survey will be deferred to September 2020 because regular 'pulse' surveys are being carried out to assess the impact of COVID-19 home-working.
• Implement the actions set out in the workforce strategy, including mapping out career paths for key roles, including increasing opportunities for apprenticeships, and defining the behaviours expected of a manager at NICE	• End of Q2	• We have introduced leadership and management apprenticeships at levels 3, 5 and 7 (MBA level) and are developing graduate opportunities in a range of areas. • We will be introducing organisational values and behaviours for managers in the coming months.
• Work with the Department of Health and Social Care to secure the future London office accommodation, and begin planning for the move to take place in the summer of 2020	• End of Q3	• Planning for the move to Stratford in November 2020 is progressing. The project is complex as 5 ALBs are sharing the floorplate. A project consultant and project management resource have developed a governance structure, RAID log, project board and working groups.
• Work with the Department of Health and Social Care to secure the future London office accommodation, and begin planning for the move to take place in the summer of 2020	• End of Q3	• We are currently working through shared IT and facilities solutions and some residual floor plate design issues.
• Develop and implement a programme of improvements for the Manchester office to ensure best use of the space available	• End of Q2	• Space planning services have been engaged and staff consulted. A proposal has been developed and, subject to funding, work will commence in 2020/21 on some areas of the Manchester office. A review of the meeting rooms and office space will be conducted in light of changing business needs as a result of new virtual working arrangements.

Appendix 2: Extracts from the Directors' reports

Director	Featured section	Section/ reference
Business Planning and Resources	Our Health and Wellbeing Group has held fortnightly meetings directly relating to the switch to homeworking. We have responded to feedback from our staff (received directly and through pulse surveys) and have developed a suite of homeworking tips in collaboration with our permanent homeworking staff.	Paragraph 55
Centre for Guidelines	We developed an interim process and methods for developing rapid guidelines on COVID-19. Topics were referred by NHS England and selected according to a set of priority criteria. The programme began on 13 March and by 31 March we had published four rapid COVID-19 guidelines. The process involved close working with clinical experts, with a targeted consultation and a quality assurance step.	Paragraph 3
Centre for Health Technology Evaluation	The diagnostic assessment team is supporting Public Health England with their evaluation of home antibody tests, and is developing evidence standards for COVID-19 tests (both antigen and antibody). The team is also supporting a review of biomarker guided antibiotic discontinuation in COVID-19 patients.	Paragraph 4
Communications	The publication of each wave of COVID-19 rapid guidelines was supported with regular and timely stakeholder communications. We expanded our stakeholder lists and adapted our normal monthly NICE News and Update for Primary Care newsletters to update 42,820 subscribers each time a guideline was published. We issued 6 such newsletters announcing the publication of new COVID-19 rapid guidelines. The open rates of these newsletters were notably higher than normal, ranging from 25% to 43%. Prior to the COVID-19 crisis we would typically expect a rate of 20-25%.	Paragraphs 15 & 16
Evidence Resources	We are completing work with a strategic partner to support the development of a digital workplace strategy enabled by the roll out of Office 365, including an information and records management strategy. Components of the digital workplace strategy were brought forward by the coronavirus	Paragraph 16

	situation including a paired down roll-out of MS Teams and training to facilitate remote working across NICE.	
Health and Social Care	The Quality in Public Health toolkit launched in March 2020 and is a spreadsheet designed for use principally by public health teams within local government in England as an aid to the implementation of *Quality in Public Health: A Shared Responsibility* and as a part of sector led improvement. It sets out how NICE guidelines and quality standards can support public health teams to improve quality.	Paragraph 18

Appendix 3: Guidance development - variation against plan April 2019 to March 2020

The variation against the business plan is explained below:

Clinical guidelines

2 additional topics published in 2019-20, which were not planned for this financial year:

- Surgical site infections: prevention and treatment: Originally planned for 2018-19. Published April 2019 (Q1 2019-20).
- Suspected neurological conditions: Originally planned for 2018-19. Published May 2019 (Q1 2019-20).

Interventional procedures

6 topics delayed:

- Pressurised intraperitoneal aerosol chemotherapy for peritoneal carcinomatosis: Resolution request received. The IP topic will be re-discussed at Committee. Publication date is to be confirmed.
- Balloon cryoablation for Barrett's oesophagus or squamous dysplasia of the oesophagus: Resolution request received. Next steps to be confirmed. Publication date is to be confirmed.
- Minimally invasive radical hysterectomy for early stage cervical cancer: Timelines extended to allow the consideration of important evidence that has not been published yet. Publication date to be confirmed.
- Insertion of biodegradable balloon for obesity: Timelines extended due to priorities of other IPs. Scheduled to publish during July 2020 (Q2 2020-21).
- Deep brain stimulation for refractory epilepsy: Timelines extended due to priorities of other IPs. Scheduled to publish during May 2020 (Q1 2020-21).
- Artificial iris implant insertion for aniridia: Timelines extended due to COVID-19. Publication date is to be confirmed.

1 additional topic published:

- Fetal surgery for myelomeningocele was split into two pieces of guidance: Open prenatal repair for open neural tube defects in the fetus and Fetoscopic prenatal repair for open neural tube defects in the fetus.

Medical technologies

1 topic withdrawn:

- SpaceOAR hydrogel spacer for reducing rectal toxicity during radiotherapy for prostate cancer: Topic was not suitable for medical technologies guidance. Has been referred to technology appraisals.

1 topic delayed:

- PneuX for preventing ventilator-associated pneumonia in intensive care: Delayed for resolution requests. Published in April 2020 (Q1 2020-21).

Public health

No variation against plan 2019-20.

Quality standards

3 topics delayed:

- Neonatal specialist care (update): Publication suspended in light of changes to NICE's priorities during the COVID-19 pandemic. New anticipated publication date not known.
- Decision-making and mental capacity: Publication suspended in light of changes to NICE's priorities during the COVID-19 pandemic. New anticipated publication date not known.
- Renal stones: Publication suspended in light of changes to NICE's priorities during the COVID-19 pandemic. New anticipated publication date not known.

Diagnostics

2 topics delayed:

- Implantable cardiac monitors (BioMonitor 2-AF, Confirm Rx insertable cardiac monitor and Reveal LINQ Insertable Cardiac Monitoring System) to detect atrial fibrillation after cryptogenic stroke: NICE has adapted its priorities to support the NHS, local authorities and the wider health and social care sector to tackle COVID-19. As NICE will only publish guidance that is therapeutically critical or focused on COVID-19-related issues at this time, the development of this guidance will be paused and publication will be delayed until further notice.
- The ARCHITECT Urine NGAL assay, NephroCheck Test and NGAL Test: NICE has adapted its priorities to support the NHS, local authorities and the wider health and social care sector to tackle COVID-19. As NICE will only publish guidance that is therapeutically critical or focused on COVID-19-related issues at this time, publication of this guidance will be delayed until further notice.

Technology appraisals

19 topics delayed:

- Leukaemia (acute myeloid, FLT3-ITD, relapsed, refractory) - quizartinib [ID1325]: Following an update received from the company, the NICE appraisal committee discussion on Wednesday 2 October 2019 was cancelled and will be rescheduled in due course. NICE will continue to monitor any development and further information regarding the timelines of this appraisal will be available once known.
- Non-small cell lung cancer (squamous) - nivolumab (CDF review TA483) [ID1559]: Topic timelines revised. This topic will now publish in 2020-21.
- Non-small cell lung cancer (non-squamous) - nivolumab (CDF review TA484) [ID1572]: Topic timelines revised. This topic will now publish 2020-21.

- Migraine (chronic, episodic) - fremanezumab [ID1368]: The company, Teva, have asked to submit additional analyses with their response to the appraisal consultation, and this request has been accepted. To allow a review of the evidence, the second appraisal committee meeting was moved to 6 February 2020 therefore publication will now be in 2020-21.
- Acute myeloid leukaemia or myelodysplastic syndrome - Treosulfan [ID1508]: The second appraisal committee meeting was delayed as NICE were unable to publish documentation from the first appraisal committee meeting pending necessary information from the company.
- Urothelial cancer - pembrolizumab (previously treated advanced or metastatic) (CDF Review TA519) [ID1536]: An appeal has been received and will proceed to an oral appeal hearing on 23 June 2020.
- Infection (cardiac implantable electronic devices) - TYRX Absorbable Antibacterial Envelope [ID1440]: The technology appraisal (ID1440) for TYRX Absorbable Antibacterial Envelope for preventing infection from cardiac implantable electronic devices has been suspended. Medtronic have offered a Patient Access Scheme, however, NHS England recently provided feedback that this proposal could not be operationalised. Consequently Medtronic requested NICE to suspend the technology appraisal while other options are explored.
- Sapropterin for treating phenylketonuria [ID1475]: Topic initially suspended in January 2019. Following a challenge to the decision to review sapropterin for treating phenylketonuria through the technology appraisal programme, NICE made the exceptional decision to pause the appraisal at that point and ask the topic selection decision making panel to reconsider whether the topic was suitable for the NICE highly specialised technologies or technology appraisal programme. Topic continued as an TA in August 2019 and was then suspended in October 2019 because BioMarin has withdrawn from the technology appraisal process.
- Abiraterone for treating newly diagnosed metastatic hormone-naive prostate cancer [ID945]: Topic was suspended in 2018/19. NICE are in discussion with the company about the price abiraterone will be available to the NHS for this indication. Once this price is confirmed the appraisal will re-start. Topic restarted in August 2019 with a November committee meeting however the meeting was then rescheduled to January 2020 due to the company submitting additional information. Will now publish in 2020-21.

- Non-bisphosphonates for treating osteoporosis [ID901]: This topic was scheduled to be discussed at the committee meeting on 29 October 2019 however a decision was made not to proceed with the Multiple Technology Appraisal (MTA) at the October meeting. NICE is considering the best way to provide guidance on osteoporosis for the NHS and will be in contact with stakeholders as soon as we have more information. Publication date is to be confirmed.
- Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer [ID1504]: The committee were unable to develop recommendations at the first committee meeting therefore this topic has progressed to 3 separate discussions and is now expected to publish in 2020-21.
- Apalutamide for treating non-metastatic, hormone-relapsed prostate cancer [ID1174]: The company that markets apalutamide has requested a meeting with OMA to determine the feasibility of conducting a molecule rather than indication specific appraisal. NICE will suspend the appraisal until the OMA engagement is complete and the most appropriate route and format to progress with the evidence submission is agreed.
- Constipation (opioid-induced) - naldemedine (Shionogi) [ID1189]: Timelines revised in August 2019 and now expected to publish in 2020-21.
- Anticoagulation - andexanet alfa [ID1101]: The timelines for this appraisal have been revised. NICE have agreed to allow the company additional time to update their submission in response to the Evidence Review Group's clarification questions. Publication date is to be confirmed.
- NTRK fusion-positive solid tumours - entrectinib [ID1512]: Topic awaiting CHMP opinion to proceed with publication of committee decision. Publication date is to be confirmed.
- Non-small cell lung cancer (ROS-1 fusion-positive) - entrectinib [ID1541]: Topic awaiting CHMP opinion to proceed with publication of committee decision. Publication date is to be confirmed.
- Short bowel syndrome - teduglutide [ID885]: The manufacturer of teduglutide has asked NICE to pause this appraisal further to them entering into discussions with NHS England about their value proposition. We have agreed to this. Therefore no appeal or publication will take place at this time.

- Breast cancer (triple negative, unresectable, locally advanced or metastatic, first line with nab-paclitaxel) - atezolizumab [ID1522]: The committee meeting scheduled for 12 November 2019 has been postponed while commercial discussions are ongoing. An update will be provided once we confirm the next steps.
- Avatrombopag for treating thrombocytopenia in people with chronic liver disease needing a planned invasive procedure: COVID-19 non-priority topic. Post appeal stage but not publishing. Publication date is to be confirmed.

13 additional topics published in 2019-20, that were not planned for this financial year, but included in the final actual figure:

- Cabozantinib for previously treated advanced hepatocellular carcinoma: Published as a terminated appraisal in May 2019 (Q1 2019-20).
- Bosutinib for untreated chronic myeloid leukaemia: Published as a terminated appraisal in April 2019 (Q1 2019-20).
- Brentuximab vedotin for untreated advanced Hodgkin lymphoma: Published as a terminated appraisal in August 2019 (Q2 2019-20).
- Lenalidomide with bortezomib and dexamethasone for untreated multiple myeloma: Published as a terminated appraisal in September 2019 (Q2 2019-20).
- Pomalidomide with bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma: Published as a terminated appraisal in September 2019 (Q2 2019-20).
- Bezlotoxumab for preventing recurrent Clostridium difficile infection: Published as a terminated appraisal in September 2019 (Q2 2019-20).
- Ramucirumab for treating unresectable hepatocellular carcinoma after sorafenib: Published as a terminated appraisal in October 2019 (Q3 2019-20).
- Ibrutinib with rituximab for treating Waldenstrom’s macroglobulinaemia: Published as a terminated appraisal in October 2019 (Q3 2019-20).
- Cladribine for treating relapsing–remitting multiple sclerosis: Updated and re-issued earlier than the scheduled review date. Published in December 2019 (Q3 2019-20).

- Atezolizumab with carboplatin and nab-paclitaxel for untreated advanced non-squamous non-small-cell lung cancer: Published as a terminated appraisal in January 2020 (Q4 2019-20).
- Recombinant human parathyroid hormone for treating hypoparathyroidism: Published as a terminated appraisal in March 2020 (Q4 2019-20).
- Daratumumab with lenalidomide and dexamethasone for untreated multiple myeloma: Published as a terminated appraisal in March 2020 (Q4 2019-20).
- Ramucirumab with erlotinib for untreated EGFR-positive metastatic non-small-cell lung cancer: Published as a terminated appraisal in March 2020 (Q4 2019-20).

Highly specialised technologies

1 topic delayed:

- Velmanase alfa for treating alpha-mannosidosis: Publication of the FED following the August 2019 committee meeting was delayed. Timelines were TBC whilst communications with the company were ongoing however this topic has not been defined as therapeutically critical in light of COVID-19. NICE staff will continue to work on the evaluation in the background up until it gets to the point at which we need to engage with the HST committee or the wider NHS. At this point, the evaluation will be paused.

Social Care

No variation against plan 2019-20.

Managing common infections

No variation against plan 2019-20.

Appendix 4: Guidance published since the Board meeting in March 2020

Since the report to the Board meeting in March 2020 the Institute has published the following guidance in 2019/20.

COVID-19 rapid guidelines

Topic	Recommendation
COVID-19 rapid guideline: delivery of radiotherapy	General guidance
COVID-19 rapid guideline: critical care in adults	General guidance
COVID-19 rapid guideline: dialysis service delivery	General guidance
COVID-19 rapid guideline: delivery of systemic anticancer treatments	General guidance

Clinical guidelines

Topic	Recommendation
Tinnitus: assessment and management	General guidance
Abdominal aortic aneurysm: diagnosis and management	General guidance
Venous thromboembolic diseases: diagnosis, management and thrombophilia testing	General guidance

Interventional procedures

Topic	Recommendation
Bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) using mesh for pelvic organ prolapse	Research
Cyanoacrylate glue occlusion for varicose veins	Standard
MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy	Special
Selective internal radiation therapy for unresectable colorectal metastases in the liver	Other

Medical technologies

No publications

Diagnostics

No publications

Public health

No publications

Managing common infections

No publications

Social Care

No publications

Quality standards

No publications

Technology appraisals

Topic	Recommendation
Recombinant human parathyroid hormone for treating hypoparathyroidism	Terminated

Highly specialised technologies

No publications

Medtech innovation briefings

Topic	Recommendation
Cor-Knot for tying suture knots in valve surgery	Summary of best available evidence
Artificial intelligence for analysing CT brain scans	Summary of best available evidence
NATROX oxygen wound therapy for managing diabetic foot ulcers and complex or chronic non-healing wounds	Summary of best available evidence
EarlyCDT-Lung for cancer risk classification of indeterminate pulmonary nodules	Summary of best available evidence
TUC Safety Valve to prevent balloon inflation in the urethra during transurethral catheterisation	Summary of best available evidence

Guidance surveillance reviews

Topic	Recommendation
CG113 Generalised anxiety disorder and panic disorder in adults: management	No update
NG24 Blood transfusion	No update
NG29 Intravenous fluid therapy in children and young people in hospital	No update
CG98 Jaundice in newborn babies under 28 days	No update
NG115 Chronic Obstructive Pulmonary Disease in over 16's (exceptional review)	No update
CG19 Dental checks: Intervals between oral health reviews (exceptional review)	No update
NG101 Early and locally advanced breast cancer: diagnosis and management (exceptional review)	No update
CG174 Intravenous fluid therapy in adults in hospital (exceptional review)	No update

Key to recommendation types

Guidelines (clinical, social care and public health):

General guidance: NICE guidelines each cover a range of practice and interventions, with recommendations ranging from 'must do' (where compliance with legislation is required) and 'should do' (where there is strong evidence of effectiveness), to 'don't do', where compelling evidence that an intervention is ineffective or harmful has been identified.

Interventional Procedures:

Interventional procedures offer advice about the safety and effectiveness of surgical techniques and some other kinds of procedures. Advice normally relates to the kind of consent (normal or special) required from patients before the procedure is undertaken, but in a small number of cases, where major safety concerns have been identified, a ‘do not use’ recommendation is made.

Medical technologies:

Guidance on new medical technologies (medical devices) is normally framed in terms of whether or not the case for use in the NHS has been successfully made by the manufacturer.

Diagnostics guidance:

New diagnostic techniques are recommended or not recommended for routine use in the NHS, or sometimes for research.

Management of common infections:

These guidelines help the NHS make the best use of antibiotics, as part of the broader antimicrobial stewardship effort.

Quality standards:

The statements in our Quality Standards identify important aspects of practice in which there is significant variation across the NHS.

Technology appraisals and highly specialised technologies:

This guidance can ‘recommend’ the use of a new drug or other treatment, ‘optimised use’, in which the recommendation is positive for some but not all uses, or ‘not recommend’ routine use in the NHS. Research only use is also sometimes recommended. Positive recommendations are subject to a legal funding requirement.

Evidence summaries and medtech innovation briefings:

Both publications provide information (but not guidance) about a particular topic.

Surveillance reviews:

Provide the basis for decision about whether to update current NICE guidance.

Appendix 5: Balanced scorecard April 2019 to March 2020

Delivering services and improvements

Development and publication of guidance and evidence outputs (as specified in Business Plan)

Outputs	Measure	Target	Planned To Year End	Actual To Year End	Cumulative performance	RAG status
Publish 3 public health guidelines	Publication within stated quarter	80%	3	3	100%	Green
Publish 23 clinical guidelines	Publication within stated quarter	80%	23	28	122%	Green
Publish 6 managing common infections guidelines	Publication within stated quarter	80%	6	6	100%	Green
Publish 1 social care guidelines	Publication within stated quarter	80%	1	1	100%	Green
Publish 78 technology appraisals or highly specialised technologies guidance	Publication within stated year	80%	78	59	76%	Amber (see note 1)
Publish 32 interventional procedures guidance	Publication within stated quarter	80%	32	27	84%	Green
Publish 6 diagnostics guidance	Publication within stated quarter	80%	6	4	67%	Amber (see note 2)
Publish 7 medical technologies guidance	Publication within stated year	80%	7	5	71%	Amber (see note 3)
Publish 38 medtech innovation briefings (MIBs)	Publication within stated year	80%	38	31	82%	Green
Deliver up to 38 commercial and up to 17 managed access briefings for NHS England to support discussions with	Publication within stated year	80%	14 Managed agreements (MAAs) published	13 MAAs published in total	94%	Green

Outputs	Measure	Target	Planned To Year End	Actual To Year End	Cumulative performance	RAG status
companies, including 'Patient Access Schemes'			38 Patient Access Scheme (PAS) final advice sent to NHS England	36 PAS final advice sent to NHS England Additionally - 39 Commercial Briefings sent to NHS England Sept 2019 - Mar 2020		
Deliver up to 4 commissioning support programme topics to NHS England	Submission to NHS England Clinical Panel within stated quarter	80%	4	4	100%	Green
Manage portfolio of up to 3 evaluative commissioning projects for NHS England	Submission to NHS England Clinical Panel within stated quarter	80%	SABR scheme completion and submission of 3 reports to NHS England	SABR scheme completed and 3 separate indication-specific reports submitted to NHS England	100%	Green
Publish 52 guidance surveillance reviews	Publication within stated quarter	80%	52	52	100%	Green

Outputs	Measure	Target	Planned To Year End	Actual To Year End	Cumulative performance	RAG status
Deliver up to 4 evidence summaries – antimicrobial prescribing	Publish within year	80%	4	2	50%	Amber (see note 4)
Deliver up to 10 evidence reviews for NHSE specialised commissioning	Delivery to NHS England within year	80%	10	5	50%	Amber (see note 5)
Deliver 8 quick guides for social care	Publication within year	100%	8	8	100%	Green
Deliver 16 quality standards	Publication within stated quarter	80%	16	13	81%	Green
Deliver 1 indicator set	Publication within year	100%	1	1	100%	Green
Deliver 30 endorsement statements	Publication within stated quarter	80%	30	25	83%	Green
Deliver 50 shared learning examples	Publication within stated quarter	80%	50	60	120%	Green
Publish 12 monthly updates of the BNF and BNF C content	Publication within stated quarter	80%	12	12	100%	Green
Deliver a regular medicine awareness service (50 MAWs)	Publication to regular schedule	90%	53	52	98%	Green
Deliver update of 16 medicines optimisation key therapeutics topics	Publication within stated quarter	80%	16	16	100%	Green
Deliver 24 medicines evidence commentaries	Publication within stated quarter	80%	24	20	83%	Green
Deliver 7 IAPT (Improving Access to Psychological Therapies) assessment briefings	Publication within stated quarter	80%	7	8	114%	Green

Note 1: 19 Technology Appraisal topics and 1 Highly Specialised Technologies topic delayed. 13 additional TA topics published in 2019-20 were not planned for this financial year but included in the final actual figures. See appendix 3 for the list of topics.

Note 2: 2 delayed diagnostics guidance topics: (a) Implantable cardiac monitors (BioMonitor 2-AF, Confirm Rx insertable cardiac monitor and Reveal LINQ Insertable Cardiac Monitoring System) to detect atrial fibrillation after cryptogenic stroke and (b) the ARCHITECT Urine NGAL assay, NephroCheck Test and NGAL Test

Note 3: 1 withdrawn medical technologies guidance topic:(SpaceOAR hydrogel spacer for reducing rectal toxicity during radiotherapy for prostate cancer) and 1 delayed medical technologies guidance topic (PneuX for preventing ventilator-associated pneumonia in intensive care)

Note 4: Antimicrobial evidence summaries are developed as new antimicrobials come to market, only 2 were launched this financial year and evidence summaries were published on them.

Note 5: Evidence reviews are commissioned by NHSE. Five topics were referred to NICE by NHSE and we delivered the evidence reviews and associated outputs within the timeframe.

Adoption and impact

Provision of support products for the effective implementation of guidance

Outputs	Measure	Target	Planned To Year End	Actual To Year End	Cumulative performance	RAG
Publish resource impact products to support all NICE guidelines, positively recommended technology appraisals, medical technologies and diagnostics guidance at the point of guidance publication	Provide within year	90%	90%	97%	97%	Green

Maintaining and developing recognition of the role of NICE

Outputs	Measure	Target	Planned To Year End	Actual To Year End	Cumulative performance	RAG
Coverage of NICE in the media	% of positive coverage of NICE in the media resulting from active programme of media relations	80%	80%	83%	83%	Green

Operating efficiently

Delivering programmes and activities on budget

Outputs	Measure	Target	Planned To Year End	Cumulative performance	RAG
Effective management of financial resources	Revenue spend	To operate within budget	2019/20 annual budget for the period was £49.0m.	Net spend was £48.6m. This was a net under spend of £0.4m (0.9%) and is mainly due to vacant posts.	Green
Effective management of non-exchequer income	Net income received from non-exchequer income sources (including Scientific Advice, Office for Market Access, research grants, knowledge transfer) measured against business plan targets	90%	The business plan income target was to receive £6.1m from non-exchequer sources.	The total income from non-exchequer sources was £7.0m.	Green

Maintaining and developing a skilled and motivated workforce

Outputs	Measure	Target	Cumulative performance	RAG
Management of recruitment	Proportion of posts appointed to within 4 months of first advertisement	80%	92.4%	Green
Management of sickness absence	Quarterly sickness absence rate is lower than the average rate (3.33% as at January 2018) across the Specialist Health Authorities and other Statutory Bodies	3.33%	2.19%	Green
Staff satisfaction	Proportion of staff reporting in staff survey that the Institute is a good, very good or excellent place to work (global job satisfaction index)	80%	94%	Green
Staff involvement	Hold monthly staff meetings	80%	92%	Green
Staff well-being	Implementation of NICE's quality standard for healthy workplaces: improving employee mental and physical health and wellbeing in respect of own staff	80% of quality statements	83%	Green

Sustainable development

Outputs	Measure	Target	Cumulative performance	RAG
Recycled waste	% of total waste recycled	90%	100%	Green

Improving stakeholder satisfaction

Outputs	Measure	Target	Cumulative performance	RAG
Improved satisfaction	Complaints fully responded to in 20 working days	80%	100%	Green
Improved satisfaction	Enquiries fully responded to in 18 working days	90%	83%	Amber (see note 6)
Improved satisfaction	Number of Freedom of Information requests responded to within 20 working days	100%	99%	Amber (see note 7)

Outputs	Measure	Target	Cumulative performance	RAG
Improved satisfaction	Parliamentary Questions contribution provided within requested timeframe	90%	98%	Green
Ensuring stakeholders have access to our websites as the main communication channel	Percentage of planned availability, not including scheduled out of hours maintenance	98%	99.99%	Green

Note 6: Between October 2018 and March 2019 capacity within the enquiry handling team was significantly impacted by long term sickness and vacancies in key posts, including management capacity. During the same period the team saw significant campaigning activity on a number of high-profile topics. The remaining team members were also required to contribute to development of a new CRM system to manage the team's workload. This combination resulted in a backlog of enquiries which has impacted the year's performance. Following successful recruitment to vacant posts, the trend in performance since Q4 2018-19 is positive and continues to improve, in March 2020 we met the 90% target.

Note 7: In Q2, one FOI was answered on day 21 due to delays in the team receiving the information and sign off.

Outputs	Measure	Target	Planned To Year End	Actual To Year End	Cumulative performance	RAG
Interest in opportunities for lay people to sit on our advisory reflected by ratio of applications to positions	2 to 1 (or greater) each quarter	100%	2:1	11.1:1	555%	Green

Improving efficiency and speed of outputs

Outputs	Measure	Annual target	Cumulative performance	RAG
Speed of production	% STAs for all new drugs issuing an ACD or FAD within 6 months of the product being first licensed in the UK	90%	92%	Green

Outputs	Measure	Annual target	Cumulative performance	RAG
Speed of production	% of multiple technology appraisals from invitation to participate to ACD in 41 weeks, or where no ACD produced to FAD in 44 weeks	85%	100%	Green
Speed of production	% of Appeal Panel decisions received within 3 weeks of the hearing	80%	100%	Green

RAG status – Key

Green = Greater than or equal to annual target

Amber = Between 50% and less than annual target

Red = Less than 50% of annual target

May 2020

National Institute for Health and Care Excellence

Resources Report

This report gives details of the financial position as at 31 March 2020 and the potential impact of COVID-19 on the 2020/21 budget and workforce plan.

The Board is asked to review the report.

Catherine Wilkinson

Acting Director, Business Planning and Resources

May 2020

Summary

Financial performance

1. Total operating expenditure for the financial year ending 31 March 2020 was £68.7m. Total funding from the Department of Health and Social Care (DHSC) and other operating income for the year was £69.1m.

2. The net variance was £0.4m underspend against budget. This satisfies our statutory duty to breakeven or better.

3. Further details on the financial position for 2019/20 are provided in the first section of this report, with a commentary on key variances against income and expenditure budgets.

2020/21 Budget update

4. We have updated our 2020/21 business plan to show the impact of COVID-19, which is likely to affect all aspects of our work. The revised business plan is included on the agenda for review in this board meeting. Budget setting for 2020/21 has also been impacted.

5. Our current assumption for planning purposes is that we have entered the year with a budget deficit of £0.4m, although in the worst-case scenario this could rise to £2.1m. This is based on the following assumptions:

    - Income from fees for Technology Appraisals is estimated to fall by between 35-50% (£3.7m - £5.4m) compared to the original business plan.

    - Income generated by the NICE Scientific Advice and Office for Market Access teams will be £0.3m lower than planned.

    - Pay underspends will total approximately £3.5m (7.6% of the pay budget). Some underspends had been expected as we have a number of vacant posts due to expansion within CHTE, Digital Services and the Transformation Unit, but these posts are likely to take slightly longer to recruit to.

    - Non-pay expenditure on travel costs and hosting committee meetings in the office is expected to reduce by £0.7m due to current travel restrictions and future expectations of social distancing measures.

6. Further details of the impact on the 2020/21 budget are provided in the second section of this report. These estimates will be kept under review and the board will be updated as the year progresses. We will continue to try and identify savings to offset the deficit. We will also work with DHSC to secure any

additional funds that may be available, including to support the COVID-19 related work we are producing.

Workforce update

7. The current situation continues to have a significant impact on the workload of the HR team in terms of workforce planning and supporting the health and wellbeing of staff. Since the lockdown commenced and the offices were closed, reported sickness levels have not risen. However, we know from surveys that at least 40% of our workforce are impacted by caring responsibilities and the school closures.

8. The third section of this report provides details of the impact of the pandemic on the workforce and the actions the HR team has taken to respond to emerging issues and gives information on the health and safety aspect of the response.

Financial position as at 31 March 2020

9. Table 1 summarises the financial position for the year ended 31 March 2020. There is a full analysis in Appendix A.

Table 1: Financial Position at 31 March 2020

Spend Category	Annual Budget £m	Outturn £m	Variance £m	*Variance %*
Pay	40.7	39.3	(1.4)	*(3%)*
Non pay	28.6	29.4	0.8	*3%*
Total Expenditure	**69.3**	**68.7**	**(0.6)**	***(1%)***
Income (non-Grant-in-Aid)	(18.6)	(18.4)	0.2	*1%*
Grant-in-Aid Funding	(50.7)	(50.7)	0.0	*0%*
Total Income Sources	**(69.3)**	**(69.1)**	**0.2**	***(0%)***
Deficit/(Surplus)	**-**	**(0.4)**	**(0.4)**	***(1%)***

10. Total expenditure to 31 March 2020 was £68.7m against a budget of £69.3m, giving a year-end underspend of £0.6m.

11. Non-grant-in-aid income received to 31 March 2020 was £18.4m against a target of £18.6m, £0.2m below target.

12. NICE received £50.7m of grant-in-aid (GIA) funding from the Department of Health and Social Care (DHSC) in 2019/20.

13. Overall, the year-end position for 2019/20 was an underspend of £0.4m.

Pay expenditure

14. The £1.4m underspend on pay was due to vacancies and staff turnover across the organisation. Underspends on pay are likely to continue in 2020/21 as recruitment is expected to be impacted by COVID-19.

Non-pay expenditure

15. The overspend on non-pay relates to a £0.4m consultancy and contractor spend within digital services. We have committed expenditure on project and consultancy work to support the IT solutions for the Stratford office move and to define, design and implement the digital workplace strategy in relation to organisational transformation (NICE Connect). This non-recurrent spend utilised some of the above pay underspend.

16. The remainder of the non-pay overspend relates to £0.5m of provisions made at year end. The COVID-19 pandemic means the London office move to Stratford is likely to be delayed. This will have a potential financial impact associated with

relocating the servers temporarily and temporary additional accommodation costs. We are also likely to incur costs associated with the temporary closure of both offices from March 2020 whilst we continue to be advised to work at home, with staff purchasing IT equipment and furniture to enable them to work safely and effectively from home.

17. In total we made £0.4m of new provisions in March 2020 relating to the above, plus a further £0.1m provision relating to the dual running costs of a new IT infrastructure contract later in 2020/21 when the contract with the current provider is due to end.

18. However, the above was offset by the late delivery of IT equipment due to shipping and distribution problems for suppliers of such equipment in the final quarter of 2019/20. This delay will result in a £0.6m cost pressure in 2020/21.

Income

19. Income from non-GIA sources was close to breakeven compared with the business plan. The income from Technology Appraisals (TA) and Highly Specialised Technologies (HST) was below target, but this was offset by surplus income from the NICE Scientific Advice team and other income generating schemes within NICE.

20. Technology Appraisals (TA) & Highly Specialised Technologies (HST) income from charging amounted to £3.6m, which was £1.2m below budget due to a review of the accounting treatment of the income, capacity issues in the team and the impact of COVID-19.

21. At the financial year-end we reviewed the amount of income recognised for each topic as at 31 March 2020, updating the income allocated based on the key milestones completed at that date rather than the time that had elapsed since the topic started. This method gives a more accurate measurement of the work completed and is aligned with International Accounting Standard 15, but also reduced the amount of income we expected to recognise in the 2019/20 accounts for TA and HST.

22. In the previous board report it was noted that 6 topics starting in 2019/20 were paused in February 2020 due to capacity issues within the team. This was compounded in March as a number of topics were put on hold due to the impact of COVID-19. Work on these topics will recommence in 2020/21, but £0.4m of income that was expected to be recognised in 2019/20 will now be completed in 2020/21 instead.

23. This change in accounting treatment, combined with the topics that have been paused due to the capacity issues and COVID-19, resulted in the fees from TA

and HST falling from the amount of £4.5m that was previously forecast to be £3.6m at the year-end.

24. NICE Scientific Advice (NSA) ended the year with a £0.3m surplus. This is attributable to several developments including a new pricing model; undertaking new collaborative projects with organisations such as NHS England and Innovate UK; and the relaunch of NICE International. As a result of the surplus generated, NSA have increased their reserves balance from £0.8m at the start of the financial year to £1.1m by 31 March 2020.

25. Overall, the Science, Advice and Research team recorded a year-end surplus of £0.4m. This is made up of £0.3m surplus from NSA and £0.1m surplus from the Science, Policy and Research (SP&R) team.

2020/21 Budget update

26. We have updated our 2020/21 business plan to show the impact of COVID-19, which is likely to impact on all aspects of our work. The revised business plan is included on the agenda for review in this board meeting.

27. The business plan sets out our revised indicative objectives and performance measures for 2020/21, to help guide the prioritisation of our work throughout the year as the pandemic evolves. Budget setting runs alongside the business planning activities and therefore the budget for 2020/21 has been adjusted in line with the updated business plan, following discussions with DHSC finance and sponsor colleagues.

28. Whilst our funding from DHSC and other fixed income (for example funding from Devolved Administrations and agreements with other healthcare non-departmental public bodies (NDPBs)) is likely to be unaffected, it is likely that we will see a reduction in income relating to Technology Appraisals and our income generating functions such as NICE Scientific Advice.

29. However, this will be partially offset by reduced costs as recruitment to vacant posts is likely to be affected. Travel costs and other variable costs are also expected to fall significantly due to travel restrictions; the closure of the offices and meetings being held virtually for at least the first quarter of the year.

Reduction in anticipated technology appraisal income 2020/21

30. The TA and HST income target in the draft business plan was set at £10.7m – this would have been the income needed to cover the full-cost of the appraisals team within CHTE, plus the indirect costs from support teams and overheads incurred in supporting the appraisal process. This amount assumed the expansion of the programme (to increase the number of new topics starting the

appraisal process each year from 78 to 88 each year) would be complete by the start of the new financial year.

31. However, due to the consequence of prioritising therapeutically critical topics during the COVID-19 pandemic (plus the time it will take to recover) and delays in recruiting to some of the new posts as part of the expansion, the capacity of the programme will be reduced in 2020/21. There are approximately 65 therapeutically critical topics in the current pipeline that could start this financial year – this would be a 10% reduction of new topics starting compared to 2019/20.

32. Finally, COVID-19 is expected to have an impact on productivity due to a combination of:

    - disruption to the committee schedule
    - availability of NHS committee members
    - a reduction in outputs from evidence review groups (contracted by NIHR)
    - delays to company and other stakeholder evidence submissions
    - staff turnover and recruitment issues
    - impact of prolonged home working of staff (exacerbated by continued school closures)
    - sickness and other absence amongst staff.

33. We have modelled several scenarios for the impact on TA and HST fees, comparing them to the business plan assumption and using 2019/20 performance as a baseline. Considering the impact on productivity listed above, and prudently assuming some of the approximately 65 critical topics will be delayed for reasons beyond our control, we have estimated a reasonable worse-case scenario is that TA and HST income will be 35% lower (£3.7m) than business plan. Our worst-case scenario is an estimated 50% reduction in income (£5.4m) and although we anticipate it is not likely, it is prudent to begin worst case scenario planning.

Revised 2020/21 business plan sources of funding

34. As noted earlier, most funding sources (including grant-in-aid funding) are expected to be secure. The business plan included an amount of £5.8m labelled other income. Approximately half of this income is fixed funding from the devolved administrations and sublet income from our tenants. The rest relates to

income generating teams including NICE Scientific Advice (NSA) and the Office for Market Access (OMA).

35. Of these, the NSA team is confident that there is still significant demand for their services, but it is more likely that they will be close to breakeven compared with the £0.3m surplus generated in 2019/20, but to be prudent we have assumed a deficit of £0.2m. The Office for Market Access (OMA) team is likely to be affected as the team is supporting NICE's input into Research to Access Pathway for Investigational Drugs – COVID-19 (RAPID-C19). It is assumed that the income generation from the OMA team will fall by 50% from £0.2m to £0.1m.

36. The above assumptions are shown in table 2 below, which is an extract from the revised 2020/21 business plan. This shows a total deficit in sources of funds compared to the original business plan of £4.0m (5.3%) in the reasonable worst-case scenario.

Table 2: Adjusted sources of funds table (extract from 2020/21 business plan)

Sources of Funds	Baseline 2020-21 funding £m	Reasonable worst-case deficit £m	Worst-case deficit £m	Rationale
Grant-in-Aid from DHSC	52.5			
TA and HST income	10.7	(3.7)	(5.4)	Reduction in planned volume of TAs
NHS England	1.8			
Health Education England	4.0			
Other Income	5.8	(0.3)	(0.3)	NSA and OMA reduced income
Total Sources of Funding	**74.8**	**(4.0)**	**(5.7)**	

Impact of COVID-19 on 2020/21 expenditure

37. To balance the budget in 2020/21, expenditure will need to be reduced to offset the above assumed deficit and contingencies identified if income reduces as per the scenarios above.

38. It is likely that we will see a large underspend on pay in 2020/21 due to the impact of COVID-19. The pay budget includes a large number of vacant posts (90wte), including new posts relating to expansion within CHTE and staffing the NICE Connect transformation unit. However, we are continuing to recruit to vacant posts remotely at a slower pace and work on guidance as usual in many respects whilst delaying publication.

39. We are also responding to new requests to produce COVID-19 related rapid guidance and supporting other organisations such as NHS England with their response to the crisis. Although we have been able to redeploy resources in the short-term, this is currently an unfunded pressure on resources. As we need to keep the guidance up to date as evidence, policy and practice changes, we may need to recast our assumptions in relation to the projected pay under spend. This may trigger a request for COVID-19 related funding from the DHSC. We will continue to work with colleagues in DHSC finance and sponsor teams in relation to this call on our grant in aid.

40. However, it is anticipated that recruitment will be more challenging in this financial year due to COVID-19 from a practical perspective and it is likely that more posts will remain vacant for longer. Based on current vacancies, known recruitment plans and historic pay growth trends, it is assumed the non-recurrent pay underspend compared to the business plan (£45.8m pay budget) will be at least £3.5m (7.6% of the pay budget).

41. The travel and subsistence budget in the 2020/21 business plan is £1.7m. However, because of the social distancing measures and travel restrictions due to COVID-19, it is expected that we will save at least one third (£0.6m) this financial year. This could increase further if restrictions persist or we plan to continue hosting more committees virtually even when the offices are reopened and some travel restrictions are relaxed.

42. It is likely other costs relating to committees (catering, external room bookings) will see a reduction in costs of at least £0.1m.

43. The expected savings on non-pay variable costs therefore totals £0.7m. However, this saving is almost fully offset by the £0.6m cost pressure of the IT equipment ordered in 2019/20 but not delivered until the new financial year. Taking the above into consideration, the savings reduce the potential deficit to between £0.4m and £2.1m as summarised below.

Table 3: Projected deficit 2020/21

COVID-19 financial impact	£m
Reasonable worst-case reduction in sources of funding	4.0
Reduced pay costs	(3.5)
Reduced non-pay variable costs	(0.7)
IT equipment cost pressure	0.6
Projected deficit: Reasonable worst-case scenario	**0.4**
TA income falls by a further 15% (from 35% to 50%)	1.7
Projected deficit: Worst-case scenario	**2.1**

Options to mitigate the deficit

44. In the reasonable worst-case scenario, it is likely that we will be able to identify savings during 2020/21 to balance the budget through restricting uncommitted non-pay budget, for example reducing spend on the MedTech External Assessment Centre contracts, which are semi-variable and can be scaled up or down to meet demand. Or, we could further delay and restrict recruitment activity throughout the year to increase the pay underspend further, but this may result in capacity issues later in the year and next year when we will be aiming to catch up on the backlog of currently paused activity.

45. If the worst-case scenario does materialise, we are likely to need additional funding support from DHSC. We expect that we will continue to expend resource on work related to the COVID-19 pandemic and as such may work with DHSC to formulate a case for funding in relation to this work.

2021/22 and beyond

46. It is likely that the impact of COVID-19 will be felt beyond the current financial year, although this is difficult to predict and plan for at this stage. The capacity of the Technology Appraisal programme may still be affected next year, although not to the extent that is likely this financial year. A review of the current prices for each type of appraisal will take place towards the end of the financial year and will take into consideration changes to the cost base and the impact of changes to methods and processes.

47. Our funding for future years will not be known until much later in 2020/21 when the next spending review is published, but the timing and nature of that review is currently unknown. Other cost pressures may arise from the delay to the move to the Stratford office and the 2021/22 agenda for change pay deal, but these are currently not quantifiable. The board will be kept up to date with developments as they occur throughout 2020/21.

Workforce

48. As the Covid-19 situation continues to unfold, the Human Resources (HR) and Organisational Development (OD) teams have responded quickly to emerging news and have done their utmost to give staff timely and accurate information on both an individual and organisational basis. We are also in regular contact with arms-length body organisations where we share resources and best-practice, to minimise duplication of effort across the sector.

Workforce planning

49. We know approximately 40% of our workforce is impacted by caring responsibilities and the school closures. We also know we have a mixed picture of capacity levels across NICE, with some areas needing additional resources to work on business-critical tasks and in other areas there is some spare capacity.

50. In response, the digital team has created a “digital marketplace” to map workforce capacity across NICE. This matches skills and resources available and also identifies areas in the business where extra resource is needed. To date there have been 69 offers of help, 19 live requests for help and 19 matches. There appears to have been some success, as the most recent employee pulse survey shows the proportion of employees with spare capacity falling from 27% capacity in the first survey to 13% in the second survey. HR is proactively working with managers to address capacity issues.

51. Long-term, this system could be modified and expanded to be used strategically to deploy our skills and capacity more effectively, particularly with NICE Connect.

Employee Relations

52. The HR operations team is continuing to support a number of ongoing employee relations cases, however due to the recent Covid-19 situation the team is experiencing a reduction in both informal and formal activity.

53. With regard to sickness absence levels, unlike front-line services we have not seen any upward trajectory of absence levels over the last five weeks, in keeping with other ALBs. We noticed a slight increase since lockdown when compared with the same period last year, but this is statistically insignificant and there are no obvious trends to report. We have also seen a delay in people recording the sickness absences on the system so that is something we need to be factor in when we report absence levels.

54. To date we have not seen an increase of stress related illnesses. Anecdotally, a number of work-related stress informal cases have seen a resolution since working from home, which we are continuing to monitor.

Wellbeing

55. Our Health and Wellbeing Group has held fortnightly meetings directly relating to the switch to homeworking. We have responded to feedback from our staff (received directly and through pulse surveys) and have developed a suite of homeworking tips in collaboration with our permanent homeworking staff.

56. We are committed to ensuring that the home environment can be adapted as far as possible to a safe and comfortable work environment. We have made it clear though various communication channels that if kit is required to make working from home easier, we will support staff to purchase and reclaim. This has seen staff buy a variety of equipment including noise cancelling headphones, footrests, chairs, desks and monitors.

57. Our Health and Wellbeing page on NICE Space received 74% more hits during the first month of homeworking than it normally does

58. We have promoted our mental health first aiders and employee assistance programme and have been in regular contact with our mental health first aiders to provide any support they may need.

Culture

59. **Staff survey:** Our annual staff survey was due to launch in May. Following discussions with the SMT, we have deferred the survey to later in the year, in favour of the short, focussed pulse surveys which have allowed us to be more responsive to our rapidly changing circumstances.

60. **Appraisals:** The launch of our refreshed appraisals approach “Appraisal: My Contribution” was delayed by two weeks as we prioritised remote working and wellbeing resources, but we have now launched the materials and will be delivering training and drop-in sessions virtually. To minimise additional workload to staff and managers, and to give us more time to finesse the system, we have deferred the launch of ESR e-appraisals.

61. **Values and behaviours:** We are continuing to progress our development of values and behaviours, and our planned focus groups have been redesigned for a virtual audience.

Professional Development

62. **Learning and development:** Although face-to-face learning is not possible, we are rapidly adapting both our internal and external L&D offering. We are producing an e-learning catalogue of quality programmes, our OD & Training Specialist is receiving training in Virtual Facilitation, and we are working with our external providers to maximise the development opportunities to our staff.

63. **Apprenticeships:** We have proactively had conversations with our apprenticeship providers to minimise any adverse impact on our learners. Module delivery and coaching sessions have now moved online, and most apprentices are reporting a positive experience, although they miss the face-to-face interaction. Some apprentice providers have furloughed some staff, so we are continuing to monitor the situation and keep our apprentices updated.

Recruitment

64. We are able to recruit as normal although remotely. Directors are reviewing and approving vacancies in order to ensure that we only advertise essential posts in the coming months so that we can adequately support new starters and take a prudent approach to ongoing resource commitments.

65. We have produced an Inducting Remotely guide and we are developing a recruiting remotely guide in collaboration with digital services and others who've already experienced remote recruitment.

Health and Safety

66. The Facilities team has developed a protocol for staff entering the office during lockdown and a process for receiving the laptop delivery. This was approved at an extraordinary Health and Safety meeting last week and presented to the SMT.

Appendix A: Summary of Financial Position

The table below is a summary of the financial position per centre and directorate as at 31 March 2020. All figures are provisional and subject to external audit.

Centre / Directorate	Annual Budget £000's	Outturn £000's	Variance £000's	*Variance %*
Centre for Guidelines	17,353	17,066	(287)	*(2%)*
Centre for Health Tech Evaluation	11,830	11,276	(554)	*(5%)*
Health & Social Care	8,957	8,754	(203)	*(2%)*
Evidence Resources	11,054	11,174	120	*1%*
Science, Advice and Research	442	(4)	(446)	*n/a*
Business Planning & Resources	8,570	8,539	(30)	*0%*
Communications	4,120	3,971	(149)	*(4%)*
NICE Connect	499	253	(247)	*(49%)*
Provisions	0	473	473	*n/a*
Depreciation	650	570	(80)	*(12%)*
Income from other ALBS, Devolved Administrations and other miscellaneous income	(9,691)	(9,931)	(240)	*(2%)*
Income from TA and HST cost recovery	(4,800)	(3,582)	1,218	*25%*
Notional Pension Costs	1,751	1,742	(9)	*0%*
Grand Total	**50,735**	**50,301**	**(434)**	***(1%)***

May 2020

National Institute for Health and Care Excellence

Business plan 2020/21

The business plan sets out our business objectives and performance measures for 2020/21 and since last reviewed by the Board it has been updated to reflect the implications of the COVID-19 pandemic on our work. This impact across the year is uncertain, therefore the plan sets out indicative objectives and forecast outputs. Performance against these will be reported to the Board throughout the year in the Chief Executive's and Directors' reports.

The updated business plan has been shared with the sponsor team at the Department of Health and Social Care (DHSC) and takes account of the feedback received. The plan will also be subject to review by NICE's senior departmental sponsor (SDS) at DHSC.

The Board is asked to approve the business plan and delegate approval of any final amendments following review by the Board and the SDS to the Chief Executive.

Professor Gillian Leng

Chief Executive

May 2020

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Business Plan:

2020/21

Table of contents

Introduction

1. NICE's purpose is to help improve the quality, sustainability and productivity of health and social care in England. We do this through a robust review of the evidence to produce guidance and advice on effective health and care practice. This enables those working in health and social care to make better informed decisions. We take account of value for money by recognising that new forms of practice need to demonstrate benefits compared with existing practice, and by identifying opportunities for disinvestment where practice is ineffective. These are challenging decisions, and NICE plays an important role in supporting the health and care system to make best use of its investment.

2. This year, our objectives have been deliberately prioritised to support the wider healthcare system in its response to the coronavirus (COVID-19) pandemic. We have developed a new programme of rapid guidelines covering COVID-19 related topics and are exploring ways to support the search for effective new therapies against the coronavirus. The impact of this decision to respond to requests for COVID-19 support, along with disruption to staff and committee member availability, makes it challenging to accurately forecast outputs in the usual way. This business plan therefore sets out our indicative objectives and performance measures for 2020/21, to help guide the prioritisation of our work throughout the year as the pandemic evolves.

3. Alongside our work on COVID-19 related activity, we will continue to support other priority initiatives in the healthcare system. This includes the Voluntary Scheme for Branded Medicines Pricing and Access, the Life Sciences Sector Deal, NHS Long Term Plan, and the Government's manifesto commitment to establish an innovative medicines fund. We are also working with the Government to ensure the UK remains an attractive place for the life sciences industry. Our remit across health care, public health and social care means we are well placed to provide a system-wide perspective at the national, regional and local levels, including supporting the Integrated Care Systems.

4. To make sure our products are delivered efficiently and continue to meet the needs of our audiences in the longer term, we have launched an ambitious project – NICE Connect – to review the way we produce and present our advice. Informed by user feedback, this project will analyse and adapt to what our audiences and digital partners need from NICE in the future.

5. Our work is framed by six strategic ambitions, which remain valid in the context of supporting the system throughout the pandemic. These ambitions are to:

    - Transform the presentation and accessibility of NICE guidance and advice, ensuring it is fully aligned to the needs of our users to support adoption to drive best practice
    - Transform the development of NICE guidance and advice in line with the learning from the COVID-19 response, so the process is efficient, integrated, and takes advantage of new technologies including artificial intelligence

- Play an active, influential role in the national stewardship of the health and care system
- Support the UK's ambition to enhance its position as a global life sciences destination
- Generate and manage effectively the resources needed to maintain and transform our offer to the health and care system
- Maintain a motivated, well-led and adaptable workforce for NICE.

6. Further information on our plans to transform and deliver our products and services is outlined below. Appendix 1 sets out specific actions to deliver the strategic ambitions within the 'balanced scorecard', and Appendix 2 sets targets based on these actions. As noted above, these are indicative objectives and will need to evolve throughout the year in the context of the pandemic and our response to it. We will review the planned outputs throughout the year.

7. The business year 2020/21 will therefore be an unusual one for NICE because of the pandemic, as it will for everyone working in healthcare. The disruption to the way we work and the need to be responsive and flexible will, however, create opportunities. We will ensure we build on the benefits of new ways of working to create a thriving organisation in the longer term.

Strategic context

Coronavirus (COVID-19)

8. The coronavirus pandemic is likely to impact on all aspects of our work in 2020/21. In February 2020, as the number of cases of COVID-19 began to rise worldwide, we put in place a coronavirus pandemic contingency plan. In March 2020, following Government advice, we took the decision to close our offices and move to complete remote working. This required significant changes to the way people work with a rapid allocation of equipment and resources.

9. We decided we should do all we could to avoid distracting the NHS at a time when it is facing unprecedented pressure. This included both supporting the release of frontline staff who might otherwise be engaged in our committees, and minimising publication of outputs that might be a distraction during this critical time. It was therefore agreed that, during the period when the NHS is under significant pressure, we should only publish guidance topics that were therapeutically critical and/or addressed COVID-19 diagnostic or therapeutic interventions.

10. This had a significant impact on other planned outputs, but released capacity for us to develop a new programme of rapid guidelines. These guidelines cover a range of topics relevant to the management of COVID-19, and were produced to a new interim process to achieve the required rapid timeline. We have also provided support for NHS England by reviewing the evidence for medicines relevant to COVID-19, and are working closely with colleagues in NHS England/Improvement (NHSE/I), the Medicines and Healthcare products

Regulatory Agency (MHRA) and National Institute for Health Research (NIHR) on the development of a rapid pathway from research into practice for potential new treatments.

11. NICE Scientific Advice is also offering free fast track advice for companies developing novel diagnostics or therapeutics for COVID-19. This service helps companies to optimise clinical trial and real world evidence generation evidence required for health technology assessment. If demand for this service increases the team will also consider offering free advice to companies with the most important technologies, where deemed appropriate.

12. During the course of the year our work programme will be kept under regular review in the context of strategic requirements to support the wider system in the fight against COVID-19.

Working with our system partners

13. We are committed to supporting the NHS, public health and social care, and organisations in the wider public and voluntary sector to help them achieve their objectives of improving health and wellbeing. We have been actively engaged in the development of the NHS Long Term Plan, and are supporting its implementation through regional networks, and through the provision of resources for Integrated Care Systems based on NICE guidance. As the role of the Integrated Care Systems grows, we reflect this in the production of guidance that integrates requirements across health and social care.

14. We work collaboratively with the Department of Health and Social Care (DHSC), NHSE/I, Public Health England, the Care Quality Commission (CQC) and our other national partners and professional bodies. Through these links, we are aiming to ensure NICE guidance is reflected appropriately in their plans to encourage the use of evidence-based advice. We are working closely with the CQC to support their inspection processes, and with the network of What Works Centres to share expertise and avoid duplication. We work closely with the MHRA, Healthcare Safety Investigation Branch (HSIB) and others to ensure that our guidance reflects the most up to date safety issues. As an active partner in the health and care system we are looking at the implications of the independent review of adult screening programmes in England for our work and stand ready to take account of the recommendations of the Independent Medicines and Medical Devices Safety Review when it is published. We are committed to the sustainability agenda and are liaising with the Sustainable Development Unit to encourage medical technology companies to publish information on environmental impact of their new products.

15. We continue to help drive the optimal use of resources, in partnership with NHSE/I. We routinely assess the budget impact of technology appraisal and highly specialised technologies guidance and provide a forward planner that shows anticipated costs, by quarter, for all future guidance. This supports the commissioning process, particularly for specialised products. We will also continue to work closely with NHSE/I to support the adoption of new guidelines

with a significant resource impact, and for selected, high impact technologies, with our partners in the Accelerated Access Collaborative (AAC).

16. Where appropriate during the pandemic, we will engage with partner organisations to identify and improve uptake and disinvestment opportunities. In particular, we will work with NHS RightCare and NHSE/I's Getting it Right First Time programmes, and coordinate and align medicines optimisation activities in order to support efforts to get the best value from medicines .

17. We continue to actively support the 'shared decision making' agenda, in which patients and clinicians work together to determine a test or treatment package that reflects patients' preferences. This approach has the benefit of improving patient satisfaction and, in many cases, of also reducing the use of more expensive, invasive technologies. Our work includes hosting an annual forum for interested partner organisations, making the evidence base for NICE guidance more accessible through NICE Connect and developing a guideline on shared decision making.

18. In order to deliver the strategic ambition of the health and care system, we will need to be in a position to respond to, and take advantage of, the digitisation of the health service and the greater availability of artificial intelligence (AI) and machine learning. AI offers the scope for more efficient working in the healthcare system and enable us to use new forms of data and analytics that will help us develop timely guidance using agile and responsive processes. Following a pilot evaluation in 2019/20 we will be expanding our evaluation of digital health technologies through our existing medical technologies and diagnostics programmes.

Life sciences industry

19. We have an important relationship with the life sciences industry. Much of our technology guidance is based on data generated by pharmaceutical, biotechnology, medical devices and diagnostics companies, as they develop and prepare their products for market. Most of our programmes make recommendations about, or provide information on, new and existing health technologies. Our guidance has an impact on the commercial prospects of companies in the life sciences sector, in this country and internationally.

20. Our relationship with the industry is complex. Our primary responsibility is to help those who use the health and care services and those who care for them, to get the best outcomes and to use the resources available effectively. However, because of the impact we have on the companies whose products we review, we also have a responsibility to consider the effect of our work on them. This requires a delicate balance but we can help the industry make it more likely that the products they bring to the NHS will address the needs of patients in an affordable and cost effective way and, as a result, enhance their prospects in the market.

21. We want to reduce the risk for companies introducing products to the UK market by helping them focus their value proposition on the most compelling

data. We also want to work with companies and the NHS to design and manage novel evidence generation processes and new data-driven funding models for fast-track approval and reimbursement, which provide benefits to patients and make the best use of NHS resources. We will support the UK in developing a world-leading approach to using data to track outcomes and in managing early access to worthwhile new technologies. Our Commercial and Managed Access function supports both industry and healthcare partners in their understanding of what could be done to facilitate patient access, especially where there is significant uncertainty about the benefits and costs of introducing a new technology.

22. Building on the international value of a positive NICE appraisal and to support the UK's ambition to enhance its position as a global life sciences destination, we continue to extend our support for companies by increasing the visibility and accessibility of the Office for Market Access and NICE Scientific Advice programmes inside and outside the UK. The Office for Market Access and NICE Scientific Advice will continue to work closely to communicate the complimentary nature of the two engagement functions, and will liaise with organisations such as the AAC to contribute to an increasingly well aligned system across the NHS that allows life sciences companies to access the right support at the right time. For scientific advice, there will be a focus on developing and further expanding existing parallel advice activities with regulators and other health technology assessment agencies, following, for example, the successful pilot with the Canadian Agency for Drugs and Technologies in Health (CADTH).

23. Our vision for a thriving relationship between the industry regulators and the NHS is an environment which enables and promotes adaptive, integrated regulatory approval, followed by the fast, data-driven evaluation, reimbursement and adoption of compelling, affordable value propositions. In 2020/21 we will continue to work with the industry and our system partners, including NHSE/I, to implement the commitments in the Voluntary Scheme for Branded Medicines Pricing and Access, the life sciences sector deals, and support the Accelerated Access Collaborative. These initiatives will benefit people using the NHS by providing access to the most clinically and cost effective new treatments more efficiently, and will help the life sciences industry by increasing the opportunities for companies to help manage the introduction of their new technologies into the NHS.

Arrangements after leaving the EU

24. We will continue to build on NICE's international reputation to support the UK's ambitions for the NHS and wider life sciences sector. This includes supporting cross-organisational work with DHSC, its arm's-length bodies and other government departments on the UK's future relationship with the EU and the rest of the world. We will continue to focus on world-leading technology assessment methodology and guideline development, including the use of real-world data, and the evaluation of digital products, including artificial intelligence. Our membership of global professional organisations and presence at international conferences will be of increasing importance.

25. We will also continue to coordinate the development and publication timeline for technology evaluation guidance with the MHRA to maintain timely patient access to effective new medicines and technologies. Our scientific advice programme has, for a large amount of its income, relied on work undertaken jointly with other EU countries and the European Medicines Agency (EMA). To ensure sustainability we have launched a concurrent advice service. This service allows companies to obtain advice from NICE within the same timelines as advice from the EMA and EUnetHTA (the European network for health technology assessment) partners. We will also consider the sustainability of the research income we currently receive from the EU for EUnetHA, Innovative Medicines Initiative and Horizon 2020 in light of the UK – EU future relationship.

26. We have assessed these areas, as well as other matters associated with the UK's future relationship with the EU, and are putting in place the necessary arrangements. We will continue to update our plans in line with the UK's future relationship with the EU and the rest of the world, and contribute to the planning and coordination work undertaken by DHSC. We have a particular interest in ensuring that we continue to attract talent from across the world to work for us in specialist roles, and will keep a close watch on whether there are opportunities to make a special case for specific NICE roles under the emerging immigration plans.

Our vision for the future: NICE Connect

27. NICE has a significant portfolio of guidelines for health and social care, guidance on new medicines and technologies, plus other advice and support products. This can be challenging for us to keep up to date, and for users to readily identify the information they need. We also need to make better use of new digital technologies and artificial intelligence (AI), and do more to embed NICE guidance in technologies used by front line practitioners and healthcare systems. We have therefore initiated the NICE Connect project to consider how we should produce and present our advice in future.

28. Our vision for the future builds on our place as an international leader in evidence synthesis, guideline development and technology evaluation. To develop and enhance this reputation, we need to make effective use of digital technologies and AI to improve the way we work internally. As the number of new technologies increases and the volume of published research rises, we need an efficient internal process to keep up to speed with a rising workload. This will not only improve the service for users of NICE guidance but make the process quicker and more efficient.

29. We also need to improve the accessibility of our guidance and advice for end users. We have set out some key features below, all of which will be tested with relevant user groups as the work progresses. Any changes to our methods and processes will be subject to the usual consultation with stakeholders.

    - Advice and guidance integrated in a care pathway format, aimed at frontline practitioners. Medicines and new technologies will be positioned in the pathway shortly after guidance is published, to facilitate their use. It

will be designed to be adopted into third party digital systems as appropriate, to increase its accessibility.

- Online, citeable publication of systematic reviews and technical reports. This will represent an important resource for researchers and academics, as well as for those interested in the detail underpinning our recommendations. This may require establishing an arrangement with a third-party publisher.
- Easy to access listings on decisions about new technologies, aimed primarily at commissioners and the life science industry. This will particularly help those with a responsibility for funding our recommendations.
- A dedicated stakeholder platform to enable stakeholders to register once, for all aspects of NICE's work. It will bring together all planned and ongoing consultations and will provide a single portal for responses.

30. Achieving our vision for the future is a multi-year programme of work, involving new ways of working for NICE and an improved external presentation. Because the COVID-19 work has prompted changes to our internal processes and a drive to use new technologies, the priorities for 2020/21 reflect internal efficiencies rather than an external presentation. The following list sets out what we aim to deliver during 2020/21, but the timing may be affected by the focus on COVID-19.

    - Delivery of internal efficiency improvements, including rollout of selected Office 365 applications for the handling of confidential information and declaration of interests, plus a review and investment decision for the use of SharePoint and MS Dynamics.
    - Improved internal handling of stakeholder comments through the implementation of the comment collection tool.
    - More efficient production of systematic reviews by rolling out the EPPI-Reviewer tool to the guideline Collaborating Centres.
    - Improved approach to surveillance of new research publications by conducting a cross-organisational review and delivering an options appraisal for integrated surveillance.
    - Generate productivity improvements by reviewing the processes used to develop rapid COVID-19 guidelines compared with standard processes .
    - Introduce one external registration point for stakeholder information on the website following an internal process review.

31. We will also continue work to develop a Life Sciences information hub, citeable publications and integrated guidance prototypes. Progress will depend on available capacity and resources.

32. These objectives will require dedicated staff to support and govern the changes, with additional input from staff across the organisation, plus external expertise where required. A new director role has been created to ensure that NICE uses

the best available evidence in its guidance to support health and care decision makers, with a specific responsibility for developing NICE's use of real-world data, and for building it into our routine assessment of evidence. We are also investing in our digital, information management and technology capacity and capability bringing together our IT and digital teams into a joint function under a single director. New governance mechanisms have been established to oversee and monitor progress and we will work carefully with staff to inspire their support and involvement. The transformation will impact across our programmes and this is outlined further below.

Our programme objectives

33. This section summarises our key areas of work and outputs for the health and care system. We have a wide portfolio of products, with differing status in the health and care system. The descriptions below list NICE's planned activity but, inevitably, some of this has been affected by the COVID-19 pandemic.

Principles for developing guidance and quality standards

34. The principles that underpin the development of our guidance and standards were updated in January 2020, and state we will:

- Prepare guidance and standards on topics that reflect national priorities for health and care
- Describe our approach in process and methods manuals, and review them regularly
- Use independent advisory committees to develop recommendations
- Take into account the advice and experience of people using services and their carers or advocates, health and social care professionals, commissioners, providers and the public
- Offer people interested in the topic the opportunity to comment on and influence our recommendations
- Use evidence that is relevant, reliable and robust
- Base our recommendations on an assessment of population benefits and value for money
- Support innovation in the provision and organisation of health and social care services
- Aim to reduce health inequalities
- Consider whether it is appropriate to make different recommendations for different groups of people
- Propose new research questions and data collection to resolve uncertainties in the evidence
- Publish and disseminate our recommendations and provide support to encourage their adoption

- Assess the need to update our recommendations in line with new evidence.

Guidance and advice

Guidelines

35. **NICE guidelines** make recommendations based on the best available evidence on a wide range of topics ranging from preventing and managing specific conditions, improving health, and managing medicines in different settings; providing social care and support to adults and children; and planning broader services and interventions to improve the health of communities. Guidelines covering clinical and social care topics aim to promote individualised and integrated care, including for example transitions between children's and adult services, and between health and social care. NICE guidelines include, where appropriate, recommendations on the organisation and delivery of care in health and social care services. Though not covered by a funding requirement or the NHS Constitution, they are an important reference for health and social care professionals and commissioners in the NHS, who are expected to take them into account, and for people who use health and care services.

36. NICE is a world leader in the development of evidence-based guidelines. Our portfolio includes over 300 guidelines across clinical, public health, social care, medicines practice, antimicrobial prescribing and cancer service topics, and there is a pipeline of topics waiting to begin. The way that guidelines are developed, maintained and distributed to their intended users is changing, driven by technology, the exponential increase in data and evidence and increasing demand and personalisation of care. Guidelines need to be rapidly updated in line with significant shifts in the evidence, relatable to individual service users, easy to access, interactive and integrated into workflows. The days of the condition-specific, linear, 'one size fits all' guideline that lags behind rapid advances in clinical research and medical technologies are numbered.

37. A number of changes are therefore proposed in the short to medium term to transform the way that guidelines are developed, maintained and presented. This is particularly important in the context of the COVID-19 pandemic, and the need for NICE to have the capacity to be responsive and flexible. We will review the principles and mechanisms by which new guideline topic referrals and updates are prioritised, to ensure we best align our capacity to the needs of our end users.

38. Our vision for our guidelines work is to build on the best, to streamline, simplify and speed up. We will adapt and focus on the things that matter most to patients and health and care professionals. This will mean a more flexible approach and more timely updating allowing us to focus resources on maintaining recommendations where we can add most value.

39. In March 2020, we were asked to produce rapid guidelines on COVID-19 topics. The necessary speed for development of these guidelines necessitated the publication of an interim process and methods guide for rapid guidelines on

COVID-19. The guidelines are produced in collaboration with NHSE/I using a cross-specialty clinical group, supported by the specialist societies and Royal Colleges. They are co-badged with NHSE/I and available for health systems around the world.

Quality standards

40. **Quality standards** are derived from our guidelines and provide clear, concise statements of high-priority areas for quality improvement, covering health, public health and social care. They help commissioners and providers improve quality by providing measures of best practice to support ongoing performance improvement. Quality standards include content related to all three dimensions of quality – safety, effectiveness and experience – and take into account overall cost impact.

41. Although quality standards are not mandatory, they are an important driver for change within the arrangements for commissioning and service delivery in health and social care. Both the Secretary of State and NHS England must have regard to NICE quality standards. Quality standards are also identified as a key tool for bringing clarity to and measuring quality, as part of the National Quality Board's 'Shared commitment to quality'. In social care, their role is reflected in Quality Matters. In public health, we continue to work with Public Health England to support their use in local government.

Guidance on health technologies

42. **Technology appraisals** (TAs) develop recommendations for the NHS on drugs and other treatments based on their clinical and cost effectiveness. We currently appraise all new and significant licence extensions for cancer drugs, and we will be appraising all new active substances and significant extensions to marketing authorisations to add significant new therapeutic indications in accordance with the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (2019 VPAS) for medicines licensed after April 2020. We currently aim to publish final guidance for new cancer drugs within 90 days of granting of the marketing authorisation and following the 2019 VPAS we will begin to extend that target to all drugs with a new active substance. Regulations provide for the mandatory funding of drugs and treatments which are recommended in a technology appraisal and that funding must normally be available within 3 months of final guidance publication. Entitlement to these drugs is set out in the NHS Constitution. The 2019 VPAS also provides the opportunity for NICE to work with companies and NHSE/I on structured approaches to confidential commercial agreements to facilitate the introduction of cost effective treatments and to work with system partners on an integrated horizon scanning initiative.

43. We also have responsibility for evaluating and developing recommendations on selected **highly specialised technologies** (HSTs) which have been developed for treating conditions which affect very small numbers of people in England. Regulations provide for the mandatory funding of drugs and treatments which are recommended in a highly specialised technologies evaluation and that

funding must normally be available within 3 months of final guidance publication. Entitlement to these drugs is also set out in the NHS Constitution.

44. In accordance with the commitments in the 2019 VPAS we are undertaking a review of the methods guides for our technology evaluation programmes, including the routing criteria for the highly specialised technologies programme, ensuring that they are robust and fit for purpose. There will be a 6-week public consultation on the case for change to methods and processes, and a second consultation presenting the draft programme manual . Before the consultation we will carry out targeted engagement with stakeholders, during which we will ask for feedback on elements of the update. Subject to Board approval, the aim is to publish the manual in Spring 2021 and implementation of the changes will take place as quickly as possible afterwards.

45. In April 2018, the TA programme implemented an updated process. The new process provides an early engagement step with companies to resolve key technical and commercial issues ahead of the first appraisal committee meeting. The aim was to maximise the opportunity to go straight to publication of the Final Appraisal Document (FAD) after the first committee meeting, avoiding the requirement for consultation and a second committee meeting. To date, this new process has not meaningfully reduced the number of topics requiring more than one committee meeting, while it has significantly increased demands on NICE staff and committee members. A contingency plan has been put in place to manage capacity constraints in the technology appraisal programme, exacerbated by COVID-19.

46. Changes to the TA and HST programmes, such as the introduction of a technical engagement step and the HST cost/QALY level, have substantially increased the need for NICE to ensure companies have meaningful opportunities to engage in commercial and managed access conversations with us and NHSE/I. Commercial negotiation and managed access activity is resource intensive, sensitive and highly complex and we have established a Commercial and Managed Access function, incorporating commercial liaison and managed access, to help us engage with companies and NHSE/I.

47. The life sciences sector deals, the NHSE/I Commercial Framework (in development), the NHS Long Term Plan, the Accelerated Access Collaborative (AAC), and the Government's commitment to establish an innovative medicines fund will continue to drive requirements for activities across the various technology evaluation programmes, the associated commercial and managed access activities, the Office for Market Access and the AAC Secretariat during 2020/21. Specific drivers are the interest in a single horizon scanning function, opportunities for early engagement, support for rapid uptake products and expansion of managed access agreements beyond cancer and the highly specialised programme. At an operational level, we are working to support NHSE/I to deliver their aims across these activities.

48. The Research to Access Pathway for Investigational Drugs in COVID-19 (RAPID-C19) is a multi-agency initiative involving MHRA, NHSE/I Specialised Commissioning, NICE and NIHR to ensure safe and timely patient access to

medicines useful in treating patients with COVID-19 infection. The RAPID-C19 horizon scanning and candidate prioritisation activities will be coordinated by NICE and will feed into the Rapid Early Access to Medicines Scheme (Rapid EAMS Covid-19), run by MHRA. NHS England and NHS Improvement will develop national interim clinical commissioning policies that assess the financial impact, the place in the pathway and the enactment of the Rapid EAMS COVID-19 Scientific Opinion (SO). This will support access across all commissioned services (not just directly commissioned).

49. Our **medical technologies guidance** aims to identify cost saving interventions and recommends them to the NHS when the sponsor's case for adoption is supported by the evidence. The guidance is based on advantages to individuals and to the NHS compared with current practice, and it includes detailed consideration of costs, settings and the whole pathway of care.

50. Our **diagnostics guidance** advises on the clinical and cost effectiveness of diagnostic technologies that have the potential to transform clinical diagnosis pathways to achieve better outcomes and, in some cases, promote efficiencies. The scope of technologies to provide a diagnosis quickly and efficiently is an important consideration. We are working with NHSE/I, MHRA and PHE to develop tools to support the system on COVID-19-related diagnostics, which may include an evidence standards framework and a template for a technical specification to provide information on tests that are approved via the Public Health England clinical evaluation process.

51. **Medtech Innovation Briefings (MIBs)** provide the NHS and social care with information on promising medical technologies as an aid to local decision making by clinicians, commissioners and procurement professionals, and inform people about new technologies. We will continue to work collaboratively, particularly with NHSE/I, to develop MIBs as a rapid responsive resource where the need for information has been identified directly from the NHS, this includes MIBs for medical devices and digital health technologies that are useful in the context of COVID-19.

52. The second sector deal relating to the Life Sciences strategy (2018) and the 2019 NHS Long Term Plan both called for NICE to increase its outputs on medical technologies and diagnostics, also incorporating the evaluation of new digital health technologies. Funding for this expansion was finalised with DHSC in 2019/20, which will be fully implemented in 2020/21. The NHSE/I medtech funding mandate, which aims to accelerate the uptake of selected NICE-approved cost saving devices, diagnostics and digital innovations will also take effect from April 2020.

53. NHSE/I commissioned us to carry out a digital health technologies (DHTs) pilot in 2019/20. We are using this to pilot a process for developing guidance on digital products and health apps. The pilot includes novel features, designed to be appropriate for these products which often have an immature evidence base. The pilot process will be evaluated to determine how best to develop guidance on these technologies in the future. Our process and methods will be amended accordingly, and from 2020/21, guidance will be produced on these products,

taking account of their distinctive features, while applying our core, robust evaluation methods via our existing medical technologies and diagnostics programmes.

54. The work included Phase II of the Evidence Standards Framework-DHTs project. The evidence standards framework for digital health technologies was developed jointly with other stakeholders in 2018/19 and has a very high degree of visibility among digital developers, being one of the most downloaded documents ever produced by NICE. Phase II was designed to address further evolution of the standards developed at Phase I, guided by feedback from stakeholders. This second phase will help enable the evidence standards framework to be operationalised, offering practical support to users in industry and other public sector bodies, and enabling robust approaches to assessment that will help de-risk adoption of new products.

55. Because of the complexity of the regulatory picture for some AI products, NICE is working with system partners including MHRA and CQC to better understand the regulatory pathway through to health technology evaluation. Funding from the NHSX Artificial Intelligence Regulator Incubator may also increase the capacity to further develop methods for the health technology assessment of AI-driven digital health technologies. In addition to the DHT pilot, NHSE/I has asked us to support their efforts on enabling limited adoption and evidence generation on promising AI products. We will produce suitable outputs on such products via our existing processes.

56. Further demand for diagnostics evaluations by the Diagnostics Assessment Programme may also arise from the recently established NHS Genomic Medicine Service, which aims to improve diagnosis and treatment both for patients with rare diseases and cancer. This could mean in the longer term, additional diagnostics guidance topics based on genomic panels. We are also looking at the potential implications of the independent review of adult screening programmes in England on our work.

Advice on safety and effectiveness

57. Our **interventional procedures guidance** provides important advice on the safety and efficacy of new interventional procedures, including those used in hospital, in the community and in people's homes. An interventional procedure is one used for diagnosis or treatment that involves making a cut or hole in the body, entry into a body cavity or using electromagnetic radiation (including X-rays or lasers). Topics for this programme are referred by any source including manufacturers, individuals, other programmes at NICE, and the health professionals who wish to use them. We continue to work with strategic partners to ensure the outputs are applied with consistency in the NHS in the 4 UK countries and in the private health sector.

58. The Independent Medicines and Medical Devices Safety Review (Cumberlege Review) is expected to report in 2020. Consideration will be given to the potential impact on the interventional procedure programme and other programmes in NICE where the conclusions are expected to be of relevance.

Medicines and prescribing

59. In addition to the recommendations in our guidelines, and technology appraisal and highly specialised technologies guidance, we provide a comprehensive suite of guidance, advice and support for optimal use of medicines. These include evidence summaries, decision aids, medicines awareness services and the NICE associates programme. Prescribing advice for the NHS is provided via the British National Formulary (BNF) and through NICE's digital evidence resource.

60. **Evidence summaries** provide information on the effectiveness, safety, resource impact and person-related factors for new medicines which are not the subject of a timely technology appraisal. We also produce evidence summaries on the use of unlicensed or off-label medicines in conditions where there is no licenced alternative, supporting cross-system initiatives to facilitate the adoption of repurposed medicines with a robust evidence base. These are commissioned by NHSE/I specialised commissioning and provide the evidence base to support NHSE/I commissioning policies. Evidence summaries do not constitute formal recommendations; they summarise the available evidence to inform commissioning policies and local decision-making.

61. The medicines and prescribing team in conjunction with the public involvement programme develop **shared decision aids** to support decision making between clinicians and people using services. People have the right to be involved in discussions and make informed decisions about their treatment and care with their healthcare team. The decision aids intend to help a person making a decision to weigh up the possible advantages and disadvantages of the different options available to them, explaining the treatment and care options in a way they can understand.

62. We are also producing rapid evidence reviews on medicines used to manage COVID-19 or its symptoms. The first topics are the short term use of NSAIDs for acute viral respiratory infection and ACE inhibitors. These will be used by NHS England as the basis for commissioning policy.

Indicators

63. We provide a range of evidence-based **indicators** to support national and local measurement of quality improvement. Currently, indicators are predominantly developed for the Quality and Outcomes Framework (QOF) used in general practice and for commissioner level outcomes, presently reported at Clinical Commissioning Group (CCG) level in two national measurement frameworks: the CCG Outcomes Indicator Set (CCG OIS) and the CCG Improvement and Assessment Framework (CCG IAF).

64. NICE indicators are underpinned by evidence-based guidance and have been through a rigorous process, which includes development by an independent expert committee, testing and piloting in partnership with NHS Digital, and public consultation. Indicators not suitable for, or not chosen for, inclusion in

specific national frameworks can be used to measure the quality of care in local quality improvement schemes.

65. From 1 April 2020, NICE will also work in partnership with NHS Digital to deliver and maintain the national library of quality assured indicators. This will involve us maintaining a subset of indicators that are already in the library and assuring a small number of new indicators which are referred from the DHSC or one of its ALBs.

Improving Access to Psychological Therapies (IAPT) assessment briefings

66. To support NHSE/I's programme to improve access to psychological therapies, we review data on the performance of a number of digitally assisted therapies for depression and anxiety which were recommended for evaluation in practice in mainstream IAPT services by a NICE expert panel. The panel use this information to assess if the technology performs at least as well as NICE recommended non-digital therapy with a reduction in the unit cost allowing an increase in activity within current resources. 2020/21 is expected to be the final year of this programme.

Adoption and impact

Implementation strategy

67. NICE guidance and advice must be effectively implemented to have any impact on the health and wellbeing of the population and the quality of care provided. To facilitate this, NICE has an implementation strategy with five specific objectives, which are to:

- produce guidance and standards that are fit for the audience's needs
- ensure relevant audiences know about the guidance recommendations, through an effective communications function
- motivate and encourage improvement
- highlight practical support to improve local capability and opportunity
- evaluate impact and uptake.

68. To keep the strategy up to date and in line with the evidence, NICE has an Implementation Strategy Group comprised of academic leaders in the field of health, care, social science, and public involvement. The group advises on new areas of implementation science and engages with the research community to stimulate evaluation of significant areas of implementation and improvement science to inform our work.

69. We also work closely with national partners, including the CQC, PHE and NHSE/I to ensure that NICE guidance is embedded as appropriate in their activities. During 2020/21 we will review our partnership agreements with all relevant national organisations, including professional bodies, and ensure they are fit for purpose as we move forward with the NICE Connect transformation programme.

Practical support

70. NICE provides or endorses implementation support products for a range of purposes, including support for commissioning, for service improvement and audit, and support for education and learning, all with the aim of making implementation of our products more straightforward. We formally endorse externally produced resources where these are in line with NICE recommendations, to help users identify high quality resources that can facilitate change.

71. Some examples of support provided directly from NICE include:

    - the web based 'Into practice' guide for organisations on how to put evidence into practice
    - a forward planner updated monthly to summarise our future work programme, provide indicative costs and highlight links with the tariff
    - a Shared Learning Collection on the NICE website highlighting effective local implementation examples.

72. We also have a regional field team that provides information about NICE and practical support, particularly around effective processes for implementation, to local and regional organisations across health and social care. The team provides tailored advice for the sustainability and transformation partnerships (STPs) and Integrated Care Systems (ICSs), and will continue to work closely with NICE's medicines and prescribing associates to maximise our impact, support and advice to the service. We will review the most effective way of using their input during the COVID-19 pandemic.

Adoption of health technologies

73. We support the uptake of new technologies through our work with the Accelerated Access Collaborative (AAC) in conjunction with the Academic Health Science Networks, the Office for Life Sciences, and NHSE/I. The vision is to coordinate and align identification of transformative technologies, identification of implementation barriers, and uptake data, with clinical engagement, to provide system learning and drive adoption and uptake. We facilitate the adoption of prioritised medical technologies across the NHS through engagement with clinical teams, commissioners, patient groups and industry.

Measuring uptake and impact

74. We measure the use of NICE guidance and capture this in regular impact reports that look at how the health and care system uses our recommendations in priority areas. The reports are based on data from national audits, reports, surveys and indicator frameworks. They are presented to our public Board meetings, published on our website and publicised through communications activities.

75. We also support the production of the innovation scorecard, the work of the Getting It Right First Time initiative, and the commitments made in the Voluntary Scheme for Branded Medicines Pricing and Access.

Engagement

Communications

76. The communications team explains what we do and why and protects and enhances our reputation. The team promotes NICE's core aim of improving quality and productivity of healthcare, public health and social care services.

77. Since mid-March 2020 most staff in the directorate have moved to providing communications support for the development and promotion of the COVID-19 rapid guidelines. Most regular communications work, not associated with COVID-19 has been paused but is being kept under review.

78. When we are able to resume regular functions, work will continue to improve the NICE website and we are developing ways to use new digital platforms, including social and multi-media, to communicate with existing and new audiences as people change the way they access information.

79. Through our audience insights programme we will continue to regularly monitor and evaluate what our audiences think about NICE's products and services, how they use them, and what we can do to improve their interactions with us.

80. In all areas of communications work – from writing and editing guidance, responding to enquiries about our work, developing and maintaining digital content, through to our public affairs work with government, and engagement with the press and other media as well as internal audiences – we will ensure that guidance and advice is easily accessible, simple to use and readily understood. Our aim is to explain NICE's key role in delivering excellence in health and social care.

Involving people who use health and care services and the public

81. We ensure that individual patients, service users, carers and community members are directly involved in the development of each piece of NICE guidance, and have the opportunity to meet with the Board at the public Board meetings and question time sessions when these resume following the COVID-19 pandemic. During 2020/21 we will continue to seek to improve our approaches to lay involvement, including implementing recommendations from our public involvement strategic review. We will also explore broader opportunities for public engagement offered as part of the NICE Connect transformation programme.

82. We are committed to working with networks of organisations that represent the interests of the public, patients, people who use services and their carers. This includes groups such as Patients Involved in NICE (PIN), the Richmond Group (a collaboration of 14 health and social care organisations in the voluntary

sector), Healthwatch England, and other voluntary and community sector organisations. These are crucial to the development of our methods and our guidance, and well as championing the use of NICE guidance and standards.

Involving health and social care practitioners and organisations

83. In addition to the work described above to support guidance implementation, we recognise the importance of engaging health and social care professionals as members of our guidance-producing advisory bodies and as external experts. Their professional experience and their ability to interpret evidence is an essential contribution to our work. Given the demands made on their time in their routine work, we will continue to make sure that the opportunities we offer to become involved in our work are as attractive as possible. As noted above, we paused most of our committee work in March 2020 to release clinical committee members for frontline healthcare during the COVID-19 pandemic, and will only restart when appropriate.

84. Our Fellows and Scholars programmes are another way in which we can draw on the experience of health and social care professionals and help to create future advocates for the role of NICE. The Student Champions programme continues to be an important mechanism for educating and informing students about NICE and the importance of using evidence.

NICE International

85. NICE International was relaunched in November 2019 as the not-for-profit advisory service for international organisations, ministries and government agencies to support the use of evidence-based decision making in health and social care systems across the globe. We are developing our external strategy, which will feature on the NICE International website and will include elements relating to objectives, governance, project selection, collaboration with external partners and safeguarding of staff. We aim to have some well-established, long-term projects initiated by the end of the financial year.

Science, evidence and analytics

86. In November 2019 the Board agreed to establish a new director post with responsibility for science, data and analytics. This new role will increase senior capacity in this important area for NICE, bringing together three related areas of our work in a single directorate. The new directorate will take on responsibility for developing NICE's use of real-world data and building it into our routine assessment of evidence, as well as continuing to develop the science, policy, research, and evidence service functions at NICE.

Evidence services

87. **NICE Evidence Services** are online evidence resources to help people working in the NHS and wider public health and social care sector make better decisions by providing them with access to clinical and non-clinical evidence-based information of the highest quality. The service draws on a comprehensive range of information sources (including local experience), providing easy access to

information that has traditionally been hard to find. The system includes a 'simple search' built around a powerful search engine, as well as an advanced database search for researchers and information specialists who need to search content across a range of bibliographic databases. The BNF and BNFC are also available as part of this service, as well as the Clinical Knowledge Summaries, which summarise practice recommendations for over 330 topics typically presenting in primary care. Access to these multiple services is integrated within the NICE website and signposted from any page of the website. As part of the NICE Connect programme, we will explore opportunities to build further synergies between some of these services and the presentation of our core products.

88. The current service is built on an 'open-access principle' – as much content and functionality as possible is freely accessible. Access to some full-text content requires users to log on because of commercial arrangements with the information providers, although this is kept to a minimum and the log-on process is as simple as possible.

Data

89. Increases in the amount and breadth of data available, the development of new and efficient mechanisms for analysis, and advances in the way information is labelled, linked and shared, have the potential to significantly disrupt our traditional approaches to synthesising research evidence. Our work to exploit these opportunities will move forward at pace in 2020/21 following the Board's approval in November 2019 of our statement of intent for the future use of data and analytics within our guidance programmes and wider products. The use of data analytics has also been catalysed by our work on COVID-19 related guidelines, where traditional research evidence is lacking.

90. We will continue to develop our relationships with a range of external organisations with an interest in data and analytics, including Health Data Research UK and the Alan Turing Institute. We will also continue to work with the University of Manchester and the Connected Health Cities in the North of England to further explore, through practical examples, how big data can provide evidence relating to the effectiveness of new and existing treatments and produce new big-picture health insights.

Science policy and research

91. The Science Policy and Research programme leads on corporate scientific affairs and develops and maintains NICE's research governance infrastructure. The programme collaborates with and influences external policy partners and the research community to define and develop research projects of strategic importance to NICE. The team works with NICE's Internal Research Advisory Group to develop our methods and encourages partners to commission research relevant to our work. This includes membership of the DHSC Research and Development Committee and proactive involvement with national health research funders such as the Medical Research Council (MRC) and the National Institute for Health Research (NIHR).

92. The programme of scientific policy and research activities, which align to NICE's research priority areas, is increasingly delivered through grant funded research projects, including Horizon 2020 (H2020) and Innovative Medicines Initiative (IMI) activities. Outcomes from the projects are translated to practice through internal engagement with the guidance producing teams, and life sciences companies engaged in developments through the Office for Market Access and NICE Scientific Advice.

Digital, information and technology

93. In September 2019, the Board approved the integration of the NICE's business IT team with the digital services team. In 2020, the two teams will merge into a new Digital, Information and Technology (DIT) directorate. The focus of the team will be three-fold. It will continue to maintain and improve NICE's portfolio of live digital services. It will provide a reliable, secure business IT service to NICE staff, ensuring a seamless transition to the new multi-tenant office location in Stratford. Critically, the new DIT team will support the NICE Connect programme, recognising the timing of delivery of the NICE Connect objectives is likely to be affected by the COVID-19 disruption.

94. As part of NICE Connect, key areas of investment will include the implementation of a new digital workplace strategy. This will include the development of our internal information management capability and enabling operational and workplace productivity through improved collaboration and process automation. The Office 365 suite will be rolled-out further to meet prioritised staff needs, with training provided. In the context of the coronavirus disruption, some elements of this transformation are being accelerated and refocused, for example around remote working and enabling virtual events.

95. To support the integrated product vision of NICE Connect, the team will contribute to the development of NICE's new content model and content management system. Where suitable, it will start to embed the use of standards to improve the interoperability of new guidance with external IT systems. It will also work with the new Science, Evidence and Analytics directorate to invest further in our evidence management systems and to strengthen NICE's technical and data architecture foundations to enable increasing data science activity.

People and resources

Sources of funds

96. We receive most of our funding directly from the Department of Health and Social Care (DHSC) through Grant-in-Aid. This funding (£52.5m) is used to pay for the majority of our core activities and is based on our baseline funding remaining the same as in 2019/20 (£49.5m) plus £2m to increase the capacity of our Medical Technology programme as set out in the 2018 Life Sciences Sector Deal 2 and £1m funding to support the NICE Connect project.

97. Since 1 April 2019, technology appraisal (TA) and highly specialised technologies (HST) assessments have been funded by fees for each new assessment from the sponsoring company. Our approach to setting fees is in line with full cost recovery rules as set out in HM Treasury's Managing Public Money.

98. We receive funding from NHSE/I to support their specialised commissioning programmes and from Health Education England to procure and provide the national core content service for the NHS. Income from the devolved administrations in Wales, Scotland and Northern Ireland contributes to the cost of guidance production, producing the British National Formulary (BNF) and some supporting services. Service level agreements and contracts set out the level of funding that will be provided and which outputs can be used by each country or support to be provided.

99. Income from other sources includes:

    - the NICE Scientific Advice programme that provides early advice to the pharmaceutical and medical technology industries.
    - working with funders including international bodies, charities and policy organisations on applied and methodological research to support changes in health and social care delivery.
    - rental income from sub-letting office space in our Manchester and London offices.

100. The table below shows the planned sources of funds for 2020/21. These amounts are subject to change, as throughout the year the technology appraisal programme and demand for services from our income generating teams such as NICE Scientific Advice are likely to be affected by the COVID-19 pandemic. Our current estimate (as at April 2020) of a reasonable worst-case scenario is that total sources of funding will reduce by £4.0m and in the worst case scenario by £5.7m. Steps will be taken to offset and mitigate the potential lost income, for example only recruiting to critical posts and reducing non-fixed costs such as travel where possible.

Sources of funds	2020-21 funding £m	Reasonable worst-case deficit £m	Worst-case deficit £m
Grant-in-Aid from DHSC	52.5		
TA and HST income	10.7	(3.7)[i]	(5.4)[ii]
NHS England	1.8		
Health Education England	4.0		
Other income	5.8	(0.3)[iii]	(0.3)[iii]
Total sources of funding	**74.8**	**(4.0)**	**(5.7)**

[i] 35% reduction in TA and HST income

[ii] 50% reduction in TA and HST income

[iii] Reduction in NICE Scientific Advice and Office for Market Access forecast income

How we apply our resources

101. The majority of our staff (with the exception of doctors and senior managers) are employed on an Agenda for Change contract which is the national pay system of all NHS Staff. The pay budget (set before the COVID-19 pandemic) for 2020/21 is £46.8m for 757 staff, including expected pay increases as part of the current NHS pay deal.

102. The non-pay budget for 2020/21 is £28.0m. This includes the costs of purchasing and distributing the BNF to the NHS, the core content purchases funded by Health Education England and contracts relating to the guideline development centres and medical technology external assessment centres. It also includes the costs of our offices in Manchester and London and running our committee meetings.

103. The Transformation Unit in the table below includes resource for the NICE Connect project and coordination of the COVID-19 response. It includes budget for staff and non-pay budget for specialist contract expertise and consultancy advice to support the content and operational productivity taskforces and complete the first phase of work on developing a strategy for a digital workplace and roll-out of Office 365.

104. The table below shows the operational budgets for each centre and directorate within NICE for 2020/21. As noted above, these budgets were set before the COVID-19 pandemic and will be reviewed regularly during the year. It is assumed that due to the pandemic there will be vacant posts that will be unfilled during the year, which will release savings to offset some of the likely funding deficit noted earlier. There will likely be savings on variable non-pay costs such as travel too.

Application of funds	Number of staff	Pay £m	Non-Pay £m	Total operational Budget £m
Centre for Guidelines	106	7.0	10.9	17.9
Centre for Health Technology Evaluation	223	13.6	3.2	16.8
Health and Social Care Directorate	127	8.4	0.7	9.1
Science, Evidence and Analytics	59	3.8	5.1	8.9
Digital, Information and Technology	74	4.6	1.8	6.4
Communications	77	4.5	0.4	4.9
Business Planning and Resources	70	3.7	5.1	8.8
Transformation Unit	21	1.2	0.8	2.0
Total application of funds	**757**	**46.8**	**28.0**	**74.8**

105. Our current best estimate is that savings on pay and non-pay will amount to approximately £3.6m. This would reduce our deficit to £0.4m in the reasonable worst-case scenario and £2.1m in the worst-case scenario. We believe we will be able to find non-recurrent savings to balance the lower of these amounts but if the worst-case scenario does materialise we will likely need additional funding support from DHSC. We expect that we will continue to expend resource on work related to the COVID-19 pandemic and as such may work with DHSC to formulate a case for funding in relation to this work.

Scenario	Reasonable worst-case scenario £m	Worst-case scenario £m
Reduction in funding	4.0	5.7
Non-recurrent savings	(3.6)	(3.6)
Current estimated deficit	**0.4**	**2.1**

Estate strategy and capital requirements

106. We are committed to the Places for Growth strategy and the smarter working agenda. As part of this, we are moving our London office from central London to a new “health hub” in Stratford. This flagship project will make efficient and effective use of shared office space between 5 ALBs. As landlord, the DHSC is meeting the costs of fitting out the new office, but there will be a need for us to invest in our IT equipment and infrastructure. In order to ready ourselves for this move and the required new ways of working in a hub we will be investing in laptops and associated kit and embracing Microsoft Office 365 in the first 6 months of 2020.

107. We had aimed to complete the move in November 2020 but it is likely to be delayed due to the disruption from the coronavirus pandemic. We are working with the DHSC and the other ALBs to establish a revised timescale for the move and are developing options and contingency plans to mitigate the impact of the delay. We are also considering the need for social distancing in our office accommodation to ensure the safety of staff. In the medium term, we will review

the use of office space in the light of improved home working as a result of the COVID-19 restrictions.

108. The Manchester office has been in operation since 2007 and is in need of significant refurbishment for us and our sub-tenants. We are planning to make investments to align with mature smarter working principles and to mirror the London hub model. This work will take place over the next 2 financial years, with a capital requirement of £2.5m over 2020/21 and 2021/22.

Workforce developments

109. We are now in year two of the Workforce Strategy, which is a three-year plan that sets out the strategic direction of the Human Resources (HR) department. It is underpinned by an annual HR business plan that sets out the specific projects and objectives to be undertaken that year to support the strategy.

110. A key activity over the year will be to manage the wide-ranging implications of the coronavirus pandemic on the workforce, including loss of staff capacity from sickness and the additional carers' responsibilities arising from the school closures. This, and the re-prioritisation of our work, means we will need to regularly review the way workforce resources are deployed to ensure capacity is matched to demand. The other key project will be supporting the business with the people strands in the NICE Connect transformation programme.

111. We will be rolling-out the in-house recruitment service across NICE. This will enhance our recruitment service and improve the hiring manager and candidate experience. The recruitment team will work closely with hiring managers to formulate specific recruitment plans to achieve more effective resourcing strategies. This will include more targeted recruitment campaigns and increased use of social media platforms to maximise our employer brand. We also need to ensure we are ready for the new points system for recruitment from the EU.

112. We will be piloting a graduate programme and continuing to drive our apprentice strategy to increase our numbers, while identifying ways to maximise our use of the apprentice levy.

113. We will be developing a suite of personal and management development programmes, which will be easy to access from home. Wherever possible, we will create interactive learning environments and develop peer support networks.

114. We continue to progress our talent management activities by engaging with the DHSC and other leadership programmes, including attending steering groups and supporting assessment centres.

115. We are committed to staff engagement and will be involving our employees with the creation of NICE values and continue with our health and well-being initiatives with a particular focus on mental health. We are also refreshing our approach to on-boarding following a review of our induction.

116. Following a review of our appraisal process involving employees across NICE we will be rolling out a new approach called “Appraisal: My Contribution” which is designed to support high-quality conversations which are aligned to our organisational context, strategy and values, and enable honest conversations about aspirations and development.

117. Equality and Diversity remains a key theme in our people plan and in 2019/20 we took part in the NHS Workforce Race Equality Standard (WRES) survey for the first time and we will use this data to help inform our strategies. We will also be updating our equality objectives to cover the period 2020 to 2024.

Appendix 1: Indicative business objectives 2020/21

Note: the extent these can be delivered, and the timescale, will depend on the evolving and uncertain impact of the coronavirus pandemic

Transform the presentation, accessibility and utility of NICE guidance and advice, ensuring it is fully aligned to the needs of our users to support adoption	Delivery date
• Delivery of internal efficiency improvements as part of NICE Connect	• Ongoing
• Undertake a discovery for a commissioner/life sciences portal incorporating process and technical considerations and user research as part of NICE Connect	• Ongoing
• Undertake a Citeable Publications feasibility study and roll out in conjunction with NIHR as part of NICE Connect	• Q3 20/21
• Introduce one external registration point for stakeholder information on the website following an internal process review	• Ongoing
• Deliver a range of tools and support for the uptake of NICE products, including resource impact support, budget impact tests, endorsement statements, and shared learning examples	• Ongoing
• Manage and maintain NICE's live digital services utilising user insight and strategic service goals to prioritise use of the available resources	• Ongoing
• Commission biennial NICE reputation research to assess key stakeholders' views of NICE, deliver a research project to understand audience requirements for implementation support, and develop and deliver an audience insights strategy to support NICE Connect	• Q2 and Q4
• Deliver multi-channel marketing activities for major initiatives through the newly established brand and marketing team	• Ongoing
• Develop and implement a new social media strategy to ensure use of the most effective channels to reach and engage with our key audiences	• Q2 and ongoing

• Review the function and monitor performance of NICE Evidence Services (CKS, HDAS, BNF microsites, Evidence Search, Medicines Awareness Service)	• Ongoing
Transform the development of NICE guidance and advice in line with the learning from the COVID-19 response so the process is efficient, integrated, and takes advantage of new technologies including artificial intelligence	**Delivery date**
• Deliver guidance, standards, indicators and evidence products and services, in accordance with the planned volumes and requirements of the COVID-19 pandemic	• Ongoing
• Review the current and planned guidelines portfolio, in conjunction with NHS England/NHS Improvement and the Department of Health and Social Care, with a view to consolidating on key areas and topics, in the context of NICE Connect and the COVID-19 pandemic	• Q4
• Complete a review of the quality standards programme to establish its future direction based on stakeholder need and their positioning and presentation, in the context of NICE Connect	• Q4
• Complete a review of technology evaluation processes and methods, consult on changes and publish updated manuals and implement changes early, on an interim basis, where they allow for faster recovery from COVID-19	• Q3/4 • Q1 2021/22 (for publishing updated manual)
• Implement the comment collection tool and roll out the EPPI-Reviewer tool to the guideline Collaborating Centres	• Ongoing
• Establish a new science, evidence and analytics directorate to lead on the opportunities offered by new scientific developments, and wide ranging sources of data and advanced analytics, in guidance development	• Q2
• Publish a detailed methodological framework for consideration and use of data analytics across NICE's programmes, following internal engagement and public consultation, ensuring a compliant data management infrastructure to host and process this data	• Q4
• Complete the pilot for the development of a digital health technology evaluation workstream, publish process and methods for routine consideration of selected digital health technologies, and further develop the Evidence for Effectiveness standards	• Q2

• Develop and embed new data and information management capability including establishing an integrated digital, information and technology directorate	• Q2
• Identify priority areas for digital investment and deliver these in partnership with the business through the NICE Connect taskforces and the wider Connect programme	• Ongoing
Play an active, influential role in the national stewardship of the health and care system	**Delivery date**
• Support the wider health and care system by producing and maintaining guidelines and other products relevant to the management of COVID-19, and to actively participate in the multi-agency initiative with the MHRA, NHSE/I and NIHR to support the transition from research to access for promising treatments	• Ongoing
• Work with NHS England and other health and care system partners to support the implementation of the NHS long term plan as part of a strategic engagement plan	• Ongoing
• Further develop the relationship with NHS England Specialised Commissioning in the areas of commercial and managed access, genomics and guidance and advice development	• Ongoing
• Design and put in place changes to our current technology appraisal processes in order to continue to ensure consistency with UK regulatory arrangements, incorporating learning from the joint response to COVID-19	• End of Q3
• Work with system partners on relevant areas of policy interest including NHS England/Improvement and Public Health England on antimicrobial stewardship, the review of adult screening programmes in England, quality of life measurements, emerging technology areas such as genomics, and relevant aspects of the Independent Medicines and Medical Devices Safety Review	• Ongoing
• Renew the national framework for content procurement for the NHS (Q3) and put in place a new contract for access to the Cochrane Library in England (Q1)	• Q3 and Q1
Support the UK's ambition to enhance its position as a global life sciences destination	**Delivery date**
• Develop technology appraisal guidance in line with the commitments in the 2019 Voluntary Scheme	• Q4
• Deliver the actions set out for NICE in the Government's life sciences sector deals, including enhancing NICE's role as an active partner in the Accelerated Access Collaborative (AAC)	• Ongoing

• Maintain and develop a fully integrated offer to the life sciences industry, including topic selection, guidance development, commercial and managed access activities, and NICE Scientific Advice	• Ongoing
• Work with NHS England/Improvement and DHSC on plans for the creation of an innovative medicines fund that extends opportunities for managed access beyond cancer, secure additional funding to support NICE's contribution, recruit staff and implement changes to business as usual processes	• Q4
• Enhance collaboration with system partners, including NHSX and the MHRA on activities supporting future regulatory and health technology assessment offers for medicines, medical technologies, diagnostics and digital/AI health technologies, including the use of real-world evidence pre- and post-licence and the provision of early scientific advice, incorporating learning from the joint response to COVID-19	• Ongoing
• Maintain and further develop NICE's global leadership role in use of health technology assessment and guideline development processes and methods to inform decision making in health and social care systems across the world	• Ongoing
Generate and manage effectively the resources needed to maintain and transform our offer to the health and care system	**Delivery date**
• Review our business processes and roll-out new tools to improve our operational productivity to enable us to do more with our resources as part of the NICE Connect transformation	• Ongoing
• Deliver against plan for all budgets and achieve or exceed on non-Grant-in-Aid income targets	• End of March 2021
• Collaborate with the research and policy communities nationally and internationally in topic areas agreed strategically important to NICE, delivering existing grant funded research projects to plan and timetable, and securing a pipeline of new projects for 2021/22	• End of March 2021
• Deliver scientific advice, including the offers in the context of COVID-19, and NICE International activities to target	• End of March 2021
Maintain a motivated, well-led and adaptable workforce	**Delivery date**
• Ensure that all staff have clear objectives supported by personal development plans	• End of Q1

• Actively manage staff engagement and morale in the context of the COVID-19 pandemic and the NICE Connect transformation, with the objective of ensuring that staff feel supported and able to work remotely when required	• Ongoing
• Review our people processes to enable different ways of working as part of the NICE Connect transformation	• Ongoing
• Implement the actions set out in the workforce strategy for 2020/21	• End of Q4
• Plan and deliver the move to the new London office, including transforming NICE's IT arrangements to fit the multi-tenant site and adjusting working arrangements across the whole NICE workforce accordingly	• End of Q4
• Begin a programme of improvements to the Manchester office to ensure best use of the space available	• End of Q4

Appendix 2: Balanced scorecard 2020/21

Note: the extent these can be delivered, and the timescale, will depend on the evolving and uncertain impact of the coronavirus pandemic, and the degree to which the programmes are able to find ways to speed up recovery and work through the backlog..

Guidance, standards, indicators and evidence

Success Criteria	Planned output	Forecast revised output due to COVID-19	Key measures	Target (against forecast revised output) [1]
Publish guidelines				
• Clinical areas	13	3	Publication within stated year	80%
• Public health	2	1	Publication within stated year	80%
• Social care	1	0	Publication within stated year	80%
• Managing common infections	4	0	Publication within stated year	80%
• COVID-19 rapid guidelines	0	21	Publication within stated year	80%
Publish technology appraisals and highly specialised technologies guidance	98	Up to 70	Publication within stated year	80%
Publish interventional procedures guidance	33	Up to 25	Publication within stated year	80%
Publish diagnostics guidance	Up to 11	Range from 5 to 7	Publication within stated year	80%
Publish medical technologies guidance	Up to 14	Range from 5 to 10	Publication within stated year	80%
Publish medtech innovation briefings (MIBs)	Up to 46	Range from 20 to 30	Publication within stated year	80%

[1] The targets have been set at a level to reflect there will factors outside of NICE's control that affect publication timelines.

Success Criteria	Planned output	Forecast revised output due to COVID-19	Key measures	Target (against forecast revised output) [1]
Deliver commercial briefing notes for NHS England to support discussions with companies	Up to 60	Up to 40	Delivery within stated year	80%
Advise on 'Patient Access Schemes'	Up to 55	Up to 37	Delivery within stated year	80%
Deliver new data collection agreements	Up to 22	Up to 15	Delivery within stated year	80%
Complete data collection projects and associated managed access agreement exits	Up to 12	Up to 12	Delivery within stated year	80%
Actively monitor existing data collection projects.	Up to 52	Up to 52	Delivery within stated year	80%
Manage portfolio of evaluative commissioning projects for NHS England	Up to 2	Up to 1	Submission to NHS England Clinical Panel within stated quarter	80%
Publish guideline surveillance reviews	20	Up to 20	Publication within stated year	80%
Deliver evidence summaries – antimicrobial prescribing	Up to 4	Up to 4	Publication within stated year	75%
Deliver evidence reviews for NHSE specialised commissioning (including COVID-19 rapid evidence summaries)	Up to 10	3	Delivery to NHS England within year	80%
Deliver quality standards	16	8	Publication within stated quarter	80%
Deliver indicator menu	1	1	Publication within stated year	100%
Deliver endorsement statements	30	20	Publication within stated quarter	80%
Deliver shared learning examples	50	25	Publication within stated quarter	80%
Publish monthly updates of the BNF and BNF C content	12	12	Publication within stated quarter	80%
Deliver a regular medicine awareness service	50	50	Publication to regular schedule	90%
Deliver medicines advice products	10	10	Publication within stated quarter	80%
Develop 'rapid action plans' in context of RAPID-C19	0	Up to 15	Develop within state year	80%

Adoption and impact

Success Criteria	Key Measures	Target
Publish resource impact products to support all NICE guidelines (excluding COVID-19 rapid guidelines), positively recommended technology appraisals, medical technologies and diagnostics guidance at the point of guidance publication	Publication within year	90%
Coverage of NICE in the media	% of positive coverage of NICE in the media resulting from active programme of media relations	80%
Ensuring stakeholders have access to our websites as the main communication channel	Percentage of planned availability, not including scheduled out of hours maintenance	98%

Operating efficiently

Critical Success Factors	Key Measures	Target
Effective management of financial resources	Revenue spend	To operate within budget
Effective management of non-exchequer income	Net income received from non-exchequer income sources (including TA/HST cost recovery, Scientific Advice, Office for Market Access, research grants, knowledge transfer) measured against business plan targets	90%
Management of recruitment	Proportion of posts appointed to within 4 months of first advertisement	80%
Management of sickness absence	Quarterly sickness absence rate is lower than the average rate (2.75% for the 12 months to September 2019) across the Arms Length Bodies	2.75%

Critical Success Factors	Key Measures	Target
Staff satisfaction	Proportion of staff reporting in staff survey that the Institute is a good, very good or excellent place to work (global job satisfaction index)	80%
Staff involvement	Hold monthly staff meetings	80%
Staff well-being	Implementation of NICE's quality standard for healthy workplaces: improving employee mental and physical health and wellbeing in respect of own staff	80% of quality statements
Recycled waste	% of total waste recycled	90%
Improved satisfaction	Complaints responded to in 20 working days	80%
	Enquiries fully responded to in 18 working days	90%
	Number of Freedom of Information requests responded to within 20 working days	100%
	Parliamentary Questions (PQs) contribution provided within requested time frame	90%
Interest in lay committee vacancies reflected by ratio of applications to positions	2:1 (or greater) each quarter	100%
Speed of production[2]	% Technology appraisals for all new drugs with a new active substance referred to NICE issuing guidance within 90 days of the product being first licensed in the UK	90%

[2] The following caveats are taken into account when measuring performance:

1. % STAs for all new drugs with a new active substance issuing final guidance within 90 days of the product being first licenced in the UK
   - The product has been identified and referred early enough to allow for guidance publication to be timely, and
   - The company has not asked for the appraisal to be scheduled at a later date, which was accepted by NICE, and
   - The technology appraisal follows standard NICE process up to and including the first committee meeting, and
   - No changes to the regulatory schedule are received after the company has been invited by NICE to make an evidence submission, and

Critical Success Factors	Key Measures	Target
	% of multiple technology appraisals from invitation to participate to appraisal consultation document (ACD) in 41 weeks, or where no ACD produced to final appraisal document (FAD) in 44 weeks	85%
	% of Appeal Panel decisions received within 3 weeks of the hearing	80%

- No changes to the regulatory schedule are communicated before the appraisal has started, where the dates are brought forward without opportunity for NICE to react (that is notification less than 43 weeks before the CHMP meeting date) and
- No requests for further submission of evidence are made after the initial submission of evidence, including for a PAS or CAA, and
- No other factors out of NICE's control are in play (for example 'purdah and a pandemic such as COVID-19)

2. % of multiple technology appraisals from invitation to participate to ACD in 41 weeks, or where no ACD produced to FAD in 44 weeks
   - The technology appraisal follows standard NICE process up to and including the first committee meeting
   - No requests for further submission of evidence are made after the initial submission of evidence, including for a PAS or CAA, and
   - No other factors out of NICE's control are in play (for example 'purdah')

National Institute for Health and Care Excellence

Collaboration with the Medicines and Healthcare products Regulatory Agency (MHRA)

NICE has a long-standing relationship with the MHRA and for the past 6 years, collaboration has been guided through a partnership agreement which will be reviewed later this year. The partnership agreement sets out NICE's and the MHRA's distinct roles and key areas for collaboration and alignment of activities across the two separate organisations.

The attached paper was produced in collaboration with the MHRA and outlines the terms of reference, membership and initial priorities of a core strategic group to take forward the joint strategic priorities identified through two CEO bilateral meetings held late in 2019 and early 2020. The work of the core strategic group is one area of collaboration under the partnership agreement. The paper was presented to the MHRA Board on 27 April 2020.

The priorities initially identified largely concerned the need to develop a compelling national life science offer following EU Exit. Subsequently, urgent COVID-19 work was identified and prioritised.

The MHRA has a UK-wide remit whereas NICE is officially an England-only body and there may therefore be scope to engage the devolved administrations in this work.

The Board is asked to note the establishment of the core strategic group and provide advice on any aspects of the work programme.

Nick Crabb

Programme Director, Science Advice and Research

May 2020

Introduction

1. This paper proposes the membership and terms of reference of a MHRA and NICE core strategic group to take forward the joint strategic priorities identified through two CEO Bilateral Meetings held late in 2019 and early 2020. In particular, the group is tasked with identifying opportunities for collaboration in building a compelling national 'offer' across regulation and health technology assessment in support of patients, public health and the life sciences industry.

2. An urgent need has also been identified to develop an integrated approach across MHRA and NICE, and other partner organisations, to pull medicines potentially useful in treating COVID-19 infections from research into clinical practice as efficiently as possible, as well as to review existing medicines in the system relevant to the COVID-19 pandemic. This should therefore be the initial focus in the context of the RAPID-C19 pathway, with learning and experience of joint working applied as appropriate to the broader national "offer". In addition, there may be opportunities as part of the COVID response to work jointly on guidance documents.

Background

3. The MHRA and NICE have developed a strong collaborative relationship in line with the Memorandum of Understanding between the two agencies. A key workstream in 2018-19 was to develop an effective interface between the proposed MHRA Targeted Assessment and NICE Technology Appraisals processes as part of Brexit planning. A process was agreed that would ensure that NICE would respond to national regulatory signals from the MHRA and ensure timely availability of NICE's guidance. Depending on the future relationship between the UK and European Communities, this or similar processes may need to be implemented from January 2021.

4. The arrangements described above are considered pragmatic and an efficient basis for a national regulatory and HTA system. Our CEOs, however, have challenged their organisations to work together to develop an even more ambitious integrated national process from regulation to patient access that:

    - Builds on the strength of UK life sciences and world leading reputations of MHRA and NICE in regulation and HTA
    - Encourages industry to launch some of their innovative products in the UK first by simplifying the passage through regulation and market access
    - Gives patients safer and earlier access to these products
    - Is responsive to NHS and patients' needs and concerns
    - Provides a seamless and predictable service to industry

5. This ambitious national process should, in particular, support timely patient access to innovative products with clear potential to offer a significant advance on current treatment options and to address unmet need. The ambition applies across innovative pharmaceuticals, biologics, ATMPs, medical devices, diagnostics and digital health technologies. However, the initial priorities are medicines with the potential to treat COVID-19 infections.

6. The work of the MHRA and NICE Core Strategic Group should take account of, build on and interface with other key initiatives including the outputs from the MHRA Tiger Team and the Accelerated Access Collaborative "Big Six" delivery areas. It is envisaged that work will initially focus on the key scientific, science policy and process issues at the regulation and HTA interface and that when useful ideas have been developed, we engage with multiple system partners including with broader relevant MHRA and NICE colleagues, NHSE&I, DHSC, AAC and OLS.

7. Based on an initial exploration, the key areas where a common understanding across MHRA and NICE is essential in delivering the ambitious national process include:

    - Understand the risks that each organisation needs to manage and any areas where risks taken by one agency impacts the other
    - Understand the appetite for risk in both organisations
    - Understand the role of enhanced vigilance and post market surveillance in managing risk
    - Develop a common understanding of what we mean by innovative medicines and health technologies
    - Develop a common approach to the use of real-world evidence and artificial intelligence in advising company product development plans and to support manufacturers' submissions to both MHRA and NICE
    - Explore integrated process options including joint scientific advice, data sharing and joint submissions to MHRA and NICE and piloting a new co-ordinated pathway
    - Take account of recommendations from major enquiries such as the Independent Medicines and Medical Devices review including those regarding patient involvement in decision-making

Membership

MHRA

Table 1 MHRA Membership

Name	Role	Comments
Patience Wilson (Until April 29) Rachel Arundale (From 4 May 2020)	Deputy Director and Head of Corporate Strategy, Accountability and Partnership, Policy Division	MHRA lead
Tori Crawford	Head of Policy and Strategic Partnerships, Policy Division	
Caroline Brennan	Policy Division, Corporate Strategy, Accountability & Partnership	Secretariat
Graeme Tunbridge	Director, Devices Division	
Ian Rees	Inspectorate Strategy and Innovation	
Sarah Morgan	Vigilance and Risk Management of Medicines	
Dan O'Connor	Expert Medical Assessor, Licensing Division	
Patience Wilson (Until April 29) Rachel Arundale (From 4 May 2020)	Deputy Director and Head of Corporate Strategy, Accountability and Partnership, Policy Division	MHRA lead
Tori Crawford	Head of Policy and Strategic Partnerships, Policy Division	

NICE

Table 2 NICE Membership

Name	Role	Comments
Nick Crabb	Programme Director, Scientific Affairs	NICE lead
Helen Knight	Programme Director, Technology Appraisals and Highly Specialised Technologies Programmes, Centre for Health Technology Evaluation (CHTE)	
Carla Deakin	Programme Director, Commercial and Managed Access programme, CHTE	
Nwamaka Umeweni	Senior Market Access Adviser	
Jeanette Kusel	Director, NICE Scientific Advice	
Jennifer Prescott	Associate Director, Business Operations, CHTE	
Geoff Ellison-Roberts	Assistant Project Manager, Science Policy and Research programme	Secretariat

Terms of Reference

8. The MHRA and NICE Core Strategic Group will drive and coordinate activities across the two agencies to identify the opportunities for collaboration and to mitigate barriers, risks and challenges to the creation of the ambitious national process outlined above.

9. The group is encouraged to think broadly and freely and be prepared to challenge current paradigms and consider radical solutions where they have the potential to lead to substantial progress towards realisation of the ambitious national process.

10. The group is expected to engage colleagues from across the two agencies and in partner organisations in delivering the work programme.

Operation of the MHRA and NICE Core Strategic Group

11. The group is co-chaired by the MHRA and NICE leads.

12. The group meets by teleconference monthly with additional meetings and workshops as necessary.

13. It is anticipated that some of the work will be undertaken in sub-groups and involve a broader range of colleagues across the MHRA and NICE and partner organisations. Parallel workstreams may be required for medicines and medical devices due to the differing regulatory systems.

14. Meeting agendas are set by the MHRA and NICE co-leads with support from the secretariat members who prepare and distribute any supporting documentation.

15. The group has no quorum, but meetings may be rescheduled if there is insufficient attendance on any given date.

Initial Priorities

Urgent workstream: The development of integrated MHRA and NICE arrangements for the expedited clinical use of new COVID-19 medicines and expediated action to review guidance on existing medicines.

- Participants: Core strategic group
- Target completion date: June 2020

16. This activity aims to develop highly efficient arrangements that proactively “pull” COVID-19 medicines from clinical trials into patient access (EAMS), flexible licensing approaches, HTA and commissioning processes. Arrangements need

to include close liaison with company and academic clinical trials including joint MHRA and NICE scientific advice.

17. It will also include expediated action to review existing medicines in the system relevant to the COVID-19 pandemic. This may include updating and/or producing joint guidance documents for established medicines and or approaches to clinical development and the acceptability of real-world data to both organisations.

18. The Early Access to Medicines Scheme (EAMS) is considered a key foundation for this work as it provides the basis for a regulatory opinion, potentially significantly in advance of licensing. The appropriate early use of medicines off-label within EAMS, together with expedited routes to licensing and patient access is viewed as the optimal strategy for ensuring patient safety and timely availability of clinically useful COVID-19 medicines.

19. NICE's processes should interface seamlessly with the reformed EAMS process aiming for final NICE guidance on the day that a COVID-19 indication leaves EAMS to emerge as a licensed product. If reforms to the EAMS allow payment for products while used off-label or unlicensed within the EAMS, it may be necessary for NICE to develop rapid HTA procedures to inform both appropriate clinical use and payments to companies.

20. In delivering the integrated process, it will be essential that MHRA and NICE can freely share logistical and scientific, technical and clinical information and data between the agencies.

21. Although this workstream is focused on COVID-19 medicines, the principles and processes developed are likely to have wider applicability to the development of integrated regulatory, HTA and commissioning processes (see workstream 4 below) for innovative medicines. It is envisaged that iterative learning of how each agency (and the wider access ecosystem) can benefit from working more closely together will be established, with key practical and sustainable approaches for joint and strengthened interactions being developed.

Workstream 1: Workshop on risk and innovation

- Participants: Core strategic group
- Target completion date: On-hold during current COVID-19 crisis

22. The workshop will explore what we mean by innovative medicines and health technologies and the risks and mitigation strategies across MHRA and NICE in driving timely licensing and patient access (see paragraph 6).

23. The output will be a technical report, including constraints mapping.

Workstream 2: Workshop on use of real-world evidence (RWE) and artificial intelligence (AI)

- Participants: Core strategic group and relevant members of CPRD and devices and the NICE data and analytics community
- Target completion date: On-hold during current COVID-19 crisis

24. The workshop will explore and develop MHRA and NICE policy on the use and potential uses of RWE and AI in company product development plans and submissions to MHRA and NICE (see paragraph 6).

25. The output will be a technical report, including constraints mapping.

Workstream 3: Workshop on process integration

- Participants: Core strategic group, representatives of NICE and MHRA scientific advice, MHRA Tiger Team and relevant members of NHS England and NHS Improvement and the AAC.
- Target completion date: On-hold during current COVID-19 crisis

26. The workshop will explore opportunities for integrated and timely end to end MHRA, NICE and NHSE&I processes. The aim of the workshop will be to identify the potential key points of intersection of a joined up end-to-end process, including scientific advice to technology developers, licensing, HTA and mechanisms for risk mitigation through managed access arrangements. The workshop should include representation from relevant AAC workstreams and the MHRA Tiger Team and take account of the EAMS and proposals for an innovative medicines fund. The workshop will also explore opportunities for data sharing and joint submissions to NICE and MHRA.

27. The output will be a report, including constraints mapping.

Workstream 4: Develop an ambitious end to end national process for medicines based on the outputs from the above workshops and learning from the COVID-19 medicines arrangements

- Participants: Core strategic group and relevant members of MHRA licensing division and NICE CHTE business operations
- Target completion date: On-hold during current COVID-19 crisis

28. This workshop will build on the outputs of Workstream 3 and will use the key points of intersection as a basis for process design, taking into account the wider political context and varying scenarios in which a national offer may need to operate.

29. The future relationship between the UK and EU is not yet clear and the level of alignment in medicines regulation is an area of considerable uncertainty. In developing a national offer, it is important to build in flexibility to accommodate differing levels of alignment. The national offer developed should be capable of operating fully stand alone with no reliance on documents or decisions from regulatory processes in other jurisdictions.

30. Such a national process could be applied in the following ways:

    - As the primary UK regulatory and HTA route for all medicines
    - As the UK regulatory and HTA route for medicines where the company launches in the UK first (with medicines launching in the EU being handled through expedited processes taking account of EMA decisions and documents – such as the targeted assessment or automatic recognition routes previously explored).

31. The national process may need to be applied to medicines in the UK regulatory process irrespective of how innovative or transformative they may be. Any mechanisms to support and recognise highly innovative products should be additional to standard process and applied where defined triggers are met.

32. It may not be realistic to develop bespoke arrangements for different product types. Learning from the AAC ATMP workstreams, for example, should ideally inform arrangements for innovative products rather than specific arrangements for ATMPs.

33. The national process developed should be “end to end” including arrangements to support product developers through scientific advice, including the use of novel trial designs.

Further Work

34. On completion of workstreams 1-4, further priorities will be considered. Potential additional workstreams include piloting the national medicines process with a volunteer company and the development of an integrated national offer for medical devices, diagnostics and digital health technologies.

Issues for decision

35. The Board is asked to note the establishment of the core strategic group and provide advice on any aspects of the work programme.

National Institute for Health and Care Excellence

May 2020

Unconfirmed audit and risk committee meeting minutes

22 April 2020 via zoom

Present

Dr Rima Makarem	Non-Executive Director (chair)
Professor Martin Cowie	Non-Executive Director
Tom Wright	Non-Executive Director

In attendance

Professor Gill Leng	Chief Executive
Catherine Wilkinson	Acting Business Planning and Resources Director
Barney Wilkinson	Associate Director - Procurement and IT
Jane Lynn	Head of Financial Accounting
Elaine Repton	Corporate Governance & Risk Manager (minutes)
Niki Parker	Government Internal Audit Agency
Andrew Jackson	National Audit Office
Andrew Ferguson	National Audit Office
Dan Spiller	Ernst & Young
Jane Newton	DHSC, NICE Sponsor Lead

Apologies for absence

1. Apologies for absence were received from Elaine Inglesby-Burke and Hassan Rohimun.

Welcome

2. The Chair welcomed Martin Cowie to his first meeting. Martin has joined the committee to replace Sheena Asthana who left NICE at the end of March.

Declaration of interest

3. There were no declarations of interest relevant to this meeting.

Minutes of the last meeting

4. The minutes of the meeting held on 22 January 2020 were agreed as a correct record, subject to Dan Spiller being added as an attendee.

Action Log

5. The committee reviewed the action log. Catherine Wilkinson gave an update on discussions with the DHSC, CQC and the building contractors to request that all areas of the new Stratford office that will be occupied by health bodies, will be fully accessible and inclusive of everyone. Currently the toilets do not meet NICE's ambition as a disability exemplar. There is work underway to ensure that they are more inclusive and discussions continue in order to encourage the landlord to improve the overall offering. The NICE Public Involvement Team is suggesting options to resolve the matter, but all building work is currently on hold due to COVID-19.

Risk Management

Business risks 2020/21

6. The committee reviewed the 2020/21 draft risk register which supports delivery of the business objectives. It was noted that the business plan has not yet been approved by the board. The risk register had been reviewed and updated by the Senior Management Team to reflect the impact of the COVID-19 pandemic across NICE's work.

7. In relation to the production of rapid guidelines to support the management of COVID-19, it was queried whether there were more mitigations to add including learning from initial stakeholder feedback as more guidelines are produced, and reducing the potential for reputational risk by NICE having responded quickly to the pandemic. It was agreed to review the mitigations and actions in risk 25/20.

ACTION: ER

8. The committee discussed whether the risk of NICE failing to meet its own business plan priorities should be lower than if it fails to meet the commitments made to commissioners (such as NHSE), and therefore also require different mitigations. Gill Leng stated that there was also a commitment on NICE to meet the expectations of all its stakeholders including patient groups. As the position was constantly changing, the mitigations, future actions and risk levels would need to be continually reviewed and updated.

9. Reference was made to the 'black swans' discussion in December and whether the risk of a pandemic had been considered, and what has been the learning from COVID-19. It was raised in December by Martin Cowie in terms of NICE needing to be flexible and agile to respond to such a national crisis. Gill Leng confirmed that NICE did have a business continuity plan for a pandemic but the reality of the current situation had not been foreseen, therefore there are lessons to be learnt.

10. The committee discussed whether cyber security should remain an amber risk in view of media coverage of fraudsters taking the opportunity to exploit any vulnerabilities whilst organisations are distracted with emergency planning. Barney Wilkinson provided assurances that IT systems were updated with latest patches and risk mitigation activities were regularly being communicated to staff including phishing alerts, IG training, advice on using the latest version of VMware and using Zoom securely.

11. The committee noted the risk register.

Risk discussion – Response to COVID-19

12. The committee noted that the board had received a comprehensive report from the chief executive on NICE's response to COVID-19 at NICE's board strategy meeting which was held in the morning preceding the committee's meeting. The committee chair confirmed that a full discussion had taken place and the board had been fully briefed on NICE's business continuity arrangements to date and planned next steps. The committee had nothing further to add.

Risk management policy review

13. The committee was asked to approve a revised risk management policy which had been updated against HM Treasury's Orange book and more closely aligned to NICE's current arrangements. Jane Newton requested that the options open to the board when considering the nature and extent of the risks that face NICE, should be extended to include "and escalation to the DHSC, where appropriate". This was agreed.

ACTION: ER

14. The revised risk management policy was agreed for recommendation to the board.

ACTION: ER

Internal Audit

Travel booking system

15. Niki Parker presented the internal audit review of the travel booking system which had received a limited assurance level with four recommendations for improvement. Niki commented that whilst the assurance level was limited, the travel booking system was a very good system used by lots of other organisations and implemented well at NICE. However, the lack of evidence to demonstrate that retrospective senior manager checks were taking place, meant that improvements were needed to strengthen the management controls.

16. The committee questioned whether having a relatively small number of people making bookings on behalf of others was efficient. Catherine Wilkinson advised that allowing everyone access to the system would significantly increase the risk of fraud, and therefore this approach was the most effective control for NICE.

17. The report was noted.

NICE Connect

18. The committee reviewed the internal audit report of the Connect project which received a substantial assurance level and made no recommendations.

19. The auditor was challenged on the assurance rating for a project which did not have defined outcomes. Niki Parker advised that the scope of the audit had reviewed the project management arrangements, governance around decision making and roles and responsibilities, rather than delivery of the project objectives. The audit team will review the Connect project again this year to provide continued assurance.

20. The internal audit report was noted.

Annual internal audit report and opinion 2019/20

21. Niki Parker presented the GIAA's annual audit opinion giving a moderate assurance level for 2019/20 based on the range of audits undertaken and the

three key compliance areas of risk management, governance and control. Niki confirmed that the reports presented to committee during the year had evidenced that comprehensive and up to date policies and procedures were in place, and staff had confirmed they were clear about their roles and responsibilities.

22. The area where there is scope for improvements is the arrangements for NICE senior management to be assured of compliance with established policies and procedures, as highlighted in the reports on contract management, conflicts of interest, and travel bookings.

23. The committee asked about the arrangements for sample checking committee member declarations of interest as it was recognised that some who are external to NICE find it difficult to understand the categories of interest. Gill Leng advised that the SMT will see a report on compliance every six months. The chair suggested that the committee should review progress again in six months and that internal audit should also do some sample checking in 2020/21.

24. The report of the internal auditor was noted and welcomed.

ACTION:ER/NP

External Audit

Audit progress report on 2019/20 financial statements

25. Dan Spiller presented the audit progress report on preparation of the 2019/20 financial statements outlining the areas tested during the interim audit. It was noted that implementation of IFRS 16 has been deferred to 1 April 2021, as a result disclosures on the impact of adopting IFRS 16 will not be required in the 2019/20 financial statements.

26. The final audit has been impacted by COVID-19, but NICE and EY/NAO have agreed remote working and secure data transfer arrangements to be able to deliver the final audit.

27. The external auditor's report was noted.

NAO Wider work in the health and care sector

28. The committee noted the NAO's wider work and publications to support the health and care sector. Andrew Jackson made reference to the decision to relax some of the disclosures required in the annual report but stressed the NAO's keenness to maintain transparency and accountability. It was expected that the current FReM requirements will still stand for this year.

Finance

Financial accounting performance

29. Jane Lynn presented the financial accounting performance report at 31 March 2020. The committee noted that the finance team had adapted well to home working and as a result the year-end financial accounting processes were not expected to be impacted by COVID-19. It was noted that NHS Shared Business Services (SBS) operate NICE's Payroll and Financial services and there has been some impact on service delivery relating to offices based in India. NICE is working closely with the SBS contract leads to ensure any delays or gaps in service are resolved quickly. At present, it was expected that their ISAE3402 audit reports (for finance & accounting and payroll services) will be delayed by two weeks.

30. The report was noted.

Report on the M9 financial position 2019/20

31. The interim annual accounts position at the end of month 9 was reviewed. The report was noted.

Forecast outturn

32. The committee received a verbal update on the forecast outturn for 2019/20. There were no issues of concern reported.

33. The NAO referred to the DHSC's requirement for ALBs to have their annual accounts signed off by the target date of 26 June, working on the assumption that they will be laid before Parliament ahead of the Summer recess.

34. Jane Lynn stated that NICE was working to the original timetable which it was keen to meet in case of staff capacity issues in the months ahead. Jane Newton advised that she was not aware of any changes to year end reporting dates but agreed to check the position.

ACTION: JN

Contracts & IT

Waivers report – January to March 2020

35. The report on contract waivers approved between January and March 2020 was noted.

Waiver report – Patient Group Direction Service

36. The committee was asked to approve a contract waiver to continue existing contractual arrangements for the provision of the Patient Group Direction (PGD) Service for one year to 31 March 2021. The PGD service consists of an email based enquiry handling service and an online repository of local, regional and national PGD information products to support clinical practice. It is regarded as an important NHS service which was taken over by NICE in 2013/14 at the request of the DHSC.

37. The committee queried when the contract was going to be re-tendered in light of the number of contract extensions. Barney Wilkinson advised that there was only one provider, and NHS England was the responsible commissioner, who had requested NICE to manage the contract.

38. The contract waiver was approved.

Corporate Office

Breaches of the declarations of interest policy 2019/20

39. The committee reviewed the annual report on breaches of NICE's policies on declaring and managing interests, which detailed one breach by an advisory committee member. The committee agreed that the lessons learned from breaches were important to take forward and share.

40. Elaine Repton reported that the recommendations in the recent internal audit review of conflicts of interest had suggested template agendas and a guidance note for committee chairs, along with periodic assurance reporting to SMT that DOI forms are being received from all members and checked for completeness.

41. The committee noted the report and welcomed the improvements to be made in response to the internal audit.

Audit and risk committee annual report 2019/20

42. The committee reviewed a draft annual report to the board summarising its activities in 2019/20. The committee's terms of reference were attached as an appendix to the report. There was a requirement to review these annually. No amendments were being proposed.

43. The report was agreed.

Annual Report 2019/20

Performance report

44. The first draft of the performance and overview sections of the annual report were reviewed. There were no comments to add at this point but it was acknowledged that the COVID-19 section would probably be more detailed in the final version.

45. It was confirmed that the next iteration of the annual report will be circulated to all board (and ARC) members via email in May, ahead of the final version being presented to this committee and the board in June for sign-off.

Annual governance statement

46. Elaine Repton presented the draft governance statement which forms part of the accountability report within the annual report and accounts. The committee noted there had not been any whistleblowing cases in the year but was advised that staff had referred matters to the two nominated Freedom to Speak Up (FTSU) Guardians. There has also been engagement with the DHSC in the year through the ALB Audit Committee chair's annual meeting and interactions with the DHSC and finance colleagues regarding the disclosures in the annual accounts.

47. Subject to inclusion of the number of cases raised with the FTSU Guardians, and details of the interactions with the DHSC, the draft annual governance statement was agreed.

ACTION: ER

Committee annual plan 2020

48. The committee noted its annual work plan for 2020. It was agreed that the topic for the deep dive risk discussion in September should be considered nearer the time, in view of the rapidly changing operating environment. There will be no risk discussion in June.

Other Business

49. There were no further items of business.

Future meeting dates

50. The Committee confirmed its future meetings would take place on:

    - 17 June 2020
    - 9 September 2020
    - 25 November 2020

The meeting closed at 3:50pm.

National Institute for Health and Care Excellence

Audit and Risk Committee annual report 2019/20 and terms of reference

The Board is asked to receive the report which summarises the work of the Audit and Risk Committee during the 2019/20 financial year.

The Board is asked to note in particular the committee's assessment of the work undertaken in 2019/20 (paragraphs 6 - 29) and the anticipated challenges for the coming year (paragraph 38).

The Board is asked to confirm no changes are required to the committee's terms of reference (appendix A).

Dr Rima Makarem

Audit and Risk Committee Chair

April 2020

Introduction

1. The committee's primary function is to provide the board with an independent and objective view of the adequacy and effectiveness of NICE's governance arrangements, system of internal controls, financial control and management of risk.

2. In order to discharge this function the audit and risk committee prepares an annual report for the board and Accounting Officer. This report includes information provided by internal audit, external audit and other sources of assurance, such as reports from management.

Background

3. The composition of the committee has been unchanged in the year although Tom Wright joined the committee in April 2019 and Sheena Asthana left the committee at the end of March 2020 when her tenure as a NICE Board member ended. Martin Cowie temporarily joined the committee on 1 April 2020 to replace Sheena. The position is to be reviewed with the new board chair later in the year.

4. Tom has previously served on audit and risk committees and therefore has experience of the role, as do the longer standing members, all of whom have a sound understanding of NICE and the challenges it faces. The committee chair is also the audit committee chair in another government body.

5. The committee has continued to have close links with the Department of Health & Social Care (DHSC) through the attendance of the NICE sponsor team at its meetings.

Audit and Risk Committee's assessment

6. The assessment of the committee, based on the totality of the work presented to it, including but not exclusively the internal and external audit work, is that financial, internal control and governance processes are well designed and managed.

7. Members of the board should acknowledge that the assurances given can never be absolute. The highest level of assurance that can be provided to the board is a reasonable assurance that no major weaknesses have been identified in NICE's risk management arrangements, internal and financial controls and governance processes.

Information supporting the committee's opinion

8. Summarised below are the key sources of assurance that the committee has relied upon when formulating this opinion.

Internal Audit

9. NICE's internal audit service is provided by auditors from the Government Internal Audit Agency (GIAA). As in prior years, should the need arise, private or specialist firms may be contracted to perform discrete audits. There was no requirement for this during 2019/20; all the work was performed by GIAA.

10. NICE's head of internal audit during the year was Niki Parker. The committee agreed an annual work programme for internal audit at the start of the year which included six business areas to be reviewed, and the findings from these audits were presented and discussed throughout the year.

11. These audits informed the head of internal audit's opinion, which the committee reviewed in draft at its meeting on 22 April 2020 covering the financial year ended 31 March 2020. An opinion of moderate assurance was issued. The final report will be presented in June when the committee will review the annual report and accounts for 2019/20.

12. The moderate opinion is the same as the assessment for last year. We consider the assessment to be a fair and reasonable judgement, and not a cause for concern. The table below sets out the full range of audit work in the year, with conclusions discussed later in the report:

Table 1 Internal audit reviews

Assignment	Final report issued	Opinion
Financial reconciliations	July 2019	Substantial
EU Exit	August 2019	Moderate
Contract management	September 2019	Moderate
Conflicts of interest	January 2020	Moderate
Travel booking system	February 2020	Limited
NICE Connect project	March 2020	Substantial

(See Table 4 on page 13 for explanation of assurance opinion levels)

External audit

13. The National Audit Office (NAO) contracts the financial audit of NICE's annual report and accounts to Ernst & Young (EY). The NAO's Engagement Director

and Engagement Manager continue to support the committee and attend each meeting, in addition to the Associate Partner from EY.

14. The responsibility for recommending the audit opinion to the Comptroller and Auditor General (C&AG) is retained by the NAO. They give their opinion on whether the accounts are a true and fair view of the financial affairs of NICE and also whether its funds have been applied to the purposes intended by Parliament. This opinion will follow their audit starting on 4 May 2020, and a clean unqualified opinion is again anticipated following a positive interim audit at the end of month 9.

Fraud, bribery and corruption

15. During 2019/20 counter fraud became an area of greater focus across the DHSC with all the health ALBs being required to comply with the Government's Functional Standard GovS 013: Counter fraud. This new obligation enabled NICE to have a renewed focus on its counter fraud arrangements. The counter-fraud, bribery and corruption strategy, policy and response plan was reviewed to align it with the functional standard. NICE was also required to complete an annual assurance checklist, develop an action plan for improving counter-fraud arrangements and produce a fraud risk register.

16. A suite of new counter fraud documents was reviewed by the committee in September 2019 when we made our first submission to the Cabinet Office. Feedback from the Cabinet Office as to whether NICE has met the required standard was expected in November but has been delayed. We have now been advised that the Cabinet Office is unable to provide feedback to ALBs as its priority has been diverted to dealing with COVID-19.

17. The DHSC's Anti-Fraud Unit has taken the lead in organising a number of counter fraud events for the health group ALBs. These have been attended by the associate director – corporate office and the corporate governance and risk manager, ensuring that NICE is contributing to the group and learning from shared good practice.

18. There were no incidents of fraud, bribery or corruption detected during the 2019/20 financial year.

Assurance framework

19. The audit and risk committee has oversight of the operation of NICE's internal control and assurance arrangements. These arrangements include the:

    - Identification of corporate risks linked to business objectives
    - Assessment and management of high, medium and low level risks
    - Monitoring of the effectiveness of the internal controls

- Monitoring of financial controls and exception reporting
- Considering any instances of non-compliance with laws or regulations
- Review of independent assurance reports
- Consideration of an assurance mapping template to be used as a risk management tool by centres and directorates when considering new projects and new areas of work.

Risk management

20. The risk management policy sets out NICE's approach to risk management. It defines risk, risk appetite, outlines roles and responsibilities and explains how risks are categorised, assessed and escalated. The policy was reviewed in March 2020 against the government's Orange book 'risk management – principles and concepts' to ensure it was aligned with best practice. The committee agreed an updated policy in April and recommended it to the board for approval.

21. Identification of risks - NICE's assurance arrangements involve an annual business planning cycle that establishes clear business objectives for the organisation and individual centres and directorates. Directors and their management teams identify potential risks that could adversely affect delivery of these objectives and develop strategies to manage them. These are included in a corporate risk register which is reported to the NICE senior management team, the audit and risk committee and to the board at the beginning of the financial year setting out the key business objectives of the organisation and listing controls and assurances for the management of those risks.

22. Management of risks – The risk management policy emphasises the directors' ownership of the risk identification and management process and requires that the senior management team (SMT) reviews the risk register regularly. It does this six times per year. The audit and risk committee reviewed the corporate risk register at each of its quarterly meetings. In doing so, the SMT and audit and risk committee assess whether the management strategies are likely to be effective in mitigating the risk level, and additional actions are agreed where necessary. They also consider whether any new risks have emerged that should be added to the register, and whether any risks have been mitigated to an extent they can be removed from the corporate register and monitored at a centre/directorate level.

23. In addition to reviewing the risk register annually, the board also undertakes an annual review of strategic ambitions and risks. The board and this committee review a strategic risk register, currently 2020 – 24, which details the wider risk

environment within which NICE is operating and focuses on the external influences which could potentially have a significant impact on NICE.

Corporate governance

24. The board and senior management team – During the year three non-executive directors (NEDs) reached the end of their term of office, including NICE's chair. The recruitment process for a new chair was delayed and during this period the chief executive announced his retirement from NICE. The committee agreed that this heightened the risk at the leadership level of the organisation and asked that it be included on the risk register for monitoring. The committee was pleased to note the mitigating actions including the deputising arrangements in place. The risk was reduced by March 2020 when the new chair, Sharmila Nebhrajani was appointed, and Gill Leng, the experienced deputy chief executive was appointed as chief executive.

25. Changes to board membership remains a risk as the number of NEDs fell below the statutory minimum of at least 6 as at 31 March 2020, until the new chair takes up her role in May. The board sought legal advice on how the remaining non-executive and executive directors could meet and exercise the board's powers. The advice was to establish a committee of the board members to undertake the board's functions. This committee will remain in operation until the new chair joins the NICE board on 25 May 2020.

26. Appointment of Accounting Officer for NICE – The chief executive is also formally appointed by the DHSC as the Accounting Officer (AO) for NICE. There are statutory duties with this role, notably production of the financial statements. As Andrew Dillon left NICE on 31 March 2020, his successor would be required to sign a set of financial statements covering a period during which they were not the AO. The NAO advised the committee that where an Accounting Officer leaves before the annual report and accounts are signed, they must prepare a letter of assurance for their successor to support the new appointee's signature of the documents. The letter gives assurances regarding arrangements for financial management, compliance with regulations or accounting standards, governance issues and decision making. The committee therefore ensured this action was taken forward and the letter was produced and sent from Andrew Dillon to Gill Leng on 30 March 2020.

27. Declaration of interests – Following the board's review of the policy on declaring and managing interests for advisory committee members in May 2019, the committee reviewed the findings of an internal audit of conflicts of interest in January 2020, which received a moderate assurance level with five recommendations for improvement. The recommendations related to more checks being undertaken to ensure registers are up to date, accurate and being published on NICE's website. The audit also recommended that management should be provided with assurance on completeness and correctness of the

declarations made by the introduction of sample checking, monitoring and reporting through a standardised process, to be agreed by SMT. This is being drawn up to inform the scope, frequency, and approach to spot-checks by guidance teams, the results of which will be provided to corporate office to inform the assurances in the annual governance statement from next year.

28. The committee also reviewed an annual report on breaches of the policy. One breach was identified during the year relating to a member of the Interventional Procedures Advisory Committee who had declared an interest in the topic under discussion but the NICE project team had failed to identify the interest as being relevant and did not to produce a register of interests of the committee, for circulation prior to the first meeting as required by the policy. Therefore, the conflict was not brought to the chair's attention. The member then did not verbally declare the interest at the first meeting of the committee. Following investigation, it was concluded that the risk to the guidance development was low: the committee had based its provisional recommendation on the published evidence base, taking much of member's explanations as context to understand how the procedure is used in the NHS. On balance it was concluded that the member's presence did not change the recommendation from what it would have been if they had been excluded from discussions in part 2.

29. Management reporting – The committee received a range of assurance reports from management throughout the year. These are summarised in the table below:

Table 2 summary of sources of management assurance

Management assurance	Description
Losses and compensation register	As required by DHSC, NICE maintains a register of such payments. This is reported at each audit and risk committee. For 2019/20 the total value of these payments was £19,654 (£34,783 in 2018/19). Of this amount £15,525 relates to train cancellation or amendment fees, £727.00 relates to flight cancellation costs /amendment fees. The remaining value (£304.00) relates to bad debts written-off.
Contract waiver report	The committee receives a report at every meeting of the tender waivers that have been authorised since the last meeting. Details are provided of the reason for the waiver, the value and the person that authorised it. The committee also receives an annual summary of all waivers granted during the year. In 2019/20 there were a total of 92 contracts awarded (valuing £11,686,918.00) of which 21 were subject to waivers, with a value of £303,812.00 (£403,517 in 2018/19). The committee reviews waivers granted and requests specific assurance from management if it has any concern.
Technical accounting issues	The committee receives reports where there are significant changes to existing accounting policies or practices. No new accounting standards were reported in the year. IFRS 16 relating to leases was scheduled to be adopted from 1 April

Management assurance	Description
	2020 which meant that preparations would have to be made in 2019/20, but the government has delayed its implementation until 2021/22.
Specific incident reports	Where there is an incident particularly relating to a loss suffered by NICE, the committee receives a report as part of its risk management duties. There were no incidents relating to accidental disclosure of confidential information, of a material enough nature that required escalation to the committee.
Annual assurance reports	There are a range of reports that the committee receives to provide additional assurance. During 2019/20 the committee received reports on information governance and compliance with the Data Security & Protection toolkit, IT security and resilience, the management of complaints, breaches of the DOI policy and compliance with the counter fraud functional standard.

Key messages from the year's work

30. From our work we wish to highlight to the board the following issues:

- We were pleased to receive in April 2019, a clean set of accounts for the financial year 2018/19 and a positive audit opinion. The work is done to very tight timetables but continues to present a positive picture of the accuracy and control of our core financial systems. This continues to be reinforced by internal audit assessments. Our internal auditors gave a 'substantial' rating to financial reconciliations, the key financial control which was reviewed in the year.
- We continue to focus part of our meetings on risk management. We receive at each meeting a statement of the main risks facing NICE and the mitigating actions taken by the executive. We also review the strategic risks twice yearly.
- We invite a senior manager to present to us at each committee meeting to hear their perspective on the challenges and risks in a specific area of responsibility. We looked at the following areas in detail:
    - an overview of the NICE Connect transformation project, describing its aim and intended benefits of presenting NICE's advice as pathways that reflect the way prevention, treatment and care are organised and delivered
    - the move to the new Stratford office and the working arrangements for sharing the space with the other ALBs
    - the guideline development framework and the supporting policies and procedures, to demonstrate how the Centre for Guidelines ensures consistency and quality across all its committees

  - review of the methods and processes for developing guidance within the Centre for Health Technology Evaluation.

- There have been six internal audit reports published (listed in table 1 above). We were assured that the audit plan covered a good spread of NICE's work. In total there were 22 recommendations for improvement (2 high, 12 medium and 8 low). The committee is satisfied that good progress has been made to implement recommendations from this year's and previous year's audit plan.
- No incidents of fraud had been detected within NICE in 2019/20 but we will need to continue to assure ourselves of the effectiveness of controls, and measure improvements through the functional standard returns.
- In November 2019 we received a comprehensive review of NICE's IT security network which provided the committee with assurance regarding the robust management arrangements in place for the security of NICE's information, communications and digital technologies including the externally hosted digital services. The report advised us of NICE's increasing use of a range of new software tools, and plans to adopt Office 365, which increasingly expose the network to potential malware from outside the NICE's security defences. The report provided assurance on how the risk is being managed and plans to continue to review the security model as part of a new digital workplace strategy being implemented from 2020. We were also advised of the results of an exercise in which simulated phishing emails were sent to staff to raise awareness of potential cyber security scams, requesting them to complete a short training exercise if they failed to recognise the risk by proceeding to open attachments.
- The committee reviewed an annual information governance (IG) assurance report in November 2019 which detailed arrangements in place to ensure the effective management of information and IG risk management. The IG and Data Protection Manager outlined the team's key achievements in the year as providing adequate evidence and maintaining compliance with the DSP toolkit, advising colleagues on GDPR compliance, supporting NICE Connect transformation including operational productivity related tasks, SharePoint/O365 implementation and the Data Management Expert Group.
- We were advised that there have been no whistleblowing cases reported during the year but we are reassured that NICE has appointed two Freedom to Speak Up Guardians to provide staff with an additional safe and confidential route to raise any concerns.
- We reviewed the committee's terms of reference in April 2020 as part of the annual review cycle and agreed that they remained fit for purpose (at appendix A).

- The committee was able to review an early draft of the annual report and accounts in April to provide an opportunity to comment on its content ahead of the approval in June 2020.

Review of the committee's effectiveness in 2019/20

31. The committee's terms of reference require that periodically, the committee shall review its own effectiveness and report the results to the board. This exercise normally takes place in April. The NAO facilitated a review of the committee's performance in 2018 and 2019 using the NAO's audit and risk committee effectiveness checklist. It was agreed that repeating the process again in 2020 probably would not add great value. It was the NAO's view that the committee was operating effectively, the level of challenge from the NEDs was good and the three-way interaction between the auditors was positive.

32. Rather than circulating a survey, it was agreed with the chair to re-visit last year's areas for improvement, to review progress against the recommendations and to hold an open discussion for views to be shared. The discussion will take place at the September 2020 meeting. Three recommendations were made last year:

    - the use of assurance mapping to identify key areas of risk – a template and guide has been agreed to be used as a management tool;
    - induction and training for new NEDs joining the ARC - this will be tailored to the individual member;
    - relationship and engagement with the DHSC and the DHSC's audit and risk assurance committee (ARAC) – the Lead Sponsor regularly attends the ARC meetings and NICE's finance team have good relationships with the Department's finance team. There is little communication to ALBs from the Department's ARAC.

Training

33. Last year, as in the previous year, the chair agreed with the NICE board chair to utilise the NEDs' December meeting as a training opportunity for the whole board. A session was facilitated by the NAO discussing potential 'black swans' – risks that are unexpected or highly unlikely to materialise, but if they did, would have a significant impact on NICE. It proved to be a really useful discussion and board members have requested a follow up session once the new chair is in post, potentially at the October 2020 strategy meeting.

Review of internal and external audit services

34. In line with governance best practice, the committee's annual work programme includes a review of the performance and effectiveness of the internal and external auditors.

35. The regular attendees at the audit and risk committee meetings were invited to complete a survey to review the performance of external audit (in November 2019) and internal audit (in January 2020). The views expressed were summarised for discussion by the committee.

36. NICE's external auditor is the NAO, appointed by Parliament. As noted earlier in the report, the NAO has contracted out auditing the financial statements to EY but the NAO still attend the committee's meetings. The report on their effectiveness was overall very positive indicating good relationships between NICE, the NAO and EY.

37. The review of internal auditor was also positive in respect of working relationships, the quality of reports and GIAA being a trusted and valued advisor to NICE.

Challenges and risks for 2020/21

38. In the coming year we will continue to review the range of risks facing NICE, consider the controls in place and assess their effective management. In terms of our focus, we are conscious of the following issues and key risks facing NICE which will guide our work:

    - **Responding to the COVID-19 pandemic** – the new and global risk of the coronavirus pandemic began to impact NICE specifically in March 2020 at which point the proposed business plan objectives for 2020/21 had to be reprioritised. The SMT responded rapidly to invoke a coronavirus contingency plan, moved all staff to home working and held daily SMT meetings to co-ordinate action and agree communications with staff and stakeholders. A Coronavirus Response Group (CRG) has also been established to support the SMT. The business plan for 2020/21 has been revised, but given the uncertainty about the pandemic's impact, the objectives and deliverables for the year-ahead will need to remain under review in light of the evolving nature of the pandemic.
    - **Delivering NICE Connect** – the scale of this transformation is significant but is critical to respond to the feedback from users and system partners about how they want to use NICE's work, and to remain a globally recognised leader in guidance development. The committee will monitor how the scale of the challenges and risks are being managed, and the impact of the COVID-19 related reprioritisation, through the risk register and individual reports. There will also be a further internal audit review on this area in 2020/21.
    - **Financial pressures** – NICE like other public bodies, continues to face financial pressure to meet its commitments to the health and care sector whilst investing to support its digital transformation programme and moving

its London office to Stratford. The committee receives assurance from its reviews of the financial risks in the corporate risk register and through the financial accounting reports.

- **Advances in digital technologies** – NICE is embracing new digital technologies to support its transformation programme as set out in its digital transformation strategy. The challenge of investing in the right digital technologies whilst also taking account of the resource constraints under which NICE operates will be a continuing difficult balance in 2020/21.
- **Workforce strategy** – The committee recognises not only the challenges of recruiting and retaining a motivated workforce but recruiting to specialist technical roles where skills are in high demand externally. Bringing the recruitment process in-house has provided the opportunity to have a flexible recruitment approach better suited and more agile, to meet the needs of NICE.

Conclusion

39. Putting the above into context, the committee concludes that NICE is well managed with effective processes and controls, strong financial, procurement, HR, information, and digital service management, and a skilled and committed workforce. That provides a resilient and strong base for the challenges ahead.

40. Finally, we should record our appreciation of the excellent work and support from those in the business planning and resources directorate whose work we most scrutinise and rely on. We are assured that management take governance issues seriously and we have particularly valued the discussions about risks with senior managers at our meetings. We also note with pleasure the effective working relationships that continue to operate with our external auditors and internal auditors.

The role and operation of the Audit and Risk Committee

41. The members of the committee during the period of the report were as follows:

Rima Makarem (chair)	from 01/01/2017
Sheena Asthana	from 24/11/2016 to 31/03/2020
Elaine Inglesby-Burke	from 16/11/2016
Tom Wright	from 01/04/2019
Martin Cowie	from 01/04/2020

42. No members declared any conflicts of interests in any of the agenda items during the year.

43. The following managers attend the committee meetings regularly to support it, present reports, respond to audit reports and answer queries from the committee:

Andrew Dillon	Chief executive (until 31 March 2020)
Gill Leng	Deputy chief executive and health & social care director (and chief executive from 1 April 2020)
Ben Bennett	Business planning and resources director
Catherine Wilkinson	Deputy director, business planning and resources (acting director from 1 January 2020)
Barney Wilkinson	Associate director – procurement & IT
David Coombs	Associate director – corporate office
Jane Lynn	Senior financial accountant
Elaine Repton	Corporate governance & risk manager (committee secretary)

Other senior managers attend as and when for specific items as required

44. Representatives also attend from:

Internal audit	Government Internal Audit Agency
External audit	National Audit Office & Ernst & Young
DHSC	NICE Sponsor Team

45. It has been the committee's normal practice to hold a private discussion at the start of each meeting between the auditors and members of the committee without the management present. This is to give the auditors an opportunity to raise any matters of concern without the presence of the management. The committee members find this session really helpful and propose to continue this in 2020/21.

46. The committee is required to meet at least 4 times a year. Meetings took place during the period and were attended as follows:

Table 3 Attendance at meetings in 2019/20

Member	24-Apr-19	19-Jun-19	4-Sept-19	28-Nov-19	22-Jan-20	22-Apr-20
Rima Makarem	P	P	P	P	P	P
Elaine Inglesby-Burke	P	P	P	P	P	A
Sheena Asthana	P	A	A	P	P	-
Tom Wright	P	P	A	P	P	P
Martin Cowie	-	-	-	-	-	P

Key: P= Present for meeting A= Absent from meeting (-) = Not a member at this time

47. The quorum for meetings of the committee is two, as the table above shows all meetings of the committee during the period were quorate.

Table 4 Explanation of internal audit assurance levels

Substantial	The framework of governance, risk management and control is adequate and effective.
Moderate	Some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	There are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	There are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

May 2020

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Audit and Risk Committee

Terms of reference and standing orders

Terms of Reference

1. The purpose of the audit and risk committee is to provide an independent and objective view of governance and internal control at NICE and to advise the board accordingly.

2. The committee's duties and responsibilities are to:

- Review the adequacy and effectiveness of NICE's governance arrangements, in particular those relating to:
  - risk management
  - information governance and cyber security
  - the use of resources and internal financial controls
  - the safeguards against fraud, corruption and bribery
  - the raising and investigation of concerns (whistleblowing)
  - the declaration and management of interests by those working for NICE as an as an employee or through contributing to the advisory committees.
- Review the annual report and accounts, together with any accompanying internal audit opinion and external audit opinion, with particular focus on the annual governance statement, consideration of key accounting policies and practices, estimates and judgements and the quality of the year-end financial statements, unadjusted mis-statements, major judgemental areas, and significant adjustments arising from the audit.
- Ensure there is an effective internal audit and external audit function in place which meets mandatory standards and provides independent assurance to the committee, chief executive and the board.
- Review the findings of internal and external audit, and review management's responses to recommendations made.
- Periodically review its own effectiveness and report the results to the board.

3. To meet these responsibilities, the committee will:

- review the risk register each quarter
- review NICE's information governance and IT security arrangements
- receive an annual report on breaches of NICE's policies on declaring and managing interests

- review the standing financial instructions, standing orders, and reservation of powers to the board and scheme of delegation
- approve the internal and external audit work plans annually and review performance against those plans
- consider the appointment and dismissal of the internal auditor within the authority delegated to NICE.

4. The committee will recommend to the board approval of NICE's annual report and accounts.

5. The committee will formally report annually to the board on the outcome of its work on the effectiveness of NICE's governance and internal control arrangements.

6. In order to meet its duties and responsibilities the committee is authorised by the board to:

- seek any information it requires from any employee
- obtain outside legal or other independent professional advice
- invite any non-NICE staff members with relevant experience and expertise to its meetings if it considers this necessary.

Standing Orders

General

7. These standing orders describe the procedural rules for managing the committee's work as agreed by the board. Nothing in these standing orders shall limit compliance with NICE's standing orders so far as they are applicable to this committee. Committee members shall comply with the committee's terms of reference, which set out the scope of the committee's work and its authority.

Membership

8. The committee will comprise a minimum of three and a maximum of five non-executive directors of NICE, one of whom will be appointed as chair of the committee. The composition of the committee will be given in NICE's annual report and accounts.

9. The chair of NICE shall not be a member of the committee.

Other attendees

10. Only members of the committee have the right to attend committee meetings. However, the chief executive, business planning and resources director, internal and external auditors have standing invitations to attend the committee. Other directors and staff shall be invited at the discretion of the committee when matters relating to their area of responsibility are being discussed.

Quorum

11. The quorum is set at two members. No business shall be transacted unless the meeting is quorate.

Voting

12. The decisions of the audit and risk committee will normally be arrived at by a consensus of those members present. Before a decision to move to a vote is made, the chair will, in all cases, consider whether continuing the discussion at a subsequent meeting is likely to lead to a consensus.

13. Voting, where required, will be by show of hands and decisions determined by a simple majority of those members present at a quorate meeting.

14. The chair of the meeting will be included in the vote and in the event of a tie, the chair will have a second, casting vote.

Arrangements for meetings

15. All members must make a declaration of any potential conflicts of interest that may require their withdrawal in advance of each meeting.

16. The audit and risk committee shall meet a minimum of four times a year in January, April, September and November. There will be an additional meeting in June solely for the purpose of reviewing the annual report and accounts.

17. The committee shall meet in private session with the internal and external auditors respectively, and together, as the chair requests, to consider matters of internal control or any other matter within its terms of reference.

18. No other business shall be discussed at the meeting except at the discretion of the chair.

Minutes

19. The minutes of audit and risk committee meetings shall be formally recorded by the corporate governance & risk manager and submitted to the next meeting for approval.

20. The minutes of audit and risk committee meetings shall be submitted to the board. The chair of the committee shall draw to the attention of the board any issues that require disclosure to the full board, or that require executive action.

21. Minutes will be published on the NICE website, subject to the redaction of any confidential or otherwise exempt material.

Other matters

22. The corporate office will provide support to the meetings.

23. The internal and external auditors shall have direct access to the chair.

Interpretation or suspension of standing orders

24. During the course of a meeting, the chair of the audit and risk committee shall be the final authority on the interpretation of the standing orders.

25. Except where this would contravene any statutory provision, any one or more of the standing orders may be suspended at any meeting provided that a simple majority of those present and eligible to participate vote in favour of the suspension.

26. Any decision to suspend standing orders will be recorded in the minutes of the meeting and no formal business may be transacted while standing orders are suspended.

Review of terms of reference and standing orders

27. These terms of reference and standing orders will be reviewed annually. The next review date is April 2021.

National Institute for Health and Care Excellence

Risk management policy

This report presents an updated risk management policy following its periodic review.

The Board is asked to consider and approve the revised risk management policy.

Catherine Wilkinson

Acting Director, Business Planning and Resources

May 2020

Introduction

1. NICE has clear arrangements in place for the management of risk which are outlined in the risk management policy. The policy has been reviewed and updated following its scheduled 3 yearly review. The policy amendments have been endorsed by the senior management team (SMT) and audit and risk committee and the updated policy is now presented for the board's approval in line with the reservation of powers to the board which requires the board to 'approve NICE's policies and procedures for the management of risk.'

Background

2. The Government's Orange book 'Management of risk – principles and concepts' states that:

    - 'in successful organisations, risk management enhances strategic planning and prioritisation, assists in achieving objectives and strengthens the ability to be agile to respond to the challenges faced'
    - 'the accounting officer supported by senior management, must demonstrate leadership and articulate their continual commitment to, and the value of, risk management through developing and communicating a policy or statement to the organisation and other stakeholders, which should be periodically reviewed'.

Key changes and points of note

3. The format of the corporate risk register has changed to align each risk to the relevant strategic ambition. All the high, medium and low rated risks are now reviewed by the SMT and audit and risk committee bi-monthly and quarterly respectively. Previously the policy stated that the audit and risk committee only reviewed the low rated risks once per year.

4. **Risk appetite** – The process whereby risks are identified, defined, assessed and evaluated remains unchanged. Previously the policy stated that 'careful planning and management will normally allow us to operate our programmes with a low level of risk… and there will be occasions on which we will incur moderate risk'.

5. Given the increased challenges facing NICE, (COVID-19, financial pressure, staffing resources, digital transformation, office move etc), it is no longer the case that programmes operate with a low level of risk. There has gradually been an increase in moderate and high level risks and this shift has been reflected in paragraphs 11 - 13.

6. Reviewing the policy with experience of the COVID-19 pandemic, the SMT agreed that the risk appetite is not static and may need to vary according to the circumstances facing NICE, which at times, may justify accepting a higher level of risk than would usually be the case. This is reflected in paragraph 14.

7. **Risk management** – The introduction of a new assurance mapping tool has been referenced at paragraph 18. The assurance map template will be used in future by SMT members as a management tool to help identify the key risks at the outset of a new project or new area of work.

8. **Identifying, evaluating and monitoring risks** - There is a new section at paragraph 21 which has been included to align with the Orange book guidance. It sets out the options available to the board to determine what action should be taken in response to a risk. When reviewing the policy at its meeting on 22 April, the audit and risk committee agreed to add an option for the board 'to escalate a risk to the DHSC, where appropriate.'

9. **Risk reporting** - The requirement for directors to include a risk assessment in SMT and board reports where there is a new development or substantive change to existing activities, has been incorporated at paragraph 24.

10. **Oversight** – Following the December board session considering 'black swans', and a request to follow up the discussion, potentially in October 2020, the policy includes a new section (paragraph 28) stating that the board will periodically dedicate time specifically for horizon scanning in order to identify and consider the nature of emerging risks, sources of uncertainty, threats and trends.

11. **Audit & Risk Committee** – the deep dive risk topics discussed at each meeting are recognised as good practice. NICE adopted this approach some time ago and therefore this has been added to the policy (paragraph 29).

Conclusion

12. The Board is asked to approve the updated risk management policy.

May 2020

NICE National Institute for Health and Care Excellence

Risk Management Policy

Responsible Officer	Business Planning & Resources Director
Author	Chief Executive
Date effective from	May 2017
Date last amended	May 2020
Review date	May 2023

Contents

Purpose of this document

1 Risk is inherent in every activity and this policy sets out how NICE will manage these risks to ensure a balanced approach to opportunity and risk. Effective risk management involves evaluating the uncertainties and implications within options and managing impacts once choices are made. Risk management must be an integral part of all organisational activities to support decision-making in achieving objectives.

2 The policy explains the approach to risk management; defines risk and how it is assessed and escalated; and documents roles and responsibilities.

Definition of risk

3 Risk is the uncertainty surrounding events and their outcomes that may have a significant effect on NICE. All our activities carry some risk, arising either from potential threats or the non-realisation of opportunities which may harm, prevent, hinder or interfere with the achievement of business objectives.

4 Risk assessment is a qualitative or quantitative evaluation of the nature and magnitude of risk to our objectives or planned activities. The evaluation is based upon known vulnerabilities and threats, as well as the likelihood of the threats being realised and the impact on our work.

5 Risk management is the process of evaluating and responding to risks for the purpose of reducing these to acceptable levels. It seeks to manage the impact of uncertainty by increasing the probability of success and reducing the likelihood of failure.

6 The process of identifying, assessing and managing risk is part of and complements the broader management process, which includes the risk management and quality assurance responsibilities of the Senior Management Team. In addition, risks associated with the production of our outputs are overseen by the Guidance and Publications Executives. These Executive teams approve our main publications by reviewing compliance with our published process and methods guides, and publicly consulting on our draft guidance.

7 Like all organisations, NICE faces risks, actual and theoretical that range from the trivial to the existential. This policy is intended to address the material risks that arise from the plans we put in place each year to manage and develop our business.

Categorising risks

8 The impact of risks is categorised as:

- **Low:** where there may be:

  a) some impact on one or more budgets, manageable within the budget(s) concerned;

  b) some changes to working practices or minor changes to staff roles; and,

  c) minimal impact on the quality, timeliness or utility of any outputs.

- **Moderate:** where there may be

  a) material financial consequences for the budget or budgets directly concerned, which can be managed within the affected budget(s) or by the use of underspending in unaffected budgets;

  b) material impact on the employment position of staff, which may need to be managed through formal change processes;

  c) some impact on the quality, timeliness or utility of any outputs, which can be resolved before publication, and;

  d) external criticism of the Institute's judgement, which can be met successfully and which is unlikely to result in reputational damage.

- **High:** where there may be

  a) material financial consequences, which can only be managed by the use of reserves and/or in year transfers from unaffected budgets, or exceptionally, transitional funding from the Department of Health and Social Care;

  b) significant impact on the employment position of staff, which can only be managed by formal change processes, with risk of redeployment and, exceptionally redundancy;

  c) significant impact on the quality, timeliness or utility of any outputs, which may require amendment, withdrawal and/or replacement post-publication;

  d) external criticism of the Institute's judgement, which may result in substantial reputational damage.

9 In assessing the likelihood of risks arising, a judgement will be made as to whether the possibility of a risk realising is deemed to be low, moderate or high. An overall assessment of each risk is made according to its impact and likelihood of occurrence based on the current controls

in place, using the scoring matrix set out in in Appendix A. The template for the risk register is set out at Appendix B.

Risk appetite

10 In developing and monitoring the implementation of our business plans, we need to assess the actions we intend to take, together with any known external circumstances that may have an impact on us, for the risks they may pose. This has to be done with an understanding of the extent to which we are prepared to accept the risks associated with the actions we plan to take. This is our 'risk appetite'; the extent to which we will tolerate known risks, in return for the benefits expected from a particular action or set of actions.

11 With careful planning and management we aim to operate our programmes with a **low** level of risk wherever possible.

12 However, there are circumstances where we incur **moderate** risk, for example if we are making significant changes to current programmes, taking on new activities or external pressures impact our work. We may also need to take account of risks that arise from the actions of other organisations that give rise to moderate risk for us. The Board will be made aware of the circumstances in which moderate risks are identified and will have the opportunity to comment and amend their underlying causes, where possible.

13 We may also need to consider accepting **high** risks in certain circumstances. This may be in situations where the actions involved represent the single, or least unpalatable option to manage the issues involved, which may have been externally imposed, and therefore over which the Institute will have little or no direct control. In addition, it may be necessary to accept high risk if an activity is central to our strategic objectives, and the risks of not proceeding outweigh the risks of the activity. The Board will be asked to consider such risks in detail and will need to have reviewed and taken a position on alternative courses of action before the risk is accepted.

14 The risk appetite is not therefore static and may need to vary according to the circumstances facing NICE, which at times, may justify accepting a higher level of risk than would usually be the case.

Risk management

15 Risk management provides a systematic process for identifying risks around new, proposed and current business activities. This process involves the categorisation and evaluation of each risk and the application of management controls to mitigate the risk based on a judgement of the likely impact if no further action is taken, combined with an assessment of the likelihood of the risk re-occurring.

16 We need to ensure that there is sufficient flexibility to respond to risks and adequate resources to mitigate risks. Risks can be most effectively managed if their management is embedded within the culture of the organisation.

17 Directors will ensure that fundamental risks in their department are identified, assessed and monitored and incorporated in the corporate risk register. Emerging risks will be added as required, and actions and controls put in place to mitigate them and provide assurance to the Board. Actions will also be identified to address any gaps in assurance as appropriate.

18 An **assurance mapping** tool is available to help Directors in discussion with their teams to assess any risks associated with a new project or new areas of work, and to identify any gaps in assurance where action is required to improve the controls.

Identifying, evaluating and monitoring risks

19 Risks are identified by Directors in discussion with their teams. These are then critically analysed by the SMT and reviewed by the Audit and Risk Committee. As part of this process, Directors will consider risk interdependencies with Department of Health and Social Care Arms-Length Bodies (ALBs), and other key partners. This will include the other ALBs NICE is dependent on to deliver its objectives and ALBs NICE might impact via the delivery of its objectives. The risk register will identify where NICE is dependent upon, impacted by or impacts other ALBs and partners, as appropriate.

20 During the development of the annual business plan and before the Board is asked to approve the business objectives, the SMT will coordinate work to identify the principal risks associated with the proposed objectives.

21 The Board will review the nature and extent of the risks that face NICE to determine the action to be taken. Options open to the Board include:

- avoiding the risk, if feasible, by deciding not to start or continue with the activity that gives rise to the risk
- taking or increasing the risk in order to pursue an opportunity
- retaining the risk by informed decision
- changing the likelihood, where possible
- changing the consequences, including planning contingency activities
- sharing the risk with another organisation (eg through a contract or partnership agreement)
- escalating the risk to the DHSC, where appropriate.

22 The principal document to facilitate the identification, assessment and recording of risks is the risk register.

23 Each risk will be assigned an overall assessment depending on its impact and the likelihood of it occurring by applying the approach set out in appendix A. This initial assessment takes account of mitigating controls and assurances already in place and provides a **current risk** rating. Any further planned actions to reduce the risk score are recorded, with the aim of reaching a **target risk** rating, using the format in appendix B.

24 Directors are required to include a risk assessment in SMT and Board reports where there is a substantive new development proposed or substantive change to existing activities.

25 Each Centre and Directorate is also responsible for maintaining their own centre/directorate risk register, using the format in appendix B to identify and assess risks to the achievement of their departmental objectives. Any risk or new emerging risk which has the potential to impact delivery of a business plan objective, is escalated to the SMT to decide whether it should be included in the corporate risk register.

26 Risk registers are also produced for significant projects and these will be used to provide mitigations and assurances to SMT.

27 The Chief Executive has overall responsibility for risk management and advises the Board on **strategic risks** facing NICE. A separate strategic risk register is produced which differs from the corporate risk register in that it focuses on NICE's strategic ambitions over a longer-term horizon, which by nature are difficult to predict with certainty. The strategic risk register is monitored by the SMT, the Audit and Risk Committee and the Board, bi-annually.

Oversight

28 The Board will determine the risk appetite and set the culture of risk management within NICE with particular regard to new initiatives and emerging risks. The Board has ultimate responsibility for risk management within NICE including major decisions affecting NICE's risk profile or exposure. It will periodically dedicate time specifically for horizon scanning in order to identify and consider the nature of emerging risks, sources of uncertainty, threats and trends.

29 The Audit and Risk Committee provides an independent and objective view of the arrangements for the management of risk. It will advise the Board on the co-ordination and prioritisation of risk management issues throughout NICE. The Committee oversees internal and external audit and reviews their recommendations and advises the Board on the effectiveness of the internal control system. It satisfies itself that risks are being actively managed with the appropriate controls in place and that they are working effectively. And it monitors and critically reviews the management of significant risks and the maintenance of the corporate risk register to ensure these are fit for purpose. The Audit and Risk Committee will review all risks at each of its meetings, including one of

the **high** or **moderate** risks in detail, as part of a 'deep dive' risk discussion. The relevant risk owner, or their deputy, will be invited to attend the meeting.

30 The Audit and Risk Committee will report to the Board on internal controls and alert the Board to any emerging issues. The Board will receive minutes of the Audit and Risk Committee, plus an annual report from the committee to provide assurance that the approach to risk management is effective, comprehensive and robust particularly in regard to the significant risks facing NICE.

31 The Chief Executive, as Accounting Officer has overall operational responsibility for the identification and management of risks that threaten the achievement of business objectives. Together with the SMT he/she will evaluate the risks identified by directors and apply handling strategies and implement policies to support the process of internal control.

32 The SMT will review the corporate risk register bi-monthly and prior to consideration by the Audit Committee. It will take account of the on-going identification and evaluation of risks and in particular the quality and timeliness of information provided on key risks and the identification of ineffective controls and new risks, to ensure that corrective action can be taken.

33 The corporate governance and risk manager has responsibility for coordinating the corporate risk register, and for supporting the SMT and Audit and Risk Committee in their responsibilities for risk assessment and management. They will proactively support directorates and centres in the risk management process, promoting consistency in the risk ratings and entries in the risk register, applying challenge as appropriate.

Annual report governance statement and role of audit

34 The annual governance statement in the annual report and accounts assesses the effectiveness and operation of NICE's risk management arrangements. The statement is informed by the work of internal and external audit.

35 Internal audit is responsible for aspects of the annual review of the effectiveness of the internal control system within the organisation. They will periodically review the arrangements for risk management and levels of assurance around the controls reported to the Audit and Risk Committee.

36 External audit provides advice and feedback to the Audit and Risk Committee on the operation of the internal financial controls reviewed as part of the annual audit, and also give a view on the completeness of the annual governance statement.

37 The Audit and Risk Committee will review the auditors' findings and management's response.

Review

38 This policy will be reviewed by the corporate office in May 2023, or sooner if a change in obligations requires it.

Appendix A: Quantifying and monitoring risks

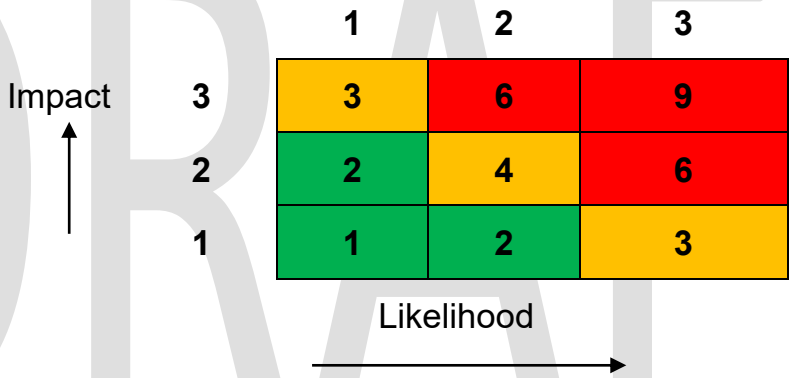
Each risk is allocated an **impact** score, using the descriptions in paragraph 8, in which low is accorded a value of 1, moderate a value of 2 or high a value of 3.

Category	Score	Examples
Low	1	• some impact on one or more budgets, manageable within the budget(s) concerned • some changes to working practices or minor changes to staff roles • minimal impact on the quality, timeliness or utility of any outputs.
Moderate	2	• material financial consequences for the budget or budgets directly concerned, which can be managed within the affected budget(s) or by the use of underspending in unaffected budgets • material impact on the employment position of staff, which may need to be managed through formal change processes • some impact on the quality, timeliness or utility of any outputs, which can be resolved before publication • external criticism of the Institute's judgement, which can be met successfully and which is unlikely to result in reputational damage.
High	3	• material financial consequences, which can only be managed by the use of reserves and/or in year transfers from unaffected budgets, or exceptionally, transitional funding from the Department of Health and Social Care • significant impact on the employment position of staff, which can only be managed by formal change processes, with risk of redeployment and, exceptionally redundancy • significant impact on the quality, timeliness or utility of any outputs, which may require amendment, withdrawal and/or replacement post-publication • external criticism of the Institute's judgement, which may result in substantial reputational damage.

Similarly, the **likelihood** of each risk materialising will be assessed on a scale of 1 to 3 as outlined in the table below.

Category	Score	Definition
Low	1	Unlikely to occur in the following 12 months
Moderate	2	May occur in the following 12 months
High	3	Likely to occur in the following 12 months

A **summative** score will be calculated, in each case, by multiplying the impact and likelihood scores, to give a total score. This will lead to an overall rating of the risk as shown in the table below.



When assessing the likelihood and impact of risk, the most credible worst-case scenario should be considered - not the worst-case.

Appendix B: Risk register

Business risk	SMT Lead	Mitigation and assurance	Current rating			Further actions to strengthen mitigation and assurance (include due dates)	Target rating		
			I	L	S		I	L	S

Risk: the risk itself, expressed in terms of a cause and an event, and their impact.

Mitigation and assurance: the actions in place to mitigate the risk, together with any timings (also known as controls). This includes reporting arrangements (e.g. to Board, SMT). **Assurance:** any assurance on the effectiveness of the controls/mitigations, with particular emphasis on sources of external assurance

Current rating: the score allocated to the impact (I) and likelihood (L) of the risk, and the RAG rating (S) allocated to it *after the application of current controls/mitigations*

Further actions to strengthen mitigation and assurance: the further actions to strengthen the controls (to move the current rating to the target rating) and to strengthen the assurance on the controls. This should include dates for completing the actions.

Target score: the target score allocated, after the additional proposed mitigating actions, to the impact (I) and likelihood (L) of the risk, and the RAG rating (S) allocated to it

Appendix C - Version Control Sheet

Version	Date	Author	Replaces	Comment
2		Julian Lewis	Risk Management Policy 2003	Incorporates information risk management
2.1	July 2016	Julian Lewis	All previous versions	
3	2 May 2017	Andrew Dillon	All previous versions	Responds to the January 2017 internal audit report and subsequent Audit and Risk Committee, and SMT discussions. Changes include the risk appetite, risk identification, evaluation and management process, and risk register template
4	May 2020	Elaine Repton	V3	Periodic review and aligned to HM Treasury's Orange Book.

National Institute for Health and Care Excellence

Directors' progress reports

The next 5 items provide reports on the progress of the individual centres and directorates listed below. These reports give an overview of the performance of each centre or directorate and provide an update on any issues of note.

Alexia Tonnel, Director, Evidence Resources Directorate (Item 10)

Dr Paul Chrisp, Centre for Guidelines (Item 11)

Meindert Boysen, Director, Centre for Health Technology Evaluation (Item 12)

Jane Gizbert, Director, Communications (Item 13)

Professor Gillian Leng, Director, Health and Social Care Directorate (Item 14)

May 2020

National Institute for Health and Care Excellence

Evidence Resources progress report

1. This report sets out the performance of the Evidence Resources directorate against the business plan objectives of the Directorate in 2019/20. Where relevant, we provide an update on activities undertaken in March and April 2020 to support NICE's response to the COVID-19 pandemic. We also highlight usage performance of the NICE Evidence suite of on-line services at the end of April 2020.

2. The Evidence Resources Directorate is responsible for the following key functions and services:

    - We provide a high-quality information service to NICE centres and directorates;
    - We manage third party access and re-use of NICE content, including internationally;
    - We support the Centre for Health Technology Evaluations (CHTE) with their digital health evaluation programme;
    - We manage the provision of NICE Evidence Services;
    - We support NICE’s digital transformation activities and maintain all NICE's live digital services;
    - Since September 2019, we have been working closely with the NICE IT team and suppliers to align technology decisions across the IT and digital portfolios of NICE.

Summary of the impact of Covid-19

3. All teams in the Directorate have been involved in supporting NICE's response to the pandemic. The Information Services team has been heavily involved in the production of the Rapid Covid-19 guidance by searching for and sourcing underpinning evidence. The Data and Analytics team has re-focused the development of their data standards, framework and data catalogue to support the use of data used in the development of rapid COVID-19 guidance. The IT and Digital teams have reprioritised their work to facilitate remote working for staff and enable the running of virtual committees.

Performance

4. Performance against the Evidence Resources objectives for 2019/20 is summarised in this section.

Information Services

5. A key objective of the directorate is to deliver efficient and high-quality information services to the NICE centres and directorates. Over 2019/20, we conducted 456 information searches for the development of guidance and advice outputs. In addition, we responded to 21 ad hoc enquiries, issued 142 current awareness bulletins, sourced 5,022 documents, provided information support to the NICE evidence services and delivered information skills training to 97 members of staff.

6. Examples of service improvement and methods research projects completed, initiated or ongoing during the year include:

    - development of search filters to improve how we find evidence on health apps;
    - development of search filters to improve how we find cost-utility studies;
    - a study into whether a machine learning technology (RobotSearch) is a potential alternative to Boolean-based filters for retrieving RCT studies;
    - a study to explore whether we can we use fewer sources and still find the evidence for public health guideline evidence reviews;
    - a study to understand whether priority screening can improve the efficiency of title and abstract screening when applied to management of common infections topics and the implications this might have on the search approach.

7. Most of the staff in the Information Services team worked on NICE's COVID programmes during March and April 2020 through evidence gathering, literature searching, document supply and copyright support. The team are contributing to the rapid guidelines and evidence summaries, surveillance and topic selection and are preparing to support medtech innovation briefings from May. Capacity is stretched and we may have to explore additional means of resourcing these work programmes.

Content re-use

8. A key objective of the team is to promote the re-use of NICE content outside of the UK. During 2019/20, the team responded to 303 domestic and international requests to re-use NICE content. Forty-nine content licences and five syndication licences were signed. The total income invoiced in the year was £117,618 against an income target of £75,000.

9. The international re-use of all NICE rapid COVID-19 guidance and evidence summaries has been exempted from our application process, licence and fee.

Digital Health

10. Our directorate is supporting CHTE to explore with NHS England the options for a digital health technology evaluation workstream and updating the Evidence Standards Framework for Digital Health Technologies (DHTs) published in 2018/19. During 2019/20, work progressed on 5 pilot topics, one of which will be published as a guidance output from the medical technology evaluation programme once the COVID-19 restrictions are lifted and two were published as medtech innovation briefings as they were relevant to the work on COVID-19.

11. We also supported the following activities:

    - Chairing the External Steering Group for NICE's pilot Digital Health Evaluation programme and Chairing the Data and Analytics External Reference Group;
    - Developing NICE's artificial intelligence business cases with NHSX for accessing funds from the AI Regulatory Incubator Fund to support proposed NICE methods development work on the evaluation of technologies with embedded algorithms and artificial intelligence as well as the use of AI within NICE to support rapid surveillance of published literature;
    - Attending the Accelerated Access Collaborative Innovator Portal project team meetings and stakeholder workshops as a key partner, ensuring strong links are made to NICE's Health Tech Connect system and medical technology work programmes.

Data Analytics

12. At the end of September 2019, the Data and Analytics team was moved to the Evidence Resources directorate until the new Science, Evidence and Analysis directorate is established. Key achievements of the team during 2019/20 were:

- Published the finalised Statement of Intent covering the use of broader data and applied analytics in NICE's work;
- Developed the draft Methods and Standards programme that will be necessary to support the ambitions within the Statement of Intent;
- Recruited and established a team to provide central oversight, advice and support to embed and improve the use of data and analytics in the development and update of NICE's outputs;
- Developed a prototype data catalogue, with over 400 data sources, as a resource to help people quickly identify sources of data which may be relevant to a project;
- Established a strategic partnership with HDR UK to ensure that health data can be used to enhance decision-making and improve patient care.

13. The team is now accelerating work to develop a (simplified) standards and methods framework for broader use of data in the development of rapid COVID-19 guidance to ensure the evidence base and analysis fully utilises the wide range of emerging coronavirus data sources and is fit-for purpose. This will help build the foundations for the development of this future work programme.

14. The team also developed an extension to NICE's existing data catalogue to cover COVID-19 and now has oversight of the monitoring of external COVID-19 data and analytic initiatives.

Digital Services

Strategic planning and resource prioritisation

15. The first objective of the Digital Services (DS) team for 2019/20 is to plan and prioritise the allocation of NICE technical resources across a portfolio of activities, including life service maintenance, transformation projects and other operational priorities. Since September 2019, this also includes activities associated with the NICE IT portfolio.

16. During 2019/20, the key activities prioritised by the team were as follows. Some of these activities have been impacted by the COVID-19 pandemic, most pro-actively as part of NICE's response:

- Through the year, we have continued to support the strategic development and planning of the NICE Connect programme;
- We completed work with a consultancy to create our future Target Operating Model (TOM) for an integrated IT and digital services team.

Work to implement the new model and communicate the team strategy will continue over the summer despite our current remote working;

- We planned the transition from our current managed IT service provider following their serving notice. In the context of COVID-19, and in agreement with the existing supplier, this transition is now being postponed to March 2021 and the plans created adjusted accordingly;
- We are working with the Stratford 2020 IT working group and programme manager to plan the technical considerations and wider impact of the London office move for NICE. To date, this work has continued unaffected by COVID-19 although new pressure on key IT staff across all ALBs involved is been monitored;
- We are completing work with a strategic partner to support the development of digital workplace strategy enabled by the roll out of Office 365 including an information and records management strategy. The pace of delivery has mostly been maintained despite the remote working arrangements under COVID-19, and this phase of work will finish in May 2020. Components of the digital workplace strategy have been brought forward by the coronavirus situation:
  - A paired down roll-out of MS Teams and training was initiated early to facilitate remote working across NICE. This started in mid-April.
  - Office 365 applications are being trialled and tested where appropriate to support initiatives such as the 'Skills marketplace' to enable capacity and skills available and required due to remote working to be matched.
  - Alongside Office 365, the DS and Information Governance teams supported the rapid roll-out of Zoom across NICE, providing training, policy guidance and user support. The configuration of the tool and training are designed to limit cyber and information governance risks.
- We selected, tendered and placed orders for approximately 500 laptops by early March 2020 but unfortunately delivery was delayed because of Covid related supply chain issues. The plan is for the build and distribution of the machines to start when the current strict lock-down situation eases but alternatives are being explored.

Delivery of strategic digital services projects

17. Our second objective is to deploy our digital expertise to deliver business-led strategic projects in line with an agreed roadmap.

18. During 20219/20, the main projects have been:

- The Evidence Management platform (delivering web tools for searching evidence, systematic review needs and building an evidence surveillance

capability). We developed the tools to support NICE teams and are rolling out the tools to the NICE collaborating centres;

- We completed work to support configuration of a new identity management solution to replace our current in-house 'NICE Accounts' solution. This solution will be planned for integration into our existing services over the course of 2020 starting with EPPI Reviewer in April;
- Operational Productivity: A multi-disciplinary team from across NICE has been conducting initial trials of tools to support changing our current processes, tools and data management practices associated with stakeholder contacts and planning information.

Live services maintenance and improvements

19. Our third objective is to manage and maintain the live digital services of NICE utilising user insight and strategic service goals to prioritise use of resource:

- Across 2019/20, NICE Digital Services operated within the service levels (99.7%) agreed with DHSC for availability (uptime) with 99.99% average performance;
- During the year, 312 defects were closed. In the same period, 34 Change Control Requests were completed.

20. Key areas of live services maintenance during the year have included:

- Work to improve the accessibility of our services and meet incoming public sector accessibility legislation. Some of this work has been deprioritised due to COVID-19 but will continue at a slower pace for key services during Q1 and Q2 2020/21;
- Work to upgrade our Transport Layer Security protocols to support confidentiality and data integrity over the internet;
- Work on the planning tool and contact database to support Technology Appraisals cost recovery processes completed in May;
- Upgrade to the platform for our Medicines Awareness Service, completed in early February 2020;
- Upgrade to the NICE Pathways Service, completed in April 2020.

Cross-cutting updates

21. Recruitment: As a result of the new Target Operating Model, the move to Stratford, and the NICE Connect programme, we are in the process of identifying priority roles for recruitment. The recruitment to a new Associate

Director for IT Operations and Infrastructure completed virtually in March with the new Associate Director joining us in late July 2020.

22. Talent management update: To support the delivery of our technical strategy we are engaging with our existing cloud network providers. Technical training will be delivered as part of our ongoing technical strategy and Digital Services/IT integration plans. Usage of our internal online training tool has been renewed for another year and continues to increase as team members complete courses targeted to their development.

NICE Evidence Services

23. A core objective of the directorate is to maintain and monitor the performance of NICE Evidence Services which include Clinical Knowledge Summaries, HealthCare Database Advanced Search, the BNF microsites, Evidence Search, the Medicines Awareness Service and UK PharmaScan.

24. During the year negotiations were successfully concluded for a new three-year England-wide licence to access the Cochrane library when the current licence ends in April 2020. Work to upgrade the technology and infrastructure that supports the medicines awareness service was completed and implemented, as was an upgrade and relaunch of the UK PharmaScan website. The team also agreed a 2-year contract extension for the Identity Provider and Access Management Federation (OpenAthens) contract until May 2022.

25. In recent months the team has worked to ensure our commissioned evidence services such as Clinical Knowledge Summaries, our daily and weekly Medicines Awareness Services and NICE Evidence Search fully reflect NICE guidance on COVID-19 and we have used relationships with publishers and key partners, such as Health Education England, to ensure NICE guidance on COVID-19 is made as widely available to the system as possible.

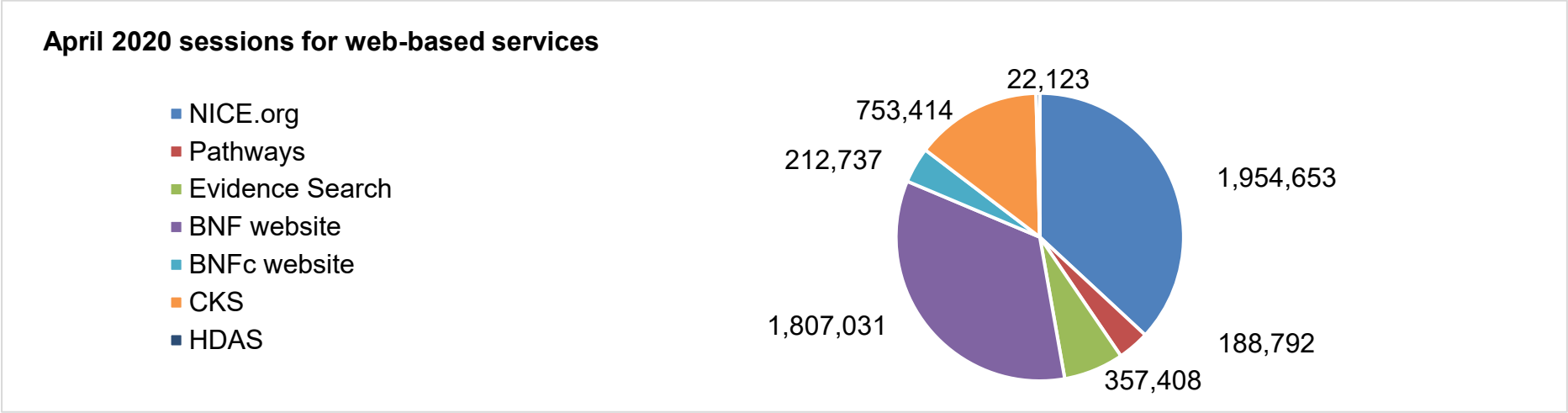
Performance statistics for NICE Evidence Services

26. Figure 1 below summarises the position of all NICE's digital services at the end of April 2020, contrasting the relative size of the externally facing services of NICE, measured in number of 'sessions'. In April NICE digital services received 5.3 million sessions in total, a fall of 7% in comparison with the previous month but a fall of less than 1% when comparing with April 2019. Overall, NICE digital services have grown 13% in the last 12 months.

27. The Coronavirus pandemic including changed work patterns, the introduction of 'rapid guidelines' and increased home working have impacted on the performance of live services. This is particularly evident in April as the UK lockdown was in place for the full month. The move to home working in mid-March introduced challenges when tracking sites performance including a need to revise how internal users were excluded from the dataset. This will have slightly reduced the representativeness of the data for approximately 2 weeks in March however the issues were largely resolved by April.

28. Generally, we can conclude that the NICE website has experienced an increase in traffic due to the provision of COVID-19 related guidance whereas other services have generally seen a decline in traffic during this period.

Figure 1 and table 1: Overview of NICE's digital services performance as of April 2020
download the data set for these charts



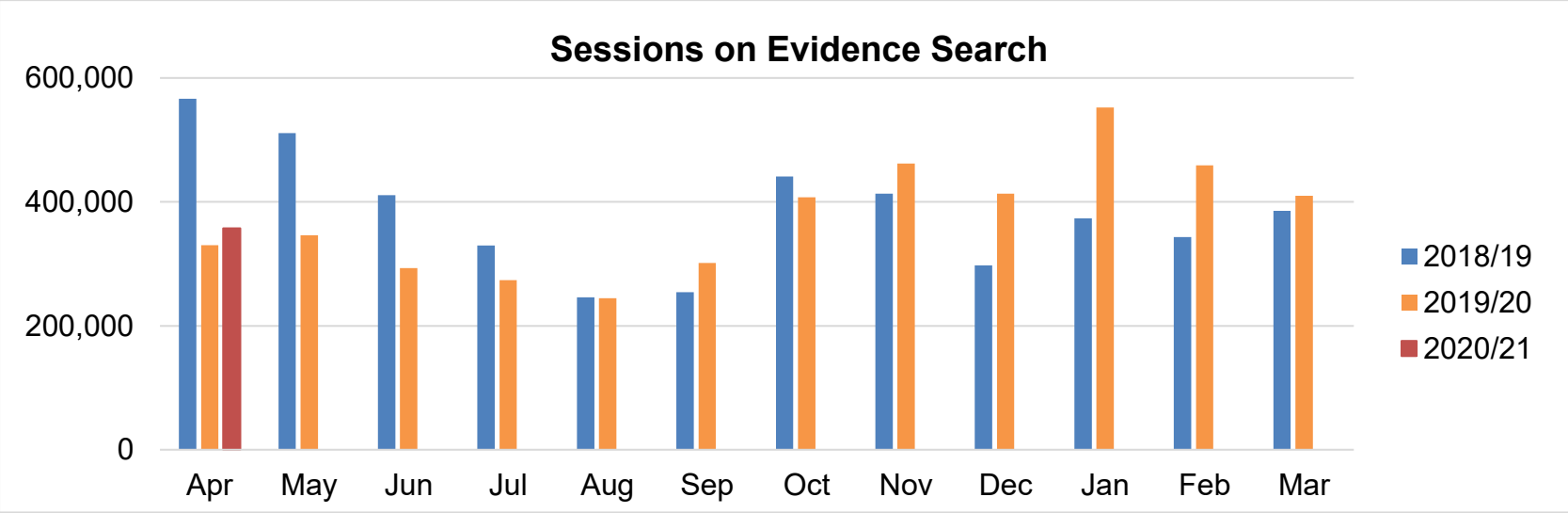
Total sessions* in April 2020 across NICE web-based services	5,296,158
% year-on-year variance	0%
% month-on-month variance	-7%
Total sessions for the full year ending in April 2020 across NICE web-based services	64,139,065
% year-on-year variance	13%

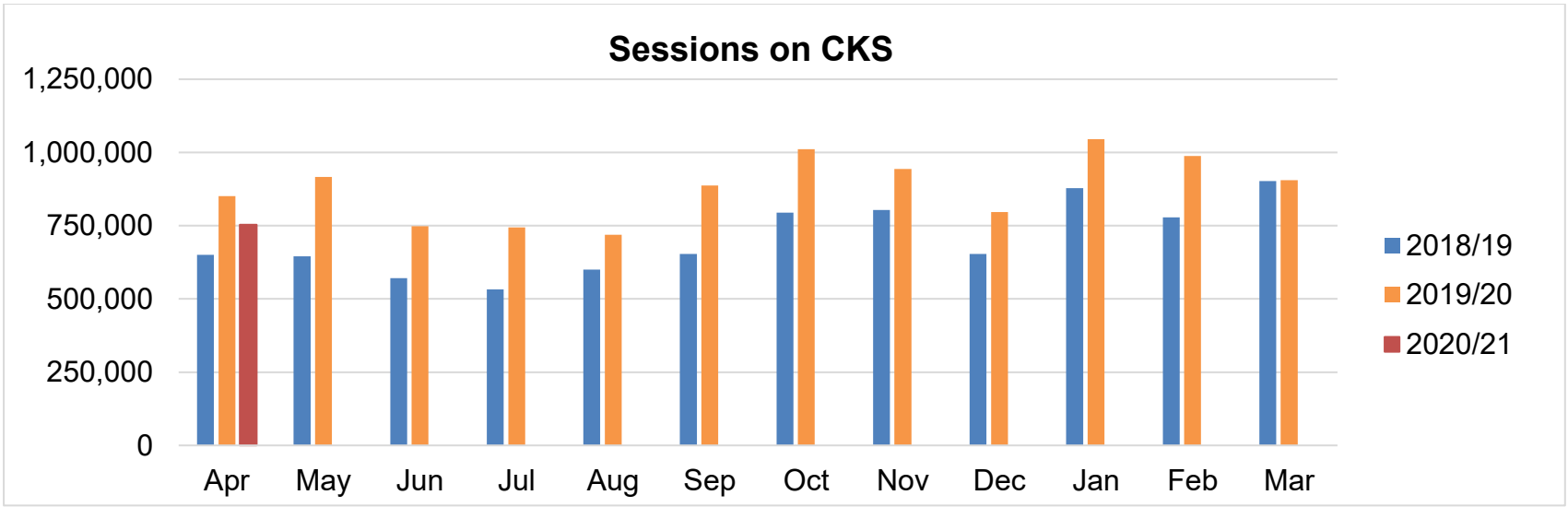
*Note: a session is a group of interactions a user takes on a website within a given time frame

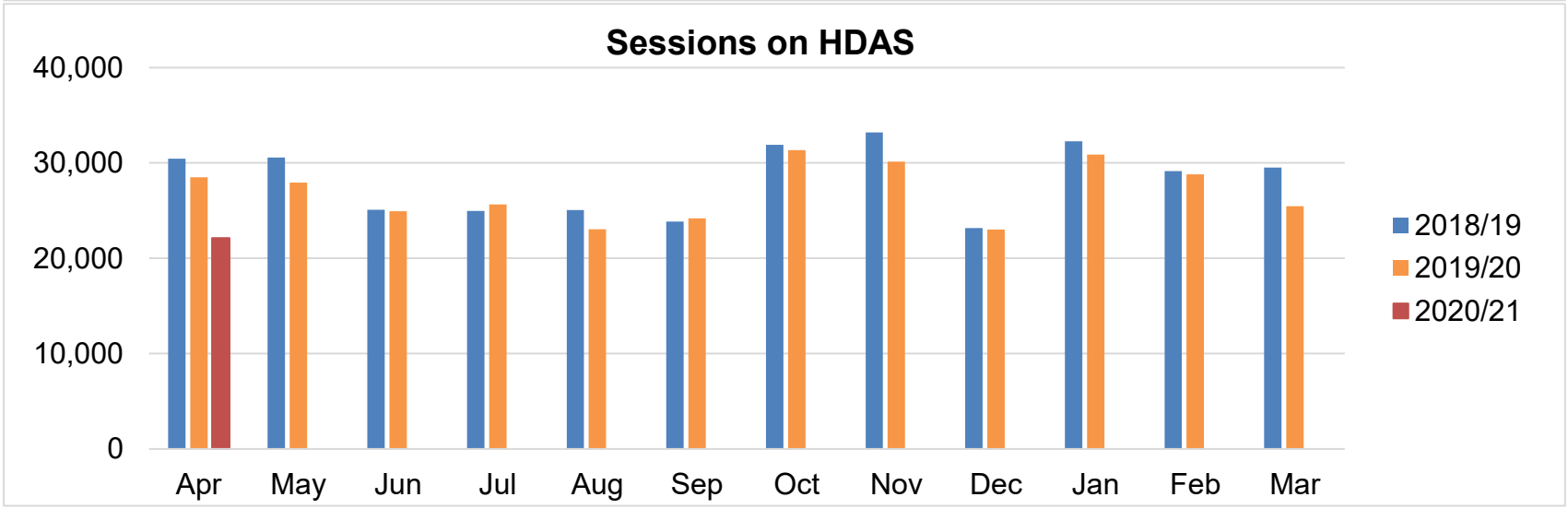
29. Figures 2-4 below detail the performance of the 3 services which provide access to evidence beyond that produced by NICE: Evidence Search, Clinical Knowledge Summaries (CKS) and HDAS.

- Sessions to Evidence Search were up 8% in April against 2019 and sessions for the 12 months ending April show a growth of 4%. However, performance in March and April has not been as strong as in the period from December 2019 to February this year.
- CKS experienced a fall of 11% in April compared to 2019, most likely as a result of measures around COVID-19. However, the growth in the 12 months to April is still strong at 21%.
- Sessions on HDAS fell significantly in March and April, with April being down 22% year-on-year.

Figures 2-4: Performance of services providing access to 'other evidence' as of April 2020

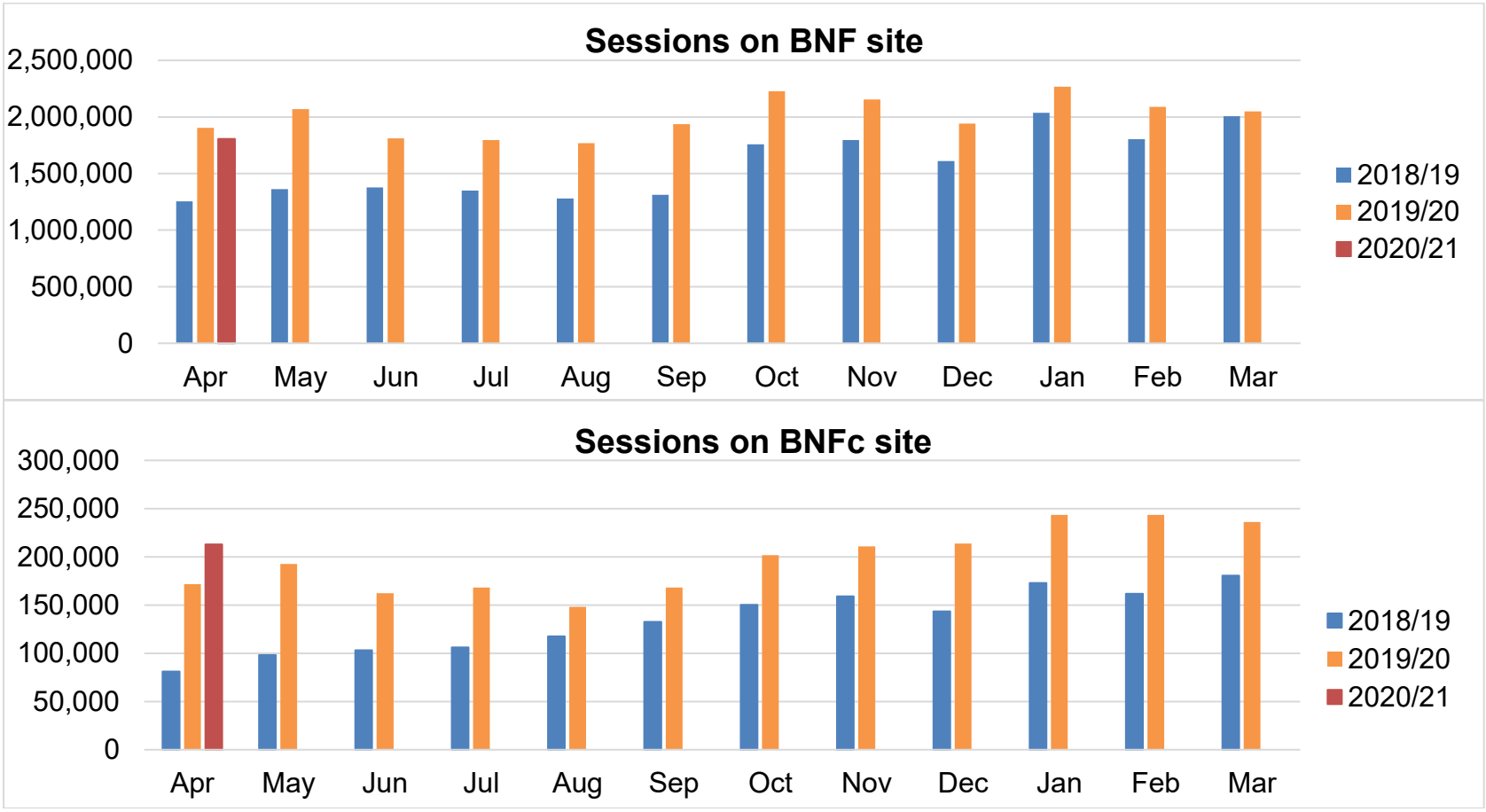



Sessions on CKS
1,250,000
1,000,000
750,000
500,000
250,000
0
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Jan
Feb
Mar
2018/19
2019/20
2020/21


Sessions on HDAS
40,000
30,000
20,000
10,000
0
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Jan
Feb
Mar
2018/19
2019/20
2020/21

30. Figures 5-6 illustrate the performance of our BNF and BNFc microsites. The BNF performed slightly worse in April with a fall of 5% year-on-year, but the BNFc is still performing strongly with April sessions up 24% against 2019.

Figures 5-6: Performance of services providing access to BNF content as of April 2020



National Institute for Health and Care Excellence

Centre for Guidelines progress report

1. This report sets out the performance of the Centre for Guidelines against our business plan objectives during March 2020. It highlights the initial impact of reprioritising outputs to support the system with rapid guidelines on COVID-19 topics, and summarises other non-COVID notable issues.

Summary of the impact of COVID-19

2. On 17 March we moved our priorities to only publish those guidelines that are therapeutically critical and/or address COVID-19 diagnostic or therapeutic interventions.

3. We developed an interim process and methods for developing rapid guidelines on COVID-19. Topics are referred by NHS England and selected according to a set of priority criteria. The programme began on 13 March and by 31 March we had published four rapid COVID-19 guidelines. A range of staff from across NICE worked remotely in teams to develop the guidelines. The process involves close working with clinical experts, has a targeted consultation and a quality assurance step. Guidelines are signed off by NICE Guidance Executive and NHS England.

4. We are working through the impact of the suspension of guideline committees and contact with committee members, which is in place to minimise disruption to the health system during the COVID-19 pandemic. The team has agreed the delays associated with guidelines that need to be paused and where review work can continue. Twelve guidelines have been paused across the programme. As the demand for new rapid COVID-19 guidelines decreases, and as the NHS starts to plan for the recovery phase, we are planning on a phased restart of paused non-COVID guidelines. We will consider two factors on a topic-by-topic basis when considering our phased approach: stage of development when paused, and topic. This will inform business planning.

5. The surveillance team has switched focus to support the reviewing and updating of rapid COVID-19 guidelines. An interim process to manage surveillance of COVID-19 rapid guidance has been established with the team implementing systems around this, adapting approaches as work progresses. The team is collaborating with our digital services team to explore potential solutions for managing the information flow used in surveillance and updating of the rapid guidelines.

6. All scheduled standard surveillance reviews have paused. The team continue to monitor key trials of relevance to the guideline portfolio.

7. The Management of Common Infections (MoCI) guidelines have been suspended until the organisation's priorities change.

Performance

8. In addition to the 4 rapid COVID-19 guideline, 3 clinical guidelines were published during March. In total 38 non-COVID guidelines were published in 2019-2020: 28 clinical, 3 public health, 1 social care and 6 antimicrobial prescribing guidelines, meeting the centre's 2019-20 business plan objectives.

9. Eight surveillance reviews were completed during March 2020, of which 4 were exceptional reviews. Of the 8 surveillance reviews completed, 4 have not published due to COVID-19 publication restrictions. A total of 52 surveillance reviews have been completed this business year, meeting the centre's 2019-20 business plan objectives.

10. Quarterly review meetings with both internal and external guidance developers and contractors have been completed for the 2019-20 business year. All developers remain within budget and are on target to complete agreed KPIs and business objectives.

11. The 2020-21 business plans have been approved for internal and external guidance developers and contractors. Business letters for year 2020-21 have been issued with associated templates for contract management.

Notable issues and developments

12. The focus of the centre's activities since 17 March has been on supporting the development and maintenance of rapid COVID-19 guidelines, but other notable developments took place.

13. The Surveillance team is leading a task force exploring a unified approach to surveillance across NICE as part NICE Connect. A working group has been formed and an initial workshop held to discuss current processes and methods of working. Further sessions have been scheduled to explore common approaches and areas for further exploration.

14. The methods and economics team continue to contribute to CHTE 2020 and are actively involved in all Task and Finish Groups and the Methods Working Group.

15. We are utilising the ONS database of NICE guideline recommendations to identify related content to support surveillance. Relationships between

recommendations is being explored through AI techniques with initial results indicating that computer models perform better than humans in the identification of related content.

16. In line with the guidelines strategy agreed by the Board in November, the commissioning team developed a new approach to updating guidelines given the planned reduction in capacity. Multiple guidelines within the same topic area were commissioned for updating into one capacity slot. This reduced the resource requirement as topics were updated concurrently. This approach is now being used across multiple developers and topic areas as we focus on the need to use resource in capacity more effectively and respond in a timely way to emerging evidence.

17. In March, two members of the team travelled to Egypt to initiate discussions with the Egyptian Health Ministry about the NICE guideline contextualisation process, in attendance the UK Department for International Trade.

May 2020

National Institute for Health and Care Excellence

Centre for Health Technology Evaluation progress report

1. This report sets out the performance of the Centre for Heath Technology Evaluation (CHTE) against our objectives during the 2019/20 business year. It also highlights key developments in the centre during that period, and starts with a summary of the impact of COVID-19 on activities of the centre in the past months.

Summary of the impact of COVID-19

2. With the prioritisation of therapeutically critical topics, the technology appraisals and highly specialised technologies work programme is currently actively working on 80% of its work programme, this will reduce to 60% over the next 2-3 months. It is not expected that the programme will have a high rate of spare capacity due to existing vacancy levels (pre-COVID-19) and the impact on relative staff availability due to caring responsibilities. The programme will re-invest any spare capacity into the ongoing methods review and preparation and implementation of the RAPID-C19 process (see below).

3. Medtech Innovation Briefings on two digital technologies (MyCOPD and Lifelight First) have been produced and published as they are relevant to the COVID-19 outbreak. Other topics for which work continued with the aim of publication were diagnostics assessments on high-sensitivity troponin for the early rule out of acute myocardial infarction and quantitative faecal immunochemical tests to guide colorectal cancer pathway referral for people with a change in bowel habit or abdominal pain, and an interventional procedure assessment for intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention.

4. The diagnostic assessment team is supporting Public Health England with their evaluation of home antibody tests, is developing evidence standards for COVID-19 tests (both antigen and antibody), and is supporting a review of biomarker guided antibiotic discontinuation in COVID-19 patients, in conjunction with the centre for guidelines.

5. Virtual meetings were successfully held for technology appraisal committees at the end of March. Learning from the early virtual committee meetings will be taken forward to continue to improve the experience for members and external attendees.

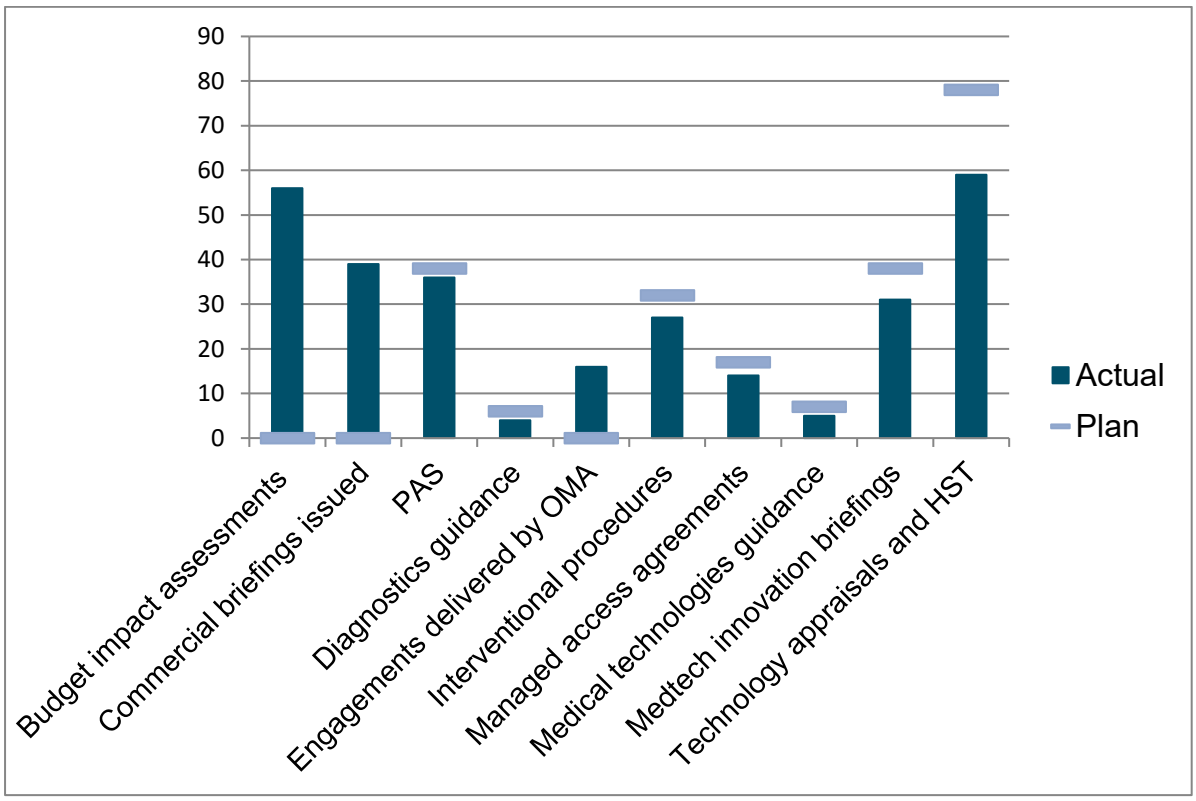
6. The managed access team coordinated the release of statements advising on the impact management of new patients, current patients on treatment, and ongoing

data collection for existing Managed Access Agreements and Commissioning through Evaluation schemes.

7. The Accelerated Access Collaborative secretariat and the Office for Market Access are supporting the development and implementation of the Research to Access Pathway for Investigational Drugs in COVID-19 (RAPID-C19), a multi-agency initiative to ensure safe and timely patient access to medicines useful in treating patients with COVID-19 infection, as well as testing implementation activities for NHS England/Improvement (NHSE/I).

Performance

Figure 1 Performance against plan for CHTE outputs in 2019/20



Download the data set for this chart.

8. The diagnostics assessment programme published 1 piece of guidance less than planned due to one ongoing assessment being delayed because independent validation of the economic model by the NICE Decision Support Unit was required.

9. The medical technologies evaluation programme published 2 less pieces of guidance than planned, one of these was Pnuex which was delayed due to resolution. The second was SpaceOAR which was deemed not suitable for MTG so was rerouted to technology appraisals. 7 less medtech innovation briefings

were published than planned, 3 of these were due to COVID-19 publication restrictions, 3 were paused as non-COVID-19 priority topics. These will complete and publish once restrictions are lifted on non-COVID-19 priority topics. 1 topic was delayed to update as a rapid MIB relevant to COVID-19 and published in April.

10. The gap in guidance publication for technology appraisals and highly specialised technologies in the 2019/20 business year is the result of suspension or delay of scheduled topics. The reasons are varied:

    - commercial discussions between NHSE/I and the company (35%)
    - company request to delay the appraisal (25%)
    - changes to the regulatory plans (15%)
    - response to internal capacity constraints (15%)
    - consideration of an appeal (5%)
    - COVID-19 non-priority topic (5%).

11. Whilst delays to topic publication are often outside of NICEs control (i.e. regulatory approval process and company requests to delay), outputs from technology appraisals during 2019/20 have largely been affected by a high vacancy rate within the internal technical team and the lower than anticipated straight to Final Appraisal Document (FAD) rate.

12. Four pieces of interventional procedures guidance did not publish in 2019/20 due to resolution requests extending the timelines.

Notable developments

Recruitment

13. At the end of March 2020, we held a virtual assessment centre to recruit to the new assistant health technology assessment analyst positions that also offer a funded Masters degree. The four successful candidates will start within the technology appraisals team in the coming months.

14. In line with the aims of the NHS Long Term plan, expansion plans for the medical technologies evaluation programme were agreed by SMT in October and recruitment took place in January 2020 to recruit to 8 vacancies. Two technical analyst vacancies remain unfilled as a result of movement within the team.

Managed access and research

15. As part of the medical technologies evaluation programme work is done to support commissioning activities for research. This includes initial feasibility studies, audits, primary clinical research, and analysis and reporting of completed studies prior to publication. Seven such projects were ongoing during 2019/20. A further six protocols were published during 2019/20 based on research recommendations developed by the medical technologies advisory committee.

16. Thirty data collection agreements are active: 24 for the cancer drugs fund, 3 linked to highly specialised technologies guidance and 3 for technology appraisals outside of cancer. A further 11 topics are preparing to exit managed access agreements and will be reappraised by NICE. The managed access team is working closely with NHSE/I to develop arrangements for a new Innovative Drugs Fund, which will build on the success of the cancer drugs fund by extending managed access to non-cancer technology appraisals.

17. Two pilots of the European network for HTA (EUnetHTA) Register Evaluation and Quality Standards Tool (REQueST) have been completed and the report from Newcastle External Assessment Centre was delivered in March 2020. Feedback on the usability of the tool has been shared with EUnetHTA and discussions about future development of the tool are ongoing.

Commercial arrangements

18. In January 2020, the commercial liaison team introduced a commercial pathway which is a set of process driven checkpoints designed to give all stakeholders a clear direction in the development of a commercial proposition. The team further provided support for four joint workstreams with NHS England and NHS improvement during 2019/20: budget impact test, commercial information sharing; early commercial triage; and review of transactability of commercial arrangements.

Digital health technologies

19. A digital health technologies pilot was implemented during 2019/20. Five topics were scoped and prepared for assessment through the medical technologies evaluation programme. Only one topic was sufficiently advanced to be taken to committee because of challenges with the regulatory status of these early technologies. Draft guidance was published in February and consultation will restart when priorities change again.

20. As part of the digital health technologies pilot, the Evidence Standards Framework was further developed during 2019/20 using the results of a survey conducted in October 2019. Additional supporting tools and materials have been

developed and some amendments have been made to improve clarity. It is expected that the revised framework document and additional resources will be published when resources allow due to the Covid-19 situation.

Topic Selection

21. HealthTech Connect has been fully operational for its first year. Over 700 companies have registered, and over 190 technologies have been submitted. 20% of submitted technologies have been selected for NICE MedTech innovation briefings or NICE guidance.

Process and methods updates

22. Following SMT approval of interim changes to the technology appraisal process, implementation is underway and the changes are anticipated to apply to topics which start from May 2020. The interim changes aim to manage the current inability to capitalise on the early engagement step with companies to resolve key technical and commercial issues ahead of the first appraisal committee meeting. This step was introduced to maximise the opportunity to go straight to publication of the Final Appraisal Document (FAD) after the first committee meeting, avoiding the requirement for consultation and a second committee meeting. Only when we use this process and achieve a one committee meeting outcome for most topics can we meet the commitment in the 2019 Voluntary Scheme for Medicines Pricing and Access to publish final guidance within 90 days of marketing authorisation.

23. The update to the CHTE programme methods guide is ongoing. Task and Finish Groups involving external members have used detailed specifications and questions, to consider the case for change in each of the topic areas. The Board have recently agreed to revise the timelines for consultation and implementation of the updated methods. All stakeholders have been informed, and the information also placed in the public domain: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation.

May 2020

National Institute for Health and Care Excellence

Communications Directorate progress report

1. This report sets out the performance of the Communications Directorate during March to April 2020. It also provides a brief summary of the Directorate's performance against its business plan objectives throughout the financial year 2019-2020.

2. These Communications Directorate business objectives are closely aligned to the NICE strategic objectives.

3. The Communications Directorate is responsible for ensuring NICE's stakeholders know about how NICE's work can help to improve quality and change practice in health and social care. We help to protect and enhance the reputation of NICE through daily contact with the public, media, parliamentarians and other key groups. And we contribute to ensuring NICE content meets users' needs and is easily accessible through our website and other channels.

Performance summary: 2019-2020 financial year in review

Events and stakeholder communications

4. On 1 April 2019 we celebrated our 20th anniversary. To mark this significant milestone we delivered a programme of activities for staff and external stakeholders during the spring and summer. Events included a stakeholder reception at the Palace of Westminster, sponsored by Baroness Nicola Blackwood, parliamentary undersecretary of state for innovation, and a staff celebration with guest speaker Nick Timmins, former public policy editor at the Financial Times.

5. On 9 May 2019 we delivered our flagship annual conference. Held in Manchester, and attended by 530 delegates, the event focused on the theme: 'Transforming Care'. Forty seven experts spoke in 16 sessions, on topics including managing the life sciences' innovation pipeline, integrating physical and mental health care, and evaluating the effectiveness of digital health apps.

6. In January 2020, we launched a campaign to raise awareness of the NICE Connect project among our external stakeholders. We commissioned a multimedia agency to develop an animated video explaining the aims and ambitions of NICE Connect, and promoted it on our website and social media channels (generating 117,227 views), along with a series of stakeholder

interview clips in which representatives from different sectors spoke about what NICE Connect could means for them.

7. We conducted an in-depth reputation research study with over 1,500 stakeholders, MPs and members of the public. The findings were disseminated to senior managers across NICE and have informed a number of work programmes, most notably NICE Connect.

8. We also developed and implemented a new corporate survey platform for teams to gather feedback from stakeholders more consistently, and to facilitate the sharing of results.

9. Accessibility has been a key theme of our digital content work during 2019-20 and we have made significant progress towards achieving the new requirements of the accessibility regulations for public sector websites. We have also developed more interactive and tailored content for our audiences. For example we developed a full suite of online resources for local partnerships. We also created a new online format for our impact reports which has proved hugely popular with our audiences and significantly increased their reach.

10. In 2019-20 we answered 10,186 enquiries of which 123 were requests made under the Freedom of Information Act, 136 were from MPs and 92 were Parliamentary Questions. We also received 37 requests for input into Coroner's reports which is a 3-fold increase on the number received in 2018-19. We began the year with a backlog of enquiries due to staff vacancies and sickness absence but this was cleared by quarter 3 and we are now operating at normal levels. Over the year we have dealt with a broad range of highly complex and sensitive issues which are reflected in the media section below.

Press and social media

11. Many of our announcements and publications shaped the media agenda in 2019-20. Stories making the headlines included: our decision in November 2019 to recommend GW Pharma's cannabis-based treatment Epidyolex as an option for treating Dravet and Lennox-Gastaut syndromes, two types of epilepsy; our recommendation that BioMarin's drug cerliponase alfa should be made available for children with Batten disease, through a Managed Access Agreement; and our publication in April 2019 of a patient decision aid on asthma inhalers, which encouraged people to consider the environmental impact of different inhalers and to make greener choices where possible.

12. As part of our anniversary celebrations, the media team published a long-read feature exploring key milestones in our 20-year history. They also made a series of 20 videos with patients, frontline health and care staff, and others, whose lives or work have been positively affected by our guidance over the years.

13. Throughout the year we continued to use social media channels to reach and communicate with our audiences. We have 194,900 followers on Twitter, which is a 11% rise since March 2019. We posted approximately 100 tweets per month across the whole of the financial year. We now have 3,687 followers on Instagram – almost double the figure we had in early 2019 (1,700) – and 13,000 followers on Facebook, which is 4,709 more than we had in the previous year.

The impact of COVID-19 in March and April 2020

14. Almost all the directorate's work during this period has focused on supporting NICE's response to the pandemic. Our objectives have been to ensure that our external communications in relation to COVID-19 are as wide and timely as possible, without unnecessarily distracting or over burdening the health and care system, and to give timely, clear information and advice to staff regarding the changes to the way we work.

Performance

Communications support and strategic advice

15. The publication of each wave of COVID-19 rapid guidelines has been supported with regular and timely stakeholder communications. Stakeholders have been notified when each wave has gone live and an alert has been issued by NHS England. We have expanded our stakeholder lists and adapted our normal monthly NICE News and Update for Primary Care newsletters to update 42,820 subscribers each time a guideline is published.

16. We have issued 6 such newsletters announcing the publication of new COVID-19 rapid guidelines. The open rates of these newsletters have been notably higher than we would normally expect, ranging from 25% to 43%. Prior to the COVID-19 crisis we would typically expect a rate of 20-25%.

17. We have provided communications support to the CEO to contact key stakeholders and partner organisations setting out how NICE is adapting its ways of working during the pandemic. In early March and April, we sent out communications from the CEO to charities and patient groups, plus the heads of ALBs and other health and care organisations.

18. As part of our strategic communications advice to the Senior Management Team and Coronavirus Response Group, we have been producing a daily round-up of key news and policy developments in relation to COVID-19. These updates are now also being shared with the Board.

Brand and marketing communications

19. We are developing a suite of marketing communications activities to promote key NICE guidance and other products that will be useful for the NHS and social care sector as they move into phase 2 of their response to the COVID-19 pandemic, and start working to build up capacity in non-COVID-19 services again in the coming weeks.

20. In line with a letter issued by Sir Simon Stevens, chief executive of NHS England, on 29 April, we will focus on promoting guidance that provides evidence-based recommendations in the following areas:

    - Mental health
    - Vulnerable populations e.g. learning disabilities, autism, dementia
    - Cardiovascular disease
    - Technologies that enable social distancing e.g. digital IAPT
    - Services that may have been displaced or decommissioned e.g. fertility
    - Social care, focusing on care homes

21. The communications will include website content, a series of infographics highlighting key guidance and other products that support recovery from COVID-19, a social media campaign, and sharing content with other arms' length bodies and key partner organisations.

Communicating with staff

22. During March and April, we increased our internal communication and engagement activities to ensure all staff were kept informed and supported as we moved to remote working. We have developed new digital content, a new virtual format for the all staff meeting, and supported the CEO in a daily email update which has been well received.

23. We have also provided strategic internal communications advice and practical support on several other projects including the London office move and the roll out of MS Teams.

24. We have seen high levels of engagement from staff during March and April. For example, a new facility for staff to post questions about the move to remote working has been popular and open rates for Your Week@NICE have increased.

Audience insights

25. We have conducted a number of short pieces of research to support learnings and inform our future strategies in response to COVID-19. Most notably we

carried out research with committee members, staff and attendees on running virtual guidance committee meetings. We also conducted 2 waves of a survey with staff on remote working.

26. There are now 275 live pathways, which consist of 2,282 guidance, advice and CKS products.

27. The publishing team started working with the BMJ on the production of summaries of our COVID-19 rapid guidelines. The first, on symptom management, has been published, and summaries for the asthma and COPD guidelines are due to publish shortly. Summaries are also being worked on for the pneumonia and rheumatology rapid guidelines.

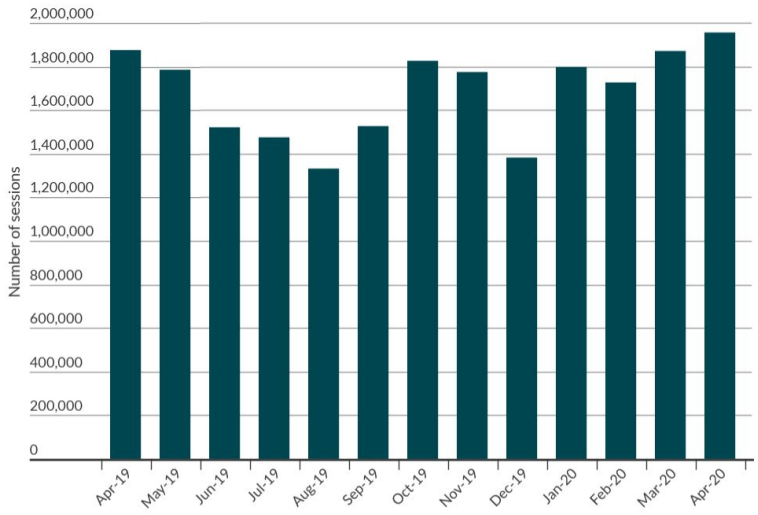
Website performance

28. There were 3.8 million sessions on the NICE website in this reporting period and 400,000 sessions on NICE Pathways.

29. Traffic to the website in this period is the highest it has been in a 12-month period, probably because of visits to the COVID-19 pages. We had 281,035 views on the on the COVID-19 landing page in March and April and 212,374 sessions.

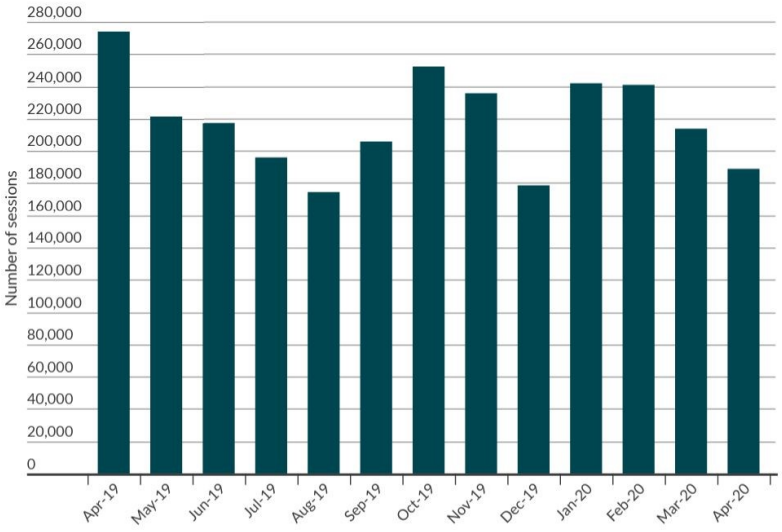
30. Visits to Pathways were down from the last period. This may have been due to our decision not to update Pathways with our COVID-19 rapid guidelines. We wanted to avoid any confusion the changing rapid guidelines may have created and to focus our limited capacity on editing and publishing the guidelines on the website.

Chart 1: Number of sessions on nice.org March - April 2020



Download the data set for this chart

Chart 2: Number of sessions on Pathways March - April 2020



Download the data set for this chart

Enquiries

31. During March and April, we responded to 1,528 enquiries which included 23 Freedom of Information (FOI) requests, 19 parliamentary questions and 10 MP letters.

32. Around half of the enquiries have been related to COVID-19 and our new rapid guidelines. We have received a few enquiries about the timelines for paused guidance but no significant concerns have been raised so far.

33. Most parliamentary questions related to technology appraisals, in particular 6 were regarding the cancer drugs fund.

34. FOIs covered a broad range of topics including our telephone system maintenance contract and the appraisal of esketamine (Sprovato).

35. We also received 6 requests to respond directly to HM Coroner's regulation 28 reports. They covered topics such as congenital heart disease in adults, sepsis, and asthma, allergy, adrenaline auto injector (AAI) pens.

Events

36. The NICE Annual Conference is scheduled to take place on 11 November in Manchester. We are keeping plans for the event under review. Currently we have paused all event marketing and speaker acquisition activities, so as not to distract NHS, public health and social colleagues as the focus is on tackling the disease.

37. All exhibitions we were planning to attend in the spring/summer have now been cancelled. Some conferences at which we are planning to exhibit in the autumn (including the Royal College of Midwives' events in October, and NCAS - the flagship social care conference - in November) are still provisionally scheduled to take place as planned. We are keeping in close contact with these events' organisers in case this changes.

38. Preparations are underway for the HTAi annual meeting, which NICE is jointly hosting with Health Improvement Scotland (HIS) and the All Wales Therapeutics and Toxicology Centre (AWTTC), in Manchester in June 2021. The Local Organising Committee, co-Chaired by Meindert Boysen, met for the first time in April.

Media

39. We issued a press release and published a news story on 21 March alerting the media to the publication of our first 3 COVID-19 rapid guidelines. All major

national news outlets and many regional publications covered the story - most incorporating it into a wider piece about pressures on critical care services.

40. Most media outlets, including the Telegraph, Independent and Evening Standard, focused on the critical care rapid guideline and our recommendation to use the clinical frailty scale to guide admissions to critical care. The reporting was generally fair and acknowledged that doctors already make decisions like this daily, irrespective of COVID-19. The Guardian referred to all 3 guidelines and included a quote from Paul Chrisp.

41. On 1 April we issued a press release and published a news story on the second wave of COVID-19 rapid guidelines on the provision of radiotherapy services and bone marrow transplant. These were picked up fairly by the Press Association and later appeared in the Times, Daily Express, the BMJ, PharmaTimes and some regional outlets.

42. We issued a press release and published a news story on 4 April, alerting the media to the publication of the third wave of guidelines on severe asthma, pneumonia, rheumatological disorders and symptom management in community settings. A number of trade outlets (Pulse, GP Online) covered them and later coverage came from the Sun and Mirror on the asthma guideline. Many articles focused on the asthma guideline and highlighted messaging that people should continue to take their medication as normal.

43. On 9 April we alerted the media to the publication of the fourth wave guidelines. All three guidelines (cystic fibrosis, chronic obstructive pulmonary disease (COPD) and dermatological conditions treated with drugs affecting the immune response) were covered in Pharma Field, GP Online and WiredGov. The guideline on COPD was covered in Care Industry News.

44. Our evidence review on NSAIDs on 17 April was picked up by the Telegraph, BMJ and the Pharmaceutical Journal.

45. On 20 April an article was published in the British Journal of Surgery about NICE's clinical guideline on abdominal aortic aneurysm. The article was critical of the decision to over-ride some of the committee's recommendations around the use of endovascular aneurysm repair, claiming that NICE had made a U-turn after being unduly influenced by stakeholders. A response from NICE outlining the reasons for its decision has been accepted by the journal and at the time of writing is pending publication.

46. On 21 April we issued a note to media on the histology independent cancer drug, larotrectinib, which was picked up by the Daily Mail and some regional outlets.

47. Our fifth wave of rapid guidelines (gastrointestinal and liver conditions, and acute myocardial injuries) was published on 23 April. This wave was picked up by the BMJ but otherwise did not receive much media coverage.

48. On 30 April The New Statesman featured an article looking at Why England's health and technology appraisal process needs urgent reform, written by Janssen UK's representative on the NICE Methods Review and sponsored by that company. We are preparing a response.

Social media and podcasts

49. Generally, the COVID-19 guidelines have been well received on social media. When the critical care rapid guideline was first published, we received some negative reaction from charities and patient groups; this focused on the use of the clinical frailty scale and has largely been addressed by the guideline updates that followed.

50. During this period, our social media posts focused on COVID-19 and related issues, reducing the number of posts each day to help ensure clear, consistent messaging. We have seen a significant increase in engagement with posts on Twitter, Facebook and LinkedIn as a result. Our Tweet announcing the first wave of COVID-19 rapid guidelines generated 576 retweets and 548 likes, with an engagement rate of 7.1%, which is the highest level of engagement for a single tweet we have ever had.

May 2020

National Institute for Health and Care Excellence

Health and Social Care Directorate progress report

1. This report sets out the performance of the Health and Social Care Directorate against our business plan objectives for the financial year April 2019 - March 2020. A summary is also provided for areas of work that have seen significant progress and are of note for the Board.

2. The Chief Executive's Report details the delivery of quality standards.

Summary of the impact of COVID-19

3. The directorate redirected its resources to support NICE's work on rapid evidence summaries and guidance in its response to the coronavirus (COVID-19) pandemic. Key elements of this include:

    - Delivering 2 rapid COVID-19 evidence reviews in March and 1 in April.
    - Providing support to the NICE COVID-19 rapid guideline programme. The directorate provided all the topic leads for the guidelines developed along with medicines advice, project management and analyst resource.
    - Undertaking rapid engagement with our voluntary and community sector organisation partners to facilitate their input to the COVID-19 rapid guidelines.
    - Releasing people to support the administrative and finance activities of the Department of Health and Social Care.
    - Developing a rapid endorsement process to support the implementation of NICE's rapid COVID-19 guidance, which in the longer term will help to inform refinements to the current endorsement process.
    - Issuing a NICE in Social Care newsletter in April with links to existing quick guides and key points from the Supporting adult carers guideline, aimed at care home and social work audiences.
    - Assuming the management of NICE's Situation Report (SitRep), developed during the outbreak to provide a single operational picture of NICE's function during the pandemic. Information in the SitRep includes the status of all NICE's functions; details of NICE's new rapid COVID-19 guidelines and evidence reviews and the impact of the pandemic on NICE's usual outputs.

4. The directorate has continued to operate a range of business functions, some at a reduced level, to support the health and care system during the COVID-19 outbreak. This includes:

    - National, regional and local engagement, with NICE's Field team responding to queries about NICE resources on COVID-19 and ongoing engagement with the Accelerated Access Collaborative (AAC) working groups.
    - Working with our networks through the Medicines Associates team.
    - Providing support for implementation, such as accreditation and renewal reports, endorsement, shared learning and resource impact assessments.

5. Some of our usual activities have been paused in line with the agreed approach to external engagement. We will review how these might restart as restrictions are lifted.

Performance

6. Appendix 1 shows the March 2020 publications for the directorate. These contributed to us achieving our balanced scorecard deliverables for the financial year 2019-20 except for:

    - Antimicrobial evidence summaries, which are only developed as new antimicrobials come to market. Two new antimicrobials were launched this financial year and evidence summaries were published for both. Four evidence summaries had been predicted during the year.
    - Rapid evidence reviews, which are commissioned by NHS England (NHSE) specialised commissioning team. Of the 10 expected topic referrals to NICE, only five were commissioned. Evidence reviews and associated outputs were delivered for each of those five topics.

7. We have also achieved the other deliverables set out in our business plan during the year, with the following work continuing:

    - Contributing to improved ways of working in the Centre for Health Technology Evaluation (CHTE) in collaboration with the Public Involvement programme and our stakeholders.
    - The development of a pilot resource with Getting it Right First Time (GIRFT) to identify barriers to the uptake of various NICE approved biologic medicines for dermatology conditions. The GIRFT dermatology clinical lead has carried out deep dive interviews incorporating questions

around levers and barriers and included the findings in a draft national report which NICE commented on.

- Following the review of patient decision aid outputs and associated processes, we are developing shared decision-making content rather than individual patient decision aids. This aligns with the vision for NICE Connect and shared decision making will be embedded in the priorities for the Content Expert Group and the Process, Methods and Analytics Expert Group.

- Eighty applications have been received for the 2020 Shared Learning Award. These have been longlisted to 32 and shortlisting is underway.

Public Involvement

8. Overall, the ratio of applications to vacancies for lay members on committees was 6.25:1; the target being 2:1 or greater, with 494 applications for 79 vacancies.

9. Seventy-three patient experts were identified to give testimony at committee meetings and at NICE's Scientific Advice meetings, and 13 people were invited to take part in QSAC meetings.

Quality Standards (QS)

10. A range of activities have been undertaken to support the use of quality standards. This includes:

    a. Promoting the Lung Cancer QS at the British Thoracic Oncology Group conference in Dublin.

    b. Developing slide sets for a National Police Chief Council conference on suicide and for a national conference on implementation of the suicide prevention QS.

    c. Presenting to the Royal Pharmaceutical Society and Community Pharmacy Negotiating Committee to support the use of the community pharmacy quality standard.

    d. Presenting to, and contributing to the work of the All-Party Parliamentary Group (APPG) on spondyloarthritis culminating in publication of the Axial Spondyloarthritis Services in England: A National Enquiry report, in January which made 5 recommendations (4 of which are identified in the quality standard) on clear diagnostic referral pathways, training for primary care professionals and access to physiotherapists and structured education programmes.

11. In February, NICE held a workshop with approximately 20 users of QS across health, public health and social care to explore the future of QS in the context of NICE Connect and we will work with the NICE Connect programme and the Centre for Guidelines to determine the next steps with this work.

12. Key messages from the workshop included:

    - Users are not overly concerned about the overall number of QS in the library so long as they have easy access to the smaller number that are in their area of interest
    - The process for updating QS needs more consideration as to how and when it happens and should carefully account for how existing content is being used
    - There is still some confusion about the intended use of QS (for example, compliance vs improvement tool and conflation with NICE guidelines)
    - Users would like support with how to use QS (for example, shared learning examples) integrated in the product, rather than presented separately.

Strategic engagement

13. An external strategic engagement plan is being developed for 2020-21, which sets out overarching engagement objectives and scenarios for engagement in different levels of recovery from COVID-19.

14. In May 2019, the directorate presented a plan to the Board for external strategic engagement in 2019-20. The metrics are set out in Appendix 2 and progress against these has been reported to Board during the year. Recent developments are detailed below:

Health

15. NICE has delivered a systematic engagement programme in Wales including the establishment of a NICE Health Network with representatives from all health boards and principal national bodies.

16. We have engaged with 70% of all Integrated care systems / Sustainability and transformation plans and all health board and health and social care trusts in Wales and Northern Ireland, resulting in NICE guidance being used to inform quality improvement programmes at system level in areas such as angina, mental health, dementia, respiratory.

Public Health

17. We have been a key member of the Public Health System Group during 2019-20, which includes a wide range of key partners across health, local, and national Government. This group has worked together to develop a framework for quality in public health 'Quality in public health: A shared responsibility' and places NICE quality standards as a key component of the support for quality improvement.

18. The Quality in Public Health toolkit launched in March 2020 and is a spreadsheet designed for use principally by public health teams within local government in England as an aid to the implementation of Quality in Public Health: A Shared Responsibility and as a part of sector led improvement. It can be used to help assurance processes and in conjunction with local quality systems as part of service development and delivery. It sets out how NICE guidelines and quality standards can support public health teams to improve quality.

Social Care

19. Our engagement campaign with national social work organisations and Principal Social Workers has seen very positive progress. After working with a national advisory group, a series of resources with scenarios which show how NICE guidance can be used to improve social work practice have been published and well received. A podcast on social work continuous professional development has also been published. The Department of Health & Social Care's Chief Social Worker and the Chairs of the Principal Social Worker network have been active in supporting the campaign and in helping us to develop links with regional networks.

20. NICE is developing good links with Economic and Social Research Council and the Health Foundation to support the development of their planned new UK centre on evidence implementation in adult social care. This new centre, which will be developed over a number of years, will support the implementation of existing evidence sources in adult social care, including NICE guidance.

21. The Social Care Institute for Excellence (SCIE) has mapped 2 NICE social care guidelines to test how they could be incorporated into pathways within NICE Connect. A focus group was also held with social care stakeholders to test out the proposed approaches for displaying information in NICE Connect and how these might work for social care audiences. A report has been prepared and will be considered by the NICE Connect steering group in due course.

Notable issues and developments

22. This section includes significant developments or issues that occurred in the reporting period.

Directorate structure and functions

23. The Programme Director for Quality and Leadership and Deputy Medical Director is now acting into the role of Health and Social Care Director and will consider longer term requirements for the structure and functions of the directorate. Any proposed changes will be submitted to Board in due course.

24. The NICE Connect Programme team has transferred from the HSC directorate and now reports directly to NICE's new Chief Executive. Existing governance structures and processes for the programme remain unchanged.

Appendix 1: Publications - March 2020

Table 1 below provides a list of guidance and advice produced in March 2020.

Product title	Product type
Evidence review: Sapropterin for phenylketonuria	Evidence review
Evidence review: Acute use of non-steroidal anti-inflammatory drugs (NSAIDs) for people with or at risk of COVID-19	Evidence review – rapid COVID-19 evidence review
Evidence review: Angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) in people with or at risk of COVID-19	Evidence review – rapid COVID-19 evidence review
Interleukin inhibitors: risk of infections and cancer in people with rheumatologic diseases	Medicines Evidence Commentary (MEC)
New MHRA drug safety advice: March 2019 to May 2019	MEC
Pharmacological and non-pharmacological interventions for treating aggression and agitation in people living with dementia	MEC
Establishing Transition Pathways for Young People with Attention Deficit Hyperactivity Disorder (ADHD)	Shared learning example
Bronchiolitis: when less is more	Shared learning example
Shining a Spotlight on Home Group's Governance for Managing Medicines Safely and Effectively by Incorporating NICE Guideline NG67	Shared learning example
Improving referral to the Critical Care Outreach Team	Shared learning example
THINK delirium in intensive care	Shared learning example
Time Out Team/Hopewell Children's Home	Shared learning example
Implementing NICE within a Learning Disability service: A service wide journey	Shared learning example
Supporting Carers in the Stroke Early Supported Discharge Service	Shared learning example
NG86: Walking in the shoes of people who experience adult social care – reframing our services with new eyes	Shared learning example
Recognising and responding to domestic violence and abuse	Social care quick guide
Promoting positive mental wellbeing for older people	Social care quick guide
Children and young people's healthcare	Topic based impact report

Appendix 2: Strategic Engagement Metrics 2019-20 performance summary

Table 2: National Strategic Engagement Metrics

Organisations	National Strategic Engagement Metrics	Progress against target	Progress Update
NHS England (NHSE) and NHS Improvement (NHSI)	100% alignment of 2019-20 GIRFT reports with NICE guidance, standards and indicators	Complete	Alignment of all 3 GIRFT reports published in October and November 2019 with NICE guidance standards and indicators
	References to NICE guidance and standards included in 80% of relevant Long Term Plan publications to support quality improvement	Not complete	NICE is referenced in the 'LTP Implementation Framework: Support Offer' document but was not referenced in the initial LTP Implementation Framework. Further publications have not yet been produced.
	NICE guidance and quality standards are included in NHS Long Term Plan action plans relating to key areas on prevention (alcohol, obesity and smoking)	Not complete	The Long Term Plan action plans have not yet been made available.
Care Quality Commission (CQC)	10% of 'outstanding' primary care inspection reports published in 2019-20 reference NICE within the inspection evidence table	Complete	Over 90% of all CQC GP practice inspection reports published rated as outstanding for the effective domain (not the outstanding rating overall) reference NICE
	20% of 'outstanding' social care inspection reports published in 2018/19 to reference NICE	Complete	29% of all CQC social care inspection reports rated as 'outstanding' either reference NICE specifically (18%) or refer to national best practice guidance / guidelines (11%)

Organisations	National Strategic Engagement Metrics	Progress against target	Progress Update
NHS Digital	Integration of evidence standards framework for digital health technologies into NHS Digital's Digital Applications Assessment Questionnaire (DAQ) as part of the application process for DHTs to be placed on NHS.UK by end of Q2	Complete	The evidence standards framework for digital health technologies published by NICE were incorporated into the DAQ process by quarter 4. NHS England intend to publish a consultation on a new NHS Standard for data driven technologies in which we expect NICE evidence standards to feature.
Office for Life Sciences (OLS)	OLS accept the business case for funding the expansion of the medtech work, including digital evaluations	Complete	Responsibility has passed from OLS to DHSC as they have the funding. DHSC making the additional funding available via our finance allocation from April 2020. The Finance team is now leading on this. MTEP and DAP teams are preparing staff and activity expansion plans accordingly
Accelerated Access Collaborative (AAC)	NICE supports an expanded and aligned horizon scanning functionality between health care partners involved in the AAC	Complete	The leadership for the Accelerated Access Collaborative has moved to the Specialised Commissioning Directorate in NHS England. Opportunities to align the activities of NICE and NHS England on horizon scanning continued. AAC horizon scanning capacity is now directed towards COVID-19
Public Health England	NICE guidance and quality standards are included in implementation plans agreed for the Quality Framework for the Public Health System, Quality in Public Health: A Shared Responsibility	Complete	NICE is referenced in the Quality in Public Health toolkit published in March, designed for use principally by public health teams within local government in England as an aid to the implementation of Quality in Public Health: A Shared Responsibility

Organisations	National Strategic Engagement Metrics	Progress against target	Progress Update
Public Health England Association of Directors of Public Health (ADPH) Local Government Association (LGA)	NICE guidance and quality standards embedded in 6 out of 10 ‘What Good Looks Like’ themed publications	Complete	NICE embedded in 7 themed publications. Target exceeded
Department for Education	Two meetings take place with key contacts in the DfE early years and schools directorate	Complete	Meetings have taken place and there are plans to focus on student mental health work
Department of Health and Social Care (DHSC)	Promotion of collaborative working (Unlocking capacity: smarter together) between health and adult social care at 4 events	Complete	6 events have taken place. Target exceeded.
DHSC/NHS Digital	Inclusion of 3 quality standards measures within the QM data framework	Complete	A Quality Matters data framework proposal has been developed, which includes reference to NICE quality standards and at least 3 measures but the proposal is currently on hold and will need to be discussed with the Quality Matters board
Social Work England	Reference to NICE in the guidance supporting new professional standards for social work, developed by Social Work England	Not complete	Social Work England has changed its approach to continuing professional development guidance and is not including references to any external organisations. They will be reviewing their CPD guidance on the anniversary of their regulatory role, in December 2020

Table 3: Regional and Local Strategic Engagement Metrics

Organisations	Regional and Local Strategic Engagement Metrics	Progress against target	Progress Update
Sustainability & Transformation Partnerships (STPs) Integrated Care Organisations (ICOs)	Engagement with work programme leads in 70% (30) STP/ICS to support use of NICE guidance, standards and resources, and to seek feedback and examples of their use to support delivery of NHS Long Term Plan priorities	Complete	Engagement with 30 leads of STPs/ICSs. Target met
NHS Provider Organisations	Engage with and support 12 NICE Manager/Leads Networks to raise awareness of new resources, support implementation and seek feedback on new initiatives (1 London, 1 Northern Ireland, 1 Wales, 3 North, 3 Midlands and East and 3 South)	Complete	Engagement with 12 networks. Target met
Strategic Clinical Networks for Mental Health	12 mental health strategic clinical networks are supported to understand and use NICE guidance and standards to deliver NHS Long Term Plan / 5YFV mental health priorities	Complete	Engagement with 12 networks. Target met
Public Health England (regional teams)	8 examples (2 per Field Team region) of NICE Field Team (and Medicines Implementation Consultants as appropriate) working jointly with PHE regions/ Centres and other system partners to support local delivery of the NHS Long Term Plan and ongoing CVD prevention work	Complete	11 examples identified. Target exceeded
ADASS	Continue to support the use of NICE guidance and quality standards in social care commissioning organisations for adult social care through work with regional branch networks of ADASS, identifying 5 examples.	Complete	13 examples identified. Target exceeded

Organisations	Regional and Local Strategic Engagement Metrics	Progress against target	Progress Update
Skills for Care	Work with Skills for Care to engage with and support 10 regional networks of principal social workers in England, Wales and Northern Ireland for adult services, identifying 6 examples (1 per FT region) of NICE guidance and standards being used to inform their work.	Complete	Engagement with 13 networks and 11 examples identified. Target exceeded

May 2020