NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

PUBLIC BOARD MEETING – MEETING AS THE BOARD COMMITTEE

Wednesday 16 September 2020 at 1:30pm via Zoom

AGENDA

20/075 Apologies for absence **(Oral)**
To receive apologies for absence

20/076 Declarations of interests **(Item 1)**
To declare any new interests and consider any conflicts of interest specific to the meeting

20/077 Minutes of the last Board meeting **(Item 2)**
To approve the minutes of the Board meetings held on 15 July and 19 August 2020

20/078 Action log **(Item 3)**
To review the actions from previous meetings

20/079 Chief Executive's report **(Item 4)**
To review the report
Professor Gillian Leng, Chief Executive

20/080 – 20/086 Directors' reports for consideration

20/080 Centre for Guidelines (Item 5)

20/081 Centre for Health Technology Evaluation (Item 6)

20/082 Digital, Information and Technology Directorate (Item 7)

20/083 Science, Evidence and Analytics Directorate (Item 8)

20/084 Health and Social Care Directorate (Item 9)

20/085 Resources report (Item 10)

20/086 Communications Directorate (Item 11)

20/087 Strategic outline business case: enabling an efficient digital workplace **(Item 12)**
To approve the proposals
Alexia Tonnel, Director, Digital, Information and Technology

20/088 The Independent Medicines and Medical Devices Safety Review: considerations for NICE **(Item 13)**
To consider the report
Professor Kevin Harris, Patient Safety lead

20/089 Research to Access Pathway for investigational Drugs – COVID-19 (RAPID-C19) **(Item 14)**
To receive an update
Meindert Boysen, Director, Centre for Health Technology Evaluation

20/090 Public involvement programme annual report **(Item 15)**
To receive the report
Dr Judith Richardson, Acting Director, Health and Social Care

20/091 NICE Impact report end of life care **(Item 16)**
To receive the report
Dr Judith Richardson, Acting Director, Health and Social Care

20/092 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 18 November 2020 at 1.30pm, via Zoom.

NICE National Institute for Health and Care Excellence

Board and Senior Management Team Interests Register

Name	Role with NICE	Description of interest	Interest arose	Interest ceased
Sharmila Nebhrajani OBE	Chairman	Non-Executive Director, Severn Trent Water plc. (remunerated)	2020	
		Non-Executive Director, National Savings & Investment. (remunerated)	2017	
		Director and Trustee, Lifesight Pensions Mastertrust. (remunerated)	2015	
		Governor and Trustee, The Health Foundation. (non-remunerated)	2018	
		Non-Executive Director, British Medical Journal	2014	2020
Prof Tim Irish	Vice Chair	Life science assets held in a blind trust and managed by an independent trustee. (remunerated)	2015	
		Professor of Practice, King's College London's School of Management / Business and a consultant to King's Commercialisation Institute. (remunerated)	2017	
		Non-Executive Director, Life Sciences Hub Wales Ltd.	2017	2019
		Chairman and Non-Executive Director, Quirem Medical BV Supervisory Board.	2015	2020
		Non-Executive Director, Fiagon AG.	2017	2020
		Non-Executive Director, eZono AG. (remunerated)	2018	
		Non-Executive Director, Feedback plc. (remunerated)	2017	
		Non-Executive Director, Styrene Systems Ltd.	2017	2019
		Board Member, Pistoia Alliance Advisory Board.	2017	2019

		Non-Executive Director, Pembrokeshire Retreats Ltd. (remunerated)	2006	
		Non-Executive Director, ImaginA b Inc. (remunerated)	2019	
		Non-Executive Director, Rutherford Health Plc	2019	2020
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). (remunerated)	2004	
		Board Member – AQuA (Advancing Quality Alliance). (remunerated)	2012	
		Professional Advisor (Secondary Care) Governing Body – St Helens CCG.	2014	2019
		Trustee – Willowbrook Hospice, Merseyside. (remunerated)	2007	
Dr Rima Makarem	Senior Independent Director	Audit Chair & Non-Executive Director, University College London Hospitals NHS Foundation Trust (UCLH).	2012	2019
		Trustee at UCLH Charity.	2013	2019
		Chair, National Travel Health Network & Centre (NaTHNaC).	2015	2019
		Independent Council Member at St George's University of London.	2016	2019
		Non-Executive Director and Audit Committee Chair, House of Commons Commission. (remunerated)	2018	
		Non-Executive Director, The Hillingdon Hospitals NHS Foundation Trust.	2019	2019

		Lay Member, General Pharmaceutical Council. (remunerated)	2019	
		Independent Chair, Bedfordshire, Luton and Milton Keynes Integrated Care System (BLMK ICS). (remunerated)	2020	
Tom Wright CBE	Non-Executive Director	Chief Executive, Guide Dogs. (remunerated)	2017	
		Trustee, Doteveryone charity.	2017	2019
		Chairman, Leeds Castle Enterprises and Trustee, Leeds Castle Foundation. (non-remunerated)	2019	
		Chairman, Imperial War Museum Development Trust. (non-remunerated)	2019	
Prof Gill Leng CBE	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. (non-remunerated)	2012	
		Association Member BUPA.	2013	2019
		Chair - Guidelines International Network (GIN). (non-remunerated)	2016	
		Spouse is an Executive Director at Public Health England.	2013	
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. (remunerated – paid to NICE)	2017	

		Member of the International Advisory Panel for the Agency for Care Effectiveness (ACE) in Singapore. (non-remunerated)	2019	
Paul Chrisp	Director Centre for Guidelines	Spouse works in medical communications offering services to a range of pharmaceutical companies which may involve new drugs relating to COVID-19.	2009	
Jane Gizbert	Director Communications	Non-Executive Director Tavistock and Portman NHS Mental Health Trust.	2014	2019
Felix Greaves	Director Science, Evidence & Analytics	Director, MedicineAfrica Ltd. (non-remunerated)	2012	
		Shareholder (<1%), Nye Health Ltd.	2019	2020
		Advisor, SameYou (a brain injury charity). (non-remunerated)	2019	
		Senior Clinical Lecturer, School of Public Health, Imperial College London. (remunerated)	2018	
		Visiting Honorary Senior Fellow, MRC Epidemiology Unit, Cambridge University. (non-remunerated)	2019	
		Priortisation Committee and Funding Committee Member, NIHR Public Health Research Programme. (non-remunerated)	2017	
Jennifer Howells	Director Finance, Strategy & Transformation	None.		
Judith Richardson	Acting Director Health & Social Care	Mentor for supported return to training (SuppoRTT) in the North West. (non-remunerated) North West School SuppoRTT Champion. (remunerated – paid to NICE)	2019	

		Faculty of Public Health, Part B (OSPHE) Examiner. (non-remunerated)	2016	
		Educational supervisor for public health training. (non-remunerated)	2007	
Alexia Tonnel	Director Digital, Information and Technology	None.		

NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Public Board Meeting and Annual General Meeting held on 15 July 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

Sharmila Nebhrajani	Chairman
Professor Martin Cowie	Non-Executive Director
Elaine Inglesby-Burke	Non-Executive Director
Professor Tim Irish	Non-Executive Director
Dr Rima Makarem	Non-Executive Director
Tom Wright	Non-Executive Director
Professor Gillian Leng	Chief Executive
Paul Chrisp	Centre for Guidelines Director
Alexia Tonnel	Evidence Resources Director
Catherine Wilkinson	Acting Business Planning and Resources Director

Directors in attendance

Jane Gizbert	Communications Director
Judith Richardson	Acting Health and Social Care Director

In attendance

Helen Knight	Programme Director – Centre for Health Technology Evaluation
David Coombs	Associate Director – Corporate Office (minutes)
Sarah Acton	Senior HR Business Partner (for item 11)
Leighton Coombs	Senior Programme Analyst – Health and Social Care (for item 14)
Grace Marguerie	Associate Director – HR (for item 11)
Xavier Vaz	Analyst – Health and Social Care (for item 14)

20/056 Apologies for absence

1. Apologies were received from Meindert Boysen who was represented by Helen Knight.

20/057 Declarations of interest

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

20/058 Minutes of the last meeting

3. The minutes of the Board meetings held on 20 May 2020 and 17 June 2020 were agreed as correct records.

20/059 Matters arising

4. The actions from the meeting on 20 May 2020 were noted as complete. There were no other matters arising from either meeting.

20/060 Chief Executive's report

5. Gill Leng presented the Chief Executive's report which provided an update on the outputs from the main programmes for the first 3 months of the year to the end of June 2020 together with information on other matters of interest to the Board. Gill noted that the period was significantly affected by the COVID-19 pandemic, with many new and unexpected areas of work initiated to support the wider health and care system. In addition, the transformation programme continued, and a significant piece of work begun to create a new strategy for NICE. Gill briefly updated the Board on the pilot evaluation of digital health technologies and agreed to provide a fuller update to a future Board meeting.

ACTION: Helen Knight (Meindert Boysen)

6. Board members praised NICE's work to rapidly develop guidance on COVID-19, which they noted was positively received by the health and care system. Board members asked whether the learning from the rapid development of the COVID-19 guidelines would be applied to NICE's future guidance. Gill Leng advised that these methods and processes would be used for specific scenarios where guidance is required very quickly; however aspects will inform the transformation programme where appropriate. In response to a question from the Board, Paul Chrisp explained the approach that will be taken to migrate, and where applicable integrate, the COVID-19 speciality guides produced by NHS England and NHS Improvement into NICE's guidance portfolio.

7. Rima Makarem, chair of the Audit and Risk Committee, asked about the controls over investment in digital transformation. Gill Leng and Alexia Tonnel explained there would be limited commitment to expenditure at the outset. Instead business cases will outline the high-level investment and anticipated benefits, with further approvals sought as the proposals are refined.

8. The Board received the report.

20/061 Resources report

9. Catherine Wilkinson presented the report which outlined the financial position at 31 May 2020, reviewed the first year of charging for technology appraisals (TA) and highly specialised technologies (HST), and provided an update on the impact of COVID-19 on the workforce. Catherine highlighted that the forecast remains a £0.4m deficit, however if the current underspend is maintained and TA/HST income increases as planned, this may reduce to a position close to breakeven. There does though remain uncertainty about the financial position, which will be monitored closely.

10. The Board discussed the assumptions behind the TA/HST income forecast and the extent this is subject to changes in companies' plans for product development and launch. Catherine Wilkinson and Helen Knight outlined the arrangements in place to regularly update the forecast as the regulatory timescales change. Alongside the decision to pause aspects of work during the pandemic, the main factor behind the reduced income has been capacity within the TA and HST programmes, with steps taken to address this.

11. The Board discussed the impact of the COVID-19 pandemic and resultant home-working on staff well-being. It was noted that the arrangements for the future use of the offices are currently being developed, and the longer term implications of the 'new normal' for the workforce will be explored as part of the wider strategy work. It was agreed that an update on the plans for restarting the use of the offices should be brought to the Board.

ACTION: Catherine Wilkinson

12. The Board received the report.

20/062 Centre for Guidelines progress report

13. Paul Chrisp presented the update on key issues and developments in the Centre for Guidelines in the period April to June 2020. The period was dominated by the COVID-19 rapid guidelines, but a phased restart of the programme of non-COVID-19 guidelines has now begun.

14. The Board discussed the lessons learnt from the development of the rapid guidelines. Paul Chrisp confirmed that the methods and processes for these guidelines have been regularly updated to incorporate the learning that has emerged. As noted earlier in the meeting, the methods and processes will not be applicable to all guidelines, but the scope to apply relevant aspects to wider guideline development is being explored, including the use of a more flexible approach to consultation.

15. The Board received the report.

20/063 Centre for Health Technology Evaluation progress report

16. Helen Knight presented the update on key issues and developments in the Centre for Health Technology Evaluation in the period to April to June 2020, including the response to, and impact of, the COVID-19 pandemic. Helen highlighted the changes to the centre's senior management structure, and the ongoing work with NHS England and NHS Improvement to develop the arrangements for a new Innovative Drugs Fund. The report accompanied a separate briefing on the methods review that had been circulated to the Board.

17. The Board received the report.

20/064 Communications Directorate progress report

18. Jane Gizbert presented the update on key issues and developments in the Communications Directorate in the period April to June 2020. The directorate's work in this period was centred on supporting and promoting NICE's COVID-19 efforts, with a new webpage created to give an overview of NICE's work in this area. A review of the website is planned, including to ensure NICE's patient safety guidance is more visible. The team will also look at the increased engagement with the recent newsletters and identify lessons that can be applied to future publications.

19. The Board received the report.

20/065 Evidence Resources Directorate progress report

20. Alexia Tonnel presented the update on key issues and developments in the Evidence Resources Directorate in the period April to June 2020. In addition to supporting NICE's COVID-19 activities, the directorate has continued to work on a range of transformation projects and maintain NICE's existing digital services. Alexia briefed the Board on the proposed restructuring of the directorate as part of the integration of the IT and Digital Services teams, alongside the creation of the Science, Evidence and Analytics Directorate. She noted that NICE has been successful in its bid for funding with partners to develop a multi-centre advice service on Artificial Intelligence (AI). The bid for funding to develop methods for the evaluation of technologies with embedded AI was not though successful, and Gill Leng will be following this up with NHSX.

ACTION: Gill Leng

21. The Board received the report.

20/066 Health and Social Care Directorate progress report

22. Judith Richardson presented the update on key issues and developments in the Health and Social Care Directorate in the period April to June 2020. The directorate has focused on supporting NICE's response to COVID-19, delivering existing work programmes where possible, and planning the best approach to

restarting activities that have had to be paused, including engagement with national and regional stakeholders.

23. The Board received the report. Further updates were requested on NICE's work to support social care with the COVID-19 pandemic, and the progress of discussions with the Care Quality Commission (CQC) about referencing NICE guidance in the CQC's emergency support framework.

ACTION: Judith Richardson

20/067 Annual people report

24. Catherine Wilkinson presented the annual people report that outlined the composition of the workforce at 31 March 2019 and key issues of note over the year. Compared to the previous year, the average size of the workforce (whole time equivalent) increased. The completion of exit interviews increased, while turnover and sickness absence rates both decreased. Catherine highlighted the information on the equalities profile of the workforce, including the ongoing underrepresentation of staff from black, Asian and minority ethnic (BAME) groups across the workforce and in the more senior pay bands. NICE's diversity and inclusion activities are under review, and revised equality objectives will be brought to the Board in November.

25. Board members highlighted the importance of delivering improvements in relation to equality, diversity, and inclusion, and highlighted the need to reflect on where actions have not been successful and improvements are required. Gill Leng and Grace Marguerie confirmed this is an area of interest for both senior management and staff, and NICE is engaged with a working group of other Arm's Length Bodies, with the aim of identifying best practice. There is an internal working group in place for staff from BAME groups and NICE currently participates in the NHS leadership development courses for BAME staff. Staff listening events in August will seek ideas and suggestions on what further actions could be taken. Grace Marguerie noted that the varying conversion rate for applicants across ethnic groups needs to be explored further. Now the recruitment service is delivered internally it will be possible to review the data more quickly and in greater detail, which will help identify what actions could be taken. This may include seeking BAME representation on interview panels, in the same way there is now gender diversity on panels; and also looking at the training given to staff. The Board highlighted the importance of demonstrating NICE is an organisation that welcomes diversity.

26. To help identify the impact of unconscious bias, it was agreed that data on selected workforce indicators such as sickness and employee relations broken down by gender and ethnicity, should be provided to the Board.

ACTION: Catherine Wilkinson

27. The Board received the report.

20/068 Annual report and accounts

28. Gill Leng presented the annual report and accounts 2019/20 which were laid before Parliament on 15 July following approval by the Board on 17 June.

29. The Board received the annual report and accounts, and thanked the staff involved in producing the document during the COVID-19 disruption.

20/069 Annual revalidation report

30. Judith Richardson presented the annual revalidation report that outlined the policies, systems, and processes in place to support the appraisal and revalidation of doctors at NICE. While some of the processes were disrupted by COVID-19, an external quality assurance took place in April 2020. This peer review commended NICE on the holistic approach to revalidation, which goes beyond legislative duties for doctors to take a multi-professional approach supporting other health and social care professionals in their revalidation and professional development.

31. The Board received the report and approved it for submission to NHS England and NHS Improvement.

20/070 NICE Impact report: respiratory conditions

32. Judith Richardson presented the latest impact report, which this month focused on how NICE's guidance is being used to help improve outcomes for people with respiratory conditions. Judith highlighted the scope to increase flu vaccination rates, which will be particularly important in the coming winter given the dual challenges of flu and COVID-19, and confirmed NICE will be working with partners to address this issue.

33. Board members noted the chart in the report which showed that the mortality rate from respiratory conditions increases with deprivation and asked whether NICE could do more to tackle health inequalities and address the social determinants of health. Gill Leng noted that NICE's public health programme has previously published guidelines focused on hard to reach groups and these could potentially be promoted in the context of the COVID-19 pandemic. It was agreed that the scope for NICE to tackle health inequalities should be explored further as part of the current work to develop a 5 year strategy, and consideration should be given to seeking an external view on whether NICE could do more in this area.

ACTION: Gill Leng/Paul Chrisp

34. The Board welcomed the report and highlighted the importance of sharing the data with key partners, such as the Royal Colleges, to drive improvements. Judith Richardson confirmed she would consider what further action could be taken to use the report in this way.

ACTION: Judith Richardson

20/071 Support from NICE for the COVID-19 response

35. Gill Leng presented the report that provided an overview of NICE's support to the health and care system for the response to the COVID-19 pandemic. Much work has been completed across NICE's centres and directorates, including producing clinical guidelines, working with system partners to enable safe and timely patient access to medicines showing evidence of benefit, and producing guidance and advice to support diagnostics and testing.

36. In response to questions from the Board and audience, Gill Leng confirmed that NICE will continue to adapt and respond, learning from the new ways of working developed at pace during the pandemic. Paul Chrisp confirmed that NICE has been in contact with NHS England and NHS Improvement to explore how guidance can be provided on the long-term rehabilitation needs of people affected by COVID-19. The case for using graded exercise therapy (GET) for post COVID-19 viral fatigue would need to be considered separately to GET's evaluation for Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome.

37. The Board noted the report and welcomed NICE's response to the pandemic.

20/072 Appointing an external member to the Audit and Risk Committee

38. Sharmila Nebhrajani presented the proposal to appoint an external member to the Audit and Risk Committee to provide challenge from a financially qualified background if the upcoming non-executive director (NED) recruitment does not appoint someone with this expertise. Rima Makarem, chair of the committee, confirmed her support for the proposal.

39. The Board agreed:
    - the proposal to appoint an external member to the Audit and Risk Committee if the upcoming NED recruitment does not appoint someone who is financially qualified and has recent and relevant financial experience.
    - to amend the committee's terms of reference to state that the membership may also include an external member in addition to the currently stated 3 to 5 NEDs.
    - the high-level terms and conditions for the external member as set out in the paper and delegated these to the Chairman for finalisation in consultation with the committee chair and Chief Executive, if the position is required following the outcome of the NED recruitment.

ACTION: Sharmila Nebhrajani

20/073 Audit and Risk Committee minutes

40. Dr Rima Makarem, chair of the Audit and Risk Committee, presented the unconfirmed minutes of the committee's meeting on 17 June 2020. In addition to reviewing the annual report and accounts and the year-end audits, the committee

agreed the waiver of tender requirements for the production of the British National Formulary due to the current publisher's ownership of the intellectual property rights.

41. The Board received the unconfirmed minutes.

20/074 Any other business

42. Gill Leng noted this was Sharmila Nebhrajani's first public Board meeting as Chairman and thanked her for the stewardship of the meeting.

Next meeting

43. The next public meeting of the Board will be held on 16 September 2020 at 1.30pm via Zoom.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Board Meeting held on 19 August 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

Sharmila Nebhrajani	Chairman
Professor Martin Cowie	Non-Executive Director
Professor Tim Irish	Non-Executive Director
Dr Rima Makarem	Non-Executive Director
Tom Wright	Non-Executive Director
Professor Gillian Leng	Chief Executive
Meindert Boysen	Deputy Chief Executive and Centre for Health Technology Evaluation Director
Paul Chrisp	Centre for Guidelines Director
Alexia Tonnel	Evidence Resources Director

Directors in attendance

Jane Gizbert	Communications Director
Judith Richardson	Acting Health and Social Care Director

In attendance

David Coombs	Associate Director – Corporate Office (minutes)
Grace Marguerie	Associate Director – HR / Acting Deputy Business Planning and Resources Director

Also present

Jennifer Howells	Incoming Director for Finance, Strategy and Transformation

Apologies for absence

1. Apologies were received from Elaine Inglesby-Burke.

Declarations of interest

2. There were no conflicts of interest relevant to the meeting.

Appointment of a committee of the Board

3. Sharmila Nebhrajani welcomed the Board to the meeting and highlighted the paper that had been circulated shortly before the meeting. Martin Cowie has indicated his intention to resign as a Non-Executive Director (NED) with immediate effect, which will mean that the number of NEDs will fall below the minimum number set out in the Health and Social Care Act 2012. Legal advice has been sought on this issue, and the recommendation is to adopt the same approach as when the number of NEDs likewise fell below the required number in April and May 2020. As then, the Board is asked to delegate its powers to a committee of the remaining Board members, in line with the terms of reference in the paper, which are materially the same as those from April and May. As before, the committee will dissolve when the number of NEDs reaches the statutory minimum.

4. David Coombs highlighted that the required notice had not been given for this meeting, which also meant it was not possible to give the public the opportunity to observe. These matters had been raised with NICE's legal adviser who advised the Board to proceed with this meeting given the need to pass this resolution before Martin resigns. The advice was that the risk of challenge was low given the nature of the decision being taken, and these issues should not invalidate the delegation.

5. Gill Leng noted that the scope to temporarily co-opt a NED is also being explored with the Department for Health and Social Care. If this goes ahead, the committee will no longer be required and could be dissolved.

6. The Board established the time-limited committee of the Board in line with the terms of reference in the paper.

Any other business

7. Sharmila Nebhrajani, on behalf of the Board, thanked Martin for his contribution to NICE over a number of years and wished him well for the future.

Next meeting

8. The next public meeting of the Board will be held on 16 September 2020 at 1.30pm via Zoom.

Board meeting	Item reference	Action	Owner	Target completion	Latest update	Status	Date closed
15/07/2020	20/060	Board to receive further update on the outcome of the pilot evaluation of digital health technologies.	MB/HK	Nov-20	Scheduled for the November Board meeting.	Open	
15/07/2020	20/061	Board to receive an update on the plans for restarting the use of the offices.	CW (JH)	Aug-20	Update provided to the August Board Strategy meeting. The Manchester office will re-open on the 8 October for a phased return.	Closed	16/09/2020
15/07/2020	20/065	Follow-up with NHSX the bid for funding to develop methods for the evaluation of technologies with embedded AI.	GL	TBC	This has been followed up but the timing for a further bid has been put back to later in the year. Funding has also be sought through the CSR process.	Open	
15/07/2020	20/066	Board to receive further update on NICE's work to support social care with the COVID-19 pandemic.	JR	Sep-20	Information provided in the Health and Social Care Director's report.	Closed	16/09/2020
15/07/2020	20/066	Board to receive further update on the progress of discussions with the Care Quality Commission (CQC) about referencing NICE guidance in the CQC's emergency support framework.	JR	Sep-20	Information provided in the Health and Social Care Director's report.	Closed	16/09/2020
15/07/2020	20/067	Data on selected workforce indicators such as sickness and employee relations broken down by gender and ethnicity, to be provided to the Board.	CW (JH)	Sep-20	Data is provided in the resources report.	Closed	16/09/2020
15/07/2020	20/070	The scope for NICE to tackle health inequalities to be explored further as part of the current work to develop a 5 year strategy, and consideration given to seeking an external view on whether NICE could do more in this area.	GL/PC	Dec-20	NICE is currently considering its role in public health in a changing public health system alongside the current work to develop a 5 year strategy. In addition, we are exploring the contribution NICE can make to tackle health inequalities through our guidance outputs.	Open	
15/07/2020	20/070	Consider further the scope to work with partners to use the impact reports to drive improvements in care.	JR	Sep-20	NICE impact reports identify gaps in implementation of guidance and quality standards. We are piloting an approach where these gaps shape our priorities for implementation support on quality improvement. This approach will initially be tested with the future report on cardiovascular disease.	Closed	16/09/2020
15/07/2020	20/072	Audit & Risk Committee's terms of reference to be amended to include provision for an external member. Terms and conditions for the external member to be finalised, if the position is required following the outcome of the NED appointments.	SN	Dec-20	Amendments to the terms of reference drafted. Issue now on hold pending outcome of NED recruitment.	Open	

Board meeting	Item reference	Action	Owner	Target completion	Latest update	Status	Date closed
20/05/2020	20/045	Further reference to social care to be added to the business plan prior to submission to the SDS at DHSC for sign-off.	GL	Jun-20	Business plan updated and approved by SDS on 3/6/2020. Now available on NICE website.	Closed	15/07/2020
20/05/2020	20/049	Risk management policy to be amended to include reference to learning from unforseen events.	CW	May-20	Policy updated and issued on 22/5/2020.	Closed	15/07/2020

National Institute for Health and Care Excellence

Chief Executive's report

This report provides information on the outputs from our main programmes for the 5 months to the end of August 2020 together with comment on other matters of interest to the Board.

The Board is asked to review the report.

Professor Gillian Leng

Chief Executive

September 2020

Introduction

1. This report sets out the performance of the Institute against our business plan objectives and other priorities for the 5 months to the end of August 2020. The report notes the guidance published since the last public Board meeting in July 2020 and refers to business issues not covered elsewhere on the Board agenda.

2. The focus of work for the Institute over the last 2 months has been on continuing to support the provision of evidence-based advice for the healthcare system on COVID-19. We have also been rescheduling our committees to facilitate recovery from the pause in our guidance work during the national Lockdown. We have taken note of the NHS England recovery plans for the NHS, and supported this wherever possible. Staff are continuing to work remotely, with plans for a phased return to the Manchester office from 8 October.

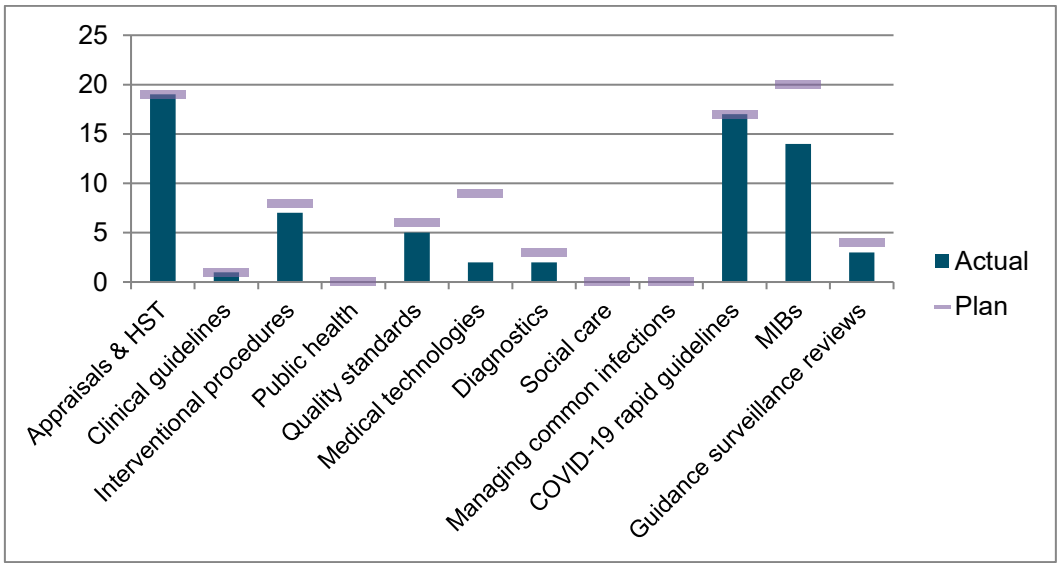
3. The financial position has improved since the £0.4m deficit forecast in the last board report. As at the end of July, we are forecasting a £0.1m deficit, and we are working towards achieving a breakeven position. The finance team has been supporting the collation of bids into the Comprehensive Spending Review process, including funding to support our COVID-19 work and NICE Connect.

Performance

4. The current position against the objectives in our 2020/21 business plan is set out in Appendix 1.

5. The performance of the main programmes between April and August 2020 is set out in Chart 1.

Chart 1: Main programme outputs: April to August 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

6. Details of the variance against plan are set out at Appendix 2. Guidance, quality standards and other advice published since the last Board meeting in July is set out Appendix 3. The balanced scorecard that shows performance against the measures in the business plan at the end of the first quarter is presented in Appendix 4.

Notable issues and developments

Response to coroners' reports

7. Since the last Board report, there have been no Coroners' reports requiring any action from NICE.

Appendix 1: Business objectives for 2020/21 - progress update

The table below provides an update on the delivery of the indicative business objectives in the 2020/21 business plan.

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**	**Progress update**
Delivery of internal efficiency improvements as part of NICE Connect	Ongoing	• Opportunities arising from COVID-19 working have been factored into the updated Connect business plan, many of which are being driven by the process, methods and analytics expert group. Early work has been undertaken on streamlining and improving NICE wide consultation processes. A project brief is being developed for agreement. • Staff engagement is planned to capture the experiences of collaborative working during rapid guidance. This includes the establishment of a new COVID-19 guidelines team.
Undertake a discovery for a commissioner/life sciences portal incorporating process and technical considerations and user research as part of NICE Connect	Ongoing	• Brief for the discovery is being developed for consideration. The work itself is planned for Q3/4 as a secondary priority and dependent on commitment of resource to live services.
Undertake a Citeable Publications feasibility study and roll out in conjunction with NIHR as part of NICE Connect	Q3 20/21	• Positive discussion with Director of the Wessex Institute at University of Southampton which hosts NETSCC and includes the NIHR Journals Library contract, in August. Next step is to bring teams together to agree scope.
Introduce one external registration point for stakeholder information on the website following an internal process review	Ongoing	• Work is underway to scope and design a central place for stakeholder registration on the NICE website. The internal process review is being scoped through the Data Management Expert Group.
Deliver a range of tools and support for the uptake of NICE products, including resource impact support,	Ongoing	• Endorsement process streamlined to support COVID-19 rapid guidance.

budget impact tests, endorsement statements, and shared learning examples		• Shared learning examples shortlisted for virtual shared learning awards to be held in autumn 2020. • Resource impact tools published for published technology appraisals.
Manage and maintain NICE's live digital services utilising user insight and strategic service goals to prioritise use of the available resources	Ongoing	• Live service maintenance and user insight continue as part of business-as-usual activity. Planned changes to the governance of digital and IT activities will enable improved prioritisation of live service work.
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	• Planning has begun on the next biennial NICE reputation research project which is scheduled for completion in 2021. • Work continues on an implementation study which explores perceptions of our offer and success factors for implementation. Initial findings being presented to the Board and senior managers. • Research conducted to support the NICE Connect Content workstream which explored initial reactions to ideas, concepts and prototypes generated in the hackathon. Findings were presented to the content expert group to inform next steps.
Deliver multi-channel marketing activities for major initiatives through the newly established brand and marketing team	Ongoing	• All 3 new posts in marketing comms team have now been filled and new recruits are in post. • Planning for an audience research project that will inform a review of NICE Scientific Advice's marketing strategy is underway, and developing a marketing strategy for NICE International. • The first two issues of 'chief executive's update' monthly message were published via Mailchimp in July and August and were well received. The update was sent to the 44,000 subscribers of our two corporate newsletters and received 200 new subscribers in July and August. • Social media graphics campaign throughout July and August highlighted existing guidance that can help health/care system as it rebuilds capacity in non-COVID services, aligned to NHSE&I priorities.

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	• Work to produce a social media strategy will restart in the autumn after being paused in March and again because of staff turnover. A report will be presented in Q3.
Review the function and monitor performance of NICE Evidence Services (CKS, HDAS, BNF microsites, Evidence Search, Medicines Awareness Service)	Ongoing	• Maintenance of these live services is delivered in line with agreed priorities. Leading to September, work has focused on delivering against accessibility legislation.

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**	**Progress update**
Deliver guidance, standards, indicators and evidence products and services, in accordance with the planned volumes and requirements of the COVID-19 pandemic	Ongoing	• Details of the main programmes' performance against plan, including explanations for any variances are set out elsewhere in this report.
Review the current and planned guidelines portfolio, in conjunction with NHS England and NHS Improvement (NHSE&I) 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	• Terms of reference agreed by Department of Health and Social Care and NHS England for cross-agency advisory group to determine the relative priority of new and updated NICE guideline topics, and coordination and alignment with other guidance and policy. • Next steps are to invite membership, set meetings and agree priorities for static and active list of guidelines.
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	• Review undertaken to ensure existing quality standards remain suitable and accurate during the COVID-19 pandemic.
Complete a review of technology evaluation processes and methods, consult on changes and publish updated manuals and implement changes	Q3/4 Q1 2021/22 (for publishing	• Review is in progress. Timelines have been amended and consultation will now take place in November.

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	Progress update
early, on an interim basis, where they allow for faster recovery from COVID-19	updated manual)	• Changes to the topic selection process were implemented in July 2020, aimed at aligning selection and routing processes across the health technology evaluation programmes.
Implement the comment collection tool and roll out the EPPI-Reviewer tool to the guideline Collaborating Centres	Ongoing	• Roll out of EPPI being progressed in collaborating centre contracts. • The Comment collection tool has been integrated with our new identity management system and work has commenced to shape the next stages looking to enable organisation-wide feedback as opposed to single individual comments.
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	• New directorate established and Science, Evidence and Analytics Director started on 1 September.
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	• The data and analytics team has prioritised its response to COVID-19 while recruiting additional staff to take forward the comprehensive standards and methods programme to utilise broader sources of data and evidence. • Ahead of the commencement of NICE's comprehensive data and analytics methods and standards programme, the team published an interim approach to assessing the quality of data and analyses used to inform NICE's COVID-19 response in Q1.
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	• The Evidence for Effectiveness Standards has been revised and published. The first MTG guidance for one of the digital pilot topics is expected to be published before end 2020. As a result of the pilot work for the digital topics, NICE will now be assessing DHTs routinely within its Medical Technologies and Diagnostics Assessment programmes.

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**	**Progress update**
Develop and embed new data and information management capability including establishing an integrated digital, information and technology directorate	Q2	• A significant management of change exercise was initiated and completed during July and August to allow for the establishment of the new Digital, Information and Technology (DIT) directorate on 1 September. • Work to recruit new specialist roles across the new DIT structure is under way.
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	• As part its approval of the new DIT structure, SMT approved the establishment of a new governance group, the Technology Governance Board which will monitor investment in both the digital transformation programme spend and live services. This will simplify the existing governance arrangement involving multiple service groups.

Play an active, influential role in the national stewardship of the health and care system	Delivery date	Progress update
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	• 21 rapid COVID-19 guidelines have been developed and being actively maintained. The migration, consolidation and integration of 62 NHS England and NHS Improvement (NHSE&I) COVID specialty guides is delayed as equality impact assessments completed by NHSE&I. • Recruitment to COVID-19 team in Centre for Guidelines underway to manage the migration, integration and maintenance of COVID-19 guidelines. • Stakeholders asked to feedback during consultation on non-COVID guidelines any issues relating to COVID-19 that should be taken into consideration when finalising each guideline for publication. The potential impact of COVID-19 on each guideline is being assessed. • The Research to Access Pathway for Investigational Drugs for COVID-19 (RAPID-C19) oversight group continues to meet weekly. To date the group has considered 24 topics. Patients have access to 2 drugs as a result. Links with the DHSC's therapeutics taskforce remain strong.
Work with NHSE&I 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	• Engagement plans refocused on supporting system with restart plans and move to phase 3. This has included engagement with the Adult Social Care Taskforce, CQC with regards to the emergency support framework and supporting restart plans at a regional level. • Work undertaken to review who we believe our key strategic partners are and ensure future plans remain relevant to the current context.
Further develop the relationship with NHSE&I Specialised Commissioning in the areas of commercial and managed access, genomics and guidance and advice development	Ongoing	• Interactions with NHSE&I colleagues on key policy areas have restarted, including about the review of health technology evaluation methods and process and the commercial medicines framework.

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	• Plans are being put in place to develop future regulatory arrangements in response to the UK leaving the EU, led by the MHRA with NICE as key partner.
Work with system partners on relevant areas of policy interest including NHSE&I 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 (IMMDS) Review	Ongoing	• The IMMDS review was published on 8 July. NICE had already taken action to improve guidance relevant to mesh and valproate (2 of the IMMDS themes). Proposed actions following the publication of the review have been developed for Board agreement. • We continue to build a close working relationship with the Genomic Medicines Service, including by considering drafts of the process for updating of the test directory. • NICE and NHSE&I project to develop and test models for the evaluation and purchase of antimicrobials has reached the important milestone of launching the procurement to select 2 antimicrobial products for the project. Current work is focused on identifying resources for the NICE-led HTA phase and recruiting the special committee required for the project.
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	• Successfully negotiated a new three-year deal for national access to the Cochrane Library for England commencing from May 2020. • Supported Health Education England (HEE) in their tender process evaluating responses for a national resource discovery service which aims to meet the evidence search needs for the majority of health professionals in England.

Support the UK's ambition to enhance its position as a global life sciences destination	Delivery date	Progress update
Develop technology appraisal guidance in line with the commitments in the 2019 Voluntary Scheme	Q4	• Plans for recovery of the guidance producing programmes following the COVID-19 pause have been put in place. Teams are working with companies to finalise new timelines for appraisals and are communicating these with stakeholders as and when agreed.
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	• Work of the AAC paused because of COVID-19. The secretariat continued to support the RAPID-C19 oversight group. • Partner organisations have collaborated on submissions for the comprehensive spending review.
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	• Earlier in the year, NICE Scientific Advice introduced a service providing free advice to developers of diagnostics or therapeutics targeting COVID-19. Through July and August, the team worked on 2 of the 9 COVID-19 advice projects completed this year.
Work with NHSE&I 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	• Work continues with NHSE&I on the development of the innovative medicines fund.

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	• RAPID-C19 process implemented in collaboration with MHRA, NICE and NHSE&I to fast-track access to COVID-19 medicines. • MHRA and NICE Core Strategic Group established and working on a substantial programme to develop innovative regulatory and access routes following the UK/EU transition period. • A £3m 3-year project in collaboration with the MHRA, CQC and HRA to design a multi-agency advice service to support developers and users of AI-driven digital health technologies started in July. A further business case for NICE to develop methods for the evaluation of technologies with embedded AI will be submitted to NHSX in early 2021.
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	• We continue to engage in collaborative opportunities coordinated by the World Health Organisation (the Evidence Collaborative for COVID-19 [ECC-19]), the Cochrane Collaboration and the International Network of Agencies for Health Technology Assessment (INAHTA), the COVID-19 Evidence Network to support Decision-Making (COVID-END) hosted by McMaster University, a new collaboration initiated by NICE between the Canadian Agency for Drugs and Technologies in Health (CADTH), and the European Network for Heath Technology Assessment (EUnetHTA). • We are supervising an internship student from Harvard University who is conducting, in collaboration with a team from McMaster University (via COVID-END), a comparative review assessing the quality and recommendations of critical care and pneumonia COVID-19 guidelines published internationally. • Preparations for the HTAi 2021 conference in Manchester continue, with staff involved in both the Local Organising Committee (LOC) and the International Scientific Programme Committee (ISPC).

Generate and manage effectively the resources needed to maintain and transform our offer to the health and care system	**Delivery date**	**Progress update**
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	• Following approval by SMT and the Connect Steering Group for the adoption of a 'lean six sigma' approach to quality and process improvement, a procurement brief has been released for a contractor to supply Lean Six Sigma Green Belt training and a Lean Six Sigma introduction and overview course to a cohort of NICE staff in October. • A business case for Microsoft 365 is being presented to the Board in September. Pending Board approval detailed planning will be undertaken to enable a pilot to commence by the end of 2020/21.
Deliver against plan for all budgets and achieve or exceed on non-Grant-in-Aid income targets	End of March 2021	• After 4 months the budget was under spent by £0.9m (5%). • Income from technology appraisals and highly specialised technologies is below target due to the impact of COVID-19, but this has been offset by vacancies and no spend on travel. • Other non-GIA income targets have been achieved in the first 4 months, including a surplus in NICE Scientific Advice.
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	• Portfolio of H2020 and IMI projects aligned with NICE's research interests progressing to plan with virtual engagement with collaborating partners going well. • Final grant agreement signed for new IMI project (HARMONY PLUS) on big data approaches to studying and combatting neoplasms in haematology.

Deliver scientific advice, including the offers in the context of COVID-19, and NICE International activities to target	End of March 2021	• NICE Scientific Advice (including NICE International) is on track to recover all costs and make a full contribution to the NICE overheads. • The team has initiated 49 different projects since the start of the financial year. Nine of these projects have involved giving free advice on COVID-19 products. • NICE International has initiated projects with Austria Social Insurance (Health and Social Care), the Latin American Patient Academy and the Philippines DOH and delivered a free webinar on NICE's response to the COVID-19 pandemic.

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	• Our refreshed appraisals approach "Appraisal: My Contribution" has been successfully launched, with virtual training available for staff and managers, which has been well-attended. The window for appraisals has been extended until the end of July. The window closed at the end of July and we are currently analysing returns so far.
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	• Our Health and Wellbeing Group continues to meet fortnightly. We are producing resources and support for staff and managers to help everyone to work as effectively as possible from home. • In August we conducted an audit so we could better understand our staff's desire to return to the office and also to understand the number of employees we have who considered themselves vulnerable. • The next pulse survey will take place in September.
Review our people processes to enable different ways of working as part of the NICE Connect transformation	Ongoing	• We are currently looking at how we learn from COVID-19 experience and plan for adaptation of virtual team/matrix team working.

Implement the actions set out in the workforce strategy for 2020/21	End of Q4	• We are continuing to progress our development of values and behaviours. Our focus groups have been well-attended. • We have now consolidated the feedback and had initial discussions with the SMT, once finalised, the plan is to share with the Board and then develop a communications strategy to promote and embed the values and behaviours. • We have produced an e-learning catalogue of quality programmes, our OD & Training Specialist continues to deliver sessions remotely, which are receiving good feedback. • We have produced a comprehensive Recruiting Remotely guide in collaboration with Digital Services and CHTE.
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	• The date for the opening of the Stratford office is being revisited due to new delays. Issues have been identified with the configuration of the main equipment room (server room) but remedial action is being planned. • A final report on COVID-19 Secure operations shows changes in the placement of desks and the use of screens means the number of desks available could be increased significantly, even within the 2m Social Distancing rules. • The development of the shared IT solutions has continued, and the high-level design for the shared infrastructure has been signed off.
Begin a programme of improvements to the Manchester office to ensure best use of the space available	End of Q4	• The Manchester office will re-open on 8 October, this will be a phased return.

Appendix 2: Guidance development - variation against plan April 2020 to August 2020

The variation against the business plan is explained below:

COVID-19 rapid guidelines

No variation against plan 2020/21.

Clinical guidelines

No variation against plan 2020/21.

Interventional procedures

1 topic delayed:

- Transcranial magnetic stimulation for auditory hallucinations: Timelines extended due to change in Guidance Executive meeting date. Due to publish September 2020 (Q2 2020/21).

Medical technologies

7 topics delayed:

- Axonics: Delayed due to COVID-19 restrictions, and further delayed due to a resolution request. Due to publish September 2020 (Q2 2020/21).
- SEM scanner: Delayed due to COVID-19 restrictions. Due to publish October 2020 (Q3 2020/21).
- Zio XT: Delayed due to COVID-19 restrictions as well as requiring a third committee meeting. Due to publish December 2020 (Q3 2020/21).

- Danis Stent: Delayed in scoping and development. Further delayed due to COVID-19 restrictions. Due to publish March 2021 (Q4 2020/21).
- Peezy: Delayed due to COVID-19 restrictions. Development now paused due to new evidence. Publication date to be confirmed.
- Endo-Sponge: Delayed due to COVID-19 restrictions. Due to publish November 2020 (Q3 2020/21).
- Magec: Guidance withdrawn due to MHRA safety alert. Guidance update is suspended indefinitely.

Public health

No variation against plan 2020/21.

Quality standards

1 topic delayed:

- Heavy menstrual bleeding (update): Delayed due to COVID-19 restrictions. Due to publish October 2020 (Q3 2020/21).

Diagnostics

1 topic delayed:

- Implantable cardiac monitors to detect atrial fibrillation after cryptogenic stroke: Publication was delayed to allow time to consider resolution requests received. Published on 2 September 2020 (Q2 2020/21).

Technology appraisals and highly specialised technologies

No variation against plan 2020/21.

Social Care

No variation against plan 2020/21.

Managing common infections

No variation against plan 2020/21.

Appendix 3: Guidance and advice published since the Board meeting in July 2020

Since the report to the Board meeting in July 2020 the Institute has published the following guidance in 2020/21.

COVID-19 rapid guidelines

Topic	Recommendation
COVID-19 rapid guideline: arranging planned care in hospitals and diagnostic services	General guidance

Clinical guidelines

No publications

Public health

No publications

Managing common infections

No publications

Social Care

No publications

Interventional procedures

Topic	Recommendation
Artificial iris insertion for congenital aniridia	Research
Artificial iris insertion for acquired aniridia	Special
Electrical stimulation to improve muscle strength in chronic respiratory conditions, chronic heart failure and chronic kidney disease	Standard and research
Transcranial magnetic stimulation for obsessive-compulsive disorder	Research
Implanted vagus nerve stimulation for treatment-resistant depression	Special
Deep brain stimulation for refractory epilepsy in adults	Special and research

Medical technologies

No publications

Diagnostics

Topic	Recommendation
High-sensitivity troponin tests for the early rule out of NSTEMI	11 tests recommended plus further research

Quality standards

Topic	Recommendation
Specialist neonatal respiratory care for babies born preterm	Sentinal markers of good practice
Decision making and mental capacity	Sentinal markers of good practice
Renal and ureteric stones	Sentinal markers of good practice

Topic	Recommendation
Faltering growth	Sentinal markers of good practice
Community pharmacies: promoting health and wellbeing	Sentinal markers of good practice

Indicators

No publications

Technology appraisals

Topic	Recommendation
Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer	Optimised
Atezolizumab with nab-paclitaxel for untreated PD-L1-positive, locally advanced or metastatic, triple-negative breast cancer	Recommended
Treosulfan with fludarabine for malignant disease before allogeneic stem cell transplant	Recommended
Entrectinib for treating NTRK fusion-positive solid tumours	Optimised
Entrectinib for treating ROS1-positive advanced non-small-cell lung cancer	Recommended
Gilteritinib for treating relapsed or refractory acute myeloid leukaemia	Recommended
Brentuximab vedotin in combination for untreated systemic anaplastic large cell lymphoma	Recommended

Highly specialised technologies

No publications

Medtech innovation briefings

Topic	Recommendation
CFHealthHub for managing cystic fibrosis during the COVID-19 pandemic	Summary of best available evidence
Prontosan for acute and chronic wounds	Summary of best available evidence
Spartan RX point-of-care CYP2C19 test to guide treatment in acute coronary syndrome	Summary of best available evidence

Topic	Recommendation
pCONUS2 Bifurcation Aneurysm Implant for complex intracranial aneurysms	Summary of best available evidence
Healthy.io test for home testing of urine albumin to creatinine ratio	Summary of best available evidence
FebriDx for C-reactive protein and myxovirus resistance protein A testing	Summary of best available evidence

Guidance surveillance reviews

Topic	Recommendation
NG151 Colorectal cancer – Exceptional review	No update
CG103 Delirium: prevention, diagnosis & management – Exceptional review	Partial update

Medicines advice products

Topic	Recommendation
MEC: Deprescribing in Older People Approaching End of Life	Summary of best available evidence
ES: Infliximab subcutaneous formulation (Remsima) for rheumatoid arthritis	Summary of best available evidence
PDA: Lynch syndrome: should I take aspirin to reduce my chance of getting bowel cancer?	Summary of best available evidence

Evidence reviews for NHSE&I specialised commissioning (including COVID-19 rapid evidence summaries)

Topic	Recommendation
ER: Baricitinib for the treatment of interferonopathies in children & adults	Summary of best available evidence

Antimicrobial evidence summaries

No publications

Shared learning

Topic	Recommendation
NG108: Using NICE guidance to inform an audit of mental capacity act assessment	Shared Learning example
Spinal cord stimulator implantation: Improving theatre efficiency	Shared Learning example
Autism and environmental adaptations within inpatient mental health units	Shared Learning example
Colonoscopic surveillance in adults with Ulcerative colitis, Crohn's disease or adenomas - Is this happening?	Shared Learning example
Dual Antiplatelet Therapy Post MI - An audit of post-acute coronary syndrome - ticagrelor prescription at Leigh Family Practice	Shared Learning example
Developing a medications policy and procedures for use in social care	Shared Learning example
Lambeth ADHD, an inner city multi-agency collaborative	Shared Learning example
Maintaining a cancer service in the midst of the COVID-19 pandemic: A single centre experience	Shared Learning example
Venous Thromboembolism Risk Assessment in Psychiatric Inpatients Audit	Shared Learning example
Sherlock 3CG Technology for PICC placement, how it has helped to develop a vascular access service at Medway Maritime NHS Foundation Trust	Shared Learning example
The Implementation of Sherlock 3CG Tip Confirmation System for PICC Placement in the Radiology Based Vascular Access Service	Shared Learning example
How can referrals of obese patients to the local exercise referral scheme be increased? A UK based primary care quality improvement study	Shared Learning example

Endorsement statements

Topic	Recommendation
E228 - UTI Rapid Update Quiz	Uptake of NICE guidance and standards
E237 – cancer, fertility and me	Uptake of NICE guidance and standards
RE005 – CARDMEDIC	Uptake of NICE guidance and standards

Topic	Recommendation
E235 – Statin intolerance Pathway	Uptake of NICE guidance and standards

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.

Management of common infections:

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

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.

Quality standards:
The statements in our Quality Standards identify important aspects of practice in which there is significant variation across health and social care.

Indicators:
NICE indicators measure outcomes that reflect the quality of care, or processes linked, by evidence, to improved outcomes.

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 reviews, medicines advice products and medtech innovation briefings:
These publications provide information (but not guidance) about a particular topic.

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

Shared learning examples:
These publications are quality-assured practical case studies written by local organisations and describe their use of NICE guidance and/or quality standards to change and improve local practice in their services.

Endorsement statements:
Tools to support the uptake of NICE guidance and standards.

Appendix 4: Balanced scorecard April 2020 to June 2020

Guidance, standards, indicators and evidence

Success criteria	Planned output to year end	Forecast revised output due to COVID-19	Key measures	Target (against forecast revised output)	Planned YTD (revised output)	Actual YTD	Cumulative performance	RAG status
Publish guidelines: clinical areas	13	3	Publication within stated year	80%	1	1	100%	Green
Publish guidelines: public health	2	1	Publication within stated year	80%	0	0	100%	Green
Publish guidelines: social care	1	0	Publication within stated year	80%	0	0	100%	Green
Publish guidelines: managing common infections	4	0	Publication within stated year	80%	0	0	100%	Green
Publish guidelines: COVID-19 rapid guidelines	0	21	Publication within stated year		16	16	100%	Green
Publish technology appraisals and highly specialised technologies guidance	98	Up to 70	Publication within stated year	80%	12	12	100%	Green
Publish interventional procedures guidance	33	Up to 25	Publication within stated quarter	80%	3	1	33%	Red (see note 1)
Publish diagnostics guidance	Up to 11	Range from 5 to 7	Publication within stated quarter	80%	1	1	100%	Green
Publish medical technologies guidance	Up to 14	Range from 5 to 10	Publication within stated year	80%	3	2	67%	Amber (see note 2)

Success criteria	Planned output to year end	Forecast revised output due to COVID-19	Key measures	Target (against forecast revised output)	Planned YTD (revised output)	Actual YTD	Cumulative performance	RAG status
Publish medtech innovation briefings (MIBs)	Up to 46	Range from 20 to 30	Publication within stated year	80%	15	8	53%	Amber (see note 3)
Deliver commercial briefing notes for NHSE&I to support discussions with companies	Up to 60	Up to 40	Delivery within stated year	80%	10	16	160%	Green
Advise on 'Patient Access Schemes'	Up to 55	Up to 37	Delivery within stated year	80%	9	8	89%	Green
Deliver new data collection agreements	Up to 22	Up to 15	Delivery within stated year	80%	Up to 4	2	50%	Amber (see note 4)
Complete data collection projects and associated managed access agreement exits	Up to 12	Up to 12	Delivery within stated year	80%	Up to 3	1	33%	Red (see note 5)
Actively monitor existing data collection projects	Up to 52	Up to 52	Delivery within stated year	80%	Up to 13	26	200%	Green
Manage portfolio of evaluative commissioning projects for NHSE&I	Up to 2	Up to 1	Submission to NHS England Clinical Panel within stated quarter	80%	1	1	100%	Green
Publish guideline surveillance reviews	20	Up to 20	Publication within stated year	80%	1	1	100%	Green
Deliver evidence summaries – antimicrobial prescribing	Up to 4	Up to 4	Publication within stated year	75%	0	0	100%	Green

Success criteria	Planned output to year end	Forecast revised output due to COVID-19	Key measures	Target (against forecast revised output)	Planned YTD (revised output)	Actual YTD	Cumulative performance	RAG status
Deliver evidence reviews for NHSE&I specialised commissioning (including COVID-19 rapid evidence summaries)	Up to 10	3	Delivery to NHS England within year	80%	0	6	600%	Green
Deliver quality standards	16	8	Publication within stated quarter	80%	0	0	100%	Green
Deliver indicator menu	1	1	Publication within stated year	100%	0	0	100%	Green
Deliver endorsement statements	30	20	Publication within stated quarter	80%	7	7	100%	Green
Deliver shared learning examples	50	25	Publication within stated quarter	80%	6	6	100%	Green
Publish monthly updates of the BNF and BNF C content	12	12	Publication within stated quarter	80%	3	3	100%	Green
Deliver a regular medicine awareness service	50	50	Publication to regular schedule	90%	13	13	100%	Green
Deliver medicines advice products	10	10	Publication within stated quarter	80%	0	1	100%	Green
Develop ‘rapid action plans’ in context of RAPID-C19	0	Up to 15	Develop within stated year	80%	N/A	19	127%	Green

Note 1: 2 delayed interventional procedures guidance topics were delayed due to COVID-19: Artificial iris insertion for acquired aniridia, and Artificial iris insertion for congenital aniridia. Both topics published in July 2020 (Q2 2020/21).

Note 2: 1 delayed medical technologies guidance topic: Axonics sacral neuromodulation system for treating refractory overactive bladder. Delayed due to COVID-19 and published September 2020 (Q2 2020/21).

Note 3: 7 medtech innovation briefings were delayed:

- Prontosan: Delayed due to COVID-19 and the need for additional expert input. Published in July 2020 (Q2 2020/21).
- Point of Care Hemolysis: Delayed due to COVID-19. Published in September 2020 (Q2 2020/21).
- Novii Wireless Patch System: Delayed due to COVID-19. Publication now due in September 2020 (Q2 2020/21).
- Tandem Insulin pump: Delayed due to COVID-19. Publication now due in September 2020 (Q2 2020/21).
- Synergo: Delayed due to COVID-19. Publication now due in September 2020 (Q2 2020/21).
- Vivo: Initially delayed due to COVID-19 and topic later cancelled as company no longer supported MIB production.
- Spinal bracing: Initially delayed due to COVID-19 and further paused to clarify regulatory issues.

Note 4: 1 MAA (Avelumab with axitinib ID1547) delayed due to extended commercial discussions between NHSE and the company. Published in September 2020 (Q2 2020/21).

Note 5: 1 MAA has been reviewed, 7 MAA reviews are scheduled and progressing, and 7 MAA reviews remain paused in the TA/HST workplan due to COVID-19.

Adoption and impact

Outputs	Measure	Target	Planned YTD	Actual To Year End	Cumulative performance	RAG
Publish resource impact products to support all NICE guidelines (excluding COVID-19 rapid guidelines), positively	Publication within year	90%	100%	100%	100%	Green

Outputs	Measure	Target	Planned YTD	Actual To Year End	Cumulative performance	RAG
recommended technology appraisals, medical technologies and diagnostics guidance at the point of guidance publication						
Coverage of NICE in the media	% of positive coverage of NICE in the media resulting from active programme of media relations	80%	80%	82%	82%	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%	98%	100%	100%	Green

Operating efficiently

Critical success factors	Key measures	Target	Planned YTD	Cumulative performance	RAG
Effective management of financial resources	Revenue spend	To operate within budget	Budget for the period April – June 2020 was £13.5m.	Net YTD spend was £13.0m. This was a net under spend of £0.5m (4%).	Green
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%	The business plan income target was to receive £3.4m year-to-date (YTD) from non-exchequer sources.	The year-to-date income recognised is £1.7m, which is £1.7m (50%) lower than target. This deficit is wholly related to reduced income from TA/HST fees than target.	Amber (see note 6)
Management of recruitment	Proportion of posts appointed to within 4 months of first advertisement	80%	n/a	TBA – we are implementing a new recruitment system, the data will be available for the next scorecard.	N/A
Management of sickness absence	Quarterly sickness absence rate is lower than the average rate (2.75% for the 12 months to September	2.75%	Below 2.75%	1.54%	Green

Critical success factors	Key measures	Target	Planned YTD	Cumulative performance	RAG
	2019) across the Arms Length Bodies				
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%	N/A	The 2020 survey was postponed due to COVID-19.	N/A
Staff involvement	Hold monthly staff meetings	80%	80%	100%	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	80%	83%	Green
Recycled waste	% of total waste recycled	90%	90%	100%	Green
Improved satisfaction	Complaints responded to in 20 working days	80%	80%	N/A – none received	N/A
Improved satisfaction	Enquiries fully responded to in 18 working days	90%	90%	92%	Green
Improved satisfaction	Number of Freedom of Information requests responded to within 20 working days	100%	100%	100%	Green
Improved satisfaction	Parliamentary Questions (PQs)	90%	90%	100%	Green

Critical success factors	Key measures	Target	Planned YTD	Cumulative performance	RAG
	contribution provided within requested time frame				
Interest in lay committee vacancies reflected by ratio of applications to positions	2:1 (or greater) each quarter	100%	2.1 or greater	10.6:1	Green
Speed of production[1]	% 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%	0	n/a	N/A

[1] 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
   - 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')

Critical success factors	Key measures	Target	Planned YTD	Cumulative performance	RAG
Speed of production	% 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%	0	n/a	N/A
Speed of production	% of Appeal Panel decisions received within 3 weeks of the hearing	80%	0	n/a – no appeal decisions due to publish	N/A

Note 6: The income target for TA/HST in Q1 was £2.6m, with £0.9m recognised in that time. This was expected due to the impact of COVID-19, with the 2020/21 business plan assuming a deficit of between 30-50% less income this financial year. Other income from non-exchequer sources (excluding fees from TA/HST) is currently achieving target (£0.8m).

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

September 2020

National Institute for Health and Care Excellence

Directors' progress reports

The next 7 items provide reports on the progress of the individual centres and directorates listed below. These reports give an update on any issues of note.

Dr Paul Chrisp, Director, Centre for Guidelines (Item 5)

Meindert Boysen, Director, Centre for Health Technology Evaluation (Item 6)

Alexia Tonnel, Director, Digital, Information and Technology Directorate (Item 7)

Dr Felix Greaves, Director, Science, Evidence and Analytics Directorate (Item 8)

Dr Judith Richardson, Acting Director, Health and Social Care Directorate (Item 9)

Jennifer Howells, Director, Finance, Strategy and Transformation (Item 10)

Jane Gizbert, Director, Communications (Item 11)

September 2020

National Institute for Health and Care Excellence

Centre for Guidelines progress report

1. This report provides an update on key issues and developments in the Centre for Guidelines in the period of July to August 2020.

Summary of activity

2. Three guidelines were published during July and August 2020. One of these was a rapid COVID-19 guideline. The interim methods and process for the development, surveillance and updating of rapid guidelines was published on 17 July on the NICE website. The interim methods and process are an update of the process and methods published on 20 March 2020 and will have a public consultation in 2021/22. We continue to engage with NHS England and Improvement on the migration of the COVID-19 specialty guides to NICE. We are building capacity in the centre to accommodate the migration, integration and maintenance of the COVID-19 guidelines. This requires diverting staff from other programmes. We are actively seeking additional funding to backfill these roles to minimise the opportunity cost of this additional unplanned work. The proposed operating model would provide a test bed where proposed new ways of working and content development can be tried out in a live working environment. The medicines and prescribing team joined the centre on 3 August.

Notable issues and developments

Ongoing response to COVID-19

3. One COVID-19 rapid guideline was published in July (Arranging planned care in hospitals and diagnostic services).

4. The surveillance team continued to support routine surveillance of existing COVID-19 rapid guidance. The team has led the first COVID-19 rapid guideline update on systemic anticancer treatments, developed with an expert panel of nine members, chaired by Tessa Lewis.

5. We are recruiting to a COVID-19 team that will be responsible for the development and maintenance of the COVID-19 guidelines, including migration and integration of specialty guides from NHS England and Improvement, once appropriate equality impact assessments are complete. We are seeking expressions of interest from staff in the surveillance and public health teams to be seconded into the team.

6. As we migrate, integrate and update the COVID-19 suite, we will take the opportunity to test new ways of integrated working and new presentations that align with NICE Connect objectives for integrated content. This should be easier for users to access, reduce duplication across the guidance, streamline surveillance and support ongoing maintenance of guideline recommendations.

7. We are working with the communications and implementation teams to identify and highlight existing guidelines that address health and care priorities in the third phase response to the pandemic. These include guidelines on obesity, mental health services for people with learning disabilities, increasing uptake of flu vaccination and recognition and referral of suspected cancer,

Restart of guidelines in development

8. Two guidelines were published in August (Perioperative care in adults and Rehabilitation for adults with complex psychosis).

9. Work has resumed on all guidelines in the centre's portfolio. All committee meetings that were paused have now restarted and were held virtually throughout July and August and into September. Timelines for all guidelines impacted by the pause have been recalculated. We are taking a flexible approach, including how committee meetings are run and timing of consultations. Committee members and guideline developers have adapted well to the new ways of working. Developers have been supported to share their experiences and learning with each other. Feedback on the virtual meetings has been broadly positive.

10. We consulted on 6 guidelines during July, August and into September. Stakeholders were asked to feedback any issues relating to COVID-19 that should be taken into consideration when finalising each guideline for publication. The potential impact of COVID-19 on each guideline is being assessed.

11. Surveillance reviews resumed in July with eleven reviews currently in development. Two reviews were published during this period (Colorectal cancer and Delirium: prevention, diagnosis, and management). The team reviewed and refreshed a recommendation in the Anaphylaxis: assessment and referral after emergency treatment guideline in response to a coroner's report. The team published an update of the lung cancer algorithm in response to two related technology appraisals publications.

12. The interim methods and process for the development, surveillance and updating of rapid guidelines was published on 17 July on the NICE website. This will continue to be updated where necessary and will be submitted for public consultation in 2021/22.

Engagement and enquiries

13. The Methods and Economics team continue to work with international groups and networks supporting the efficient development of high quality and trustworthy guidelines for the treatment and management of COVID-19. These groups include the Evidence Collaborative for COVID-19 (ECC-19) coordinated by the WHO, the Cochrane Collaboration, and the COVID-19 Evidence Network to support Decision-Making (COVID-END) hosted by McMaster University.

14. Reflecting our experience and expertise in developing social care guidelines, members of the Methods and Economics team are contributing to ongoing international efforts to reach consensus on what best practice looks like when developing guidelines in social care, and to assist the set-up of Social Technology Assessment International (STAi).

15. We have received a small number of enquiries about the guideline on arranging planned care in hospitals and diagnostic services, and there was media interest on 4 August following the publication for consultation of our draft guideline on chronic pain. The guideline recommends that common analgesics (opioids, paracetamol and non-steroidal anti-inflammatory drugs) and other drugs including ketamine, benzodiazepines and gabapentinoids, should not be offered because there is little or no evidence that they made any difference to people's quality of life, pain or psychological distress, and there was evidence that they can cause harm, including possible addiction. Consultation on the guideline closes on 14 September.

Guidelines strategy

16. On 6 August we secured agreement from colleagues at the Department of Health and Social Care, and NHS England to proceed with the new advisory group to advise on the draft principles, a process and a clear rationale to limit the number of new guideline topic referrals and updates, and only develop or update recommendations that are considered high priority to our users. We will invite members for the group and work on agreeing a list of 'static' and 'active' topics.

17. In parallel, we are also piloting different processes for updating suites of guidelines in the same area to support the NICE Connect approach. We are consolidating related guidelines in three areas: diabetes, cardiovascular disease and obstetrics. Overlapping recommendations will be identified and resolved or removed, and emphasis given to high priority areas. This is expected to reduce the size of the existing portfolio both in terms of number of discrete guidelines and total number of recommendations. This will optimise surveillance and updating and facilitate the integration of related recommendations.

18. The medicines and prescribing team joined the centre on 3 August.

Key issues and challenges

19. Building capacity to support the migration, integration and updating of COVID-19 guidance in time to meet system needs remains a challenge. There is a risk that the team will not be fully in place before a possible second COVID-19 peak in the autumn. This approach also takes capacity that was intended to support NICE Connect objectives. We are seeking additional funding to backfill the roles required for COVID-19 and Connect.

20. Permission has been granted for a judicial review of the guideline on cannabis-based medicinal products on the grounds of alleged inadequate consultation and alleged failure to take into account relevant considerations.

September 2020

National Institute for Health and Care Excellence

Centre for Health Technology Evaluation progress report

1. This report provides an update on key issues and developments in the Centre for Health Technology Evaluation (CHTE) during July and August 2020.

2. Please see the Chief Executive's report for guidance outputs during this period and figure 1 at the end of this document for non-guidance outputs.

Summary of activity

3. We implemented COVID-19 recovery plans for health technology evaluation topics paused between March and June 2020.

4. We continued to work on transformation projects under CHTE 2020 and NICE Connect, focussing on topic selection, reviews/surveillance, committee operations, and implementation.

5. We agreed new timelines for the review of methods and processes for health technology evaluation.

6. We launched the project to design a multi-agency advice service supporting developers and users of AI-driven digital health technologies.

Notable issues and developments

Response to COVID-19

7. We advised patients, carers and clinicians about the consequences of COVID-19 for data collection for existing non-cancer managed access agreements and commissioning through evaluation projects. Virtual oversight meetings were held with key stakeholders to monitor the impact of COVID-19 on the outputs of the agreements.

8. Work is ongoing to develop rapid Medtech Innovation Briefings (MIBs) on diagnostic tests for COVID-19 that have been approved through NHS England and NHS Improvement's new test approval process. The MIBs will include a decision on whether the tests meet the MHRA's target product profile for their class and will be aimed at those purchasing tests in health, social care and private sector settings.

9. We are completing an assessment of exploratory economic modelling of SARS-CoV-2 viral detection point of care tests and serology tests to explore the key drivers of cost effectiveness in different use cases. Modelling of hospital-based

testing is well underway and we plan to hold the first committee meeting in the autumn.

10. We continue to lead on the work of the RAPID-C19 oversight group, a multi-agency approach that enables safe and timely patient access to medicines showing evidence of benefit in treating symptomatic COVID-19 patients or for disease prevention. The initiative has already facilitated rapid access to 3 treatments within the NHS:

    - Remdesivir, an anti-viral nucleotide analogue that inhibits RNA polymerase.
    - Dexamethasone, a low-dose steroid treatment, which was made available to the system in within 2 days of a positive signal from an urgent public health study.
    - Hydrocortisone, another corticosteroid included in an urgent public health study.

11. Plans for recovery of the guidance producing programmes have been put in place. Teams are working with companies to finalise new timelines for appraisals and are communicating these with stakeholders as and when agreed. We will use members of the HST committee to form an additional TA committee to aid the COVID-19 recovery exercise.

12. The HealthTech Connect website advises innovators with technologies relevant to the COVID-19 emergency to contact the HealthTech Connect team directly to fast track information about their technology to Data Accessors. 86 technologies have been fast tracked or signposted accordingly.

13. Earlier in the year, NICE Scientific Advice introduced a service providing free advice to developers of diagnostics or therapeutics targeting COVID-19. Through July and August, the team worked on 2 of the 9 COVID-19 advice projects completed this year.

14. We held meetings with international partners; the Canadian Agency for Drugs and Technologies in Health (CADTH), the Australian Pharmaceutical Benefits Advisory Committee (PBAC) and the Scottish Medicines Consortium (SMC) with the aim of sharing learnings in COVID-19 and other areas of mutual interest.

Supporting innovation

15. We continue to work closely with NHS England and NHS Improvement to develop arrangements for a new innovative medicines fund, which will build on

the success of the cancer drugs fund, by extending managed access to non-cancer technology appraisals.

16. We updated guidance on high-sensitivity troponin tests for the early rule out of NSTEMI in response to a request from the Accelerated Access Collaborative (AAC) to support the implementation of DG15 after the technologies recommended in the guidance were selected as a 'rapid uptake product'.

Digital technologies

17. We initiated a £3m 3-year project in collaboration with the MHRA, CQC and HRA to design a multi-agency advice service to support developers and users of AI-driven digital health technologies. The secretariat for the new service sits with NICE Scientific Advice. NICE Scientific Advice is also supporting the AI Award competition run by NHS England by working with 7 different digital health technology developers, using the META Tool to identify relevant research questions.

Transformation

18. Timelines for the public consultation on the methods review were revised to provide additional time to respond to comments raised through the task and finish activity and address policy considerations, and timelines for the process review proposals have been revised to allow additional time to consider impact of leaving the EU for regulatory arrangements, plans for an innovative medicines fund, and the impact of COVID-19 on guidance development. Stakeholders have been informed and are overall supportive.

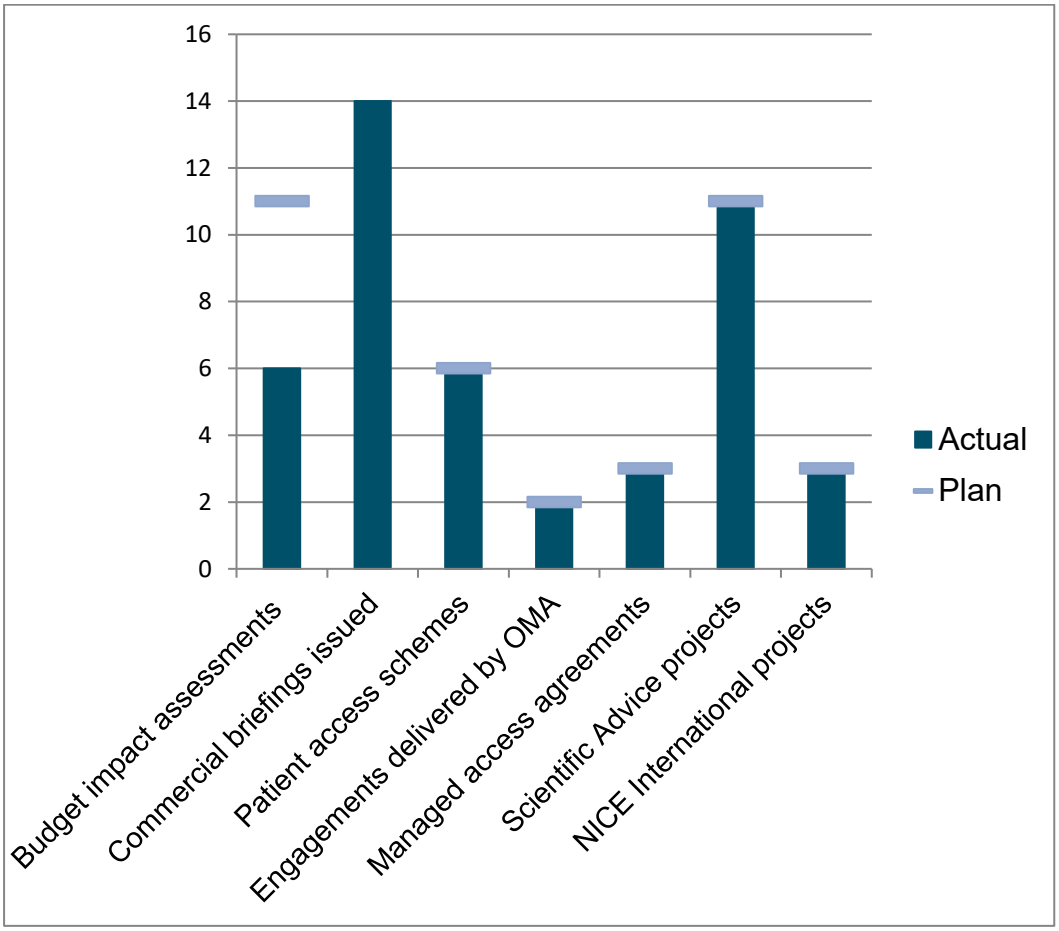
19. The new CHTE Topic Selection Oversight Panel (TSOP) has met twice since receiving support from the Board, introducing an efficient and transparent form of decision making for CHTE guidance selection and routing.

International collaboration

20. NICE International signed an MOU with the Colombian Institute of Health Technology Assessment (IETS) to share expertise in developing world-leading HTA guidance and to exchange experiences around the development of specific clinical guidelines and other areas including quality standards.

21. Preparations for the annual conference of Health Technology Assessment international (HTAi) in Manchester next year are well underway. We expect abstract submission facilities to be launched in early September.

Figure 1 Performance against plan for non-guidance outputs in July and August 2020



Download the data set for this chart.

September 2020

National Institute for Health and Care Excellence

Digital, Information and Technology progress report

1. This report provides an update on key issues and developments in the Digital, Information and Technology (DIT) directorate in the period July-August 2020.

2. The DIT directorate came into force on 1st September, bringing together the Digital Services and IT teams of NICE. The new DIT team comprises 4 teams:

    - Strategy & Governance; an area to drive the strategic alignment between business needs and digital/IT initiative ensuring informed ownership of priorities and the overall plan of digital activities by the business. This area is also responsible for central operational support, budget management and resource planning for DIT.
    - Product Development; this function takes the business needs of NICE and translates them into effective solutions. It comprises the software engineering, QA and testing and user centred design functions.
    - Information and Data Architecture; this group focuses on structuring and modelling NICE's information assets through deep expertise in data and content engineering and modelling.
    - Infrastructure & Operations; this team provides and operates the necessary technology infrastructure for NICE (network, servers, communications, applications) in line with agreed service levels.

3. The Information services and data analytics teams of the former Evidence Resource directorate transferred to the new Science, Evidence and Analytics (SEA) directorate on the same day. Updates on these activities are provided as part of the SEA directorate progress report.

Summary of activity

4. In line with the agreed digital and IT delivery roadmap and Connect plans, key project activity in the period included:

    - Development of a strategic outline business case for enabling an efficient digital workplace through the use of SharePoint Online and the Microsoft 365 (M365) suite of products. The business case features on the agenda for the NICE September public board;
    - Ongoing work with the NICE guideline collaborating centres to roll out the use of the EPPI Reviewer (web tools for searching evidence, systematic review needs and building an evidence surveillance capability). One of our

collaborating centres has signed the licence which formalises the use of EPPI for work on guidelines commissioned by NICE;

- Progress with our work on the Comment Collection tool, to enable organisation-wide feedback;
- Development of planning and scoping briefs for two agreed Connect deliverables: the Stakeholder Hub Discovery and the Planning Timelines Alpha. These were discussed at the Data Management Expert Group in July. The Stakeholder Hub work is scheduled for Q4 whilst the Planning Timelines work is being set up for an October start;
- Agreed approach to upgrading NICE's instance of MS Dynamics with the Communications team and the Senior Management Team (SMT).

5. Work on maintaining live services continued:

    - We maintained NICE live services' availability at 99.98% and 100% over July and August, against agreed performance levels of minimum uptime of 99.7% across all front end/client services;
    - In August, the team launched an upgraded instance of the Clinical Knowledge Summaries microsite. It is now fully accessible, faster and delivers much improved and useable results from search engines such as Google. Work on a similar upgrade to the BNF microsites is in progress;
    - Work has continued to identify and implement a new compliant cookie management solution, initially for the nice.org website. Work on accessibility standards has also continued across a range of live services;
    - A service penetration test was completed in July. Multiple other tests are planned for September and October.

6. We continue to work with the cross-arm length body IT Working Group that oversees the IT component of move to the Stratford office. Over the last two months, we have contributed to the development of a test strategy for the IT solutions, we supported the review of the main equipment room (server room) requirements, and started to engage with the solution for room and desk booking, which we hope can be used in Manchester too. The low-level design by the 3rd party contractor has not yet started but we expect to review these details in September. Also expected in September is a proposal for the IT support service model for the shared infrastructure and proposals for the AV/VC solution in meeting spaces.

7. We made good progress with the roll-out of laptops during July and August with over 300 laptops now despatched. We are now roughly half-way through the process.

Notable issues and developments

Ongoing response to COVID-19

8. Teams across the directorate have continued to contribute to NICE's response to the COVID-19 pandemic. Notable new activities in July and August include:

    - Worked with the communications and guideline teams to prepare to provide access to NHS England's speciality guides on the NICE website;
    - Continued to support the use of Zoom by the organisation and to deliver training to staff. Over 8000 meetings were held via Zoom in July and August (compared with 56 in February 2020);
    - Worked with the guideline team to develop detailed processes and methodology for the use of Zoom to provide virtual committees. Guideline committees have restarted and to date, we have received excellent feedback for our technical support.

Integration of the Digital and IT teams and recruitment drive

9. On 15th July, following approval from our Senior Management Team, we launched a group consultation with the Digital and IT teams on a new structure for the Digital, Information and Technology team. The group consultation closed on 19th July and consultation with affected members continued until 21st August. Minor but relevant changes were made following consultation and the new structure was launched on 1st September.

10. Alongside the consultation, we successfully appointed to three internal roles and launched external recruitments for 5 key roles (including Office 365, and infrastructure) which we hope will conclude in September. Now that consultation has closed, we will launch a second wave of recruitment addressing a range of vacancies across the new structure.

NICE web services - usage statistics

11. Summary: sessions for the month of August across NICE's key external web-based services were up 10% year-on-year. For the last 12 months this portfolio of services has also grown 9%. In August, most services kept growing year-on-year in comparison with August 2019 except for HDAS (-22%) and Pathways (-13%). NICE.org experienced a slightly better month when comparing year-on-year in August; we had not seen this since April when we had a spike in usage related to COVID-19 content. Finally, CKS also had a strong month. We are going to closely follow up the performance of this service to understand the impact of our recent upgrade.

Figure 1: August 2020 sessions for all NICE web-based services

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

Total sessions in August 2020 across NICE web-based services	4,830,107
% year-on-year variance	10%
% month-on-month variance	-3%
Total sessions for the full year ending in August 2020 across NICE web-based services	65,224,954
% year-on-year variance	9%

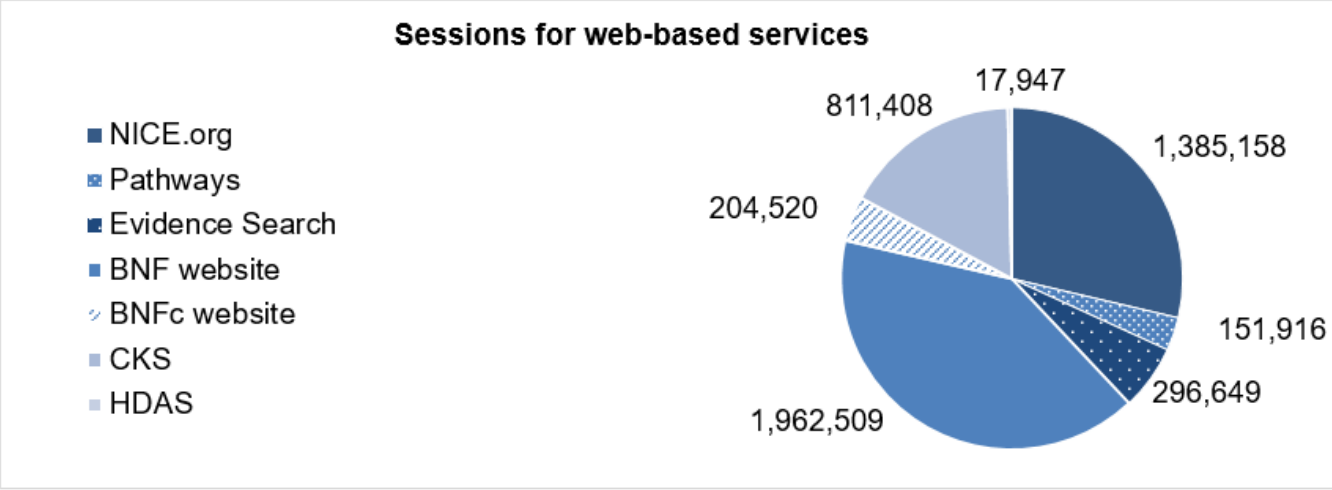
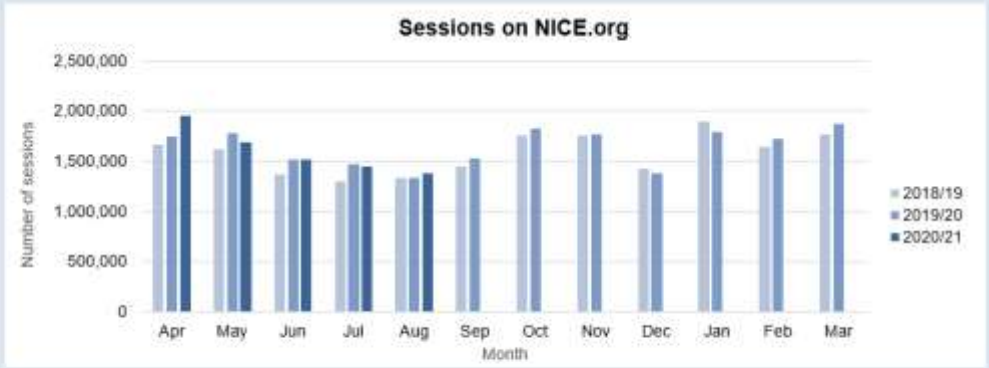


Figure 2: Performance of web services providing access to NICE guidance and advice

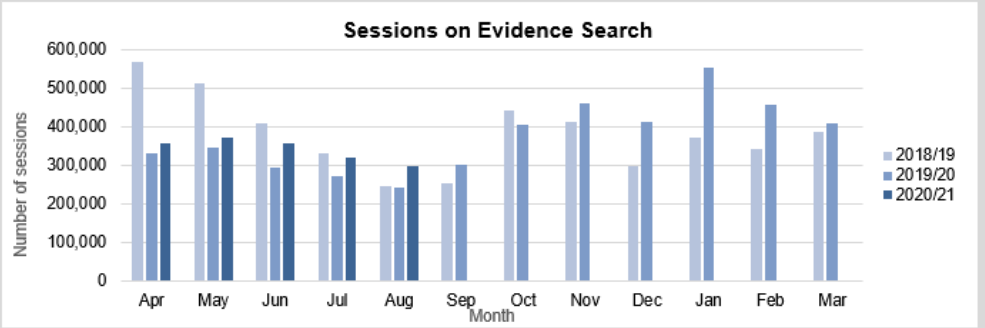
Total sessions on NICE.org in August 2020	1,385,158
% year-on-year variance	4%
% month-on-month variance	-4%
Sessions on NICE.org in year ending August 2020	19,900,552
% year-on-year variance	2%



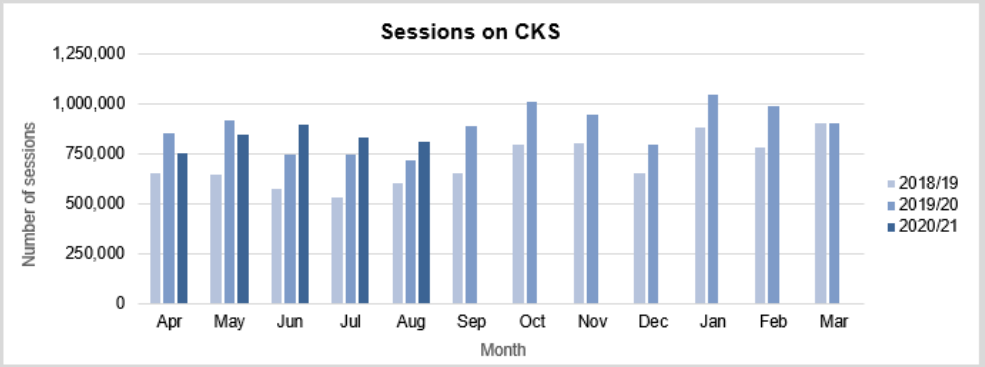
Total sessions on Pathways in August 2020	151,916
% year-on-year variance	-13%
% month-on-month variance	-3%
Sessions on Pathways in year ending August 2020	2,443,995
% year-on-year variance	-13%

Figure 3: Performance of services that provide access to other sources of evidence

Total sessions on Evidence Search in August 2020	296,649
% year-on-year variance	21%
% month-on-month variance	-8%
Sessions on Evidence Search in year ending August 2020	4,711,397
% year-on-year variance	18%



Total sessions on CKS in August 2020	811,408
% year-on-year variance	13%
% month-on-month variance	-3%
Sessions on CKS in year ending August 2020	10,715,081
% year-on-year variance	13%



Total sessions on HDAS in August 2020	17,947
% year-on-year variance	-22%
% month-on-month variance	-20%
Sessions on HDAS in year ending August 2020	302,551
% year-on-year variance	-9%

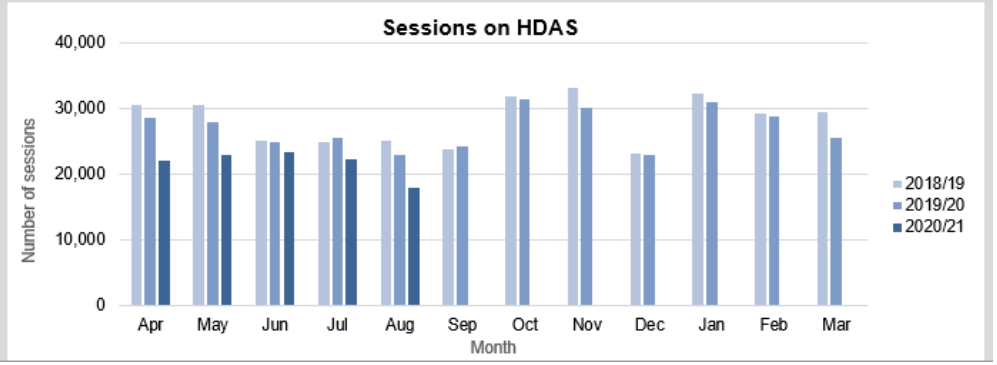
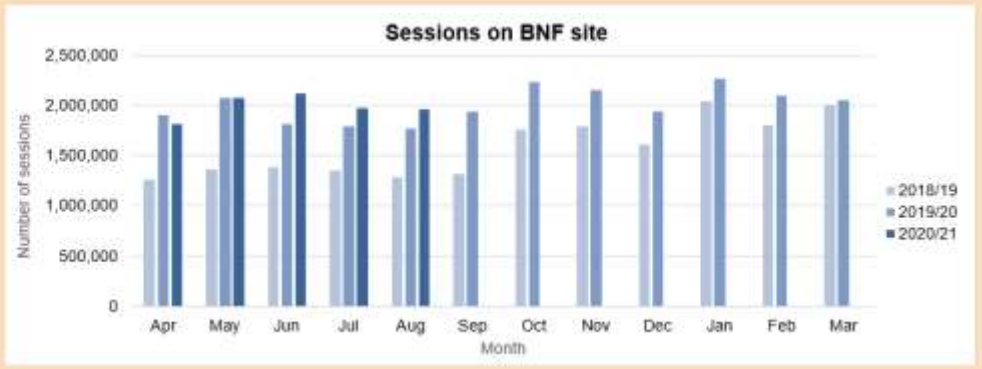
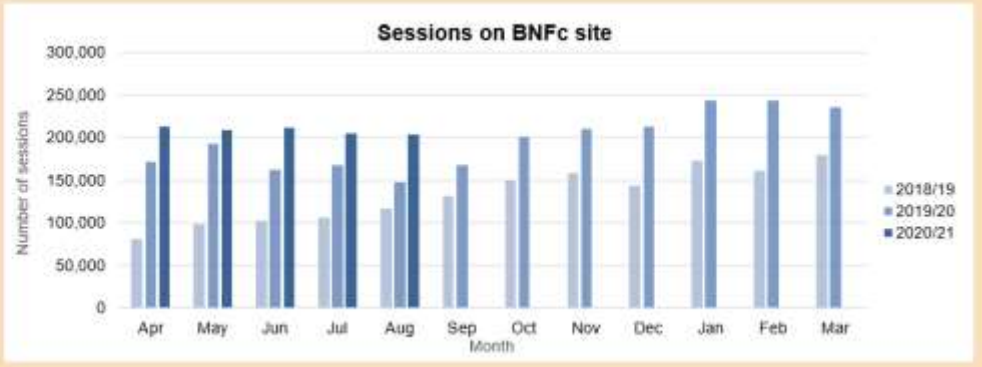


Figure 4: Performance of services providing access to the BNF content

Total sessions on BNF site in August 2020	1,962,509
% year-on-year variance	11%
% month-on-month variance	0%
Sessions on BNF site in year ending August 2020	24,590,312
% year-on-year variance	14%



Total sessions on BNFc site in August 2020	204,520
% year-on-year variance	38%
% month-on-month variance	0%
Sessions on BNFc site in year ending August 2020	2,561,066
% year-on-year variance	32%



Download the data set for the charts.

September 2020

National Institute for Health and Care Excellence

Science, Evidence and Analytics progress report

1. This report provides an update on key issues and developments in the Science, Evidence and Analytics directorate in the period July and August.

Summary of activity

2. This is the first progress report of the new Science, Evidence and Analytics directorate which formed on 1st September 2020. A summary of the work of the teams is described below, covering their activity in July and August.

Information Resources

3. In addition to work on COVID-19, the information resources team provided information expertise and searches for the development of 74 NICE products and produced 26 current awareness bulletins, providing information skills training to NICE staff.

Data and Analytics

4. The data and analytics team has prioritised our response to COVID-19 whilst recruiting additional staff to take forward the comprehensive standards and methods programme to utilise broader sources of data and evidence.

Science Policy and Research

5. The Science Policy and Research programme continues to deliver activity to 9 projects aligned to NICE's research priorities funded by the European Union's Innovative Medicines Initiative (IMI) and Horizon 2020 grants. A number of policy-related projects are progressing, including: Extending the QALY, Children's Quality of Life, EQ 5D 5L Valuation Set for England and plans for a new approach for deliberative public engagement.

Notable issues and developments

Ongoing response to COVID-19

6. Supporting the COVID-19 response remains a central focus of our work. The information services team continues to support the trial tracking, systematic literature searching activity, document supply and copyright advice that underpins development of NICE guidance on all COVID-19 topics across NICE and supports the surveillance and monitoring processes to ensure these

guidelines are kept up to date. The team is continuing to assess the utility of new data sources that have appeared in response to the pandemic.

7. A central repository of evidence on COVID-19 has been created which is used to inform surveillance decisions for rapid guidelines as well as technology appraisal scoping monitoring.

8. We are actively considering areas of uncertainty in our rapid guidelines suitable for research projects using data and have joined both the CVD COVID-19 UK Consortium and the FDA diagnostics and therapeutics evidence accelerator.

9. We continue to play an active part in the European Health Data and Evidence Network (EHDEN) - Europe's largest federated health data network. This responded to the pandemic by seeking new data partners with COVID-19 relevant data, who wished to map their data to a common data model. This work will allow rapid data analysis on European data from 11 countries, covering more than 150 million patient records. NICE staff contributed to publications on the safety of hydroxychloroquine, which has prompted a review by regulators of safety issues associated with long-term use.

Information Resources Developments

10. The team has been working closely with the centre for guidelines on assessing machine learning tools to automate the identification of RCT papers in search results; these are known as RCT classifiers. The RCT classifiers appear to be very accurate while offering significant reductions in the time required to sift search results. We will be recommending that RCT classifiers are built into our evidence management systems.

11. Our paper on The NICE UK geographic search filters for MEDLINE and Embase (Ovid): Post-development study to further evaluate precision and number-needed-to-read when retrieving UK evidence was published in Research Synthesis Methods.

Data and Analytics Developments

12. The team created a prototype 'trial tracking' script which aims to free up resource in information services, reduce time spent monitoring relevant trials in trial registries and searching for associated publications. The current approach requires an individual to manually check hundreds of web pages periodically for changes, which can only be done periodically and takes a considerable amount of time. It is currently being evaluated alongside the existing method to gauge its level of accuracy and usefulness.

Science Policy and Research Developments

13. The Science Policy and Research programme continues to deliver activity to European wide projects aligned to NICE's research priorities. This includes:

14. The GetReal project is finalising work on establishing an independent member-led institute based in the Netherlands. The not-for-profit institute will serve as a future hub for collaborative development and co-creation of solutions to advance use of real-world evidence in healthcare decision making. Members will include national regulators and health technology assessment bodies, payers, patient organisations, academic institutions, and pharmaceutical companies. The formal establishment of the institute will take place in Q1 2021 and NICE will have an option to join as a founding member at that stage.

15. As part of the IMPACT-HTA project, the team hosted a workshop with international HTA experts to discuss the role of non-randomised evidence in HTA decision making. A report that incorporates recommendations is in preparation.

16. The NEURONET project provides coordination and support to a portfolio of 18 projects on neurodegeneration. The NICE team is leading the impact analysis to provide important insights into how new knowledge on neurodegenerative diseases is produced and disseminated.

17. Several policy-related projects are progressing in the Science Policy and Research programme, including:

18. The EQ-5D value set informs almost all economic models used by NICE and has a substantial impact on cost-effectiveness results. In October 2019 NICE decided to support a new valuation study and the team is on the steering group for this. The researchers and quality-control team have been appointed and a protocol is being developed.

19. NICE recently decided that it needs a process for engaging deliberatively with the public on complex issues involving morals, ethics and social values (to replace the NICE Citizens Council). The team proposed a new and more flexible process called 'NICE Listens' to the Board in August and a proposal is being prepared for discussion at a future Board meeting.

EUnetHTA and International Relationships

20. NICE is coordinating the work of the European Network for Health Technology Assessment (EUnetHTA) project to develop the scientific and technical elements of a future model of European HTA cooperation. The next phase of the activity is to initiate work to address the areas for improvement and to bring together the

different strands of the EUnetHTA project into a single framework to describe a model of future HTA cooperation.

Innovative models for the evaluation and purchase of antimicrobials project

21. NICE is working with NHS England and NHS Improvement and DHSC to develop and test models that pay companies for antimicrobials based primarily on a health technology assessment of their value to the NHS, as opposed to the volumes used. Such purchasing models, if developed and adopted internationally, will lead to more predictable payments to companies based on value to the NHS rather than volume of prescribing, and have the potential to achieve much-needed pull incentives for increased investment in antimicrobial product development.

22. Currently, the key activities are selecting 2 antimicrobials for the project through a procurement process and preparing for the HTA stage of the project, including recruiting a special NICE Committee for the project.

MHRA and NICE Core Strategic Group

23. Building on the long-standing Partnership Agreement between NICE and MHRA, the Core Strategic Group was launched in Spring 2020 to support even closer collaboration. Current work is focused on the development of new medicines regulatory arrangements for the UK from 2021 onwards. Joint work will ensure that new licensing arrangements align with NICE's Technology Appraisals and Highly Specialised Technologies guidance production, ensuring timely patient access to clinically and cost-effective medicines. The work includes developing a novel UK 'innovative licensing and access pathway'. The intention is to engage companies early; provide end to end advice and allow flexible regulatory review opportunities that lead to reduced development timescales, early UK licensing and early UK patient access to important transformative medicines. This innovative route will provide a compelling offer to patients, the NHS and the life sciences industry, encouraging companies to partner with the MHRA, NICE and the broader UK healthcare system and launch their products in the UK first.

September 2020

National Institute for Health and Care Excellence

Health and Social Care Directorate progress report

1. This report provides an update on activities, key issues and developments in the Health and Social Care Directorate for July and August 2020.

2. The Chief Executive's Report details the delivery of quality standards (QS), endorsement statements and shared learning examples.

Summary of activity

3. During this reporting period most of our work has been in supporting the health and care system to use our guidance, quality standards and advice. The nature of the health and social care environment in which we are operating means that almost all this work is linked to the pandemic in some way, even where not directly related to specific NICE COVID-19 resources.

4. The work we have done is based on the principles set out in the NICE implementation strategy. This includes developing products and tools to support the use of NICE guidance, disseminating key messages, engaging with key partners to ensure the system is conducive to the use of NICE guidance and, assessing the impact of our guidance

5. We have also directed some resource to support the NICE response to COVID-19 as well as restarting elements of the work programme that had been paused.

Notable issues and developments

Ongoing response to COVID-19

6. We have undertaken a review to ensure existing quality standards remain suitable and accurate during the COVID-19 pandemic, particularly given the publication of the rapid guidelines. We have made amendments to signpost new guidance that may help support the use of quality standards in this context. We also ask stakeholders to highlight any issues related to COVID-19 that we should account for in quality standards in development.

7. Staff within the directorate have continued to support the update of COVID-19 rapid guidelines.

Restarting work paused during COVID-19 pandemic

8. The quality standard and indicator committees have restarted with 5 committee meetings via Zoom. We have seen positive impacts of this approach, including a 5-fold increase in the number of public observers at these committees.

Developing products and tools

9. In July, changes to our resource impact assessment manuals and tools were proposed at an external stakeholder event. Feedback was positive including on planned changes in the way the resource impact tools are presented, and on the methodology used for the financial impact assessment.

10. We have endorsed resources and identified shared learning examples on the use of COVID-19 guidelines as outlined in the Chief Executive's report. The first COVID-19 shared learning example describes the provision of a cancer service for people in a COVID-19 secure environment.

11. The second wave of rapid uptake products for the Accelerated Access Collaborative is now being identified. We are working through the due diligence process with NHS England and NHS Improvement and the Academic Health Science Networks.

Disseminating key messages

12. Two 'NICE in Social Care' e-bulletins have been published. These highlight existing NICE guidance and quick guides which can support the sector during the COVID-19 pandemic. They focussed on end of life care and promotion of the forthcoming guideline consultation on safeguarding adults in care homes. The bulletins are distributed to over 3,300 subscribers from a range of audiences across the adults' and children's social care sectors.

Engaging with partners

13. Our Chief Executive sent a message of support and gratitude to public stakeholders, who we know are adversely affected by COVID-19. Issues faced by this group of stakeholders, and affecting their ability to engage with NICE, include compromised funding streams, furloughed staff, redundancies, and redeployment of resources to support the front line. This is the first step in ensuring we consider constraints on stakeholder organisations alongside the work on NICE's strategic direction.

14. NICE was invited to become members of the advisory group on good practice, guidance and innovation reporting to the Adult Social Care Taskforce led by David Pearson. The role of the taskforce is to implement the government's

social care action plan and support care homes over the winter period. We have briefed the group on the role of NICE in social care and the NICE guidance that aligns with the priority areas identified by the group.

15. We continue to maintain regular contact with the CQC, sharing updates on workplans and considering areas for joint working. We reviewed a joint action plan developed in January 2020, paused due to COVID-19, and identified areas that we can restart from Quarter 3 2020/21. We attended workshops, and responded to a survey, to inform CQC's work to develop its strategy for 2021 onwards and shape the future of health and social care regulation in England. The CQC has included NICE COVID-19 rapid guidelines, rapid evidence summaries, medtech innovation briefings and clinical knowledge summaries in information for inspection teams across all directorates (Adult Social Care / Hospitals Acute, Mental Health and Community Health Services / Primary Medical Services). This information now forms part of the overall Emergency Support Framework (ESF) resource package. At the start of the pandemic all our usual meetings with the CQC were cancelled but we now have meetings arranged to continue with this key relationship.

16. A national review is being held in Northern Ireland (NI) to understand current processes and challenges on implementation of NICE clinical guidelines. We have supported the process including interviews with each Health and Social Care Trust in NI, Health and Social Care Board and the Regulation and Quality Improvement Authority (RQIA). This will inform the revision of the NI NICE policy circular.

Assessing the impact

17. We feedback intelligence from the field across NICE each month. This includes updates on the use of COVID-19 guidelines and challenges facing the health and care system as services are restarted. The intelligence has also been used to inform field team engagements including the delivery of webinars for social care providers and trainers, and briefings for NICE leads in NHS Trusts. Notable points for NICE include:

    - Academic Health Science Networks (AHSNs) are facilitating rapid reviews across health and care systems to capture learning from the COVID-19 pandemic. We are linking with this work to bring learning back into NICE.
    - Local systems are working to maximise efficiency, progressing a "virtual first" approach. Their priorities include redesigning pulmonary rehabilitation services, delivery of immunosuppressant chemotherapy (to minimise exposure to COVID-19 for patients) and hypertension/cardiovascular disease (CVD) prevention.

- Hospital providers report people presenting with increased severity of illness, particularly across mental health conditions. This may be due to people delaying seeking help, and to the reduction in services during the peak of COVID-19.
- NHS provider NICE implementation leads continued to meet virtually in their regional networks. The groups shared insights on their organisation's use of NICE rapid guidance and impact of COVID-19 on their NICE processes.

18. Our networks of NHS NICE managers have responded to SNAP surveys to collect intelligence on the use of the COVID-19 rapid guidelines at local level. Feedback continues to be positive on level of detail, helpfulness, and confidence in the rigour of our guidance.

19. The field team has collated all feedback from their engagement campaign with the Association of Directors of Adult Social Services in England (ADASS) regional networks. This provided examples of use of guidance to deliver local impact on: asset-based approaches to social care; person centred approaches for people with learning disabilities; and making the case for proper support for carers. These examples are shared between the ADASS regional networks to encourage further guidance uptake. NICE guidance and quality standards are now used by over half of upper tier (County Council) and unitary local authorities. However, there is still the need for effort to raise NICE's profile within this diverse and extensive sector. The feedback has been used to inform the field team's social care engagement campaign for 2020/21.

Directorate Structure and Functions

20. On 1st August, the medicines and prescribing team transferred to the Centre for Guidelines to further align functions in support of NICE Connect and COVID-19 guidance.

September 2020

National Institute for Health and Care Excellence

Resources Report

This report gives details of the financial position as at 31 July 2020 and the ongoing impact of COVID-19 on the workforce.

The Board is asked to review the report.

Jennifer Howells

Director of Finance, Strategy & Transformation

September 2020

Year to Date Financial Position as at 31 July 2020

1. Table 1 summarises the financial position as at 31 July 2020. There is a full analysis in Appendix A.

Table 1: Financial position at 31 July 2020 and estimated outturn to 31 March 2021

Spend Category	Year to Date Budget £m	Year to Date Actual £m	Year to Date Variance £m	*Year to Date Variance %*	Annual Budget £m	Estimated Outturn £m	Estimated Outturn Variance £m	*Estimated Outturn Variance %*
Pay	15.3	13.7	(1.6)	*(10%)*	46.1	43.6	(2.5)	*(5%)*
Non pay	10.1	8.9	(1.2)	*(12%)*	29.5	27.8	(1.7)	*(6%)*
Total Expenditure	**25.4**	**22.6**	**(2.8)**	***(11%)***	**75.6**	**71.4**	**(4.2)**	***(6%)***
Income (non-Grant-in-Aid)	(7.6)	(5.6)	1.9	*25%*	(22.4)	(18.0)	4.3	*19%*
Grant-in-Aid Funding	(17.8)	(17.8)	-	*0%*	(53.2)	(53.2)	-	*0%*
Total Income Sources	**(25.4)**	**(23.5)**	**1.9**	***8%***	**(75.6)**	**(71.2)**	**4.3**	***6%***
Deficit/(Surplus)	**-**	**(0.9)**	**(0.9)**	***(5%)***	**-**	**0.1**	**0.1**	***0%***

2. Overall, the year to date position to 31 July 2020 was an underspend of £0.9m (5%). The underspend comprised of:

   - £1.6m pay underspend due to vacancies and staff turnover across the organisation.
   - £1.2m non pay underspend relating to unspent travel and subsistence budgets as a result of the COVID-19 restrictions, and lower than expected spend on contracts, including the MedTech External Assessment Centres.
   - £1.9m under recovery of income, mainly due to the expected reduction in income from the technology appraisal and highly specialised technologies programme arising from the impact of the COVID-19 pandemic.
   - The under recovery in income above is partially offset by a year to date surplus of £145,000 generated by NICE Scientific Advice (NSA) due to higher than expected income generation.

Pay expenditure

3. Up to 31 July 2020, pay expenditure was £13.7m against a budget of £15.3m, resulting in an underspend of £1.6m due to vacancies and staff turnover across the organisation.

4. It is expected that the pay underspend will fall gradually over the year as we recruit to vacant posts, in particular new posts established to support the NICE

Connect transformation programme and the digital services team to implement the digital workplace strategy.

Non-pay expenditure

5. Up to 31 July 2020, non-pay expenditure was £8.9m against a budget of £10.1m, resulting in an underspend of £1.2m.

6. The non-pay underspend includes:

    - A £494,000 underspend against the travel budget due to lockdown restrictions.
    - £247,000 relating to the variable call-off element of the MedTech External Assessment Centre contracts.
    - £148,000 underspend against the NICE Connect non-pay budget for consultancy and other project costs.
    - £140,000 underspend due to lower than planned spend on course fees, conferences and external meeting room hire.

7. Spend against the NICE Connect budget is expected to vary month on month over the year due to the nature of project spend. The NICE Connect Steering group will monitor commitments and spend against this budget on a regular basis.

Income

8. The deficit in income relates almost wholly to Technology Appraisal and Highly Specialised Technologies (TA/HST) income being lower than planned. We noted in our business plan that we expected TA/HST total income raised in year to fall by 35%, with 50% noted as the worst case.

9. After the first 4 months of the year we have recognised £1.4m in income. This is 60% lower than the original plan and, therefore, currently lower than the worst-case scenario of 50%. However, this level of performance at this point in the year was expected due to the impact of COVID-19 as topics had to be prioritised and no committee meetings were held in April.

10. The July Resources Board paper stated that we expected TA/HST income to meet the reasonable worst-case scenario of £7m income in 2020/21. However, following a review of topics currently in progress and those scheduled to commence in the latter part of this year, we have reduced this to £6.2m forecast income this year. This remains above the worst-cast scenario of £5.4m. This is being reviewed on a monthly basis by the TA/HST Project Team.

Forecast Outturn

11. As at the end of July, we are forecasting a £0.1m deficit as shown in Appendix A. This is an improvement from the £0.4m deficit forecast in the previous board paper. Although the forecast income from TA/HST has reduced from the worst-case scenario as described above, spending on travel costs are now expected to be very low for the whole of the financial year and it is assumed that much of the MedTech External Assessment Centre (EAC) variable budget will not be utilised this financial year due to the pause in the development of NICE guidance, MIB's and guidance reviews which has reduced the amount of work needed from the EAC's to support these activities this year.

12. We are working towards achieving a breakeven position. The forecast includes prudent assumptions about phased recruitment of vacant posts, planned spend on the NICE Connect non-pay budget on projects and potential legal costs and set-up costs associated with the move to the new Stratford office. If some of these costs can be avoided and TA/HST income achieves the revised forecast of £6.2m, then breakeven or better financial position may be achieved. We will continue to monitor the situation closely.

Comprehensive Spending Review 2020

13. The 2020 Comprehensive Spending Review (CSR) was launched in July, the aim being to set revenue budgets for the years 2021-24 and capital budgets for the years 2021-25. We are working with our DHSC sponsor team to submit appropriate bids for new activity and cost pressures during September.

14. Our CSR bids include funding to support our response to COVID-19 and our NICE Connect transformation programme. We are also working with organisations such as MHRA and NHS England to support the innovative regulatory pathway work and projects such as testing new models for the evaluation of antimicrobials.

15. The CSR process will continue throughout the autumn, it will take several months for submissions to be prioritised and agreed. The board will be kept up to date with developments as part of the ongoing Strategic Planning process.

Human Resources update: July/August 2020

16. This section is to provide an update on people issues and activities in July and August 2020, as well as updating the Board on some additional diversity data requested by the Board at the July public board meeting.

17. Almost all NICE staff continue to work from home, with the exception of a few key Facilities and IT staff who are working on rolling out new laptops and ensuring the offices are COVID-19 secure.

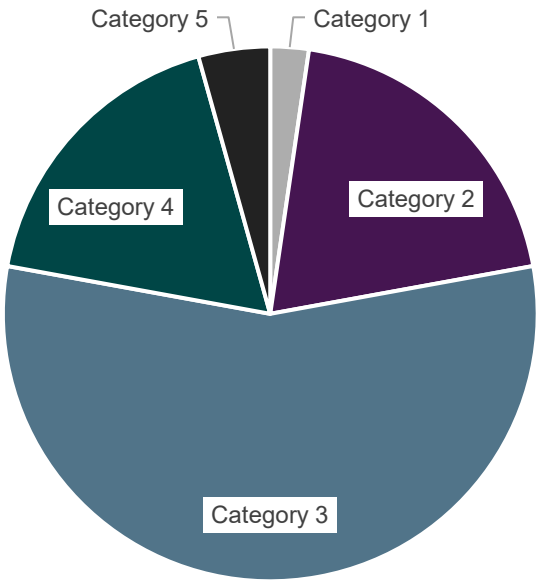
Understanding our workforce

18. In August 2020 we asked all line managers to have a conversation with their teams, so we could better understand our staff's desires to return to the offices. We asked staff to place themselves in one of 5 categories:

    - Category 1: Staff who need or strongly desire to be office based for all or part of their work.
    - Category 2: Staff who are broadly content to work from home but would like to do 1 or 2 days in office
    - Category 3: Staff who are broadly content to work from home
    - Category 4: Staff who in the short term consider that they should avoid working from the office and therefore only work from home
    - Category 5: Staff who would like to return but will struggle due to childcare

19. We had a response rate of 93%. Around 5% of staff were on short- or long-term leave while the audit was conducted, and some of our permanent homeworkers did not feel any of the categories reflected their circumstances.

Chart 1: Returning to the offices



Download the data set for this chart

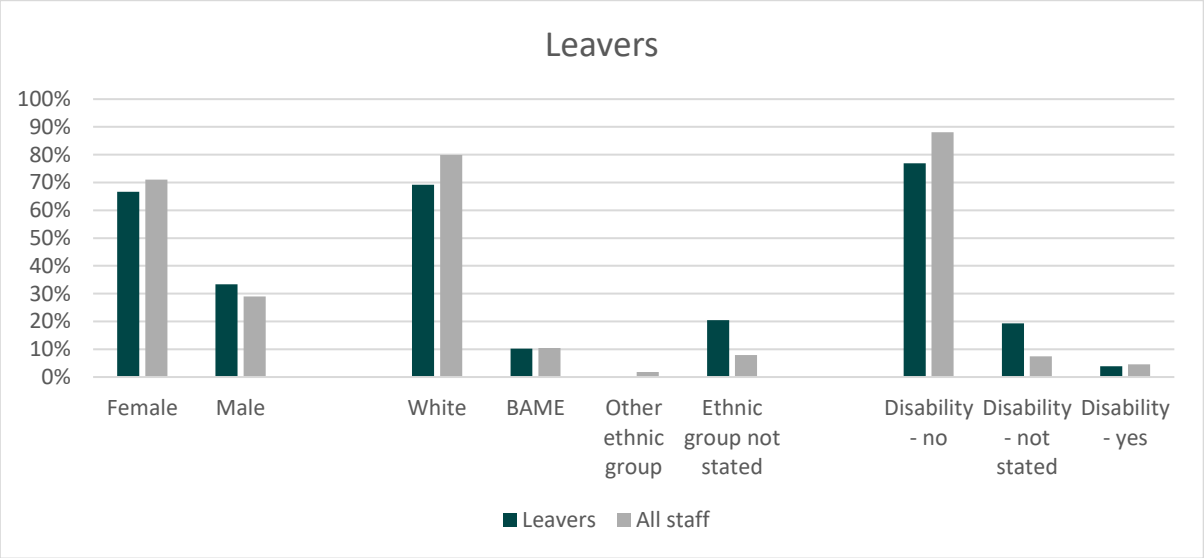
- 2% of staff (around 15 people) have a need or strong desire to return to the offices. Around half of these are from the Facilities teams in Manchester and London.
- Staff in category 2 are happy to work from home but would like to go to the offices 1-2 days per week.
- Staff in category 3 are broadly content to work from home, but happy to attend the offices as required.
- Nearly a fifth of staff are in category 4: vulnerable, shielding or otherwise concerned about travelling to the offices.
- Many people cited public transport as a concern.
- 4% are in category 5 and are unable to commit to long-term plans at this stage because of uncertainty around caring responsibilities.
- We are planning a phased return to the Manchester office from 8 October.

Diversity and inclusion

20. **Listening events:** In August, a series of listening events were held to help us gather staff insight into our new equalities objectives, including those which will be featured in our public sector equality duty objectives which will be presented to the Board in November.

21. **Spotlight on diversity data:** The Annual People Report was presented at the July board meeting. The report provided a range of data on our workforce, we were asked to provide additional information on staff diversity at NICE, particularly in the contexts of ethnic group, gender and disability. The figures relate to the information stored on our Electronic Staff Record (ESR) system for the period 1 April 2019 – 31 March 2020.

Chart 2: Leavers by protected characteristics



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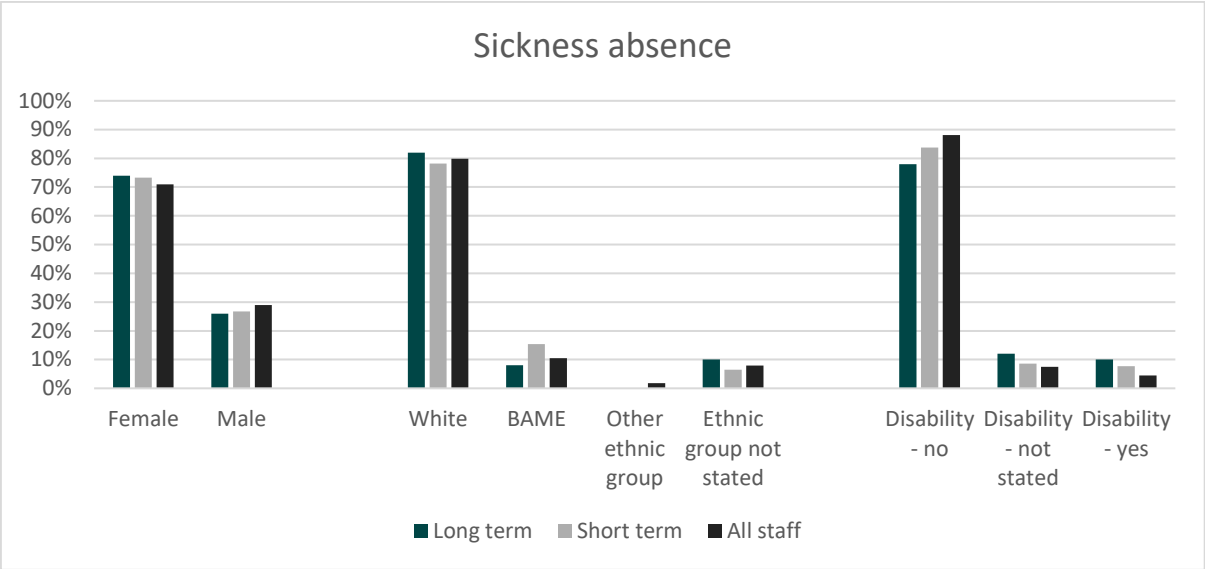
22. Chart 2 shows the percentage of leavers by protected characteristic, when compared to all staff. 69% of leavers were white, compared to 79% of staff. 10% of staff and 10% of leavers are from a black, Asian and minority ethnic background.

23. 5% of staff have not stated their ethnic group, compared to 20% of leavers.

Chart 3: Sickness absence by protected characteristics



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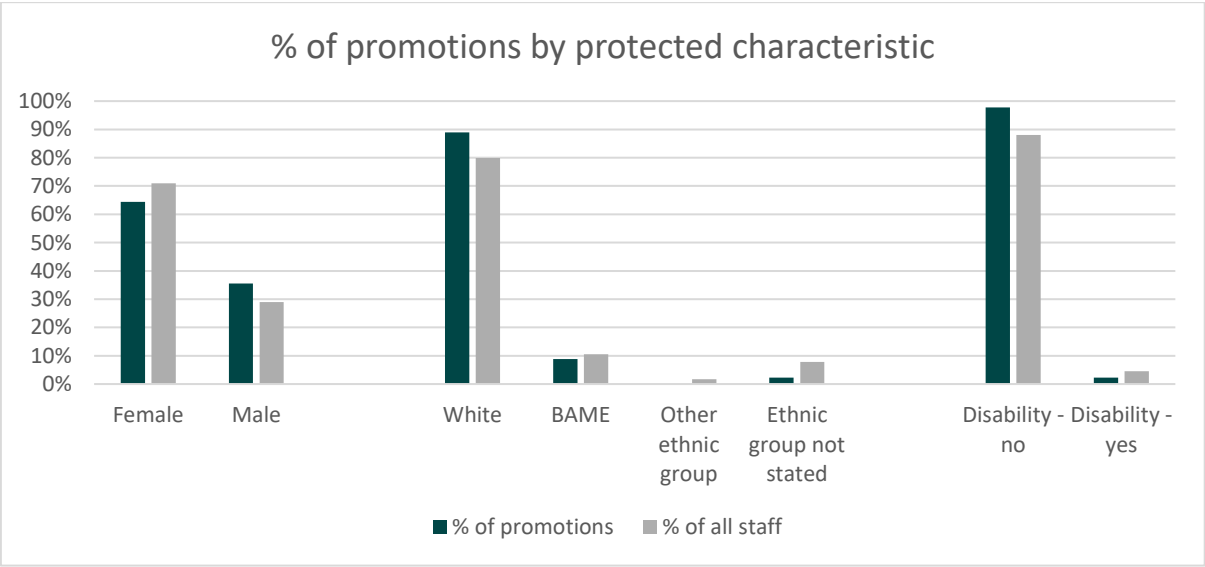
24. Chart 3 shows days lost to sickness absence, broken down by protected characteristic. The graph distinguishes between short-term and long-term absence.

25. Staff from a BAME background are slightly more likely to be off work with short-term absence compared to other groups but less likely to be off for long term absence. Staff who have a disability, or have not stated whether they have a disability, are more likely to be off work with both long- and short-term absence.

Chart 4a: Internal promotions by protected characteristics

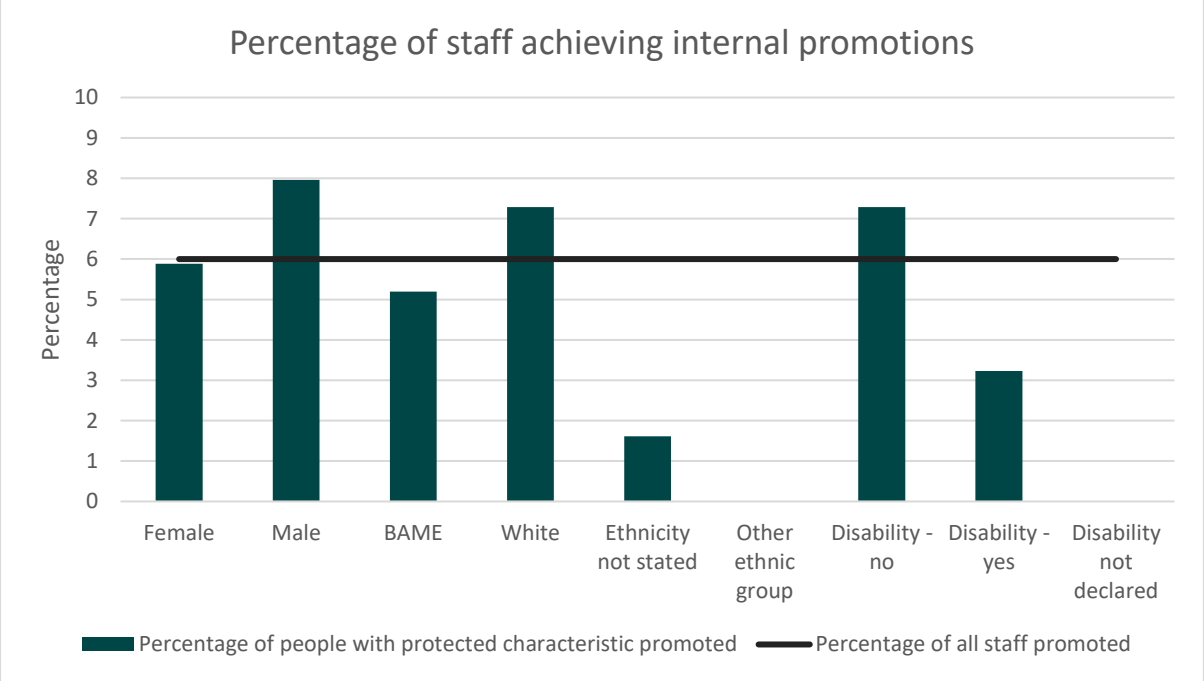


Download the data set for this chart

26. Staff can achieve internal promotions by going through an application and selection process when roles are advertised. Our Electronic Staff Records (ESR) system records internal promotions by looking at increases in salary band. The reports do not include sideways moves and if people achieved two promotions within the same financial year, the most recent one has been reported.

27. Chart 4a shows internal promotions by protected characteristics, compared to the overall staff makeup. As a percentage, men are more likely to be promoted than women, and staff from a white background are more likely to be promoted than from other ethnic groups, and particularly those who have not stated their group. Those who have not stated they have a disability are more likely to be promoted than those who have declared a disability.

Chart 4b: Percentage of staff achieving internal promotions

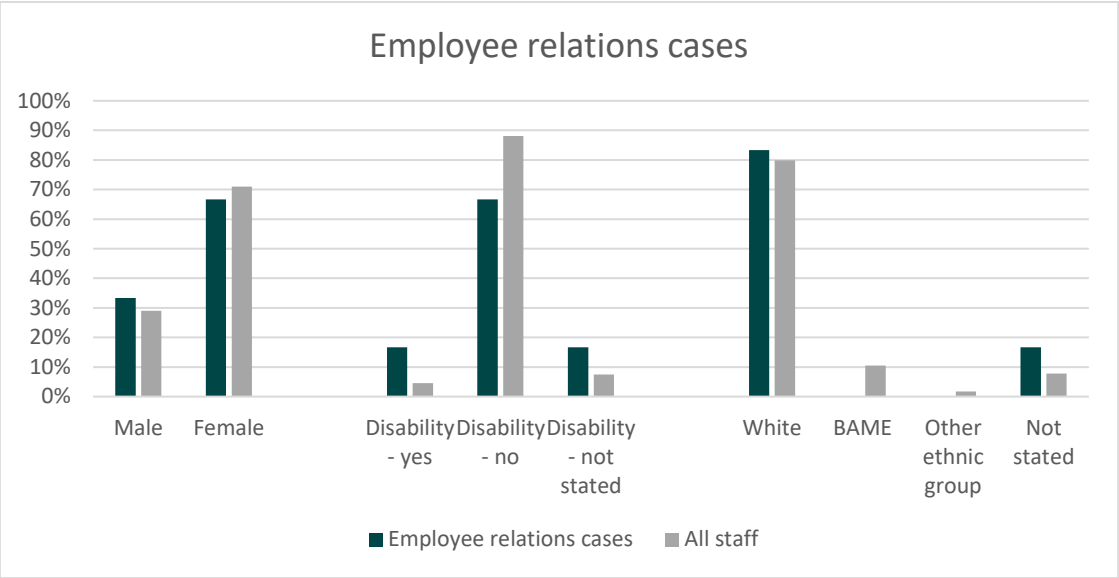


Download the data set for this chart

28. Chart 4b shows the percentage of people from a range of protected characteristics who have achieved an internal promotion in 2019/20, compared to the organisational figure of 6% of people (45 staff) achieving a promotion. These small numbers may affect the percentages.

29. The chart shows that in 2019/20, the proportion of men, white and non-disabled staff achieving promotions was higher than the proportion of female, BAME and disabled staff achieving promotions.

Chart 5: Employee relations cases by protected characteristics



Download the data set for this chart

30. These are encouraging figures, which show that staff from a range of protected characteristics are not more likely to be involved in employee relations cases, with the exception of people with a disability. However, we do only have small numbers of employee relations cases each year, which may affect the percentages. All cases will continue to be monitored on a month by month basis, including informal and formal cases.

Workforce planning

31. We know approximately 40% of our workforce are impacted by caring responsibilities and the school closures. A working group was established to look at ways we could support employees to work their contracted hours each week. The working group developed a set of recommendations to support carers in better balancing their caring responsibilities with their workload. A managers guide to the flexible options has been created and a number of polices have been updated to include the additional flexibilities that have been agreed.

32. Our digital marketplace, which was established to match skills, capacity and demand more effectively, is a great tool to use more strategically to deploy our skills and capacity more effectively. We are now considering the next steps for the marketplace.

Employee Relations

33. The HR operations team are continuing to support a number of ongoing employee relations cases. Although there was a slight slow-down in employee relations activity at the start of the COVID-19 lockdown and move to

homeworking, we have returned to our usual activity levels and are successfully managing employee relations issues remotely, albeit with appropriately adapted processes to ensure that everyone affected has the support that they need.

34. There has been a small upward trajectory of sickness absence levels in March, April and May with a decrease in June when compared against absence levels last year. Absence levels remain low across the organisation. We are continuing to monitor the time it takes for absences to be recorded and to monitor the affect this has on absence figures across the organisation.

35. Mental Health and Stress related absences have shown an increase in June and July. Any stress related illnesses have been supported informally by the HR team and we continue to see resolution on an individual level. We are continuing to monitor any work- related stress cases.

Wellbeing

36. Our Health and Wellbeing Group continues to meet fortnightly. We are producing resources and support for staff and managers to help everyone to work as effectively as possible from home.

37. Our first virtual Healthy Work Week will be held week commencing 7 September. As with our usual healthy work weeks, the week will be based on five ways to mental wellbeing, and will incorporate opportunities for staff to reflect on their mental and physical health during the pandemic, and offer a range of activities and resources for staff to learn more.

38. We are continuing to encourage all staff to use at least 10 days of annual leave by the end of September (pro-rata for part-time, excluding bank holidays). Most directorates have met or exceeded this target. Our communications on this have featured a joint statement with our Union and a range of senior leaders talking about the importance of taking breaks.

39. We will be doing another pulse survey in September to review issues such as staff wellbeing and workload.

Culture

40. **Appraisals:** The launch of our refreshed appraisals approach “Appraisal: My Contribution” has been well-received, despite the challenges of having these important conversations remotely.

41. **Values and behaviours:** We are continuing to progress our development of values and behaviours. The SMT have now seen the initial feedback from the survey and focus groups, and we are now finalising the wording and developing a communications strategy to promote and embed the values and behaviours.

Professional Development

42. **Line management training**: We are refreshing our training for first-line managers so that a couple of cohorts can be delivered remotely before the end of the financial year. We will monitor the feedback and effectiveness of this delivery model carefully.

Recruitment

43. We are continuing to recruit as normal, albeit with virtual interviews, assessments and inductions. We continue to see considerably higher application numbers for some roles as a result of the external labour market.

Appendix A: Summary of Financial Position

The table below is a summary of the financial position per centre and directorate as at 31 July 2020 and gives an estimated outturn to March 2021.

Centre / Directorate	Year to Date Budget £000	Year to Date Actual £000	Year to Date Variance £000	*Year to Date Variance %*	Annual Budget £000	Estimated Outturn £000	Estimated Outturn Variance £000	*Estimated Outturn Variance %*
Income from TA and HST cost recovery	(3,567)	(1,428)	2,138	*60%*	(10,700)	(6,200)	4,500	*42%*
Other funding From other ALBS, Devolved Administrations	(2,608)	(2,608)	0	*0%*	(7,713)	(7,662)	50	*1%*
Centre for Guidelines	5,962	5,724	(238)	*(4%)*	18,372	17,990	(382)	*(2%)*
Centre for Health Tech Evaluation	4,301	3,874	(427)	*(10%)*	13,564	12,807	(757)	*(6%)*
Health & Social Care	2,259	2,092	(167)	*(7%)*	6,964	6,594	(370)	*(5%)*
Evidence Resources	4,795	4,610	(185)	*(4%)*	13,882	13,758	(124)	*(1%)*
Science, Advice and Research	159	(61)	(220)	*n/a*	492	198	(294)	*n/a*
Business Planning & Resources	2,557	2,471	(87)	*(3%)*	7,810	7,773	(37)	*(0%)*
Communications	1,410	1,344	(66)	*(5%)*	4,519	4,355	(164)	*(4%)*
NICE Connect	304	130	(173)	*(57%)*	1,298	1,182	(116)	*(9%)*
NHS Pension costs (6.3% increase)	583	619	36	*6%*	1,750	1,904	154	*9%*
Depreciation (non-cash)	233	184	(49)	*(21%)*	700	651	(49)	*(7%)*
PYE Pay budget adjustment	*1,457*	*0*	*(1,457)*	*n/a*	*2,286*	*0*	*(2,286)*	*n/a*
Grand total	**17,847**	**16,952**	**(896)**	***(5%)***	**53,225**	**53,350**	**125**	***0%***

September 2020

National Institute for Health and Care Excellence

Communications directorate progress report

1. This report provides an update on key issues and developments in the communications directorate in the period July - August 2020.

Summary of activity

2. Much of the work of the directorate during this period has centred around marketing and promoting existing NICE guidance to help the health and care system in this phase of the Covid-19 pandemic. In other areas, plans are taking shape for the programme of virtual events in the autumn; work continues to ensure we meet government accessibility regulations coming into force this month, and our new marketing team is now up and running and developing marketing strategies for various initiatives across NICE.

Notable issues and developments

Ongoing response to COVID-19

3. We ran a social media campaign throughout the reporting period, highlighting how existing NICE guidance - for example, on recognising and diagnosing cancer, preventing obesity, and delivering mental health services - can help the NHS and wider care system restore capacity in non-COVID services as it continues to respond to the pandemic, in line with NHS England's priorities.

4. We developed new web content to promote and support our work on COVID-19. This has included signposting from a new email promotional signature to a suite of resources that reflect the third phase of the NHS' response. The initial COVID email signature resulted in more than 22,000 click-throughs to the corporate COVID page of the website.

5. Other content developed for COVID-19 includes a page for the RAPID C-19 initiative, a Guide to our approach to setting standards for data and analysis in the context of COVID and an Evidence collection guide for medicinal products to prevent or treat COVID-19.

6. Social media posts relating to our work on COVID-19 topics, including announcements of new rapid guidelines and the campaign to promote how existing guidance can help the system restore capacity in non-COVID services, earned the most impressions and typically had higher engagement rates than other content. On Twitter these posts had an average engagement rate of 1.6%

which is above industry standard and above our usual level of engagement which is about 0.9%.

Strategic communications advice and support

7. We prepared a briefing for the chief executive to support her attendance at the women and equalities select committee hearing on 22 July, in connection with the committee's inquiry entitled: 'Unequal impact? Coronavirus, disability and access to services.'

8. We developed a written response to the Science and Technology Select Committee's inquiry into the UK's science, research and technology capability and influence in global disease outbreaks. Our written evidence focused on capacity and capability of the UK research base in providing a response to the outbreak and the flexibility and agility of institutions, government departments and public bodies, and processes to respond appropriately during the crisis.

9. Working towards the new website accessibility regulations coming into force this month we have successfully reviewed and updated the top 100 corporate pages on the website. We have also worked with colleagues in the corporate office to develop a solution for publishing the board papers to significantly improve their accessibility. The new accessible format will apply from November.

10. Using our internal communication channels we are engaging with staff on NICE Connect. Following a highly successful virtual event in July, we have created a suite of infographics to provide an overview for staff of the Connect workstreams and the benefits to internal and external audiences.

11. Work to replace our intranet, NICE Space, has begun with a discovery phase to scope out options and inform a tender exercise.

Enquiries

12. During July and August, we responded to 1,131 enquiries. 95% were answered within 18 days. We responded to 20 requests for information under the Freedom of Information Act. We responded to 15 MP letters and 8 parliamentary questions.

13. Notable enquiry topics in this reporting period included:

    - The COVID-19 rapid guideline on planned care; the COVID-19 evidence summary on vitamin D; and the rapid guideline on managing pneumonia in the community.

- The draft guideline on chronic pain: assessment and management. We are working closely with the guidelines team on our response to enquires as the consultation continues.
- The statement published on the ME/CFS guideline development page which clarified that the current guidance did not cover people with post-COVID-19 fatigue prompted stakeholders to request further detail. There was a lot of interest amongst the ME/CFS community which was picked up by the press and on social media.

Media

14. During the reporting period, the press office issued 3 press releases and 5 notes to media, highlighting new guidance. They responded to 46 incoming media enquiries, 8 of which related to COVID-19.

15. Sentiment percentages for media coverage in July and August were as follows:

    - Positive 84%
    - Neutral 8%
    - Negative 8%

16. Our draft guideline on chronic pain received wide media coverage - much of it positive - but we are aware of the considerable public interest in the guideline seen particularly on social media and we will continue to monitor closely.

17. NICE's decision to rescind its endorsement of Dr David Unwin’s graphics translating the glycaemic load of foods into teaspoons of sugar (supporting our guideline on type 2 diabetes) led to extensive discussion on social media and a petition led by the Public Health Collaboration calling for us to reinstate the endorsement. Much of this focused on the role of the Mail on Sunday in purportedly forcing NICE’s hand to make the decision to withdraw the resource following its story (12 July 2020) questioning the resource’s scientific evidence-base. We subsequently published a statement on the NICE website clarifying that the decision was prompted by an internal review which had highlighted errors in the endorsement process for Dr Unwin's graphics.

18. Our website news stories within this period received more views than we would normally see, with an average increase in views of 45% compared to the same period last year.

Audience insights

19. The insights team has been working on a dissemination plan for the recent implementation study which includes a presentation to the Board. As we have

previously reported, we reduced the scope of the study in response to COVID-19 as we had limited access to front line users of our guidance. However, the findings to date, are being used as part of NICE's strategy development work and have informed the question design for the opinion leader interviews.

20. We have reviewed and consolidated findings from previous research studies including the reputation research carried out in 2019. We have prepared reports summarising what we know about our audiences for both the Connect transformation project and the strategy development work.

21. We are also preparing the next wave of our pulse staff survey which will be conducted during September.

Events and conferences

22. The events team has confirmed plans for a programme of virtual events for delivery in the autumn, targeted at different audience segments as follows:

    - For frontline NHS staff, managers, and commissioners: a panel discussion event exploring what it takes to deliver guidance to a health and care system dealing with COVID-19.
    - For the life sciences industry: an exploration of NICE’s offer to the sector both now and in the future and what has been learnt from COVID-19.
    - For the social care sector: the event will focus on the importance of collaboration across the health and social care system to help achieve better medicine control and improve people’s experience of care.

23. The 1-hour long events will be delivered as Zoom webinars and will be promoted via a multi-channel marketing campaign.

Marketing communications

24. In July we launched the first issue of the chief executive's monthly update, a letter-style communication from the chief executive to stakeholders, addressing a key topic in depth each month. In the July issue, Professor Leng focused on how NICE is continuing to respond to the COVID-19 pandemic, and in August she highlighted work underway at NICE to increase diversity across our workforce and work programmes. The chief executive's update received very good open rates in July (31.8%) and August (25.9%).

25. Our corporate newsletters, NICE News and Update for Primary (UPC), continue to be popular with a monthly open rate of between 20-25%. Subscriptions to NICE News continue to grow, with 360 new subscriptions in July and 225 in

August bringing the total of subscribers up to 32,184. Subscriptions to UPC stand at 12,551.

26. We are planning a full review of NICE News and Update for Primary Care, which will aim to ensure we are delivering targeted, data-driven newsletter content, which meets our audiences' needs.

27. Our new marketing team is working with a number of teams including NICE International and social care to identify their unique marketing needs, and we are planning research that will inform a review of NICE Scientific Advice's marketing strategy.

Publishing

28. The publishing team has prioritised the 'top 100' most visited html guidance web pages for each of our guidance products, to fix any accessibility issues with our existing content. We have also completed work on adapting the Microsoft Office templates that the guidance teams use across NICE, so the final products will be accessible in the future. The NICE style guide has been updated to reflect accessibility issues. This is phase 1 of our undertaking to meet the accessibility regulations which came into force in September 2018.

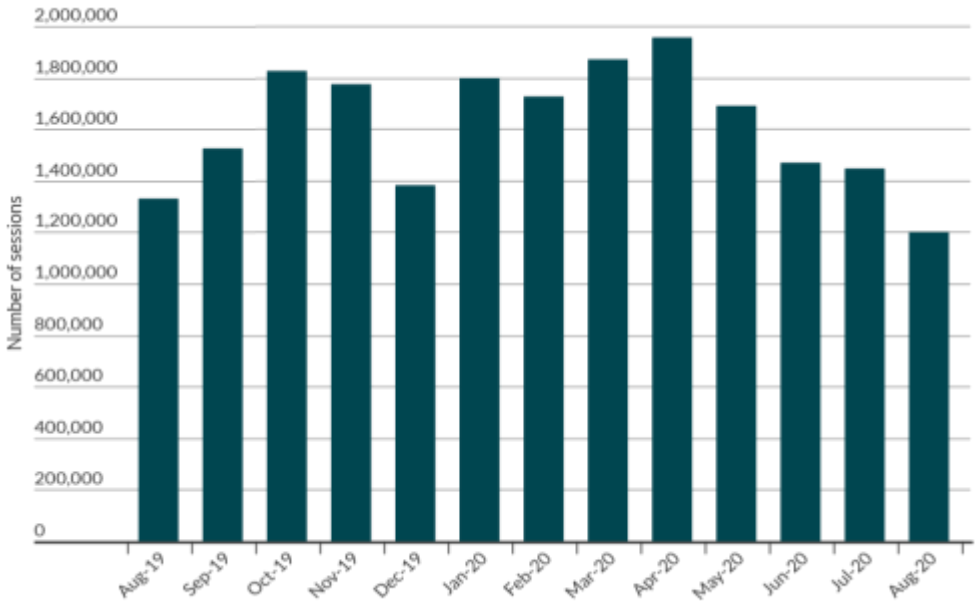
29. In response to the changes in how we work during the pandemic, the Publishing team launched virtual, interactive modules of 'Writing for NICE'. Our internal training course helps people understand the importance of writing clear, accessible content that is easy to read. We also ran a session on writing minutes and formatting and templates. In the first month we trained more than 100 members of staff and we are fully booked for the next 5 weeks.

Website performance

30. There were over 2.6 million sessions on the NICE website during this reporting period. Following the peak in sessions earlier this year which coincided with the publishing of the rapid guidelines for COVID-19, the number of sessions has now returned to a more normal level for this time of year.

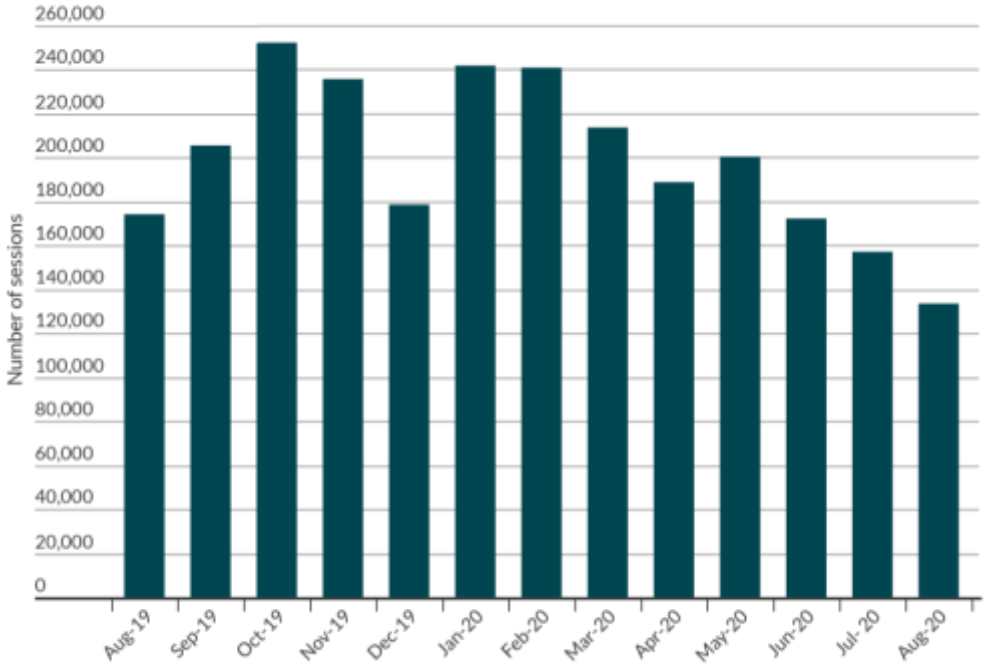
31. There were just over 290k sessions on Pathways. Although the number of sessions varies over time, we are continuing to see a downward trend from the beginning of the year.

Chart 1: Number of sessions on nice.org August 2019 - August 2020



Download the data set for this chart

Chart 2: Number of sessions on NICE Pathways August 2019 - August 2020



Download the data set for this chart

September 2020

National Institute for Health and Care Excellence

NICE strategic outline business case: Enabling an efficient digital workplace

This report presents a strategic outline business case for investment in a 'digital workplace' through the implementation of SharePoint and Microsoft 365 suite.

The Board is asked to note the overall costs and additional budget required to deliver this programme and approve proceeding 'at risk' whilst further work to prepare detailed information on the source of funding is completed and further opportunities to scrutinise and benchmark expected costs and benefits are sought.

Alexia Tonnel

Director, Digital, Information & Technology

September 2020

Executive Summary

Background

1. The NICE Connect Case for Change presented to the Board in September 2019, outlined the strategic priorities of the programme. This included previous independent reviews that had highlighted the critical need to develop much improved approaches to records and data management at NICE, and to introduce collaborative platforms to enable this as well the implementation of a records management solution.

2. In May 2020, the Board was presented with the output of a digital workplace strategy, that considered how the above data and records management priorities could be delivered. This work was delivered by Capgemini consultancy who worked with teams at NICE to develop a proposed approach. The recommendations included the implementation of SharePoint and Microsoft 365 across NICE.

3. This strategic outline business case addresses these recommendations with a proposed approach to deliver this business-critical implementation for NICE. It provides initial high-level consideration of expected benefits, the forecast investment in external consultancy support, and the commitment of resource from NICE staff to achieve this.

Benefits

4. The key benefit of this programme is to create capacity across the organisation through more efficient ways of working. The target capacity benefits arise from time-savings through the reduction of staff manual effort and automation, as well as facilitation of communication and collaboration activity by shifting from ad hoc email and document sharing to online activity with groups working together simultaneously. Delivering these efficiencies is critical to allow NICE to manage the increasing complexity, volume and pace of the demands placed on our organisation. Improving our operations means we can also free on-going capacity to continue to transform.

5. Greater collaboration will not only result in efficiency internally, but will also increase the speed and collaborative engagement with our external partners who support the production of our guidance and advice (e.g. MHRA or Life Science partners).

6. Whilst there is no direct measurable benefit to end users of NICE guidance and advice, SharePoint provides the necessary opportunities for us to collaborate more effectively and produce our guidance and advice more efficiently with our partners in the system.

7. At present, we estimate that the financial value of target capacity savings to be achieved, provides a payback on programme investment at year 5. However, the timeframe for realisation of these benefits as cash releasing through the removal of vacancies or cost avoidance through the absorption of additional work will need to be forecast in more detail with the business as part of the first phase of the programme.

Cost of the programme

8. Detailed costs for the full programme cannot be accurately calculated at this point as the programme will evolve in line with business needs as they emerge over phases. However, the entire lifespan of the programme is forecast to be 24 months at a total cost of £4.97m. This figure includes internal resource expected to be required for delivery, the expected cost of consultancy support through our strategic partnership with Capgemini (inclusive of VAT), and the additional costs for the employment of fixed term contract programme management capacity. In line with best practice we will be implementing the programme using an agile approach which will reduce the risks and ensure that we achieve best value throughout the programme.

9. Existing business plans and indicative business plans for subsequent years contain much of the expected cost, but there is currently a shortfall of £1.36m to deliver the programme as planned.

Table 1 - Summary of full programme and first phase cost

	2020-21 £000s	2021-22 £000s	2022-23 £000s	Total £000s		M1-6 £000s
Pay	277	1,108	831	2,216		554
Non-Pay	568	1,430	751	2,749		1,135
Total Cost	845	2,538	1,582	4,965		1,689
Within existing financial plan*	(676)	(1,862)	(1,067)	(3,605)		(1,351)
Funding Requirement	169	676	516	1,360		338

** business plan for 2020/21 and outline Connect programme costs approved by the Board in September 2019 for subsequent years.*

10. A request has been submitted for this additional funding as part of the Comprehensive Spending Review (CSR) currently being assessed. At this point, the programme is dependent on this funding to proceed. If this funding is not approved, given the strategic and operational importance of this programme to NICE, we will continue to seek other sources of funding, including through further negotiation with the DHSC.

11. The outcome of the CSR bid will not be known until later in 2020. The importance of the programme is such that we recommend that preparatory activity commences before this, 'at risk'. Programme mobilisation including recruitment of key fixed term roles that provide NICE capacity to do this work and the commercial negotiation with Capgemini will be required to begin in October 2020 so that delivery of the programme can begin as planned in January 2021.

12. Proceeding at risk without the confirmed source of funding, will be mitigated through the use of fixed term contracts in the recruitment of key programme roles. If no longer required these resources will be released or redeployed within NICE.

13. NICE's contract with Capgemini requires a 'statement of work' to be created and agreed. This will cover only the initial 6-month period, and will provide for the termination of the work with a notice period if required.

14. The first 6-month phase of this programme (Jan - Jun 2021) will require additional funding of £338k. Of this figure, £169k is required in the 2020/21 financial year. This is expected to be funded through underspend. The remaining £169k will be considered in subsequent business planning for 2021/22.

Next Steps

15. Over the next couple of months, additional work will be undertaken to further scrutinise the value for money of the proposed approach. This will include further detailed review and amendment to the initial high level staffing model put forward by our external partners in line with our plan for internal recruitment. We will also seek external organisational benchmarking of the estimated internal and external cost of the programme. The Board will be updated prior to commencement of the initial 6 months of work.

16. In the initial months of the first 6-month phase, we will prepare detailed plans for benefit realisation and will establish the governance arrangements to provide on-going delivery and financial scrutiny of the programme.

17. It is then proposed that drawing down of further budget from months 7-24 is accessed through an updated and more detailed business case which will be reviewed in line with key milestones that will be established. This will provide ongoing assurance of value for money and that appropriate decisions on scope and direction are being taken to maximise benefits realisation for NICE.

18. It should also be noted that, prior to commencement of the full programme, additional approval will be sought from DHSC as the proposed accumulated further expenditure on Capgemini consultancy will exceed the £1m delegated threshold set for Professional Services.

19. The Board is asked to:

    - Note the indicative forecast costs of the full programme of £4.97m over 24 months and that £1.36m of this is currently not contained in existing or indicative future business plans.

    - Approve proceeding at risk with preparing for a kick-off of the programme in January 2021. This requires immediate fixed term recruitment and commercial planning with Capgemini.

    - Approve commencement of the subsequent 6-month phase of work from January 2021 conditional on the following being completed ahead of that date:

        - Confirmation of the successful outcome of the CSR to provide a source of funding for this programme;

        - SMT assurance that robust governance processes have been established to provide on-going financial and delivery scrutiny

20. In the event of the CSR request being unsuccessful, we will return to the Board at the earliest opportunity for discussion regarding the best way to move forward.

Content

21. This outline business case sets out how we will run a digital transformation of operational ways of working, underpinned by robust records management, to enable NICE Connect ambitions and objectives. This will be done through the use of SharePoint Online and the Microsoft 365 (M365) suite of products to help staff work more efficiently and collaboratively.

22. The following items are covered in the business case:

    - the organisational context
    - why we are using M365, the scope of the work and our approach to implementation
    - the expected benefits that will be realised
    - the risks associated with this programme
    - the timescales and the costs, including indicative costs for 24 months as well as firm costs and budget request for the first 6 months to commence a series of pilots

Organisation context

A key component of the Connect programme

23. The NICE Connect Transformation business plan 2020/21 lays out the vision and priorities for the Connect programme for this financial year in order to progress further toward our longer-term transformation goals:

    - "Our vision for the future builds on NICE's 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.
    - 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."

24. One of the key priorities from the Connect business plan is: ‘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.’

25. This business case for enabling an efficient digital workplace, directly supports the NICE Connect programme to deliver that investment decision for the use of SharePoint.

26. SharePoint further offers opportunity in the automation of operational processes using a combination of M365 apps such as Forms, and PowerBi with SharePoint functionality. This replaces traditional ‘copy and paste’ activity, email approvals and passing of separate information between multiple individuals. Some process automation will take place as a natural part of the SharePoint migration work but where possible, the programme will also explore opportunities to enable automation of larger operational processes (such as the declaration of interest process).

27. Whilst the implementation of the M365 platform will not directly impact on external end users, it will provide significant benefit to our external partners through the introduction of technology to collaborate more effectively in the production of our guidance and advice.

28. In addition, the implementation of the M365 platform will be an enabler to achieving other Connect business plan objectives, although these are not an immediate, explicit focus of this business case. For example, although SharePoint is a document management solution it may offer opportunities to advance the work on structured content by:

    - Implementing records management standards and application of metadata to documents

    - exploring alternative workflows that better support structured content authoring

    - practical modelling and testing of SharePoint functionality and capabilities within a prototype site to both understand what could be usefully leveraged within SharePoint and define requirements for a connecting Componentised Content Management System (CCMS).

Barriers to achieving NICE's transformation vision

29. The work outlined within this business case will tackle some of the barriers to change that exist as a result of current ways of working.

30. The use of online collaborative tools at NICE is behind the curve of many public sector organisations and results in inefficiency and the need to invest additional capacity to close the gap. This was evidenced in the findings of a data management health check undertaken by Civica in 2019. The report stated that:

    - "an estimated average of one working day per week per person is being spent on manual manipulation of data through activities such as repeated copy and pasting of information from multiple disconnected sources into different documents and systems.

    - the tools, including network drives and email currently in place are driving and reinforcing a culture of siloed working which is not only inefficient, but creates a significant overhead when trying to achieve a corporate view of NICE data, and that;

    - the current NICE data landscape cannot enable the digital transformation required by NICE Connect. The report identified that to realise operational efficiencies and opportunities that emerging technologies provide, we must build strong information management foundations."

31. Similarly, further work by Capgemini on a digital workplace strategy in May 2020 concluded that:

    - "the current staff-user experience is frustrating, in particular with manual, inefficient and outdated ways of working;

    - inconsistent labelling of documents and lack of standardisation results in staff not being able to quickly and efficiently find the right information to work on or share and that;

    - NICE should deploy the M365 suite strategically, leveraging its capabilities to maximise the opportunities to address (these and other) existing pain points."

32. Therefore, we need to transform how we work to facilitate and automate efficiency alongside strengthening information and records management compliance. To affect these changes, we need better tools to support collaborative working, both internally and externally. This need has grown over time in our day to day operations, including guidance development, and has been further increased in priority in response to COVID-19 and our new virtual ways of working.

33. Without removing these barriers to change, and creating capacity and efficiency internally, NICE will be unable to achieve the broader aspirations of NICE Connect.

Objectives

34. This programme of work will be a significant, organisation wide transformation, impacting all staff at NICE. We will be introducing new ways of working and a shift in our approach to information and records management, using technology, specifically M365 products, as an enabler.

35. The overarching objectives of this change programme are:

    - Improve operational productivity and allow staff to work more efficiently
    - Enable staff to work more collaboratively both internally and externally in a secure way
    - Improve compliance with legal and regulatory requirements – for example data protection and freedom of information legislation.

36. Through strategic delivery of M365 and the implementation of robust records management foundations, we will give staff quick and easy access to the right information and the right tools to do their jobs, while maintaining high levels of information security and compliance.

Rationale for using Microsoft 365 as a core technology enabler

37. M365 has been available to NICE since 2018 (previously called Office 365), when it was purchased to upgrade licences. At the time there was no formal, corporate approach to its implementation. Use of applications grew organically until March 2020 when a structured accelerated roll out of Teams took place to aid collaborative working in response to the COVID-19 impact on NICE. This roll out is recognised as a temporary 'holding' position as it is not supported by robust practices that would be implemented through this programme. There have been no centrally controlled pilots conducted to date.

38. NICE has already invested in licensing (c. £140k p.a.) for the full suite of M365 applications including OneDrive and SharePoint Online. In order to continue using Microsoft Office (Word, Excel, PowerPoint) which have been in use at NICE for 20 years, NICE will continue to pay for these licences as part of the M365 suite and there are no plans to move away from this.

39. A detailed list of the tools making up the M365 suite, along with further information about SharePoint can be found in Appendix A.

Benefits

40. The key benefit of this programme is to create capacity across the organisation through more efficient ways of working.

41. The target capacity benefits arise from time-savings through the reduction of staff manual effort and automation, as well as facilitation of communication and collaboration activity by shifting from ad hoc email and document sharing to online activity with groups working together simultaneously. Delivering these efficiencies is critical to allow NICE to manage the increasing complexity, volume and pace of the demands placed on our organisation. Improving our operations means we can also free on-going capacity to continue to transform.

42. Greater collaboration will not only result in efficiency internally, but will also increase the speed and collaborative engagement with our external partners who support the production of our guidance and advice (e.g. MHRA or Life Science partners).

43. The programme will use evidence from the pilots in the Foundational phase to baseline and validate the efficiency savings forecasts. This will be used to update the business case at each future submission to SMT and the Board to ensure robust ongoing justification for continuing the programme.

44. The productivity and efficiency benefits are targeted to start being realised during the first 12 months and accumulate over the remainder of the lifetime of the programme then continuing into business as usual activity after the programme has closed.

45. The cost of investment in this programme is offset by target efficiency savings year on year over a 5-year period which could amount to £1.7m by year 5 as explained in the table below. This would mean a payback period for the programme of 5 years.

Table 2 - Programme benefits years 1 to 5

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
% efficiency saving realised in selected roles	2.5%	5%	5%	10%	10%	n/a
Estimated savings	£425,000	£850,000	£850,000	£1,700,000	£1,700,000	£5,525,000

46. The target savings are indicative at this point and have been calculated using the following assumptions:

    - Civica analysis work during the Data Management health check identified that up to 20% of NICE staff time is currently spent on manual activities. A prudent approach has been taken to calculations by assuming a figure of up to 10%.

- Capgemini user research and analysis identified that there are 447 staff (420 FTE) that will most benefit from implementation of M365 and SharePoint. These are the roles of Analyst, Programme and Project Manager, Editor, Advisor, Specialist and Digital specialist covering agenda for change bands 6 - 8b.

- Workforce statistics from 2019 have been used to identify the number of FTE by band and role that fit the Capgemini profiles for costing and calculation purposes. The efficiency savings of up to 10% have only been applied to these staff roles.

- Payback period on the programme investment is forecast at 5 years i.e. during the 3rd year after the 24-month programme has completed.

47. Benefits will be realised through the ability to deliver additional services and generate further income; absorb additional requests from our funders or release headcount through vacancy reduction or attrition. Overall, this programme is required to increase capacity and capability for improved ways of working with our stakeholders to provide guidance and other products, thus improving our reputation for speed and responsiveness to meet healthcare priority needs.

48. This will enable:

    - capacity to increase the level and quality of products and services offered across the guidance teams

    - capacity to explore opportunities and activities to add value and continuously improve products, processes and stakeholder engagement as identified from feedback from stakeholder groups such as the medtech industry

    - supporting the 2019 NICE Staff survey Action Plan objective relating to ‘workload & demands’ and reducing unacceptable levels of pressure in staff in key areas. This reduction in pressure will lead to reduced absence and staff turnover.

49. The table below summarises these benefits, demonstrating how they will support achieving the programme objectives:

Table 3 Benefits summary

Objective	Enabler / recommendation	Benefit
1. Improve operational productivity and	Make best use of the M365 tools to automate processes and reduce reliance on multiple copy and paste activity	Increased efficiency and productivity as manual ‘copy and paste’ overhead

Objective	Enabler / recommendation	Benefit
allow staff to work more efficiently	Apply document metadata aligned with an organisation taxonomy enabling consistent categorisation and easy searching of information Define and test the right ways of working, how information is organised and best approaches to governance, security, change management and migration of information for NICE through a pilot(s) before implementing NICE-wide	is substantially reduced and processes are automated Increased staff morale as repetitive manual tasks are minimised, and staff equipped with appropriate tools for the job they need to do
2. Enable staff to work more collaboratively both internally and externally in a secure way	Use a 'functional' rather than organisational approach to arranging information, i.e. structuring information based on the functions/ activities staff carry out, rather than the labels attached to a team/directorate Design SharePoint sites that enable sharing and collaboration both internally and externally safely and securely Ensure staff have access to the right technology to support their ways of working and are trained from an information governance, records management and IT perspective to use that technology effectively to do their job	Improved employee collaborative working and reduction in silos as information is managed and shared functionally rather than in team/directorate folders Efficiently collaborate and share information with colleagues and partners both internally and externally Improved reuse of information and insights for MI/BI as it will be easily available and accessible via automated systems
3. Improve compliance with legal and regulatory requirements	Automate and embed records management and classification policies as part of SharePoint design and implementation. Protect confidential/sensitive data with clear marking and digital safeguards so it can only be shared and accessed as appropriate Ensure clear governance of records management is designed to work with SharePoint and users are trained to understand this and take ownership	Reduce risk of data breaches, regulatory action and fines and reputational damage

Scope of programme

In scope

50. This programme focuses on the operational information used across NICE teams and with external stakeholders to support efficient ways of working in managing, sharing and collaborating on documents and information. SharePoint will take on the role of a records management system, and will, as far as possible replace use of the network drives with OneDrive replacing personal drives.

51. Information identified as suitable for migration will be moved to SharePoint. The extent of this will depend on the approach taken to archive and store records and the specific needs of different business functions.

52. The following formats of information are assumed to be in scope (although this list is not exhaustive):

    - information held in documents (Word, Excel, PowerPoint, OneNote, PDFs etc) that currently resides in the folder structure on the NICE network including personal drives

    - information held in email / Outlook public folders for collaboration purposes

    - information held in MS Teams and other Software as a service (SaaS) tools used by teams e.g. Confluence (used by Digital Services for collaboration)

    - use of forms, management information dashboards, task management tools.

53. This programme will need to work alongside other initiatives on the Connect roadmap and in the 2020/21 business plan. There will be dependencies on flow of information and interoperability/ integration between M365 and other tools and projects.

Out of scope

54. Whilst we will work closely with these initiatives and proactively monitor and consider them at the appropriate time they are out of direct scope of this programme. They include:

    - the existing evidence platform tools supporting evidence management and surveillance (EPPI) and other externally facing digital services such as Comment Collection

- ongoing work on the planning tools, stakeholder hub discovery and defining a NICE-wide approach to developing a customer data model
- work relating to the new form of intelligent componentised content and specific needs relating to 'analytics' data that underpins guidance models.
- the focused development of detailed NICE-wide approaches to the management of our data and information including establishing a centralised data function outside of the consideration of long-term records management staff requirements.

Approach

55. Implementing SharePoint Online and M365 requires bringing together organisational ways of working, governance, technology, and security with an agreed approach to how the organisation classifies, manages, and retains information. The goal is to build a technical structure and functionality that facilitates these business needs while remaining intuitive for staff and supportable from an IT, records management and information governance perspective.

56. It is assumed that we will take a 'functional' approach to designing and structuring SharePoint. This involves moving away from the traditional 'organisational' approach of arranging information (where information takes the structure of the teams and directorates in which the staff who use it are based) currently in place on the NICE network drives.

57. This current approach can make it hard to find information needed as teams can change over time and change names, directorate or merge with others. Organisational structures are not static, whereas the underlying business functions being carried out do not change very often. Information may be generated by and 'belong' to different teams and directorates but someone is still creating the same information as before.

58. Functional arrangements base the structure of information on the functions (activities and processes) staff are carrying out, rather than the labels attached to a team or directorate. This allows information created for a function to be kept intact, instead of artificially splitting it up to fit a changing organisational structure, or to allow different teams to have their 'own' copy.

59. The difference is some cases may be subtle, but the impact and benefits a functional structure can bring are less so – structuring information functionally makes identifying 'master records' easier, reduces duplication, breaks down silo working, makes information more visible and easier to find and makes it easier to apply appropriate access controls and safeguards. Taking this approach has

been a key recommendation by both Civica and Capgemini as critical to removing barriers to collaboration and easy sharing of information.

60. Examples of how information could be arranged by 'function' in SharePoint may be:

    - A 'process management' function – a SharePoint site could be designed to manage a process such as Declaration of Interest (DOI) or 'Starters and Leavers'. Any member of staff would fill in an online form and all the responses would be collected in a SharePoint list, managed by the people who own this process.

    - A 'topic' function – a SharePoint site could be designed to manage collaborative work relating to a specific healthcare topic or guideline. This could help remove the need for communications, decisions, multiple versioning and any other activities spread across multiple different channels (email, drives, Teams).

    - A 'temporary project'– a SharePoint site could be designed to enable full collaboration across all documents and communication needs for a project e.g. London office move.

    - Management of NICE Board papers. A SharePoint site could be designed that would allow any member of staff to submit a paper and access previously submitted papers.

61. We will run a series of controlled pilots in low risk areas to test and refine our approach to key recommendations like functional arrangement. This is critical prior to the full larger rollout and migration of information and onboarding of our staff to avoid costly and time-consuming mistakes. The pilots will also help us understand the business changes required on a broader scale and the resources a team/function will need to enable a continued rollout and migration of information on the scale agreed.

62. Each pilot is likely to involve 6-8 people involved in a particular function and will have a SharePoint site created for them that fits their business need. Business need will be identified through workshops and process mapping. Depending on the activity we are focusing on, the pilot may involve a small number of people or could use a process that touches on the whole organisation e.g. DOI.

63. The group will be asked to 'work' in that site undertaking their business as usual while testing different aspects such as usability, security, permissions, document classification and metadata application. During the pilot this feedback will enable the site to be iterated to an accepted state of readiness for use.

64. Expectations and outcomes for pilots will be discussed and agreed with participants before commencing. Participants will be able to take advantage of early training and understanding of the new technology and will be ideally placed to support their own teams/functions further at the later implementation and migration phases.

Migration of information

65. A critical aspect of the programme is our approach to migrating information from the network drives (and potentially other locations e.g. Outlook) into SharePoint. The volume of information migrated will have a direct impact on the cost, timescale and complexity of the project – the more we migrate the more work there is to do for the programme team and staff. A defined migration approach is also needed to remain with indicative costs agreed with NICE SMT and the Board.

66. Our approach to migration can be broken into three distinct areas:

    - Early communication to staff about the programme will begin by asking teams to start information cleansing activities – this will include conducting retention and disposal reviews, deleting information that has reached its retention period, deleting duplicate information and rationalising folder structures. This work will be ongoing, but the more obsolete information that can be deleted before and during the 'foundational' phase, the more focused later stages of the project can become, for example the programme team will not risk wasting time and effort creating structures for, or applying metadata to information no longer needed by the business.

    - Only dealing with information that has ongoing business value (or needs to be retained for legal/ statutory requirements) will also enable us to better judge the volume of data that will need to be managed, even in the event that we are only left with information that has ongoing business value, it is not anticipated that all of this information will be migrated, during the foundational stage we will establish a broad strategy, including migration principles that will help identify information suitable for migration, these are likely to be guided by factors such as how often the information is accessed and its quality.

    - Our strategy and principles will be tested and refined as part of early pilots and in the early stages of the roll out.

Timeline and key activities

Foundational phase

67. The approach proposed by Capgemini in their report on the digital workplace strategy is summarised in the diagram below (fig. 1) with a timeline (fig. 2). There will be an initial 4-6 month 'Foundational' phase which will focus on:

    - Designing key information/records management policies (e.g. retention and disposal rules, business classification scheme, basic metadata application)
    - Establishing SharePoint governance, including how access and security will be managed and monitored.
    - Assessing business readiness for the changes and migration of data

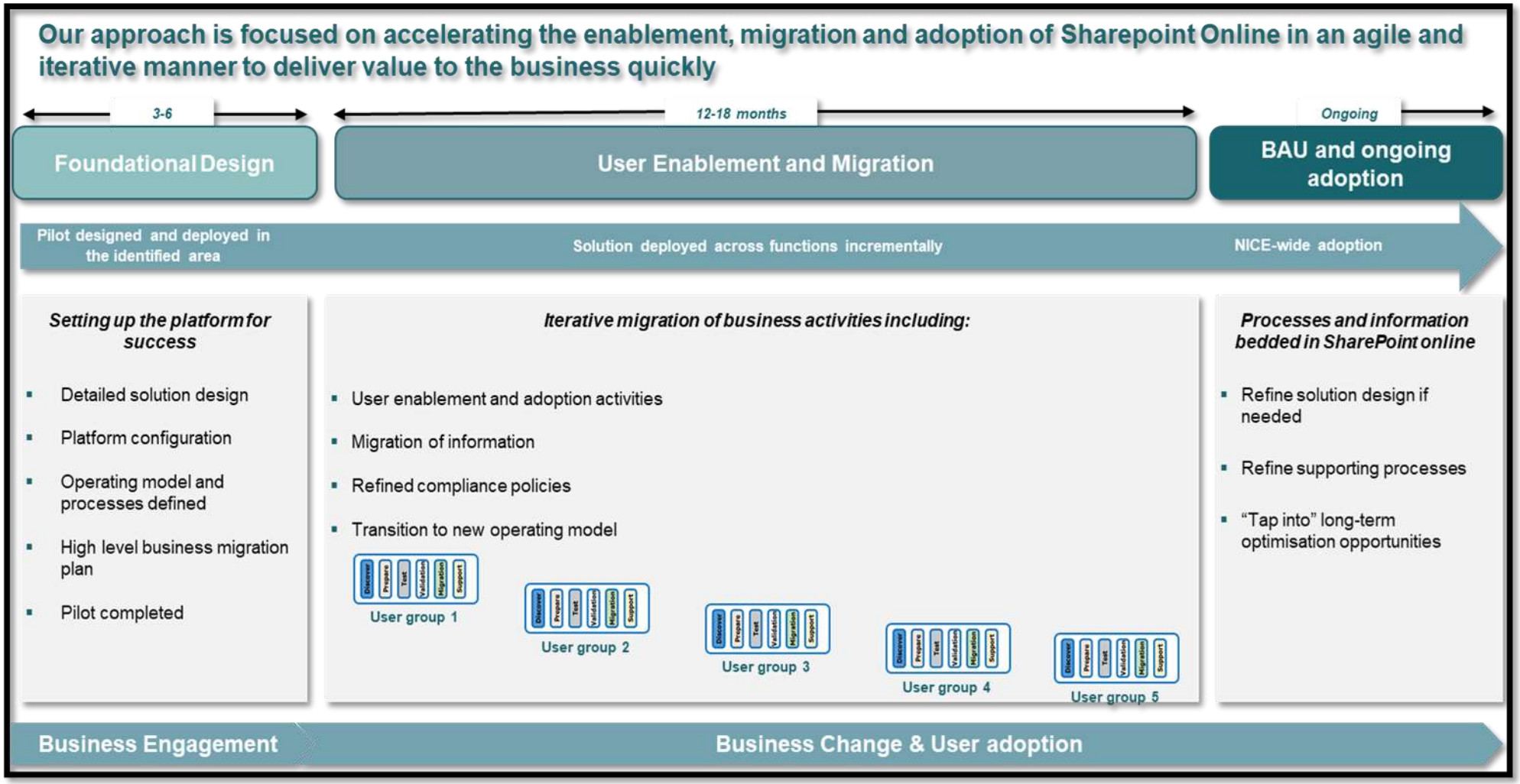
68. This will involve exploring and defining our approach to 3 key decision points:

    - That we should take a phased transition and data migration approach to SharePoint rather than 'big bang' implementation – and as a result consider how staff will work for a period of time in two different systems, including mitigating risks of staff not knowing where information is stored or continuing to use the familiar network drives when they should be working in SharePoint
    - That we should take a functional approach to the SharePoint implementation and design structure
    - Defining and clarifying what information to migrate, and what standards to apply

69. Early small-scale pilots will also start to run from the middle of the Foundational phase to enable an agile approach to quickly iterating initial design work on SharePoint sites and structures, document classification and metadata and the sharing, security and migration of information to meet user and business needs.

70. A plan for the next phase of deployment and migration of information will be produced before the programme can move to the next phase.

Fig. 1 High Level Approach



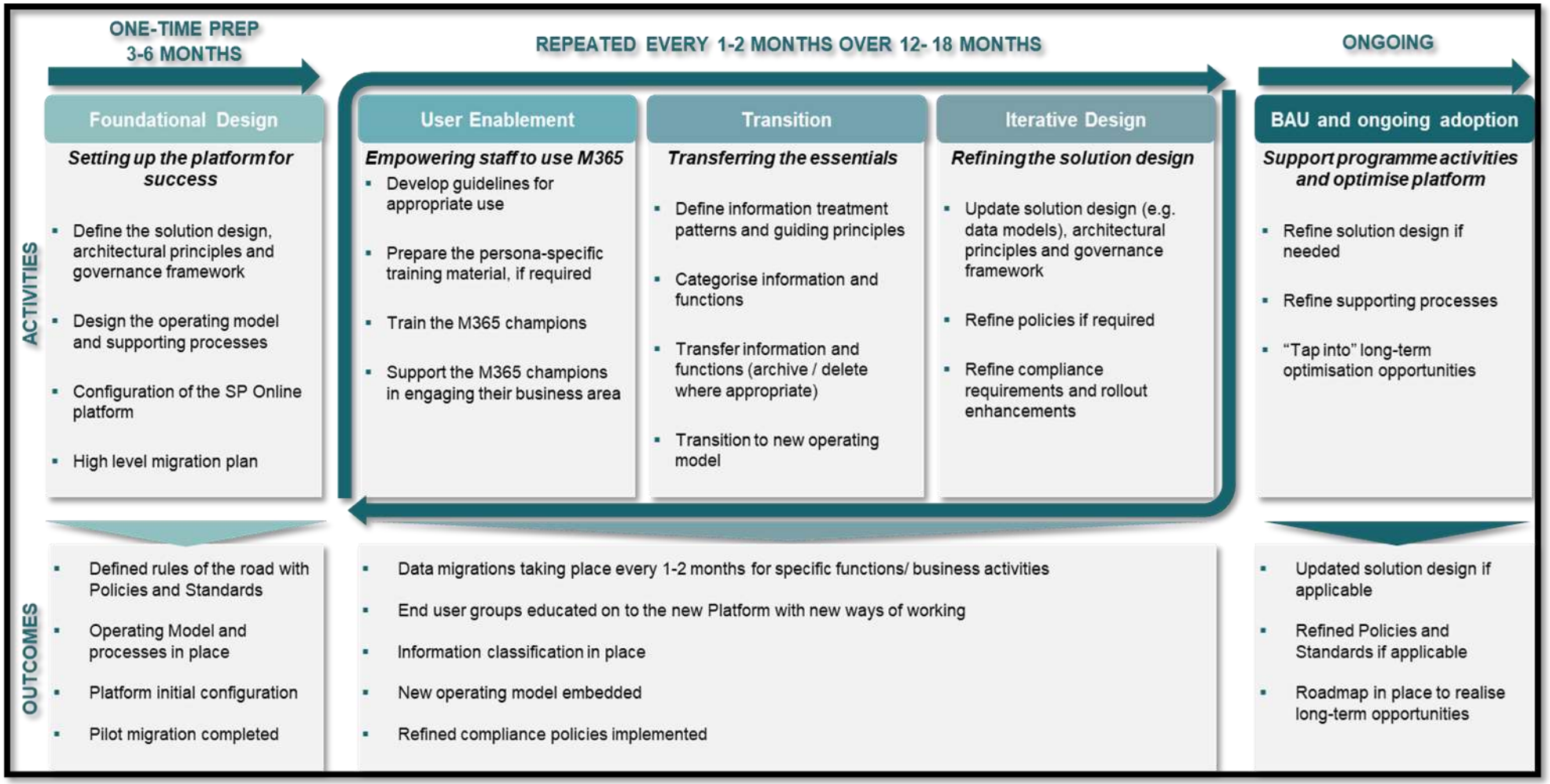
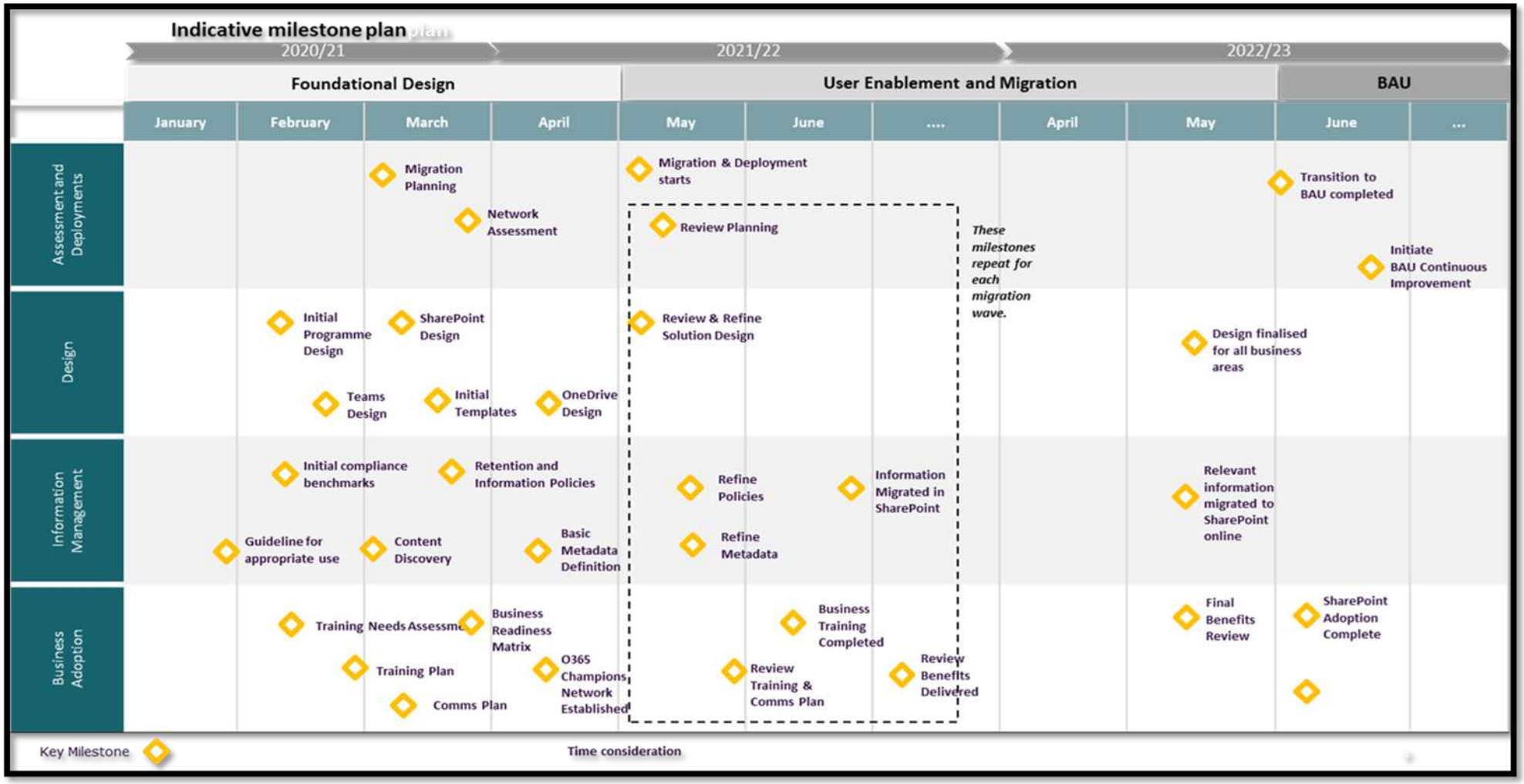

ONE-TIME PREP
3-6 MONTHS
REPEATED EVERY 1-2 MONTHS OVER 12- 18 MONTHS
ONGOING
Foundational Design
Setting up the platform for success
Define the solution design, architectural principles and governance framework
Design the operating model and supporting processes
Configuration of the SP Online platform
High level migration plan
User Enablement
Empowering staff to use M365
Develop guidelines for appropriate use
Prepare the persona-specific training material, if required
Train the M365 champions
Support the M365 champions in engaging their business area
Transition
Transferring the essentials
Define information treatment patterns and guiding principles
Categorise information and functions
Transfer information and functions (archive / delete where appropriate)
Transition to new operating model
Iterative Design
Refining the solution design
Update solution design (e.g. data models), architectural principles and governance framework
Refine policies if required
Refine compliance requirements and rollout enhancements
BAU and ongoing adoption
Support programme activities and optimise platform
Refine solution design if needed
Refine supporting processes
"Tap into" long-term optimisation opportunities
ACTIVITIES
OUTCOMES
Defined rules of the road with Policies and Standards
Operating Model and processes in place
Platform initial configuration
Pilot migration completed
Data migrations taking place every 1-2 months for specific functions/ business activities
End user groups educated on to the new Platform with new ways of working
Information classification in place
New operating model embedded
Refined compliance policies implemented
Updated solution design if applicable
Refined Policies and Standards if applicable
Roadmap in place to realise long-term opportunities

Fig. 2 Indicative timelines with mobilisation work starting in October



Success criteria

71. The Foundational phase will be deemed completed when the following are in place and have been accepted by NICE as meeting expected quality standards:

    - A business readiness matrix has been completed and the following defined as a result: an M365 training programme plan, a migration strategy and migration engagement process and plan
    - Agreed scope of data cleansing and preparation (prior to migration) across business teams has taken place
    - Governance and compliance decisions have been taken and needs defined resulting in: Records and information management policies, M365 security and governance models, a SharePoint structure and site templates designs, an M365 detailed solution design
    - All planned pilots completed with decisions taken on whether these will now cease or transition to business as usual
    - An overarching internal stakeholder communication and engagement plan in place for the next 6-12 months

End of phase decision gate

72. End of Foundational phase is a critical governance and decision milestone and may require a pause before launching the next phase. At this point the programme will need to ensure that:

    - The success criteria listed above have been achieved to the expected standards and;
    - A roadmap for migration of business functions to SharePoint is in place
    - A resourcing plan where business teams have agreed to release of resource and key roles such as change leads and SharePoint administrators are identified is in place
    - Costs of funding next phase including role/dependency on Capgemini are clear
    - benefits are refined and reforecast based on the pilot work and measured efficiency savings
    - NICE SMT and Board are assured of progress and delivered value of work to date and approve release of budget for the next phase

Implementation phase – months 7-24

73. Once the foundation work is complete, the programme will move into the deployment of SharePoint and M365. We anticipate this will involve delivering a rolling plan of 6-8 weeks across NICE, identifying which functions and information generated are suitable for migration and how.

    - The migration strategy informed by early pilots will be agreed
    - We will identify the priority functions for realising benefits and focus on these, in an increasing level of risk and complexity of need. This will enable iterative growth as more functions and processes are brought into SharePoint, realising the collaboration benefits of shared cross-working between teams as early as possible.
    - Functions that involve the processing of highly sensitive commercial or personal information are likely to be sequenced later in the programme so that they can benefit from the ongoing learning and testing from the migration of less complex and lower risk functions. Not only will this mitigate risk but it will mean that more time and focus can be given to them to ensure that the delivered solutions are designed to effectively support the required levels of risk/complexity.

Business as usual

74. The Implementation phase will enable a regular cycle of deployment, migration of information, then ongoing use as business as usual. Business as usual will be assumed when:

    - the design work for the agreed scope for a particular business function is complete
    - the information associated with that function has been migrated and/or archived as agreed
    - staff have been appropriately trained in records management and operational governance and;
    - the roles needed to administer the SharePoint solution are recognised and in place
    - SharePoint is confirmed as the permanent repository of information generated by the function in question.

Transition and cultural change

75. This transformation will bring significant changes to current ways of working and culture. While M365 technology facilitates collaboration and automated ways of working, this makes all aspects of working practices visible and transparent. It will be very clear who last worked on a document, when 'approvals' for decisions have taken place and how and where a document has been shared.

76. The Corporate Office and Digital, Information and Technology team (DIT) will receive ongoing reporting on usage, management of information and compliance with policies. In addition, features such as 'e-Discovery' and ability to technically 'freeze' information when needed to support an investigation, subject access or freedom of information request means that ways of working will be tracked and scrutinised much more heavily in a way not possible with the network drives.

77. Overall, business teams and functions will become visibly accountable for ongoing management of their information within the SharePoint sites they manage and access. They will need to commit to identifying people that will be responsible for managing their SharePoint sites both during the implementation phase and as part of busines as usual which may impact job roles and responsibilities.

78. This level of change will require dedicated resource to help teams identify the impact of change, make the change happen, and embed it for the longer term. This programme will work closely with the People, resources and governance expert group (PRG) to ensure best practice approaches to change management aligned with other Connect planned outputs such as producing an organisational development and skills analysis plan.

Business teams' resource commitments

79. This programme will require a high level of resource commitment from the whole organisation which should not be underestimated:

80. Foundational phase:

- staff input into workshops and consultations on new governance and polices such as the business classification scheme, metadata model, information security classification policy, retention schedule and appropriate use policy
- preparatory 'cleansing' of shared drives– deleting obsolete and duplicate information and preparing information for migration
- for those (estimated 6-8 people at a time, from across NICE) involved in pilots up to 50% of FTE for 6-8 weeks

- input and planning of business change leads (see below) to support initial planning in preparation for implementation

81. Implementation phase:

    - in line with the ‘function by function’ rollout and migration approach there will be intense 2-month periods where individuals will undertake adoption of the new solution and manage information migration on behalf of their team (again, estimated 6-8 people at a time, up to 50% of their time for 4-6 weeks)

    - ongoing input of business change leads to manage change within directorates and centres

    - identification of who will take on managing a team/function SharePoint site as part of their BAU role and attendance at relevant training

    - mandatory training of all ‘users’ of a new SharePoint functional solution so they can use it as part of BAU covering both technical and records management and governance aspects

82. Business as usual:

    - ongoing administration and management overhead for SharePoint Owners for each function/team

    - ongoing mandatory training for new staff and where existing roles and responsibilities change

    - ongoing communication and training as Microsoft release new features and functionality that NICE adopts

Programme resourcing and governance

83. This programme will require close governance, in particular to support risk, benefits tracking, budget and internal stakeholder management. The business expectations are high and most teams are extremely keen to use new technology; however, understanding and awareness of the complexity and commitment required is currently low outside the core team involved. In addition, the programme will need to make difficult decisions regarding selection and sequencing of business functions for both piloting and onboarding to SharePoint which may not meet all teams’ expectations of priority.

84. The programme will need programme governance and a programme board which both holds the delivery team to account and supports stakeholder management throughout the business. It is proposed that the SMT senior

accountable owner will be the Director of Digital, Information and Technology with further programme board attendees to be agreed as the programme is fully established.

85. The programme board will ensure that ongoing assurance of progress and realisation of benefits is provided to SMT at regular (c. 6 monthly) stages throughout the programme. Although budget will have been approved as part of ongoing business planning cycles, SMT will be asked to continue to approve ongoing expenditure on consultancy at each of these checkpoints. SMT will be provided with a list of success criteria at each checkpoint to support assessment of readiness to proceed.

86. Delivery of a programme of this nature will require a full-time Implementation Programme Manager (day rate contractor) and an Assistant Programme Manager (band 6) for two-year, fixed term contracts to manage delivery of the programme. They will be directly supported by a full-time Business Change Manager, and part-time Communications Manager and a Benefits Manager funded by existing Connect budget. These roles will be housed within the DIT Strategy & Governance Team alongside the Head of Digital Workplace and will be accountable to the Programme Director, DIT Strategy & Governance on behalf of the senior accountable owner.

87. Subject matter expertise and leadership for the programme will be provided by existing roles in DIT and Corporate Office: the Information Governance Manager and the Head of Digital Workplace. DIT already has some roles to support our existing use of M365 within the organisational structure budget and has commenced recruitment of these. In addition, two permanent roles to support records management have been approved by SMT to increase capacity and capability within the Corporate Office team.

Provision of external expertise - strategic supplier partner

88. M365 expertise will be sourced from the Capgemini contract which was competitively procured under the Crown Commercial Services Digital Outcomes framework. This runs for a two-year period to provide call off services to NICE for M365 including data and records management capability relating to SharePoint. The contract runs from January 2020 – January 2022 with an option to extend by a further 6 months. All activity within this planned programme is in scope of the original tender and existing contract.

89. To date, NICE has committed spend on work with Capgemini of £562k. This work developed a vision, strategy and blueprint for a digital workplace for NICE covering technology, culture, benefits and governance design at a high level.

90. Current estimates provided by Capgemini indicate a further total spend of £2.5m (inclusive of VAT) over 24 months on external support for the programme; this estimate has been used for this business case but will be further scrutinised ahead of the programme commencing to ensure a most effective support model is adopted. This will include external organisational benchmarking. Further, over the lifetime of the programme, we will be continuously seeking approaches to reduce the spend where possible (dependent on recruitment to permanent roles as well as internal capability and capacity).

91. As the proposed accumulated further expenditure on Capgemini consultancy will exceed the £1m delegated threshold for Professional Services set by DHSC we will need to seek further approvals for this work before commencing. We will be seeking guidance from DHSC on how to proceed as NICE has not had to ask for approvals at this threshold before.

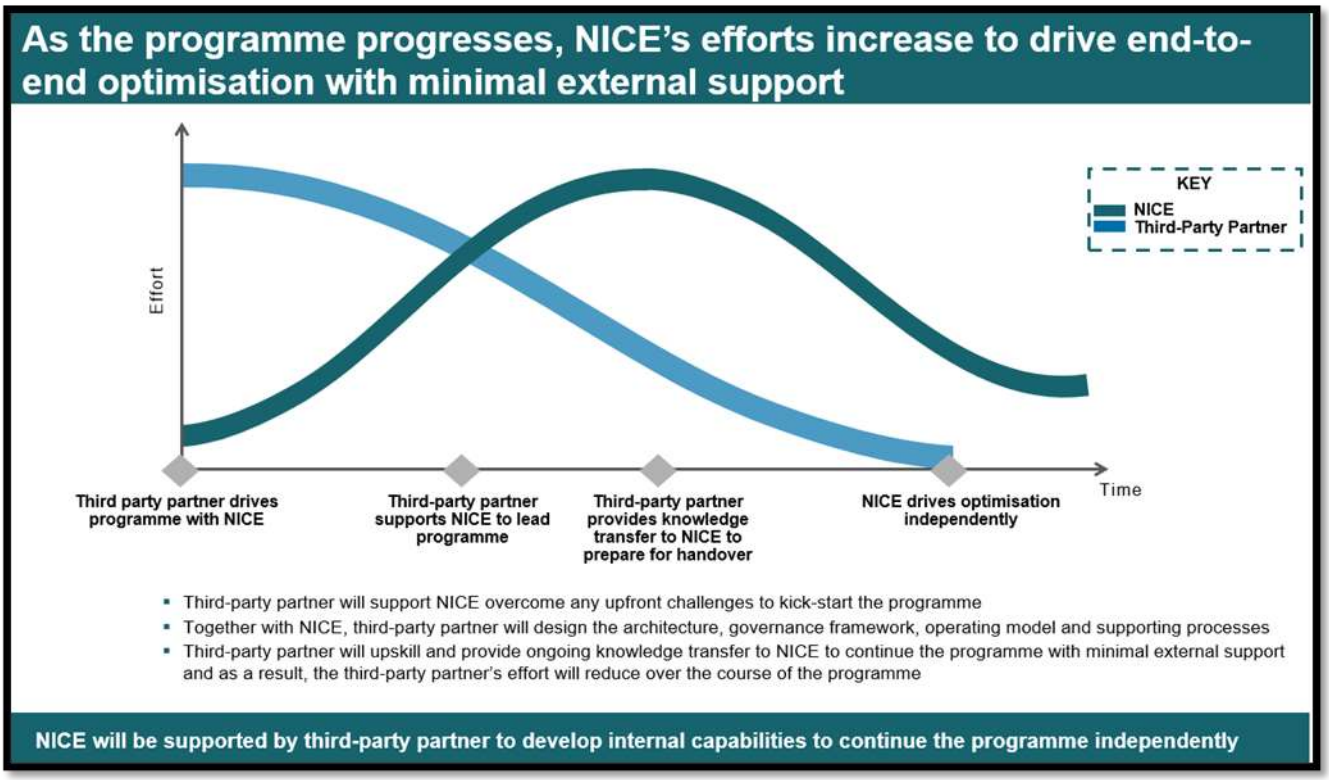
92. Capgemini will provide initial subject matter expertise to support complex, bespoke work for the first 6 months to design and deliver the technology and data architecture, governance and operating model. This involves full-time high day rate consultants and front-loads the costs (currently estimated at c£1.1m inclusive of VAT for the first 6 months).

93. Before commencing further work with Capgemini, a Statement of work (SOW) will be developed with a full breakdown of roles, costs and deliverables for the initial 6 months. The staffing model put forward by Capgemini for this critical phase will be further scrutinised over the coming months to ensure no duplication with internal roles and to ensure there is sufficient internal capacity to absorb and support the advice and support provided by these external experts. The SOW will be reviewed by NICE Procurement team to ensure terms and conditions are appropriate and within scope of the call-off contract and approved budget.

94. However, once Foundational phase is completed, Capgemini resource costs will reduce with less need for higher day-rate subject matter experts and more need for lower day rate resources to support activity such as data migration. The more of these repeated, operational activities that can be handed over and undertaken by internal DIT / records management staff, the less input will be needed from Capgemini over the remaining 18 months.

95. Therefore, cost forecasting assumes that NICE will be able to reduce reliance on consultancy support through the recruitment and onboarding of permanent digital and records management expert resource, who will be able to take on supporting and implementing the work as the programme and business maturity grows. See figure 4 below for the approach to working with Capgemini.

Fig. 4: NICE's approach to working with Capgemini within a strategic partnership contract



Business teams' roles and resource commitments

96. The programme team Business Change Manager will implement the Digital Workplace Communication strategy developed during the previous blueprint and strategy work with Capgemini. They will lead the development of the business change methodology and work closely with a network of business change leads in each directorate to support consistent messaging, and approaches to enabling and embedding changes.

97. Business Change Leads will be required from the business teams on an ongoing basis to enable changes to process and ways of working to become embedded. These resources will manage delivery of the change into their business areas, undertake training on their new processes or ways of working, cascade programme communication and guidance and work to ensure benefits are identified captured and realised.

98. We will need to identify and agree individuals who are able to represent multiple teams in a centre/directorate with a detailed knowledge of those activities and the impact of SharePoint and M365 on them. At present the total number of these resources is unknown but for each individual we assume to require 0.5 – 1 FTE based on the number of teams they will be asked to represent and support as a business change lead for the lifetime of the programme.

99. There is currently NICE Connect budget to backfill up to 4 FTE to support business change with our current assumptions requiring a total of 10 FTE from across NICE. The additional 6 FTE backfill estimates contribute £642k of the additional pay budget that is requested for the programme over the 2-year period.

100. Before confirming this approach and utilising this budget, it will need to be discussed pragmatically with each directorate as it is unlikely that single full-time individuals will be seconded for long periods. It is more likely that a number of individuals will be needed on a part-time basis for perhaps two months at a time. Therefore, it may be more practical to absorb into business as usual rather than seek backfill resource. Each directorate or centre may prefer a different approach based on their needs.

101. Business Change Leads will be further supported by M365 Champions who will be individuals who are enthusiastic about adopting and testing new features and communicating to others in their team. They will be part of a user group that will feedback on their experience of new technology and how their teams can be better supported in adoption. This role requires less ongoing resource commitment but will need to carry through into business as usual. This is assumed to be up to 2 days per month ongoing (unless the Champion is also part of a pilot or function undergoing migration). It is proposed that this is absorbed within BAU resource by business teams.

102. SharePoint Owners will be required during the lifetime of the programme and as a key ongoing BAU role. Their responsibilities will need to be reflected in changes to job descriptions. They will receive a more in-depth level of training on SharePoint and manage the site for one or more functions. Depending on what is defined by the new governance policy for SharePoint, this role could typically manage sites including enable access to the information held, and working with central owners to add pages or subsites, adding new apps and features. Resource commitment is up to 0.5 FTE during implementation but will reduce to c. 2 days per month per team/function once migration to business as usual has taken place. It is proposed that this is absorbed within BAU resource by business teams.

Estimated costs

Overall Estimated Programme Cost

103. The following table shows the projected overall cost of the programme of £4.97m. This includes both budgeted costs and non-budgeted costs and gives an illustration of the resource required across the organisation to deliver the rollout of SharePoint and M365 over the 2-year period. Consultancy expenditure are presented inclusive of VAT.

Table 4 - Summary of 2-year programme cost (Jan 2021 - Dec 2023)

	2020-21 £000s	2021-22 £000s	2022-23 £000s	Total £000s
Pay	277	1,108	831	2,216
Non-Pay	568	1,430	751	2,749
Total Cost	845	2,538	1,582	4,965

Funding requirement

104. Existing business plans and indicative business plans for subsequent years contain much of the expected cost, but there is currently a shortfall of £1.36m to deliver the programme as planned. This is explained in the table below.

Table 5 - Summary of 2-year funding requirement (Jan 2021 - Dec 2023)

	2020-21 £000s	2021-22 £000s	2022-23 £000s	Total £000s
Total Cost	845	2,538	1,582	4,965
Within existing financial plan*	(676)	(1,862)	(1,067)	(3,605)
Funding Requirement	169	676	516	1,360

** business plan for 2020/21 and outline Connect programme costs approved by the Board in September 2019 for subsequent years.*

Table 6 - Make up of additional budget requirement

	2020-21 £000s	2021-22 £000s	2022-23 £000s	Total £000s	Recurrent £000s
Pay	141	566	424	1,132	0
Non-Pay	28	110	91	229	60
Total Cost	169	676	516	1,360	60

105. Following completion of the programme there is £60k of non-pay recurrent costs that are also not currently budgeted for.

106. A request has been submitted for this additional funding as part of the Comprehensive Spending Review (CSR) currently being assessed. At this point, the programme is dependent on this funding to proceed. If this funding is not approved, given the strategic and operational importance of this programme to NICE, we will continue to seek other sources of funding, including through further negotiation with the DHSC.

Pay costs

107. A significant proportion (£1.1m) of the programme pay costs are already funded from existing directorate budgets or money allocated to NICE Connect.

108. Of the additional £1.1m that is required for the programme over the 2 years, there is no recurrent commitment.

Non-pay costs

109. Non pay costs are predominantly associated with consultancy support (assumed to be Capgemini). Funding for this (£2.5m inclusive of VAT) is assumed in this costing to come from the existing NICE Connect non-pay budget. The profile of expenditure with Capgemini would frontload £1.1m of investment in the first 6-month period.

110. The remaining £229k is currently unfunded and predominantly provides for training and contingency. Of this, £60k is a recurrent commitment.

The First 6 Months

111. An investment of £338k is required for the initial 6-month pilot phase of the programme (Jan 21 to June 21), over and above existing budgets. This is split between pay - £283k, and non-pay - £55k.

112. The investment within 2020/21 (£169k) is expected to be funded from underspend this financial year.

113. The following table is a high-level summary of the first 6 months:

Table 7 - Summary of additional budget requirement - first 6 months

	Jan-Jun 21 **£000s**
Pay	283
Non-Pay	55
Total Cost	338

Ongoing budget and business case assurance

114. The programme will return to SMT at agreed key milestones with a revised business case and report on benefits realisation and request approval for the next tranche of budget. These checkpoints will be scheduled on commencement of the programme.

Risks to Delivery

Risks to delivery

115. The table below identifies the key risks to the delivery of this programme. These will be managed as part of ongoing risk and issue management within the programme and overall Connect programme governance procedures.

No	Risk	Impact	Mitigation
1	Recruitment to the 'core' delivery team is unsuccessful – unable to recruit the specialists required. May need to continue to rely on contractor resource, thus increasing costs.	High	Contingency budget built in and regular financial reviews to consider resourcing position, i.e. should the need arise to procure additional contract backfill until recruitment is successful.
2	Teams across NICE are unable to release sufficient resource to engage with the programme impacting timescales and requirement gathering.	High	Programme discovery to define a roadmap and sequencing for pilots, estimating business team resource needed as a priority Timely engagement with teams to secure resource needed against the roadmap Pilots kept small and incremental Consideration of delay to the programme if resource is unavailable
3	Resources released by business teams may not have the skillsets required to undertake the roles they have been assigned e.g. Change/ M365 champions	High	Draw on change management capability sourced as part of the 'core' delivery team to support staff with the business change aspect of the roles Training resource to provide ongoing – priority support to M365 champions Job descriptions to be created outlining responsibilities – to be circulated to teams to help understand skills required

			During the mobilisation of the team identify training and workshops to upskill resources
4	Unable to utilise the strategic contract with Capgemini to deliver this business case resulting in a significant delay to the project.	High	Director of DIT working with Associate Director of Finance to clarify process
5	Assumptions made regarding implementation approach may not represent the full requirements of the end programme and therefore impact the costs or time to deliver – in particular our assumptions about the level of information to migrate could be too low	High	Phased approach to pilots will allow assumptions to be tested and refined so that prioritisation and decisions can be made within any fixed budget or timeframe required Migration principles and strategy established and refined during foundational/ pilot phase to provide a clear framework for information migration
6	Business awareness of the programme remains low – impact on ways of working and job roles is not understood. Support for and uptake of new technology is low.	High	Business Change manager will be responsible for producing a communications plan for this programme and work with the communications directorate and transformation unit Utilise the communications strategy developed by Capgemini during their discovery work Business Change Leads will help disseminate messages cascaded from the Business Change Manager Early awareness raising through current governance mechanisms (Connect steering group, DMEG, PRG)
7	Business expectations relating to M365 capability and the required speed of implementation are not realistic. Many teams are lobbying to 'be first' in relation to pilots – this pressure could	Medium	Ensure robust approach to pilot selection for value and risk mitigation of the full programme Strong programme management and business change leadership used to manage expectations and clearly communicate priorities Roadmap developed and communicated to business Clear objectives and goals mapped to benefits realisation

	compromise scope and objectives impacting benefits realisation.		No change to scope without formal assessment and agreement
8	Business teams will need to work across SharePoint and network drives simultaneously– this could result in slow benefits realisation and slow uptake of new ways of working, or a rejection of new tools if staff prefer the familiar 'old' systems	Medium	Clear governance agreed as part of pilot planning with risk assessment on impact on files/versions etc Clear rollback plan should a pilot site need to be deleted or restructured Clear communication with team before committing to the pilot on the risks and impact on resourcing and information Clear plan on making folders/ network drives read only as new functions are transferred to SharePoint to prevent staff reverting back to old/ familiar tools.
9	Capgemini may not be able to provide expertise consistent from previous phase of programme	Medium	Capgemini will be responsible for mitigating this risk through appropriate handovers; they will have a contractual commitment to deliver to our agreed standard and provide appropriate expertise to enable this.

Conclusion

116. The implementation of SharePoint and M365 will be a significant investment of NICE resource and budget over the lifetime of the programme but is forecast to deliver benefits to the organisation that will support fast and more efficient ways of working in the longer term for our internal staff users and external collaborating partners.

117. Implementation of SharePoint and M365 are also enablers of other NICE Connect goals that will transform the presentation of our guidance and advice for end users.

Issues for consideration

118. Additional budget is required to deliver this programme as scoped. This has been requested through the CSR process which is currently under assessment.

119. Business teams will need to support the release of individuals who hold 'corporate knowledge' on team processes to enable new ways of working to be designed. Some of these costs may be backfilled but some may require absorption into day to day activity. The scale of this is yet to be determined.

120. Whilst the programme is forecast for 2 years, we will return for additional approval at key milestones to ensure budget and benefits management in line with best practice programme management processes.

121. Prior to commencement of the full programme, additional approval will be sought from DHSC as the proposed accumulated further expenditure on Capgemini consultancy will exceed the £1m delegated threshold set for Professional Services.

122. Over the next couple of months, additional work will be undertaken to further scrutinise the value for money of the proposed approach, including seeking organisational benchmarking of the estimated internal and external cost of the programme. The Board will be updated prior to commencement of the initial 6 months of work.

Issues for decision

123. The Board is asked to:

- Note the indicative forecast costs of the full programme of £4.97m over 24 months and that £1.36m of this is currently not contained in existing or indicative future business plans.

- Approve proceeding at risk with preparing for a kick-off of the programme in January 2021. This requires immediate fixed term recruitment and commercial planning with Capgemini.
- Approve commencement of the subsequent 6-month phase of work from January 2021 conditional on the following being completed ahead of that date:
  - Confirmation of the successful outcome of the CSR to provide a source of funding for this programme;
  - SMT assurance that robust governance processes have been established to provide on-going financial and delivery scrutiny;

124. In the event of the CSR request being unsuccessful, we will return to the Board at the earliest opportunity for discussion regarding the best way to move forward.

Appendix A - The M365 suite of applications

Name	What does it do?	Features & benefits	Typical user
SharePoint	Document Management & Collaboration Central hub which interfaces with other services	Enables functional 'sites' to be created where documents are managed collaboratively between groups. Records management policies, monitoring and reporting is applied and automated. Document metadata is applied aligned with an organisation taxonomy enabling consistent categorisation and easy searching of information Access permissions can be managed to enable internal and/or external people collaborating together	Intensive users – core NICE roles e.g.: Analysts, project managers, business managers, digital specialists; anyone managing processes, information reporting or documents needing wide circulation, reviews and version control
OneDrive	Personal document storage	This acts as someone's own portable personal file store, perfect for mobile and flexible working Offline synchronisation File protection from hardware failures	Intensive users – staff who travel regularly or work across different devices Intermediate users– line managers who hold staff personal /performance data
Exchange Online	Online email management Web access	Increased storage E-Discovery– 'ability to perform legal searches to freeze all content based on certain criteria to prevent deletion, editing, downloading, etc.'. Integration with web conferencing booking, meeting rooms and resources, teams, Skype in terms of notifications. Staff can organise meetings within Teams and it transfers directly into the calendar. FindTime functionality – like Doodle poll	Intensive users – all staff

Delve / Graph API	Intelligent search engine across M365	Relevant targeted and personalised searching, based on their understanding of you, your colleagues, and the broader organisation Filtering and parameter searches	All staff
Power Automate	Business workflow engine Document approval based	Automation of manual tasks (e.g. sending a document for approval and publication, providing management / exec summaries of complex data) Automation of manual tasks Process re-modelling	Intensive users - anyone involved in the document creation and publication space
Power BI	Data surfacing application Intelligent dashboard modelling Connectors into multiple cloud platforms	Data consolidation Management / exec reporting Cloud share of data Can bring together data from multiple sources and automatically present it in a dashboard Reduces manual analytics tasks	Intensive users – Finance, data analysts, anyone who needs to develop dashboard. Intermediate users – Back office staff who have to develop forms, such as the comms team for surveys, Finance for expense forms, etc.
Forms	Online form creator Logic driven & device friendly	Simple form creations Data surfacing to simple interfaces Forms are currently in Excel or Word and are difficult to populate and collate. This will significantly reduce the manual work required to develop and collate data from a form.	Intensive users – all staff.
Teams	Communication and team collaboration Replacement for Skype and OCS	Team communication (video, messaging, document focused) Reduces the number of emails sent Teams is the hub where everything comes together – calls, web conferencing, share documents etc.	Intensive users – all staff Around 30% - 50% of staff already use Teams. It is fully embedded within Digital Services.

Planner	Task based activity management Dashboard reporting	Provides project task control and management, very task based, where you don't need a comprehensive critical path and dependencies – any scenario where you need a lot of tasks	Intensive users – any teams that run projects or need task management for a collaborative group
Office Online	Office applications (Word, Excel)	No more service pack and version updates Simultaneous online commenting and updating with multiple people – collaborative editing Automatically updated	Intensive users – all staff
Sway	Web page creation service Easy to create web pages	Word to Web page conversion Display multiple media formats Can look visually impactful – moving storyboard	Intensive users – Comms & HR teams
Yammer	Social and community collaboration	Cross-team engagement Development of NICE employee identity	Intensive users – any teams wanting to network and push information out to external groups
Stream	Media hosting platform	Video hosting in multiple formats It will help to address current concerns on storage and retention of large video files	Intensive users – Comms, HR any teams creating training or information videos for staff

September 2020

National Institute for Health and Care Excellence

The Independent Medicines and Medical Devices Safety (IMMDS) Review: Considerations for NICE

This report gives details of the Independent Medicines and Medical Devices Safety (IMMDS) Review. It describes NICE's engagement with the Review and outlines the proposed actions NICE now needs to take. In addition, it provides analysis of the potential opportunities offered to NICE by the Review's recommendations.

The Board is asked to:

- Note that NICE has already taken steps to improve collaborative working with system partners to ensure a more integrated approach to patient safety and support that this work continues
- Note the recommendations and actions for improvement from the IMMDS Review
- Consider and approve the proposed responses in regard to the specific issues highlighted by the Review which relate to the work of NICE. Specifically that NICE should:
    - commit to undertaking an exceptional review of NG123: urinary incontinence and pelvic organ prolapse in women: management
    - consider how to facilitate the production of a single and collaboratively produced patient decision aid
    - work with NHS X and other system partners to co-create databases and registries which could be used to inform our guideline development
    - work with regulators and professional organisations to reinforce the use of NICE guidelines through their professional standards and inspection or accreditation processes
- Support the proposal that NICE engages with and supports other system partners in a co-ordinated system response to the IMMDS Review. This will be overseen by the DHSC.
- Note that the proposals outlined in this paper may have resource consequences; this will be the subject of further work and consideration by SMT.

Professor Kevin Harris

Programme director and clinical advisor – Interventional Procedures Programme / NICE SRO for Patient Safety

September 2020

Introduction

1. The IMMDS was announced in the House of Commons on 21st February 2018 by Jeremy Hunt, the then Secretary of State (SoS) for Health and Social Care. The purpose was to examine how the healthcare system in England responds to reports about harmful side effects from medicines and medical devices and to consider how to respond to them more quickly and effectively in the future.

Background

2. Baroness Cumberlege was asked to chair the Review and to specifically look at:

    - Primados (a hormonal pregnancy test – withdrawn from sale in UK in 1978)
    - Sodium Valproate (in pregnancy) and
    - Surgical Mesh (for pelvic organ prolapse and stress urinary incontinence).

3. Baroness Cumberlege developed her own terms of reference which broadened the scope of the Review beyond these three specific themes. In particular it was the intention from the outset that:

    "the Review may make additional recommendations that bear on the healthcare system's response to, and responsibility for, patient safety issues, having considered the effectiveness of the relationships between those public bodies and commercial interests that have a role to play in bringing safe medicines and medical devices to market, in post-marketing surveillance and in responding speedily and appropriately to safety concerns when they need to. Whilst not seeking to redesign the regulatory framework, the Review may comment on aspects of it, including how the reporting of patient safety concerns may be improved."

4. The Review team consulted widely with a wide range of system partners as well as patients and their families. It was explicit from the beginning of the Review that in the three specific cases that the system had not responded in a rapid, open and compassionate way to resolve issues when they were raised in the way that the SoS would have expected. However, it was also acknowledged that such failings might be much more widespread and generalised and not different for other surgical procedures and devices or other medications.

5. In July 2018 the government and NHS accepted a recommendation from the Review team that the use of vaginally inserted surgical mesh for stress urinary incontinence (SUI) should be paused until a set of conditions to ensure that patients receive safe and high-quality care are met. This pause was extended to include vaginally inserted surgical mesh for pelvic organ prolapse (POP) and

was implemented through a high vigilance programme of restricted practice. In practice all such use of mesh for SUI and POP in the NHS stopped at this point.

6. The Review was published on 8th July 2020 (the date of publication was delayed at the Review team's request due to COVID-19).

NICE and the review

7. From the start the Review team welcomed input from NICE, seeking our views and making reference to us in its public announcements (for example actions from NICE were highlighted in the conditions required to consider the lifting of the "pause" on the use of vaginal mesh).

8. Specific considerations related to the topics considered by the Review:

Primodos

9. NICE has not produced any guidance on Hormone Pregnancy Tests (Primodos) which were withdrawn in the 1970s and NICE has made no comments on this aspect of the Review.

Sodium Valproate

10. NICE has a number of guidelines in which sodium valproate is referred to. NICE has worked with the MHRA on sodium valproate and other valproate medications for women of child bearing age, since 2014. The relevant guidelines have been updated with links to the MHRA advice and a warning highlighting the pregnancy prevention plan on the guideline web page. NICE also disseminated the MHRA alerts and our response to these alerts through registered stakeholders, the NICE medicines and prescribing network and the NICE newsletters.

Surgical Mesh

11. Since 2003 NICE has published a number of pieces of guidance where surgical mesh was used, including:

    - A Technology Appraisal (TA56: 2003.) This guidance was updated and replaced by a NICE guideline on the management of urinary incontinence in women in 2006.
    - Interventional Procedures Guidance dealing with specific procedures using mesh to treat pelvic organ prolapse and stress urinary incontinence in women. These were published between 2005 and 2009.
    - Clinical Guidelines on the management of urinary incontinence (first published 2006).

12. All of NICE's guidance relating to the use of Surgical Mesh guidance typically recommended:

    - MDT selection of patients
    - Procedures were undertaken by appropriately trained surgeons
    - Detailed consent was obtained with explanation of potentially serious complications
    - Data collection was undertaken with analysis of outcomes.

13. In response to the concerns which emerged over the use of mesh, NICE decided to update all of its existing pieces of evidence based Interventional Procedures guidance relating to mesh used in the treatment of pelvic organ prolapse and stress urinary incontinence during 2016 and 2017.

14. NICE also updated its clinical guideline on urinary incontinence in women; extending the scope to include the treatment of pelvic organ prolapse. This was published in April 2019 and satisfied one of the conditions laid out by the IMMDS team for the pause on the use of vaginally inserted mesh, to be lifted.

15. NICE published patient decision aids on Urinary incontinence and pelvic organ prolapse in women: management in April 2019. The Review team contacted NICE about patient decision aids and have stated that they were impressed by the process of development of the pelvic mesh Patient Decision Aid in Ayrshire, Scotland. NICE responded to this enquiry outlining the rigour of the process employed at NICE.

16. In February 2019 NICE provided written and oral evidence to the Review.

Ongoing work during the Review

17. During the duration of the review NICE continued to work with all system partners (including but not limited to the DHSC, NHSE&I, NHS D, NHS X, the MHRA, and Royal Colleges) to implement system improvements. In 2019 NICE appointed an SRO for patient safety who helped co-ordinate this work on behalf of the Institute.

18. NICE and the MHRA have strengthened their collaborative working to make sure that where possible the processes of regulatory action and clinical guidance production are joined up and timely. For example, following the advice of the Commission on Human Medicines on the risks of anti-epileptics in pregnancy there is ongoing work to ensure the guidelines on the use of sodium valproate properly reflect this advice including consideration of guidance on switching from sodium valproate to alternative treatments.

19. Preliminary consideration has been given to how any recommendations from the Review might be implemented. Inevitably this work was speculative as the recommendations were not known until the Review was published in July 2020.

20. A number of improvements to patient safety were made in conjunction with system partners during the period of the Review. However, inadequate data collection and analysis was recognised to be one of the major issues in relation to the concerns raised around surgical mesh use. In addition it seems likely that similar issues are present for all other activities the NHS undertakes.

21. In February 2018, the Government committed £1.1m to the development of a registry for surgical mesh by NHS D. A "pelvic floor registry" is in the advanced stage of development (delayed by COVID-19). The registry is not limited to procedures that use an implanted device (such as mesh) but will collect data on all women having any type of surgery for stress urinary incontinence or pelvic organ prolapse. It is intended that patient related outcome measures will be collected as part of this pilot.

22. This registry work has been funded specifically in relation to the use of surgical mesh, but if it proves successful it would provide a model which could be implemented for data collection and analysis of outcome in relation to any interventional procedure. However, this would require provision of additional resource and at this stage there is no identified funding stream for this.

Findings and Recommendations from the Review

23. The report is critical of a number of aspects of the broader healthcare system making the point it *"is disjointed, siloed, unresponsive and defensive. It does not adequately recognise that patients are its raison d'etre. It has failed to listen to their concerns and when, belatedly, it has decided to act it has too often moved glacially."*

24. The Review recognises the NICE has a major role to play within the system. Significantly, the review recognises that guidance issued, including NICE guidelines, was appropriate to the known risks and alternatives. Importantly the Review states that *"more should have been done to ensure that healthcare professionals were aware of and following guidelines. In theory, regulators and professional organisations (such as the CQC, GMC and medical defence unions) reinforce their use through their professional standards and inspection or accreditation processes".* This view echoes the position laid out by NICE in our BMJ response to an article on surgical mesh (BMJ 2018; 363 doi: https://doi.org/10.1136/bmj.k4748 (Published 13 November 2018)).

25. The Review makes 9 overarching recommendations (listed in Appendix 1).

26. None of the 9 recommendations have specific actions for NICE to consider. However, recommendation 7 *(A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures)* could offer significant opportunities to enhance the future work of NICE.

27. The Review also identified a number of "Actions for Improvement" which were organised into 11 themes. Some of the actions for improvement did include suggestions for NICE to consider and this paper further elaborates on these.

28. Subsequent to the publication of the report, the Government has:

    - Issued an apology for the time the system took to listen and respond
    - Thanked Baroness Cumberlege, for carrying out her work with thoroughness and compassion
    - Acknowledged that the response to these issues from those in positions of authority has not always been good enough
    - Pointed out that while the review has been progressing, the Government and the NHS have taken a number of steps relating to the concerns it has raised
    - Committed to taking time to give the review the full consideration that is absolutely deserves.

Issues for NICE to consider

Sodium Valproate:

29. Although there are no direct actions for NICE with regard to sodium valproate, there are opportunities for NICE to work with other stakeholders including the MHRA and patient groups to:

    - advise on the establishment of a prospective registry for all girls and women of child bearing age prescribed an antiepileptic drugs, to include mandatory reporting of data relating to them and their child(ren) collated over lifetimes. This registry could have the potential to help inform specific NICE guideline development in the future
    - improve the Pregnancy Prevention Programme
    - enable clinicians to follow guidance regarding prescribing of valproate and alternatives for all indications.

Surgical Mesh:

30. The Review states that:

    - *"In their guidance NICE have consistently stated that pelvic mesh should remain available, that the benefits outweigh the risks. In our view such a stance does not fully reflect an understanding of all the risks. As we have outlined above, adverse outcomes are not always reported in the medical literature. NICE's most recent guidance states that the TVT-O should not be offered routinely. In the future, we feel the TVT-O should only be used in exceptional circumstances, if at all."*
    - *"There is currently no consensus among specialist surgeons over the relative risks and benefits of full and partial mesh removal, or which techniques and approaches should be offered, and hence over what is best for each woman. NICE is silent on these matters." "We strongly recommend that NICE actively monitor the situation and update their guidance promptly once a consensus has been reached."*

31. The Clinical Guidelines team have reviewed the IMMDS Review and consulted with the Topic Adviser for Urinary Incontinence for the Clinical Guideline.

32. The topic advisor for the Clinical Guideline has advised that NICE's guidance with respect to TVT-O is already essentially the same as that suggested by the IMMDS Review, although worded slightly differently. (NICE currently recommends: "Do not offer a transobturator approach unless there are specific clinical circumstances (for example, previous pelvic procedures) in which the retropubic approach should be avoided.")

33. Currently NICE does not make a specific recommendation on the relative risks and benefits of full and partial mesh removal, or which techniques and approaches should be offered.

34. To address these points raised and subject to a direction from the Board, and Guidance Executive approval, SMT agreed to commit to undertaking an exceptional review of NG123: urinary incontinence and pelvic organ prolapse in women: management.

Patient Decision Aids:

35. The Review states that:

    - *A single patient decision aid (or core set of information) should be produced for each surgical procedure or medical intervention, co-designed by patients and clinicians. The National Institute for Health and Care Excellence (NICE) should take the lead on facilitating this.*

36. SMT have proposed that NICE should undertake further work to scope how it might take a lead in collaborating with the health system on the production of patient decision making aids for each surgical procedure or medical intervention. Preliminary discussions with system partners suggest that they would welcome NICE taking a lead on this work. However, this is a potentially complex and resource intensive task which will need to consider the methods for the production of the aid, its quality assurance, how it is optimally presented and how best it might be validated. It is recognised that in due course the functionality offered by "NICE Connect" could prove a significant enabler to this work. In the interim, the exact form this activity would take and how it would be resourced would need to be further considered by SMT following completion of the scoping work.

Data Collection:

37. The Review recommends that:

    - *A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures. Patient reported measures such as Patient Reported Outcome Measures (Recommendation 7)*
    - *(PROMs) and Patient Reported Experience Measures (PREMs) should become common currency in the assessment of the benefits and risks of current and new interventions.*

38. NICE proposes to work closely with NHS D, NHS X and the MHRA to advise on the DHSC response to recommendation 7.

39. It is recognised that the co-creation of newly established databases and registries has the potential to help inform NICE's guideline development. A focus on the collection of clinical outcome data which could be linked to data from post market surveillance, will in itself provide a step change in the monitoring of safety and efficacy of interventions and therefore be of enormous benefit to both patients (at an individual level), to regulators and to guideline producers. Where registries are subsequently created, NICE has the expertise and experience to ensure they are of sufficient quality to support its work. In addition, such a database could also capture spend/cost data which would be beneficial in terms of information that enables continuous monitoring & evaluation of the value of an intervention.

40. The Medicines and Medical Devices Bill (necessary UK legislation that is required as a result of Brexit) could provide an opportunity to implement an effective response to this recommendation. NICE will also work with MHRA on

this as they move forward in implementing the necessary work in the UK on device regulation and approval.

Guidance implementation:

41. The Review identifies that:

    - *Annual appraisal of doctors should include providing evidence of awareness of relevant guidance in the doctor's area of practice. Colleagues should report failure to follow guidance which is detrimental to patient safety. This should apply in the private or independent sector as well as in the NHS.*
    - *The GMC should be alert and act, if any doctor's practice causes concern in respect of failure to follow guidance.*
    - *Hospitals should encourage clinical audit and should have robust systems for monitoring quality at Board level. The Care Quality Commission (CQC) should also assure itself that hospitals both in the NHS and in the private sector, have robust quality assurance programmes including following appropriate guidance.*
    - *Those responsible for introducing new procedures should factor in the particular responsibilities of clinicians and organisations to monitor risks during this period, including the training time taken to acquire the necessary competencies and skills.*
    - *When the system has monitored guidance or standards, and identified an issue, there must be clarity on who is responsible for co-ordinating action, and sufficient support and resource for implementation of remedial action.*

42. These suggested actions for improvement offer a number of significant opportunities to NICE, and could further strengthen NICE's position and influence by reinforcing the use of our guidelines use through their professional standards and inspection and accreditation processes.

43. NICE will seek to strengthen collaborative working with relevant system partners (including CQC, GMC and Royal Colleges) to explore these matters further.

Recommendations

44. The Board is asked to:

    - Note that NICE has already taken steps to improve collaborative working with system partners to ensure a more integrated approach to patient safety and support that this work continues

- Note the recommendations and actions for improvement from the IMMDS Review
- Consider and approve the proposed responses in regard to the specific issues highlighted by the Review which relate to the work of NICE. Specifically that NICE should:
    - commit to undertaking an exceptional review of NG123: urinary incontinence and pelvic organ prolapse in women: management
    - consider how to facilitate the production of a single and collaboratively produced patient decision aid
    - work with NHS X and other system partners to co-create databases and registries which could be used to inform our guideline development
    - work with regulators and professional organisations to reinforce the use of NICE guidelines through their professional standards and inspection or accreditation processes
- Support the proposal that NICE engages with and supports other system partners in a co-ordinated system response to the IMMDS Review. This will be overseen by the DHSC.
- Note that the proposals outlined in this paper may have resource consequences; this will be the subject of further work and consideration by SMT.

September 2020

Appendix 1. Recommendations of the IMMDS Review

1. The Government should immediately issue a fulsome apology on behalf of the healthcare system to the families affected by Primodos, sodium valproate and pelvic mesh.

2. The appointment of a Patient Safety Commissioner who would be an independent public leader with a statutory responsibility. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices.

3. A new independent Redress Agency for those harmed by medicines and medical devices should be created based on models operating effectively in other countries. The Redress Agency will administer decisions using a non-adversarial process with determinations based on avoidable harm looking at systemic failings, rather than blaming individuals.

4. Separate schemes should be set up for each intervention – HPTs, valproate and pelvic mesh – to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim.

5. Networks of specialist centres should be set up to provide comprehensive treatment, care and advice for those affected by implanted mesh; and separately for those adversely affected by medications taken during pregnancy.

6. The Medicines and Healthcare products Regulatory Agency (MHRA) needs substantial revision particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work.

7. A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures.

8. Transparency of payments made to clinicians needs to improve. The register of the General Medical Council (GMC) should be expanded to include a list of financial and non-pecuniary interests for all doctors, as well as doctors' particular clinical interests and their recognised and accredited specialisms. In addition, there should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians.

9. The Government should immediately set up a task force to implement this Review's recommendations. Its first task should be to set out a timeline for their implementation.

National Institute for Health and Care Excellence

Research to Access Pathway for Investigational Drugs - COVID-19 (RAPID-C19)

This report describes our progress with RAPID-C19, the multi-agency initiative enabling safe and timely patient access to medicines showing evidence of benefit in treating or preventing COVID-19. We provide an overview of the programme, its success to date, the process used to deliver NICE's activities and an insight in lessons learned.

The Board is asked to:

- confirm support for NICE's participation in the RAPID C-19 initiative
- note the interim process guide

Meindert Boysen

Deputy Chief Executive and Director, Centre for Health Technology Evaluation

September 2020

Introduction

1. The Research into Access Pathway for Investigational Drugs (RAPID-C19) is a multi-agency approach enabling safe and timely patient access to medicines showing evidence of benefit in treating symptomatic COVID-19 patients or for disease prevention.

2. It is a collaboration between NICE, NHS England and NHS Improvement, the Medicines and Healthcare products Regulatory Agency (MHRA), the National Institute for Health Research (NIHR), the Therapeutics Task Force at the Department of Health and Social Care (DHSC). Representatives from the Scottish Medicines Consortium (SMC), the All Wales Medicines Strategy Group (AWMSG) and the Northern Ireland Health and Social Care Board. NICE's Senior Management team confirmed its support for RAPID- C19, and its support for NICE's participation in RAPID-C19 in April 2020.

3. Given our expertise in translating system horizon scanning information into action, focus on appraising evidence, emphasis on structured decision making, and skills in project management, we offered to lead and coordinate the RAPID-C19 process. We decided that the team best placed to deliver on the programme would be the secretariat providing specialist skills to the Accelerated Access Collaborative (AAC) Office. Supported by others in the Centre for Health Technology Evaluation (CHTE) to ensure alignment with the guidance producing programmes.

4. The RAPID C-19 Oversight Group was established as part of this process and meets on a weekly basis. It provides a forum for the key health partner agencies in England and those in devolved nations to consider potential COVID-19 medicines in development and to prioritise those with promise for consideration of expedited patient access in the NHS and across the devolved nations.

5. The processes to deliver the RAPID C-19 initiative have continued to evolve since implementation in April 2020. To support wider understanding of this initiative and processes involved, we developed a webpage and an interim process guide which is included as Appendix 1.

6. This paper provides a summary of the process and highlights progress made, benefits to NICE and lessons learnt.

Overview of the RAPID C-19 process

7. Primary horizon scanning and initial stratification is undertaken by the NIHR Innovation Observatory (NIHRIO). It builds upon work already undertaken by the AAC in developing an integrated horizon scanning system across the

system. NIHRIO scans for all COVID-19 treatments with international trials, including all anti-virals, both anti-inflammatory and immunomodulatory, cell-based therapies and other treatments, and applies a set of filtering principles, agreed between RAPID-C19 system partners, to identify and stratify the most promising products with ongoing studies.

8. These stratified horizon scans provided by NIHRIO are reviewed by the NICE team and enriched with additional intelligence to identify candidates for consideration by the RAPID C-19 Oversight Group. Further intelligence is gathered through a combination of sources (UK and international) on individual COVID-19 medicines/therapeutics.

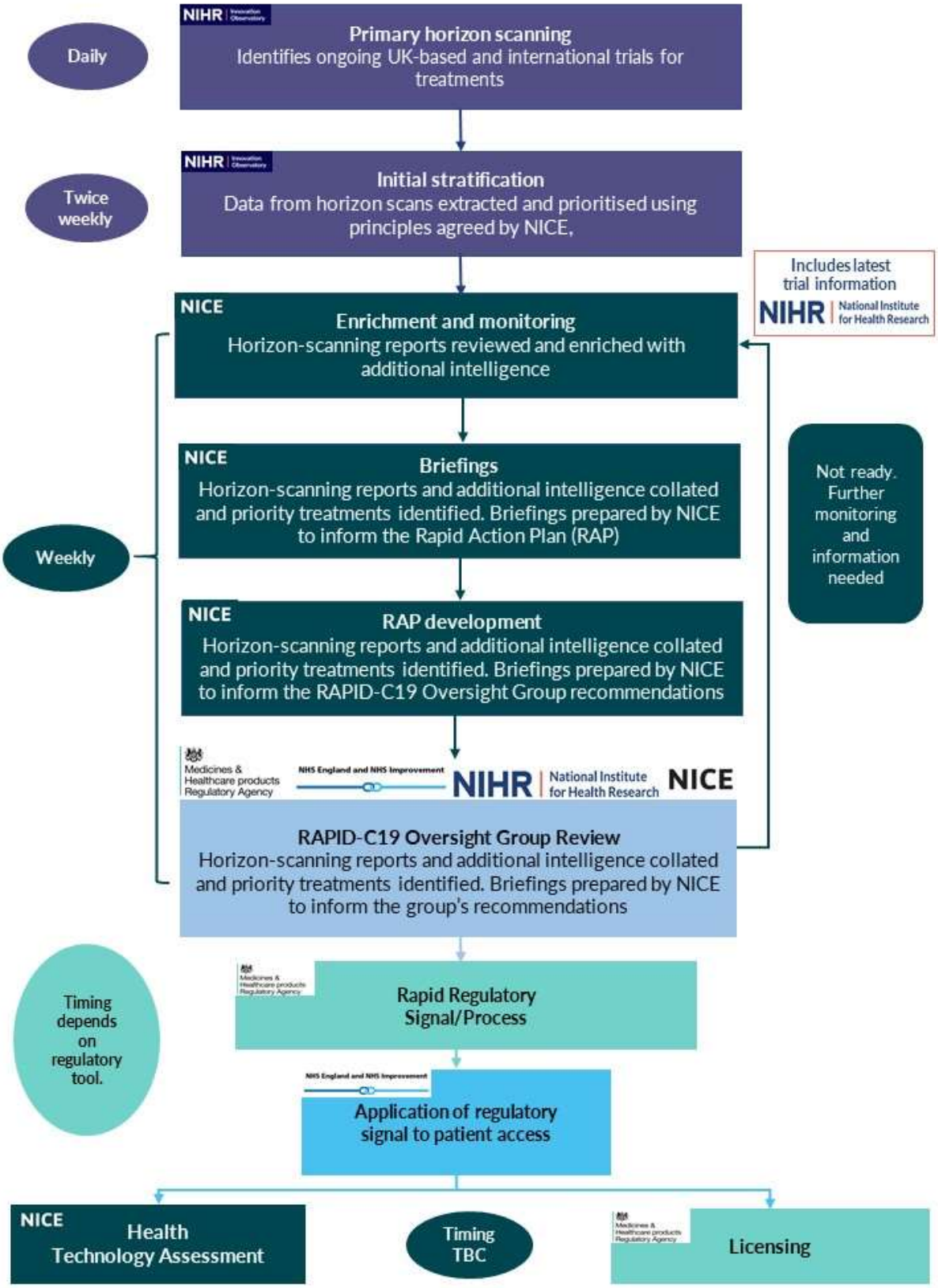
9. The NICE team prepares a comprehensive briefing on the most relevant candidate topics. These rapid action plans (RAPs) present a shared vision on the approach to deployment and patient access. Actions included in the RAPs are:

    - The MHRA will apply a rapid regulatory approach to the selected treatments
    - NHSE&I will develop an interim clinical commissioning policy
    - The Therapeutic Task Force at DHSC will explore medicine availability and supply chain to secure/purchase stock as required
    - NICE will start the HTA process and the MHRA will start their licensing process at the appropriate point in time for each of the selected treatments.

10. If the RAPID-C19 Oversight Group agrees that a topic is not at a stage where it can be prioritised or progressed for further actions, it is actively monitored. When an associated trial is due to report the briefing will be updated and presented again to the Oversight Group at the next possible meeting.

11. An overview of the RAPID C-19 process is provided in figure 1.

Research to Access Pathway for Investigational Drugs – COVID-19 (RAPID-C19)



Progress

12. Since inception the RAPID-C19 oversight group has met 19 times (correct up to 3 September 2020), reviewed 30 topics (includes 3 from outside the prioritised list referred by the TTF) out of which 25 topics are being actively monitored and 3 topics have patient access (with further trial outputs anticipated).

13. The RAPID-C19 initiative has supported rapid access in the NHS to 3 treatments:

    - Remdesivir for patients hospitalised with COVID-19
    - Dexamethasone and hydrocortisone for patients with severe or critical COVID-19 as defined by the WHO

14. Details of the prescribing arrangements for these products are communicated via the MHRA's Central Alerting System (which includes reference to a UK-wide clinical commissioning policy for remdesivir), and NICE's rapid evidence summaries and prescribing advice.[1]

Benefits and lessons learned

15. Being a key contributor in RAPID-C19 places NICE in a unique position to contribute to an initiative that has demonstrated unparalleled collaboration across system partners. We have been instrumental in developing and delivering a multi-agency trust based working relationship in an environment more conditioned to working in silos. The team has developed a strong coordination role in the RAPID-C19 process which has resulted in the multiple agencies working closely, sharing information and acting more collegiately, balancing individual organisation remits to deliver a shared outcome.

16. By chairing the RAPID-C19 oversight group and by leading the coordination of activities, we are able to plan a clear set of proactive actions to take when a promising clinical signal is generated from a relevant clinical trial to enable medicines to be available to patients in an expedited time frame. Briefings/RAPs developed by the NICE team enable system partners to make clear and efficient decisions for regulatory considerations (MHRA), interim clinical policy development (NHSE&I) as well as giving clear signals on timelines for NICE guidance production. This coordination function ensures that we are actively aware and well prepared for requests from system

[1] https://www.cas.mhra.gov.uk/Home.aspx / https://www.nice.org.uk/advice/es27/resources/covid-19-rapid-evidence-summary-remdesivir-for-treating-hospitalised-patients-with-suspected-or-confirmed-covid19-pdf-1158180847045 / https://www.nice.org.uk/guidance/ng159/resources/covid19-prescribing-briefing-corticosteroids-pdf-8839913581

partners such as for evidence summaries, guideline requests and subsequent HTA submissions, reducing duplication, enabling more efficient planning of resource and relevant NICE outputs.

17. We have established links with a range of system partners, companies and principal investigators of key trials, all have actively engaged to support information gathering e.g. monitoring trial progression/readout dates to enable early access to key data and support system preparedness. These enhanced relationships are already underpinning more collaborative working on other complex projects such as the work ongoing at the MHRA in relation to EU Exit.

18. The work undertaken in RAPID-C19 showcases the strengths of NICE's specialist technical skills in translating horizon scanning information into actionable information and driving structured decision making. It has provided a perfect environment to demonstrate NICE's strengths and ability to develop and deliver constructive robust processes while maintaining complex confidential dialogue.

19. RAPID -C19 has provided a living example of the key overarching aim of the AAC in showing that the access/innovation pathway can be considerably shortened if system partners pull together and are willing to collaborate/push and adapt traditional methods of access.

20. The success of the RAPID-C19 initiative has been underpinned by many factors, one of the key factors has been regular/systematic engagement with system partners which has enabled:

    - A clear shared common objective for all agencies to focus on, which has increased engagement and collaboration leading to faster implementation of agreed actions that accelerate access.
    - The different agencies to share relevant information and act more collegiately/balancing individual organisation remits and positions to deliver shared outcomes.
    - Iterative refinement of the scope of the horizon scanning search strategy and function from a multi-agency viewpoint.
    - Swift feedback when things have gone well and where further refinement is needed
    - A better understanding of the skills mix required along with which agencies may have access to specific information, reducing the time spent in the enrichment process.

Conclusion

21. This multi-agency approach has been successful in enabling safe and timely patient access to medicines showing evidence of benefit in treating symptomatic COVID-19 patients or for disease prevention. Close coordination, proactive planning and engagement from the partners in the healthcare ecosystem has achieved accelerated access to medicines and has the benefit of delivering a more efficient process for NICE and other partner agencies.

22. The approach and process has provided the AAC secretariat a test bed in which to demonstrate how the AAC should operate to meet its objective to support and accelerate the innovation pathway.

Issues for decision

23. The Board is asked to:

    - confirm support for NICE's participation in the RAPID C-19 initiative
    - note the interim process guide

September 2020

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Research to Access Pathway for Investigational Drugs in COVID-19 (RAPID-C19): interim process for NICE activities

1 Introduction

1.1 This document describes NICE's interim process for the Research to Access Pathway for Investigational Drugs in COVID-19 (RAPID-C19).

1.2 The document sets out the main stages of the RAPID-C19 process. Because of the need for rapid action the stages and the steps within them will often run in parallel and may evolve as needed. An overview of the process is provided in Annex 1.

2 RAPID-C19 partners and Oversight Group

2.1 RAPID-C19 is a multi-agency initiative. It involves the following partner agencies:

- the Medicines and Healthcare Regulatory Agency (MHRA)
- NHS England and Improvement (NHSE&I) Specialised Commissioning
- NICE
- the National Institute for Health Research (NIHR)
- the Department of Health and Social Care (DHSC)
- the Scottish Medicines Consortium (Health Improvement Scotland)
- the All Wales Therapeutics and Toxicology Centre
- the All Wales Medicines Strategy Group and
- the Northern Ireland Health and Social Care Board.

The aim is to ensure safe and timely patient access to treatments that show evidence of benefit in preventing and treating COVID-19.

2.2 NHSE&I has overall responsibility for establishing RAPID-C19, in close collaboration with NICE, NIHR, MHRA and the Therapeutics Task Force (TTF) at DHSC. Different activities in the RAPID-C19 process are done by different partners. For example:

- NICE with the NIHR Innovation Observatory (NIHRIO) coordinates horizon-scanning activities, supports NHSE&I's clinical policy development and is responsible for health technology assessments of approved topics.
- The MHRA is responsible for regulatory and authorisation functions (clinical trials, early access and marketing authorisation).
- NHSE&I is responsible for clinical policy development.
- The TTF at DHSC is responsible for purchase and supply.

The RAPID-C19 Oversight Group and Rapid Action Plans

2.3 The RAPID-C19 Oversight Group considers potential COVID-19 topics in development and prioritises those likely to be expedited for patient access in the NHS. It is a forum for decision-makers and advisory members from MHRA, NHSE&I, NICE, DHSC and NIHR. Health technology assessment representatives from the devolved nations also attend.

2.4 For topics in development and likely to be expedited, the RAPID-C19 Oversight Group agrees a Rapid Action Plan (RAP). A RAP is a shared vision and joint agency agreement on the approach to development, implementation and patient access. This includes the period between significant data emerging and a marketing authorisation being granted (if applicable).

2.5 Topics considered by the RAPID-C19 Oversight Group are expected to be off-label or unlicensed treatments entering a pathway to be licensed. The scope of the work is currently limited to preventing and treating COVID-19. This excludes vaccines and devices unless the device is a necessary part of delivering the treatment (such as a nebuliser).

3 Process overview

Primary horizon scanning

3.1 Every day, the NIHRIO does primary horizon scanning. This identifies ongoing trials for COVID-19 in the UK and internationally. The horizon scan reports are available at the NIHRIO website.

Prioritisation

3.2 The data from these scans is extracted and prioritised using a set of agreed filtering principles (see Annex 2). These include:

- trial location
- size
- phase of trial and
- timing of reporting.

This helps to identify topics with the most positive attributes that may provide most value to the system.

3.3 The outputs of these scans are sent to NICE twice weekly. This list is used to identify topics for discussion at the weekly RAPID-C19 Oversight Group meeting.

Enrichment and monitoring

3.4 After being prioritised, the NIHRIO horizon-scanning reports are reviewed by NICE and enriched with additional intelligence to identify topics for consideration by the RAPID-C19 Oversight Group. Further intelligence on individual topics is gathered from several sources in the UK and internationally.

3.5 More information on the progress of the clinical trials and the likelihood of substantive new evidence becoming available for each topic is derived from:

- engagement with principal investigators or commercial sponsors of prioritised UK studies
- engagement with principal investigators of non-prioritised UK and international studies
- clinical development strategy and key trial reporting dates
- preliminary results from commercial sponsors, if available.

3.6 When possible, more information on market access plans for individual topics is collected from commercial sponsors. This may include:

- Regulatory intention, such as if there are plans to apply for an Early Access to Medicines Scheme (EAMS), which aims to give patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need. This might also include plans to seek regulatory and scientific advice, or if there will be a licence or licence extension (and if so, the anticipated population, indication and timings).
- Clinical development strategy and key trial reporting dates/available preliminary results.
- Commercial availability and supply (particularly for treatments not currently available in the UK) and the company's ability to upscale production. This information will be used to support TTF discussions at DHSC.
- Identifying and clarifying the outcome of any previous engagement with relevant organisations such as NHSE&I, MHRA or DHSC.

3.7 When there are ongoing trials of generic drugs sponsored by academic centres or hospitals but without a commercial sponsor, information on identifying a commercial sponsor is first sought from the British Generics Medicines Association.

Briefings

3.8 NICE collates and interprets the horizon-scanning outputs and additional intelligence to identify the most promising topics with studies due to report imminently. Priority topics are scheduled for briefing development.

3.9 NICE prepares briefings on these priority topics for the RAPID-C19 Oversight Group to consider. These briefings inform how the treatment-specific RAPs are made. Each briefing takes up to 7 days to develop.

RAPID-C19 Oversight Group meeting

3.10 The RAPID-C19 Oversight Group meets weekly and considers each topic using the briefing document. Papers are circulated by the NICE secretariat using NICE's secure document sharing system (NICE Docs) no later than 24 hours before the meeting.

3.11 The RAPID-C19 Oversight Group agrees the next steps for each topic. Options include:

- Progress (where good evidence of efficacy is sufficient for further action to be taken).
- Monitor (where good evidence of efficacy is currently insufficient but there are other ongoing trials).
- Stand down (where no evidence of efficacy is sufficient to remove the topic from monitoring).

3.12 For each prioritised topic, the RAPID-C19 Oversight Group agrees a treatment-specific RAP.

3.13 If the RAPID-C19 Oversight Group agrees that a topic is not at a stage where it can be prioritised or progressed for further actions, it goes back to the enrichment and monitoring stage to be kept under regular review. When an associated trial is due to report the briefing will be updated and presented again to the Oversight Group at the next possible meeting.

Rapid Action Plans

3.14 The NICE secretariat drafts each treatment-specific RAP to include the following:

- Timelines for an early-stage regulatory support package, for example joint MHRA and NICE scientific advice.

- Suggested steps and timelines for sponsor submission to MHRA for an EAMS Scientific Opinion.
- Suggested steps and timelines for an NHSE&I commissioning policy or different commissioning approaches from NHSE&I for patient access.
- Plans for development of an early NICE output, such as an evidence summary to support an NHSE&I commissioning policy.
- Plans for development of formal NICE guidance (if applicable), in the context of existing arrangements for NICE topic selection.
- Suggested steps and timelines for management of the supply chain for the treatment, including liaison with the TTF at the DHSC.
- Allocation of named members of each agency responsible for progression of relevant activity and tasks.
- Appropriate document administration, such as version control and date created or updated.

3.15 The RAP will be shared with the RAPID-C19 Oversight Group for comment 2 days after the meeting unless there is an urgent need to formally approve earlier. If this is needed, approval will be sought from the Oversight Group via email.

3.16 Relevant and appropriate information in the RAP will be shared with companies and be available on NICE's RAPID-C19 webpage.

3.17 If any member of the Oversight Group has new information or makes an internal decision that requires a change to the RAP, they should inform the NICE secretariat as soon as possible. The NICE secretariat will make the appropriate changes and schedule for approval at the next possible Oversight Group meeting. Changes to the RAP can be made within 48 hours of new information or a decision being communicated to the NICE secretariat.

4 Contact and confidentiality

4.1 The NICE secretariat is the first point of contact for the RAPID-C19 Oversight Group meeting attendees and is responsible for collating and

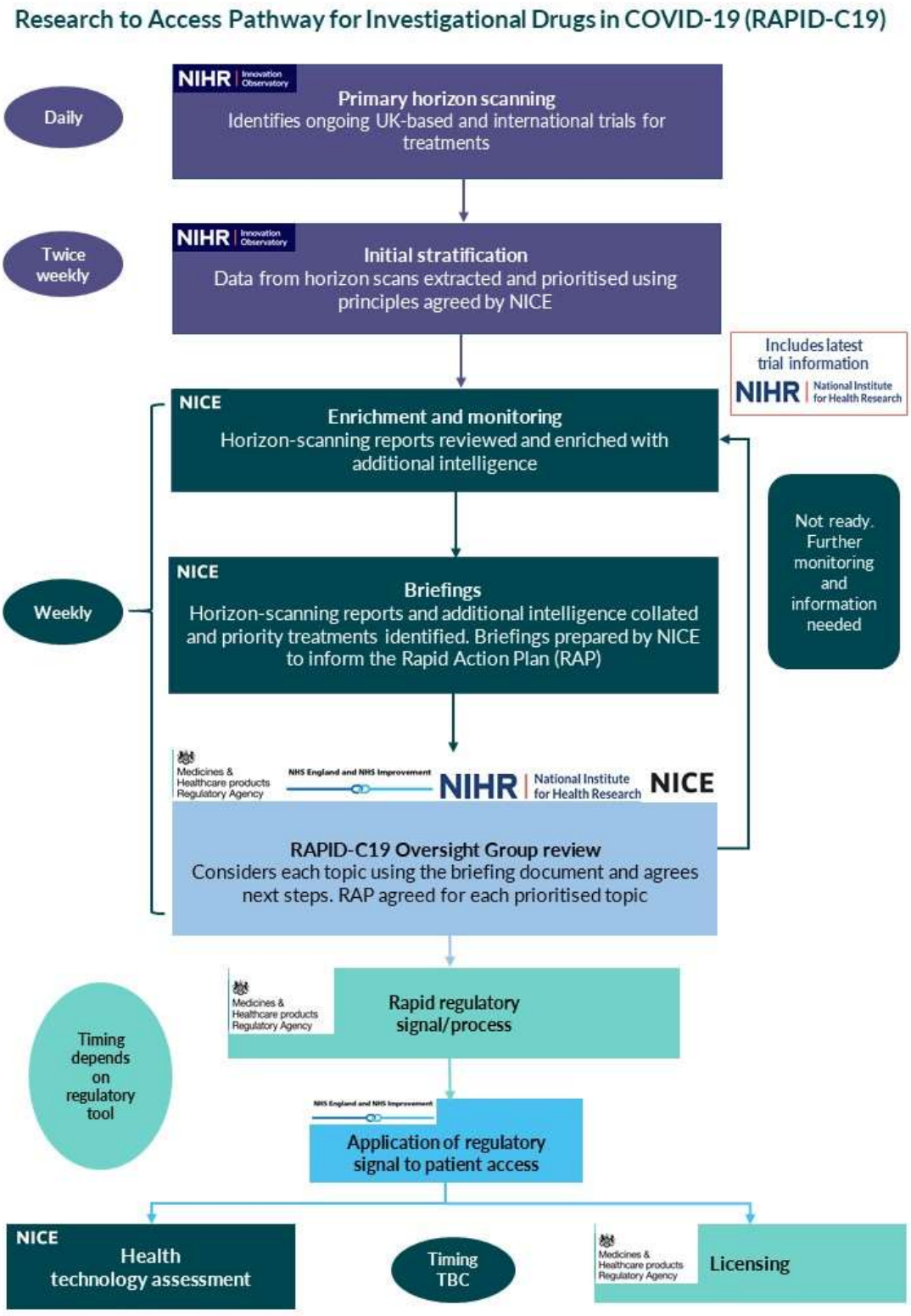
disseminating the agenda and papers in advance, along with noting relevant actions and decisions from the meeting.

4.2 All member organisations of the group are required to sign a Confidentiality and Undertaking agreement that states how confidential information can be shared with and used by all agencies. Individual members are required to sign a Declarations of Interest form for each briefing before every meeting and receiving the meeting papers.

5 Review and update

5.1 Because of the ongoing pandemic this process will be regularly reviewed and updated.

6 Annex 1: Process overview



7 Annex 2: Horizon-scanning prioritisation principles (reviewed on regular basis)

Principle		Rationale
1	Level of investigative activity (volume of trials and studies)	A high level of activity is a potential indicator of early positive evidence of efficacy and/or strong scientific rationale for activity
2	Location of trials and studies	We are already potentially aware of trials and studies conducted in the UK and it may be easier to obtain access to these results
3	Trial phase/design	Trials in later phases (phase 2 onwards, and particularly randomised trials) are likely to produce more robust and clinically interpretable data, potentially including comparative efficacy evidence
4	Trial size	Larger trials will provide more robust evidence than smaller trials
5	Regulatory status	It will be easier to accelerate access to and supply of treatments that already have a UK licence
6	Special populations	Trials in special populations, for example, children, may be an important consideration
7	Timing of data availability	Results that are already available or will be available in the next few months are needed to enable the RAPID EAMS C-19 programme to deliver on its immediate goals and map future topics to the EAMS access pathway

These principles will be operationalised by applying scoring to each treatment, as follows.

Principle		Scoring	
1	Volume	1 trial only	1
		2 to 5 trials	2
		More than 5 trials	4
2	Location	Rest of world	1
		EU/US/Canada/Australia	2
		UK	4
3	Phase/design	Unknown or early (phase 0-1)	1
		Phase 2+	2
		Phase 2+ and randomised	4
4	Size	Less than 100 participants	0
		100 - 999 participants	2
		1,000 or more participants	3
5	Regulatory	No UK/EU licence	0
		EU licence (not UK)	1
		UK licence	2
6	Special populations	Active paediatric trials	1

Information on criterion 7 (timing of data availability) will be sourced from additional intelligence gathering.

National Institute for Health and Care Excellence

Public Involvement Programme annual report 2019/20

This report is the Public Involvement Programme's Annual Report 2019 to 2020. The report presents key activities from NICE's Public Involvement Programme over the period April 2019 to March 2020. It also includes brief reference to the additional involvement activities undertaken over the last few months in response to the COVID-19 pandemic.

As well as submitting this report to the Board we hope to use its contents to help promote our approach to public involvement. Marketing and promotional approaches will include:

- 'snapshot' summary version of the report on the NICE website
- sections of the report used for a Twitter campaign to promote our work
- case studies from the report to form the basis of 'stories' for the website, and on Twitter
- using the recommendations emerging from the Centre for Health Technology Evaluation 2020 transformation work to consider developing a patient evidence framework.

The Board is asked to:

- receive the report
- agree the proposed marketing and promotional approaches, and for the report to be made available on the NICE website

Judith Richardson

Acting Director, Health and Social Care

September 2020

NICE

National Institute for Health and Care Excellence

Public Involvement at NICE
Annual report 2019/2020

Contents

Introduction

1. From our inception working with patients and the public, and the organisations who support them, has been core to NICE's work. It is embedded in our principles and our patient and public involvement policy. This report describes the work of the Public Involvement Programme (PIP), and broader public involvement activities across NICE, in the financial year 2019 to 2020.

2. We have supported the involvement of patients, people who use services, their families, carers and the public in the development of guidance and standards. We have recruited, trained and supported people to enable them to take part meaningfully in our work. We have also worked with our voluntary and community sector stakeholders to build relationships and improve how we involve those stakeholders in our work.

3. We have continued to support and promote public involvement at a national and international level through our work with the Health Technology Assessment International (HTAi) Patient and Citizen's Involvement Group (PCIG), the International Network of Agencies for Health Technology Assessment (INAHTA) Patient Engagement Learning Group and through the Guidelines International Network (G-I-N) Public Working Group.

4. We have supported the growing shared decision-making agenda, holding the 6th meeting of our Shared Decision-Making Collaborative and contributing to ongoing developments in the field.

5. Finally, although extending beyond this reporting period, we have included information on public involvement work in response to the COVID-19 pandemic and our plans for the future in the extraordinary times in which we find ourselves.

Acknowledgements

6. We would like to acknowledge the huge contribution that patients, people who use services, their families, carers and the public have made to our work across the breadth of our activities, and to thank them for their dedication and commitment. We would also like to acknowledge our patient, voluntary and community sector stakeholders who have continued to participate in our work, help us to improve our processes for public involvement, and to act as a critical friend to NICE.

Facts and figures

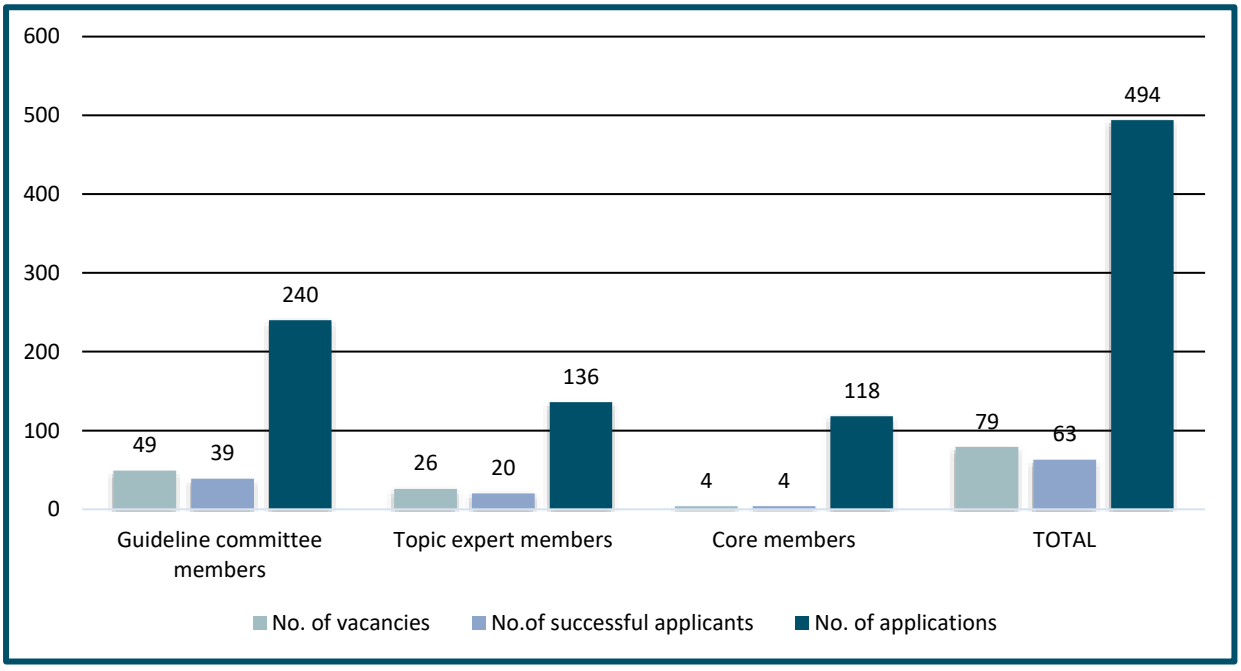
Recruiting and identifying people to take part in our work

7. PIP supports the recruitment of patients, people who use services, their families, carers and members of the public across all NICE work programmes; in most cases we describe the people we recruit as 'lay members' (although some variation in that terminology occurs across the organisation). Our policy states that committees should have a least two lay members as part of their membership. In 2019/20 we received 494 applications for 79 committee vacancies and in the end recruited 63 people to join a variety of committees.

8. The disparity between the number of vacancies and the number of people recruited was a result of several factors, including:

    - challenges in recruiting in topic areas where there is low voluntary and community sector activity – for example infectious skin conditions and 'flu
    - recruiting for topics affecting very young children and babies
    - the diabetes suite of topics, where a range of different experiences was required, resulting in 9 potential vacancies. Ultimately either not all elements of experience could be recruited to or one applicant was able to speak to more than one type of experience.

Figure 1 – recruited lay members and applicants



Download the data set for this chart

9. As well as recruiting lay members we have supported 13 lay people to join our quality standards advisory committees as invited specialist committee members, 16 lay people to contribute to NICE Scientific Advice meetings, and 57 lay people to share their knowledge and experience with committees as a patient expert.

Involving individual people

10. Once recruited to a committee, lay members receive induction and training as well as ongoing support from a named member of the Public Involvement Programme. They also receive support from the team who are running their committee.

11. We are keen that our support meets the needs of the people who we are working with. In some instances we need to adapt the way we work to ensure that people's needs can be met.

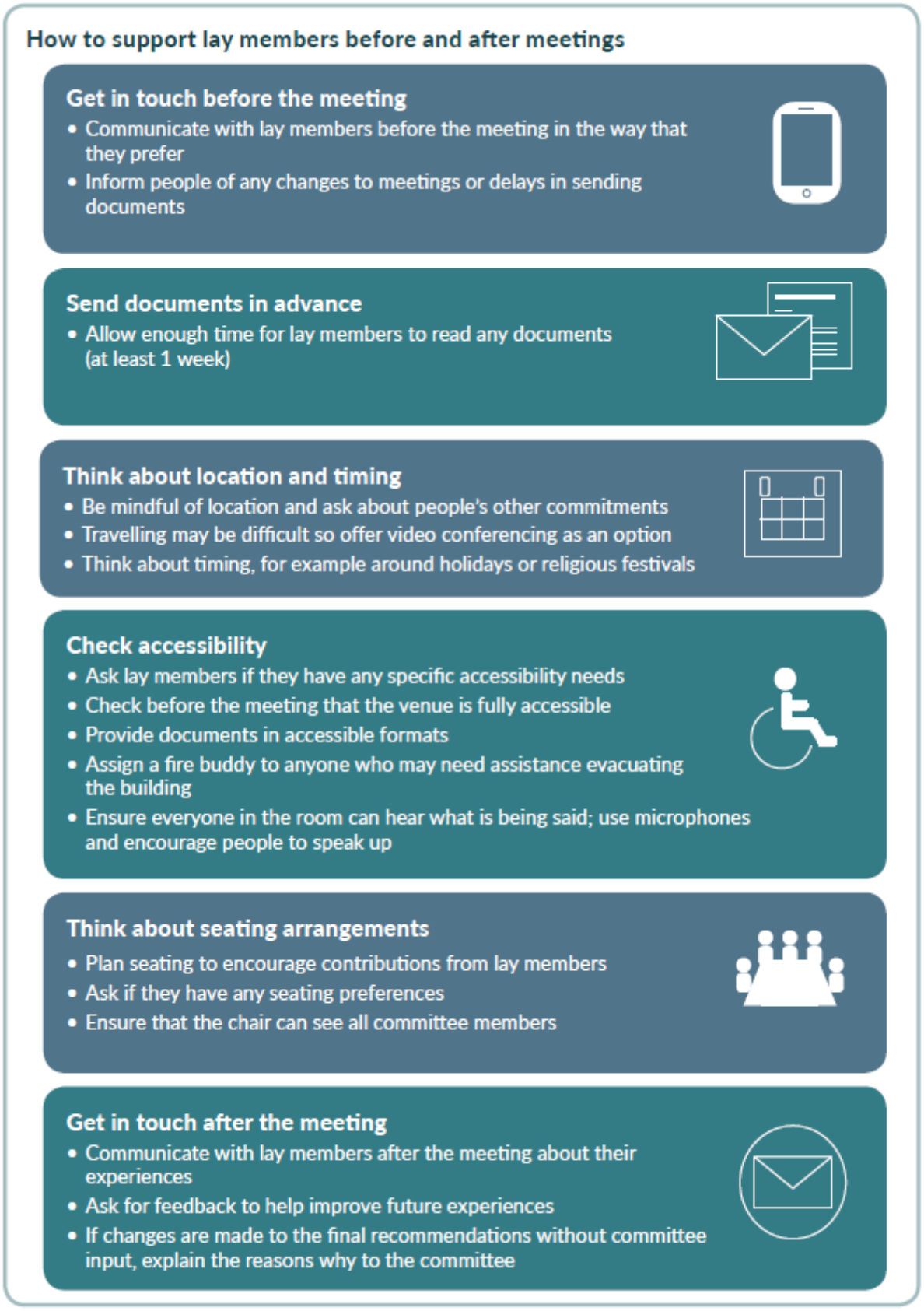
Case study: supporting lay members with ME/CFS

The Guideline Committee (GC) for ME/CFS (Myalgic Encephalomyelitis (or encephalopathy)/chronic fatigue syndrome) includes 5 lay members, 4 of whom are living with diagnosed ME/CFS. Due to the impact of the condition and the demands of GC meetings, the PIP team and the guideline developer have made significant adjustments to our regular process to safeguard the health and wellbeing of our lay members. This includes special seating arrangements (recliners) during training and GC meetings; additional overnight accommodation before and after meetings as needed, to allow for additional rest; longer lunch breaks than other GC meetings to allow for rest; lap desks to use for papers while using recliners and overnight accommodation at the same venue as GC meetings to minimise travel.

Lay members were consulted on what might help them and these adjustments were led by suggestions from them. This has also had a significant resource impact which was accounted for. Feedback from lay members has been extremely positive and they feel that the expected payback on their health has been much mitigated due to these adjustments.

12. In 2019/20 we created a guide for NICE staff which outlines the role and value of lay members and gives tips and suggestions from lay members themselves about how to support them during their work with us (shown in Figure 2). Please note that the guide was developed before the introduction of virtual committee working as a consequence of COVID-19. This will be amended to reflect new ways of working once these have bedded in.

Figure 2: How we support lay members – a guide for NICE staff

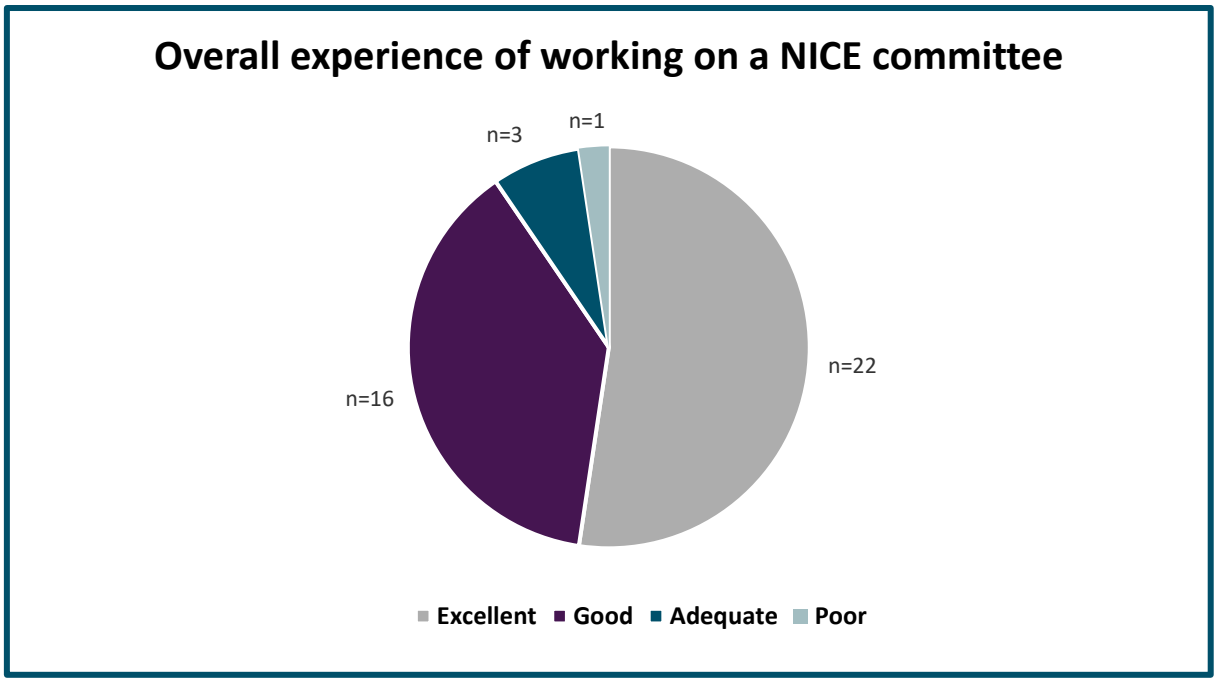


Exit surveys

13. When a lay member finishes their work with us we ask them to complete an exit survey to hear about their experiences, and to hear any suggestions they might have for improvements. The data we receive is shared with internal teams and our external guideline developers, and an annual exit survey report is produced.

14. In 2019/20 we sent out 76 exit surveys and received 42 responses - an overall response rate of 55%. This is an increase from the response rate of 47% for the previous year. Ninety percent of respondents rated their experience of working with us as 'good' or 'excellent' this is down from ninety-five percent in the previous year, however the result still represents a positive picture of people's experiences.

Figure 3 – overall experience of working on a NICE committee



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15. Participants reflected on both the positive and negative aspects of their work with NICE and our guideline developer centres. Committee working and the role of the chair were highlighted as particularly positive elements of lay members' experiences. The following factors were also identified as being influential in their experience of working on a committee:

    - being listened to and having their views considered, respected and valued (n=12)
    - being an equal committee member (n=6)

- a ‘friendly committee – made to feel welcome’ (n=5).

16. In response to the question 'What went well during your time on the committee?', 18 respondents (43%) across a range of programmes specifically complimented their committee chair, mentioning a key aspect of creating a constructive, open, calm and friendly environment.

> *‘The chair of the committee made it really accessible, and so as a lay person I didn't feel lost or left out. The environment…was open and calm.’* – NICE lay member

17. Where chairing was felt to have been poor [n=3], respondents indicated that this prevented lay members from contributing effectively, demonstrating how crucial the role of the chair is to effective involvement. Other challenges that lay members faced related to meeting arrangements and administration – just over half (16 out of 29) of lay members who mentioned meeting arrangements and administration noted that they had had a problem. This included papers being sent late or tight deadlines being given [n=4], IT issues in meetings [n=3] and poor communication with developer teams [n=2].

18. Ninety percent of respondents were able to give at least one example of the impact they thought they had made on their committee. Eighteen respondents (43%) commented that their greatest achievement was ‘simply being there and representing the patient/carer view’. Nineteen other people (43%) were able to elaborate on how their involvement impacted on the guidance. The following themes demonstrate where lay members thought they had had an impact on the guidance:

    - influencing rationales and recommendations (n=9)
    - creating decision aids (n=2)
    - identifying gaps in committee expertise and recruiting new members (n=1)
    - challenging professionals’ views of the patient (n=4)
    - highlighting patient views from consultation comments (n=1)
    - influencing health economic factors (n=1)
    - publishing the guideline (n=1).

Support and learning

Training days

19. As part of our support for new people joining guideline committees, we ran 3 face-to-face training days to equip them with the knowledge and skills to get the most out of their time on the committee. The training was focused around making an impact and covers:

    - developing guidelines – what evidence NICE uses and how we look for and assess that evidence
    - preparing for meetings - what to expect and how committees use evidence
    - making an impact – sharing knowledge, experience and ideas with former lay members.

20. Speakers from both within NICE and our developer centres contributed to each training session. Former lay members took part to share their experiences and knowledge of working with us. In total 32 people received training this year.

21. We asked attendees to provide feedback following each training day. Participants were asked to score (1-10) for each aspect of the workshop, where 10 = very good; 1 = very poor. Twenty-one participants completed a feedback form and an overview of this feedback is provided in table 1.

Table 1 – Summary of training day feedback scores

Session	Range	Mean score
I know what support and training is available to me	6 to 10	9.0
I understand my role as a lay member	7 to 10	9.2
I understand the guideline development process	5 to 10	8.9
I understand the different types of evidence that my committee will be looking at	6 to 10	9.1
I understand how evidence is prepared for my committee	6 to 10	9.1
I understand how committees develop recommendations	6 to 10	9.0
I know how to prepare for meetings	7 to 10	9.4
I feel confident that I can have a positive impact in meetings	6 to 10	9.2

Online training modules

22. We have continued developing a suite of online training modules for lay members, which will enable them to access training resources at a time which is convenient for them. We developed training content in the Electronic Staff Record (ESR) platform, using the functions available for staff training. Lay members then tested the training modules using ESR as the platform to access them. We received valuable feedback from our users. Challenges with different web browsers and incompatibility with Apple products meant that ESR did not ultimately meet our requirements.

23. Following the user testing we have continued to explore how and where we can make training modules available to lay members. We have continued to develop modules using PowerPoint and voice-overs. In 2020/21 we will trial NICE Share as a potential platform to enable access to training modules. This will give us less sophisticated content as it will be in PowerPoint format but should enable the modules to be made available and easily accessible to our users.

Building relationships with voluntary and community sector organisations

24. Voluntary and community sector (VCS) organisations are a key stakeholder group for NICE. They make an invaluable contribution to our work throughout guidance development, and in supporting and promoting the uptake of our guidance. Developing and strengthening our relationships with VCS organisations is a key component of PIP's work and one of the means by which we can achieve meaningful patient and public involvement.

Speaking engagements and meetings with voluntary and community sector organisations

25. In 2019/20 PIP took part in 9 national and international events as a speaker or panel member to share our learning and experiences of involving patients and the public in guidance development. We also held 12 meetings with voluntary and community sector organisations or umbrella groups. These meetings discussed NICE work in a specific topic area, gave an induction to the organisation for those who are new to working with us, and provided opportunities to address any issues raised.

Training and support for voluntary and community sector organisations

26. During the year we held two masterclasses for voluntary and community sector organisations. These were free to attend and were held in our London office.

27. Eighteen participants attended our ‘Intro to NICE’ masterclass and took part in interactive sessions exploring the range of guidance NICE produces as well as the opportunities to get involved in our work. The masterclass also included insight from two organisations who have worked extensively with NICE and who shared their experiences around involvement and the implementation of NICE guidance.

> *‘Overall really helpful and I would definitely recommend to anyone thinking of engaging with NICE process.’* – masterclass participant

28. Our second masterclass specifically explored the highly specialised technologies (HST) programme. Fifteen participants from a range of rare disease organisations attended and took part in a range of activities to both build their knowledge about HST evaluations and discuss effective participation in the programme.

29. For both masterclasses we received detailed, thoughtful, and generally positive feedback from participants which is invaluable for planning future sessions. We are grateful to NICE staff, lay members, and the staff from voluntary and community sector organisations who contributed to the agenda for our masterclasses, and to all participants for their engagement and interest.

30. A further masterclass was planned for March 2020 with an agenda specifically covering implementation and the role of voluntary and community sector organisation in supporting and promoting the uptake of our guidance. Due to the COVID-19 pandemic this masterclass was postponed and will be rescheduled to take place virtually.

Patient involvement in health technology assessments: taking a coproduction approach

31. Starting in late 2018 and concluding in late 2019 we engaged voluntary and community sector organisations in a piece of work to look at ways of improving patient involvement in health technology assessments across NICE. This was part of a broader programme of transformation work undertaken by the Centre for Health Technology Evaluation.

32. The work took a co-production approach, overseen by a working group which included 6 people from voluntary and community sector organisations, working alongside NICE staff. Wider engagement and consultation took place with voluntary and community sector organisations including an independently-facilitated stakeholder workshop attended by 22 organisations. We conducted a

targeted consultation, via a survey, which yielded responses from 52 organisations. Throughout the project external engagement, such as speaking engagements and meetings with organisations, took place to encourage participation in the work.

33. Areas for development within our processes, as identified by our voluntary and community sector stakeholders, included:

    - providing information about uncertainties that patient evidence might help address
    - exploring the role of real-world evidence in patient involvement
    - providing training and support to patient organisations
    - creating inclusive committee cultures
    - including additional steps during HTAs to incorporate patient evidence.

34. A final report, containing 18 detailed recommendations has been submitted to the Centre for Health Technology Evaluation and these will be considered for inclusion in updated process and methods guides which will be subject to public consultation during 2020. We will also consider how these recommendations might apply in relation to the Centre for Guidelines and across other NICE programmes.

Beyond guidance development

35. Voluntary and community sector organisations have engaged with NICE beyond our usual guidance development processes. They have contributed perspectives and insight to NICE Impact reports and helped to develop a number of NICE patient decision aids.

Working internationally

36. In 2019/20 PIP has maintained and built on its profile as a world leader in patient and public involvement.

Guidelines International Network (G-I-N)

37. The G-I-N Public working group (currently chaired by a PIP staff member) promotes good practice on involving patients and the public in developing and implementing guidelines across international guideline developers. Led by NICE and including chapters written by members of the PIP team, the G-I-N public working group is updating the G-I-N Public Toolkit and aims to publish an updated toolkit in 2020/21.

Health Technology Assessment International (HTAi)

38. PIP have continued our involvement in the Health Technology Assessment International's Patient and Citizens' Involvement Group (HTAi PCIG), including as a member of the steering group for the PCIG. This year we have worked on a number of projects with our colleagues, including:

    - Co-leading work to develop a summary of information for patients (SIP) for patients and organisations taking part in an HTA. The SIP provides information about the medicine or device, written in plain language, to enable patients to provide targeted input into HTAs. The key deliverables from the work will be a template SIP for use by industry, plus guides for patients, industry and HTA agencies and an introductory slide deck.
    - Presenting two vignettes, an oral presentation and taking part in a panel session and workshop at the HTAi 2019 conference in Cologne.

PARADIGM

39. We took part in the HTAi PARADIGM workshop on Early Dialogues (similar to NICE Scientific Advice) in October 2019. The workshop explored tools to support the rationale for patient involvement, to review methods and frameworks and to develop tools for recruiting, interviewing and supporting patient experts in Early Dialogues. Several agencies took part from France, Germany, UK, Italy, Hungary, Spain, Norway and Sweden. NICE was invited to provide expertise and insight to support the development of standardised tools and resources.

    There were several outcomes, including agreement on:

    - documents to support the rationale for patient involvement in Early Dialogues for all stakeholder groups (e.g., values statements, fact-sheets, including the goals of patient involvement, and case studies to highlight the value of involvement)
    - a process framework for in Early Dialogues: interviews and the meetings (despite variation between agencies)
    - the types of resources needed to support the process, including guidance for stakeholders (e.g., what companies and patients can expect) and templates (e.g., invitation emails, conflict of interest forms and contracts)
    - tools to support the interview and meeting processes, including logistical preparation checklists for meetings and guidance on interview techniques or support for the interviewer.

International Network of Agencies for Health Technology Assessment

40. PIP joined the International Network of Agencies for Health Technology Assessment (INAHTA) Patient Engagement Learning Group in 2019. The group's purpose is to share knowledge and experience about patient engagement amongst member HTA agencies. We presented NICE's approach to patient engagement and involvement in HTA via a webinar, focussing on our work evaluating the impact of patient input into the highly specialised technologies and interventional procedures programmes.

EVOLVE

41. PIP has taken part in the EVOLVE (giving patients a mEaningful VOice in the design and deLiVery of care) study as a steering group member, contributing to the research protocol and advising the project team. The aim of the EVOLVE study is to evaluate patient and public involvement (PPI) in clinical practice guidelines and to design and test an involvement model for PPI in urological cancer guidelines. The University of Aberdeen is the sponsor for the study with endorsement from European Association of Urology (EAU) Guidelines Office. The study is funded by Scottish urological cancer charity UCAN.

Supporting shared decision-making

NICE Shared Decision-Making Collaborative

42. In June 2019 PIP convened the 6th meeting of the NICE Shared Decision-Making Collaborative. Forty-eight people attended the event representing academia, voluntary and community sector organisations, professional organisations, regulators, Arm's Length Bodies and commercial organisations, all of whom have a commitment to and interest in shared decision-making. The agenda facilitated updates on shared decision-making from a range of speakers, capturing national and international developments and addressing issues around health literacy and risk communication.

43. A 'World Café' approach was taken for the afternoon session where participants moved through a number of different groups, discussing key areas for action around shared decision making. New actions for the Collaborative were identified and refined at a follow-up meeting of core Collaborative members in November 2019. Launch and promotion of the new areas for action was planned for March 2020 but has been postponed to a more appropriate time given the COVID-19 pandemic and consultation on the upcoming shared decision-making guideline.

Communications

Social media

44. We have increased our presence on social media using the PIP team's @NICEGetinvolved account. This has helped us to reach more members of the public and different communities, work and communicate more effectively with our stakeholders, and to take part in campaigns with our voluntary and community sector stakeholders.

45. In 2019/20 we achieved:

    - 715 tweets
    - 951,200 impressions
    - 8 thousand profile views
    - 18% more followers.

46. In October 2019 @NICEGetinvolved ran a twitter campaign for World Mental Health day. The campaign was delivered in partnership with our lay members and key stakeholders, promoting relevant NICE guidance, user experience, and examples of how services are being improved. 516 users directly engaged with the campaign, with messages generating 57,151 impressions.

Public involvement in a pandemic – meeting the challenge of COVID-19

47. The emergence of the COVID-19 pandemic in the spring of 2020 has had a profound effect on the way we work, and on the challenges faced by those we seek to involve. Although largely beyond the parameters for this annual report (2019/20 financial year) it would be remiss not to provide an update on the impact of COVID-19 on our work, and the contributions of voluntary and community sector organisations to NICE's response to the pandemic.

COVID-19 rapid guidelines

48. Early on in the pandemic NICE was commissioned to develop and publish rapid guidance on a range of issues related to COVID-19. This necessitated a highly accelerated development process, in some cases reduced to one week. A targeted consultation exercise with stakeholders formed part of the process with a consultation period in some cases of only 5 hours, with 2 or 3 days' notice.

49. PIP worked to identify voluntary and community sector organisations to take part in the targeted consultations and engaged with those organisations to explain

the constraints we were working under and to encourage their participation where possible. As a consequence of our work building relationships with those stakeholders, as detailed earlier in this report, the response from voluntary and community sector organisations was overwhelmingly positive and they stepped up to the challenge magnificently, providing insightful comments across the COVID-19 rapid guideline topics.

50. We are aware however that the COVID-19 pandemic has had a profound effect on the voluntary and community sector with significant numbers of staff being furloughed and with huge uncertainty over funding for those organisations. PIP has maintained a dialogue with key voluntary and community sector umbrella groups to understand the impact on organisations and work with them to support their continued involvement where we can.

Involvement in a virtual world

51. The lockdown implemented in response to the threat from COVID-19 has moved patient and public involvement into the virtual world. NICE committee meetings are now held via videoconference which presents new challenges and opportunities for the meaningful involvement of lay members and patient experts in committee meetings.

52. Led by a cross-NICE team, training and support has been provided to committee members to enable them to take part in meetings successfully in the new virtual environment, and to train other members of staff to run virtual meetings. PIP has supported lay members in this change and regularly gathers informal feedback about people's experiences of working in this way to ensure their contributions continue to be meaningful.

53. Use of virtual meeting software has allowed PIP to engage with patient experts attending committee meetings in a different way. An adviser from PIP has attended each technology appraisals committee meeting to provide support to patient experts joining those meetings. We have implemented a group waiting room for patient experts where PIP can provide information and answer any questions people might have before they move to the main committee group. The chat function in virtual meeting software means that participants have been able to ask PIP questions privately, or ask for clarification during a meeting – something that wouldn't be possible face-to-face in a large meeting room.

Conclusion and future plans

54. As ever the Public Involvement Programme's future plans will be guided by NICE's overall strategic development. However there are several strands of work for which we have ambitions over the coming months. These include:

Policy and service review

55. We will initiate a formal policy review to ensure that we are adhering to best practice in relation to public involvement. As part of this we are planning to develop a conceptual framework for involvement so that our intentions and practice are transparent and explicit. This will lead into a review of our services and what we can offer to the internal and external landscape.

Strategic relationships with patient, voluntary and community stakeholders

56. We will develop and plan our future strategic relationship with patient, community and voluntary sector organisations, particularly building on the experience and learning during the pandemic which has significantly adversely affected our stakeholder community. Working with external stakeholders and internal colleagues from the Audience Insight team we will consider how stakeholder engagement might be reconceptualised in a way that works well for our stakeholders, enables them to contribute to our work efficiently and effectively, and is useful for us. Our relationship with patient, community and voluntary sector organisations is fundamental to our work and we need to make sure that it is fit for the future and takes into account the challenges that our stakeholders face, especially in the ongoing context of COVID-19.

Deliberative public engagement

57. We will work with our colleagues in the Science Policy and Research team to revive NICE's activities in relation to deliberative engagement with members of the public, enabling us to gain the UK citizen's perspective on issues of ethical concern and debate.

Equality and Diversity

58. We will work to support NICE's ongoing commitment to supporting equality and increasing the diversity of our lay members and of the organisations with whom we work. We will also work with our colleagues in the guidance producing centres on any future developments of the equality impact assessments associated with all guidance.

International work

59. We will work with our colleagues in the Communications directorate to help plan and deliver NICE's hosting of the 2021 HTAi conference, to be held in Manchester. One of the key plenary sessions is 'patients at the heart of innovation' which is an opportunity to showcase the different methods and processes by which patient organisations and individual patients are involved in supporting access to new medicines and other technologies.

60. We will continue to support international initiatives such as the European Patients Academy for Therapeutic Innovation (EUPATI) of which we are part of the founding and ongoing faculty. This gives patient advocates across Europe the opportunity for intensive and practical study in the field of medicines development from the laboratory, to licensing and health technology assessment.

61. Our role as Chair of the G-I-N public working group continues, and we will play a key role in developing and publishing the revised G-I-N public toolkit for developing guidelines in a patient-centred way. We will also work with INAHTA to publish a Patient Engagement Position Statement.

62. We will collaborate with our colleagues within NICE International to ensure that patient and public involvement is high on the agenda for international engagement

‘People like us’

63. The collaboration with our colleagues in the other Arm’s Length Bodies (through the People and Communities Forum) will be maintained, to ensure we are sharing good practice and working jointly and collaboratively wherever possible on matters of engagement with patients and the public.

64. We will also offer advice to other organisations within the health and social care field who wish to develop their patient and public involvement strategies, in order to build capacity and promote good practice.

September 2020

National Institute for Health and Care Excellence

NICE impact report: end of life care in adults

This report gives details of how NICE's evidence-based guidance is being used to help improve outcomes on end of life care in adults.

It provides information about NICE's communication activity in relation to the previous impact reports on respiratory conditions and children and young people's healthcare.

The Board is asked to review the NICE impact end of life care in adults report, and to note the communications activities.

Dr Judith Richardson

Acting Director, Health and Social Care

September 2020

Introduction

1. The attached NICE impact report focuses on end of life care in adults and reviews the uptake of NICE guidance in this area. It covers: care of people approaching the end of life, recognition and assessments in the last days of life, shared decision making in the last days of life and support for carers.

System support for implementation

2. The system support for implementation (SSI) team is currently reviewing this impact report and will consider how to address any implementation issues highlighted.

3. Following a request from the Board, in July, to initiate change where a NICE impact report identifies low uptake the SSI team's contribution to these reports has been extended. The team will be included in conversations with key stakeholders at the scoping stage of each report. This new way of working is being implemented for the cardiovascular disease management impact report which will be published in January 2021.

Promoting NICE impact reports

4. The NICE impact report on children and young people's healthcare was published on 16 June 2020, followed by an impact report on respiratory conditions on 20 July 2020. Publication of both reports had been delayed due to NICE's focus on responding to the COVID-19 pandemic.

5. The following is a summary of key communications and engagement activities to promote the two reports. It should be noted that many stakeholder organisations have been focussing on COVID-19 and have either reduced the number and range of e-newsletters they produce (in which we might usually seek to achieve coverage) or have diverted the focus of their newsletters exclusively onto COVID-19.

Impact report: children and young people's healthcare

Working with partners and stakeholders

6. The report was shared widely across the health and care system, including NHS England and NHS Improvement's regional communications teams so that they could cascade it to providers and commissioners in their regions.

    - Partner organisations involved in the report were encouraged to share it through their networks. The partner organisations were NHS England, the Royal College of Paediatrics and Child Health, Evelina London Children's Hospital and University College London Hospital.
    - Healthwatch shared details of the report on its network of workplace Facebook sites, an internal network with all 151 local Healthwatch organisations represented.
    - C4CC (Coalition for Collaborative Care) included details of the report in its partner information email, which goes to the 67 partner organisations that are part of the C4CC network who, in turn, can share the details through their networks.
    - National Health Executive featured a blog on their website in which Judith Richardson, acting director for health and social care, discussed the main findings from the report. The blog was also published in the NHE magazine which reaches up to 300,000 people across the health sector.
    - Activity on Twitter included retweets and likes by the ADHD Foundation (20,800 followers), Baby Friendly UK (16,200) and the NIHR Innovation Observatory (2,765).

NICE Newsletters and Website

7. The June issues of NICE News and Update for Primary Care featured the report, reaching a total of 44,000 subscribers.

8. Between 16 June and 14 August the impact report was viewed more than 2,000 times.

Social media

9. We promoted the children and young people's impact report over a 3-week period on Twitter, Facebook and LinkedIn using a mix of infographics, quotes and images. By posting on 3 channels we reached a varied audience: professionals in health and care on Twitter and LinkedIn and the general public on Facebook.

Twitter:

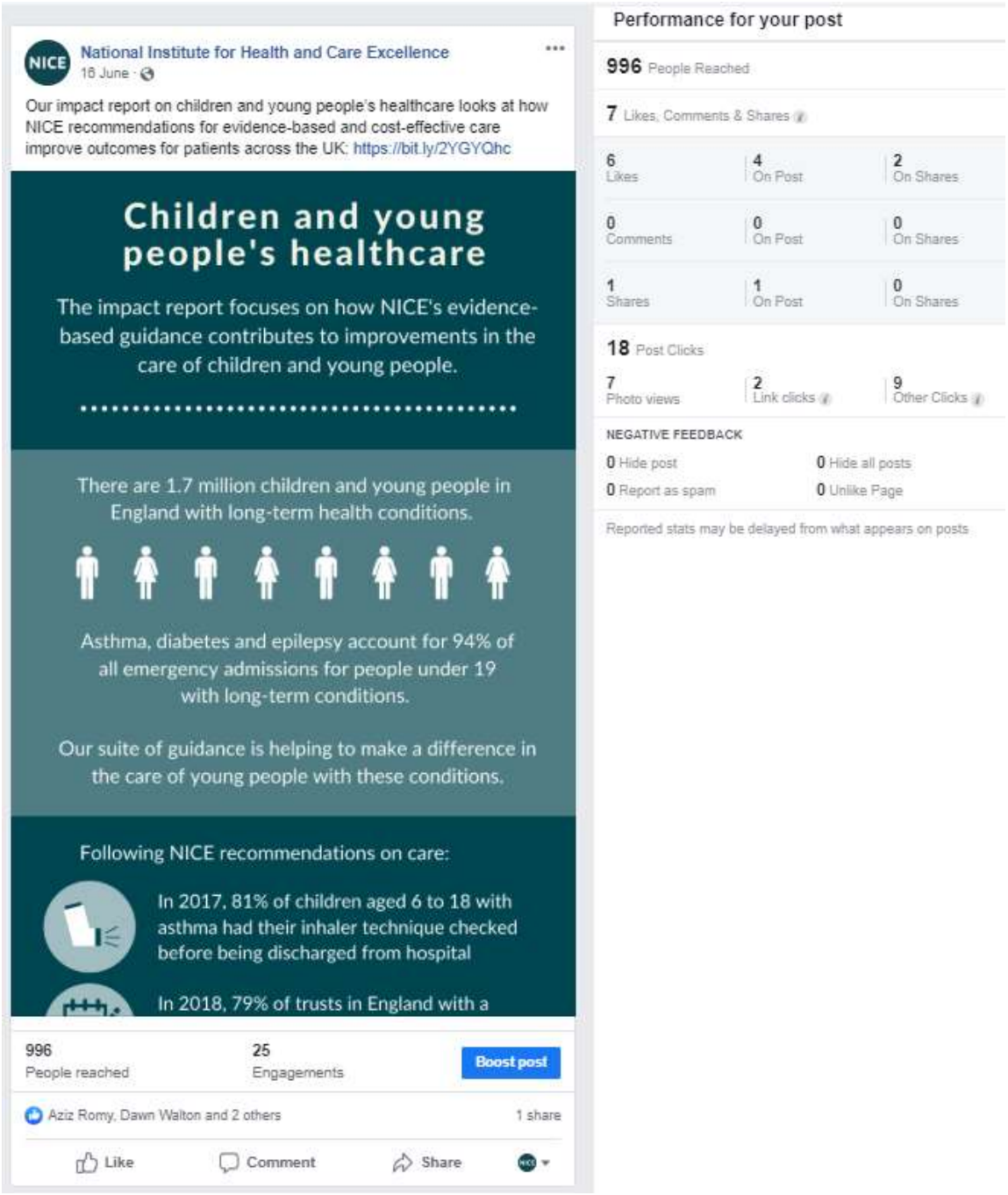
On Twitter our 7 posts were viewed 95,651 times overall and received 808 total clicks, likes, comments or shares. Our first infographic post received the highest engagement rate of 1.1%. This is positive because Twitter gets, on average, 0.06% on an individual post.

LinkedIn:

Our 2 posts on LinkedIn reached 14,414 people and led to 213 clicks through to the impact report and to the blog by Judith Richardson posted on the National Health Executive website.

Facebook:

Our 5 posts were viewed 4,025 times overall and received 49 clicks, likes, comments or shares. Our infographic on long term conditions (below) received a good engagement rate of 2.51%.



Impact Report: respiratory care

Working with partners and stakeholders

10. As with the impact report about children and young people's healthcare, this report was shared widely across the health and care system.

    - Partner organisations involved in the report were encouraged to share it through their networks: Asthma UK, British Lung Foundation, Public Health England, NHS England and NHS Improvement, University

Hospitals of Leicester, NHS Digital, the National Asthma and COPD Audit Programme, Healthcare Quality Improvement Partnership, TB Alert and University College London Hospitals.

- The report was featured in the Academy of Medical Royal Colleges' newsletter, whose recipients include the chief executives and communications directors of all the medial royal colleges.
- National Health Executive published a blog by Jennifer Watts, interim programme director for system support and evaluation, in which she discussed the report's main themes. The blog was also published in the NHE magazine reaching up to 300,000 people across the health sector.
- Retweets and likes on social media included Asthma UK (52,300 followers) and the British Lung Foundation (23,200).

Newsletters and NICE Website

11. The July issues of NICE News and Update for Primary Care featured the report, reaching a total 44,000 subscribers.

12. Between 20 July (when the report was published) and 14 August, there were 1,201 views of the report's online page.

Social media

13. The respiratory impact report was promoted over a 3-week period on Twitter, Facebook and LinkedIn using a mix of infographics and images. By posting on three channels we reached varied audiences: professionals in health and care and members of the public. We were careful to include notes in each post explaining that the findings relating to pre-COVID work.

Twitter:

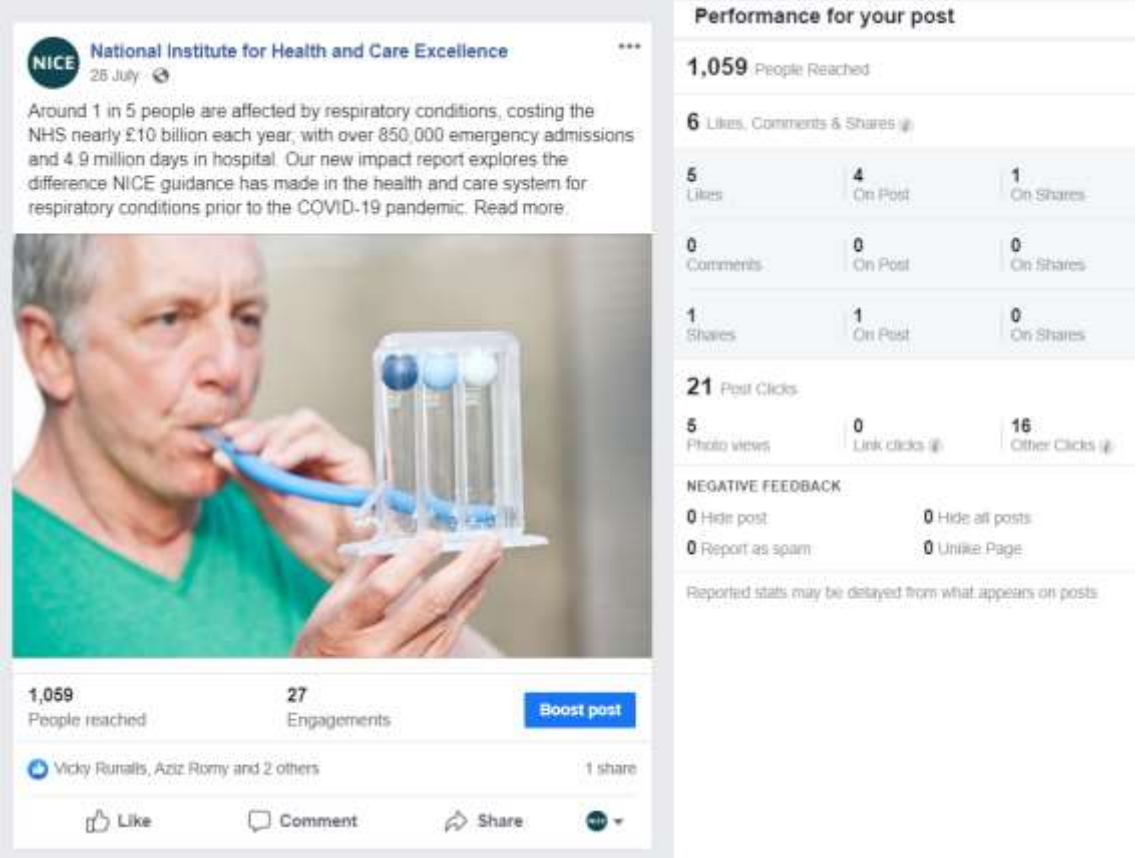
Our 4 different posts on Twitter were viewed 34,478 times overall and received 431 total clicks, likes, comments or shares. Our first post received the highest engagement rate of 2.3%.

LinkedIn:

Our 3 posts on LinkedIn reached 20,478 people and led to 305 clicks through to the impact report and Jennifer Watts' blog post

Facebook:

Our 4 posts were viewed 3,956 times and received 75 clicks, likes, comments or shares.



September 2020

NICE National Institute for Health and Care Excellence

NICE impact end of life care for adults

September 2020

Contents

Impact of the coronavirus (COVID-19) pandemic

This report looks at the impact of our guidance using data collected before the COVID-19 pandemic.

In response to COVID-19, care has been delivered differently. As a result some people, and those important to them, may have had a less positive experience.

We do not yet know the full impact the pandemic has had on end of life care. It is likely that changes made during this time will influence how care is delivered in the future.

Insight from Marie Curie

Julie Pearce (Chief Nurse and Executive Director of Caring Services) and Dr Sarah Holmes (Medical Director, Service Transformation & Innovation).

Together they consider NICE's role in improving end of life care.

Many people are unable to access support at the end of life. The quality of care can be variable depending on location, social and cultural background, and diagnosis.

The COVID-19 pandemic has shone a light on many gaps in service provision and organisation. Now, there is a need for more evidence to help drive improvements in accepting a prognosis, preparing for death, loss and bereavement, and closing gaps in quality of care across all settings. We need to understand and strengthen the impact of NICE guidance on people's experience of end of life care.

Why focus on end of life care for adults?

Around half a million people die in England each year. With an ageing population, the annual number of deaths is projected to increase. In addition, the COVID-19 pandemic has led to an increase in the excess death rate.

The One chance to get it right report from the Leadership Alliance for the Care of Dying People states that people are 'approaching the end of life' when they are likely to die within the next 12 months. This includes people whose death is imminent as well as those with conditions that mean they are expected to die within 12 months.

End of life care enables supportive and palliative care needs to be identified and met throughout the last phase of life and into bereavement. Palliative and end of life care is provided by disease-specific teams, generalists in the community and hospitals, and specialists in palliative care in all settings. This care ensures that people live well until they die.

Effective end of life care improves the quality of life of the dying person and those important to them. It is achieved by early identification, assessment and treatment of pain and other distressing symptoms, while integrating the psychological, social and spiritual aspects of the person's care.

There is a lack of published data about end of life care services for the last 12 months of life, so the main focus of this report is on care in the last 2 to 3 days of life in acute settings.

We have published

4 Guidelines

2 Quality standards

1 Technology appraisal

1 COVID-19 rapid guideline

Care of people approaching the end of life

The NICE guideline on end of life care for adults: service delivery and quality standard on end of life care for adults say that people approaching the end of life should be identified in a timely way. Effective and timely identification can allow people, and those important to them, to make decisions about their care. This can help health and social care providers ensure that peoples' priorities are recognised and, where possible, met.

Only 60% of people in their last 3 months of life knew that they were likely to die
(National Survey of Bereaved People [VOICES], 2016)

Either health or social care practitioners in any setting can start identification. They should talk to the person, and their family and carers, about the benefits of being identified and this being recorded on a register or similar system. This conversation should be carried out sensitively and take into account that not all people want to be identified as approaching the end of their life.

'I ask myself whether I would be surprised if they were not alive in 12 months. This depends on their degree of frailty and dependency on others but also their stage of disease. I usually ask them how they see their health changing over the next few months or year. Most will know that they are dying so then we can move on to conversations about care planning and death.'
GP, North West England

A national measure of end of life care services

The NHS has adopted the key performance indicator 'The percentage of deaths with 3 or more emergency admissions in the last 3 months of life' to measure the quality of end of life care services. From 2009 to 2018, the percentage of people with 3 or more emergency admissions in the 3 months before they died increased from 5.6% to 7.5%. This could indicate that there are issues with identification of people at risk of death, planning and availability of services, integrated urgent care response to unscheduled needs or communication, coordination and information sharing.

'Sometimes identifying a patient as being in their last year of life is opportunistic and relies on a GP either knowing a patient or taking the time to review their history. Unfortunately, time pressures mean sometimes seeing a snapshot isn't enough. Fortunately, our chronic disease reviews through the nursing teams allow a more in-depth assessment.'
GP trainee

Condition-specific identification of people approaching the end of life

The Care Quality Commission's (CQC) end of life care review found that certain conditions, such as dementia, are not always recognised as life limiting. Because of this, people approaching the end of their life can often be identified at a late stage, with end of life care planning not always done effectively. The CQC found that healthcare professionals did not always consider the communication needs of people with dementia and sometimes assumed that the person with dementia lacked capacity. The CQC's review found that only a third of people with dementia had a mental capacity assessment.

Personalised care planning

NICE's quality standard on end of life care for adults says that the opportunity to develop a personalised care plan, which may include an advance care plan, should be part of a comprehensive holistic assessment for people approaching the end of life.

Advance care plans involve people making decisions about their future care with the help of health and social care practitioners. These plans can include:

- priorities and preferences for care and treatment
- decisions about resuscitation
- views about how and where they would like to be looked after in their last days of life
- who they would like to have with them
- any spiritual or religious beliefs they would like to be taken into account
- who they would like to make decisions for them if they become unable to make them for themselves.

People with an advance care plan before their final hospital admission

(National Audit of Care at the End of Life, 2016 and 2019/20)

The National Audit of Care at the End of Life found that there has been an increase in advance care plans, but the latest audit still shows that 9 out of 10 people did not have one on arrival at their final hospital admission. Around half of people in their final hospital admission lacked capacity to make decisions about their care and may have benefited from an advance care plan.

A survey by the Motor Neurone Disease (MND) Association in 2019, observed that only 36% of people with MND were given the chance to make an advance care plan and less than half had the opportunity to discuss end of life issues. The CQC report, A different ending: people with a learning disability, found that unidentified health needs among people with a learning disability can result in late recognition that they are at the end of their life, meaning fewer opportunities to plan their care.

Coordination of care

NICE's quality standard on end of life care for adults says that people approaching the end of life should receive consistent care that is coordinated effectively across all relevant settings and services at any time of day or night. This should be delivered by practitioners who are aware of the person's current medical condition, care plan and preferences.

Care is well coordinated in the community, but there is room for improvement in how hospitals work with other services outside of the hospital.

(National Survey of Bereaved People [VOICES], 2016)

The National Survey of Bereaved People (VOICES) was completed by over 21,000 people in 2015. The survey reported that 83% of people who had a bereavement said community-based services, for example community nursing

and home care workers, worked well together during the last 3 months of the person's life. This compares with 67% who said hospital services worked well with services outside the hospital, such as general practices.

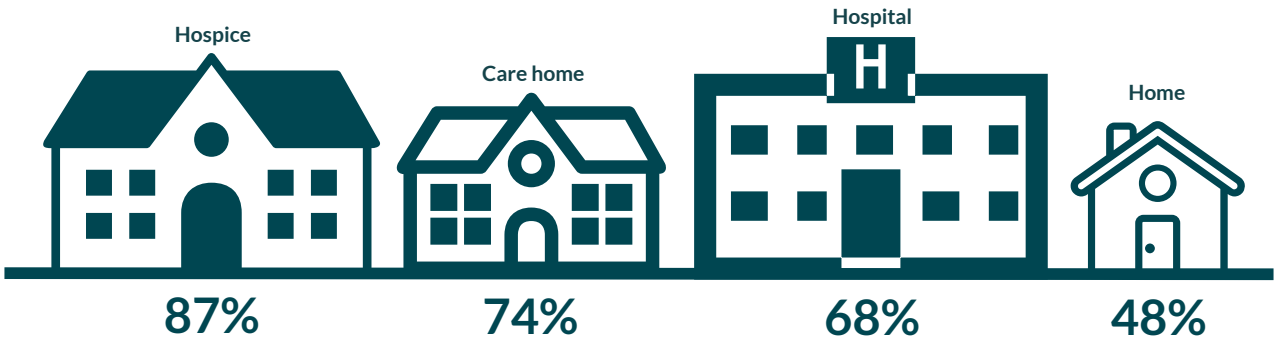
'The Electronic Palliative Care Coordination System (EPaCCS) document is extremely useful and there is good communication between ourselves, the community nursing team and palliative care. However, it can take 24 to 48 hours for the EPaCCS document to be circulated and I have recently experienced it not reaching the ambulance service in time, resulting in an elderly patient who had a "do not attempt CPR" decision in place almost being resuscitated. Her daughter was understandably distressed by this.'
GP trainee

Pain relief

NICE's quality standard on end of life care for adults says that people approaching the end of life should have their needs safely, effectively and appropriately met at any time of day or night, including access to medicines and equipment.

The National Survey of Bereaved People (VOICES) results suggested that pain relief was generally more readily available to people dying of cancer compared with people who had other conditions, such as cardiovascular disease. This may be because hospice care is mostly provided to people who have cancer.

Achievement of complete pain relief (all or some of the time) across different care settings



(National Survey of Bereaved People [VOICES], 2016)

'Once he was at home after surgery and chemotherapy he was not offered any community support. The GP had made it clear that his services would not be needed as the hospital would control everything. His pain control was poorly managed by the hospital with instructions to only take morphine if necessary at night. Without a clear pain and symptom control assessment clearly this was not going to achieve relief. He returned to hospital on numerous occasions due to intractable pain and vomiting.'
Friend of a bereaved wife

Access to care settings

According to the CQC's end of life care review, people with conditions like dementia often face an additional barrier to dying in their preferred place because certain care settings, for example hospices, are not always offered as an option for them.

Some hospices stated that they only accept patients with dementia who are 'able to cooperate'.
(CQC. A different ending: people with dementia, 2016)

Insight from Marie Curie

There is a real need for data on patient and family experience of end of life care in order to understand where progress has been made and what gaps in care remain. The National Audit of Care at the End of Life should be extended to community settings to give us the richness of data that we have about end of life care in hospitals. The vast majority of people die in nursing or residential care settings and yet this is not reflected in the way that data is captured and portrayed.

It is likely that changes to commissioning of palliative and end of life care will focus much more on outcomes and encouraging providers to work together to offer more comprehensive and less fragmented 24/7 services. These changes would be widely welcomed.

Everyone should have access to good quality end of life care, wherever they access that care. There is an urgent need for services and their IT systems to work together, so that patients can transition seamlessly between services and have their plans and preferences follow them.

A good first step for many providers is education, allowing them to respond to the needs of all patients, especially those with comorbidities or non-cancer diagnoses. Effective communication and relationship building with the person and their family or social network is key. Person-centred interactions focused on 'what matters' to the person are fundamental and is the hallmark of being able to anticipate what is important to that person and what will make a difference to their overall experiences.

Recognition and assessments in the last days of life

NICE's guideline on care of dying adults in the last days of life recommends that adults with signs and symptoms that suggest they may be in the last days of life are monitored for further changes to help determine if they are nearing death, stabilising or recovering. As soon as it is recognised that a person may be entering the last days of life, the most appropriate team member should discuss this with the person and those important to them, unless they do not wish to be told.

Recognising and weighing up factors that may indicate someone is in their last days or hours of life is complex and can prove a difficult task, even for an experienced palliative care doctor.

Recognition of and discussions about imminent death (death within days or hours)

2015		2019	
83%	↑	88%	Recorded recognition of imminent death (% of all deaths)
23%	↑	27%	Healthcare professional discussed the possibility of imminent death with the person (% of expected deaths)
95%	↔	95%	Healthcare professional discussed the possibility of imminent death with those close to the dying person (% of expected deaths)

(National Audit of Care at the End of Life, 2016 and 2019/20)

The NICE guideline on care of dying adults in the last days of life sets out the assessments that should be undertaken for adults in their last days of life, such as assessing mouth care, pain, breathing, nausea, agitation or delirium, anxiety and distress. These should be part of an individualised plan of care for the last days of life (see page 14).

Many of these symptoms can be debilitating and distressing for the dying person and those important to them. Identifying the underlying causes can help guide the course of treatment.

The National Audit of Care at the End of Life found that, over the last 2 audits, less than half of people who were dying received an assessment of their spiritual or religious needs, and just over half received an assessment of their emotional or psychological needs. People who were in their last days of life were much more likely to have an assessment of their physical health. However, the latest figures showed a decrease in some areas of physical assessment.

Recorded health assessments in the last days of life, changes between 2018 and 2019

(National Audit of Care at the End of Life, 2019/20)

Insight from Marie Curie

We know that in the acute care setting staff often recognise that death is imminent, but they do not always have conversations with patients about their options and preferences for end of life. Examples of good communication with dying patients from all settings, including community palliative care, need to be shared and replicated.

One way to improve this in the future is by having highly trained and well-supported volunteers. They can be 'companions' to patients who are dying in hospital who do not have relatives or friends with them.

A review of and ongoing support for training around communications with dying patients and their families is needed to ensure that all people at the end of life have the option to talk about dying and their plans and preferences. We believe that compassionate conversations can provide a hopeful context and enable people to feel in control of what happens to them so that they can focus on living well until the end.

There is an emphasis on the physical needs of the patient, and further work needs to be undertaken to understand the barriers to providing emotional and spiritual care. The lived experience of people and their families is influenced by a holistic understanding of what is important and matters to that person.

Shared decision making in the last days of life

The NICE quality standard on care of dying adults in the last days of life says that people in the last days of life and those important to them should be talked to and offered information in an accessible and sensitive way. The person who is dying should have opportunities to be involved in decisions about their care and to express their personal needs and preferences.

In 2019, 79% of people close to the dying person said that staff communicated sensitively, a rise from 68% in 2018.
(National Audit of Care at the End of Life, 2019/20)

Involvement of people close to the dying person in decisions about their care has remained static at just over 70% for the past 2 National Audits of Care at the End of Life.

Good communication is crucial when a person is entering the last days of life. It allows the dying person and those important to them to prepare for death and make any necessary arrangements. The More care, less pathway review of the Liverpool care pathway highlighted many examples of poor communication, for example using euphemisms such as 'making them comfortable'. Poor communication at the end of life can lead to misunderstandings and unnecessary distress in people who are dying and those important to them.

Discussions about risks and benefits

The NICE guideline on care of dying adults in the last days of life and quality standard on care of dying adults in the last days of life say that a discussion should take place about the risks and benefits of different hydration options. They also state that there should be an assessment of the medicines that may be needed to manage symptoms that often occur during the last days of life, such as agitation, anxiety, breathlessness, pain, nausea and vomiting. When medicines are prescribed in anticipation of symptoms, this is known as anticipatory prescribing. Anticipatory prescribing enables rapid relief of distressing symptoms.

The needs and preferences of the person who is dying should be discussed with the person, those important to them and the multiprofessional team caring for them.

Discussing options with the person who is dying, and those important to them, allows their wishes and preferences to be considered.

Discussions with the dying person about the risks and benefits of hydration options (% of expected deaths)

10% Had a discussion

61% Did not have a discussion because the dying person was unconscious or lacked capacity

21% Did not have a discussion and no reason was recorded

Discussions with the dying person about anticipatory prescribing (% of expected deaths)

13% Had a discussion

69% Did not have a discussion because the dying person was unconscious or lacked capacity

15% Did not have a discussion and no reason was recorded

(National Audit of Care at the End of Life, 2019/20)

The 2019/20 National Audit of Care at the End of Life shows that many conversations could not take place because the dying person was unconscious or lacked capacity. Conversations between a healthcare professional and those important to the dying person happened more frequently. A conversation about the risks and benefits of hydration options was documented in 35% of records and a conversation about anticipatory prescribing documented in 60% of records.

Individualised care planning

The NICE guideline on care of dying adults in the last days of life says that adults in the last days of life, and the people important to them, should be given opportunities to discuss, develop and review an individualised care plan for the last days of life. This is separate to the personalised care plan, which is made much earlier.

Discussion and review of individualised care plans (% of all deaths)

2018		2019	
20%	↑	25%	Person had an opportunity to discuss their care plan
62%	↑	90%	Those important to the dying person had an opportunity to discuss the care plan
64%	↑	80%	Care plans reviewed

(National Audit of Care at the End of Life, 2019/20)

The care plan should encompass the person's goals and wishes, preferred care setting, and current and anticipated care needs, including preferences for symptom management, maintaining hydration and care after death. Opportunities for discussion should continue so the plan can reflect any changes in the person's wishes or needs in the last days of their life.

Results from the National Audit of Care at the End of Life show that there has been an increase in individualised care plans for people in the last days of life, rising from 56% in 2015 to 65% in 2019.

Preferred place of death

As part of the individualised care plan for the last days of life, NICE's guideline on care of dying adults in the last days of life says the dying person's preferred place to be cared for and to die should be discussed and recorded. However, it is not always possible for people to be in their preferred care setting and this should be explained as part of this discussion.

End of life care rapid transport service

NICE says that systems should support smooth and rapid transfer between care settings for adults approaching the end of their life.

Planning transport for people in the last days of life can be very difficult given the unpredictable nature of a person's decline. A shared learning example describes how healthcare professionals were not always clear on who to call to arrange transport to a preferred place of death and often resorted to calling 999 in cases where there was a rapid decline in the persons health. As 999 calls are prioritised for treatment of the sickest people with potentially reversible causes, this often resulted in delays in transport for the dying person. The Welsh Ambulance Services NHS Trust created a dedicated booking system for end of life care transport that was clear and understandable for all healthcare professionals. The system made use of the Non-Emergency Patient Transport Service and gave priority to end of life care journeys.

Since implementing the new service, average transport waiting times to the busiest hospice in the country have reduced by almost 2 hours. Evaluation of the service has provided positive feedback from healthcare professionals who say that it has improved end of life care.

The National Audit of Care at the End of Life found that there had been a small decline in the number of cases where there was documented evidence that the preferred place of death was indicated by the patient, from 28% in 2018 to just over 26% in 2019.

Insight from Marie Curie

It is encouraging that most people close to the dying person said that staff communicated sensitively, but still a fifth of people did not have this experience. Improvements in discussions about hydration, anticipatory medications and care plans are also welcome but again there are significant gaps. Further improvement is needed in communication training and skills development for professionals across all care settings.

It is heartening to see that the audit has demonstrated improvement in the opportunities for patients and their families to discuss the plan of care for the last few days of life and that these plans are more regularly reviewed.

However, 75% of patients still have not had the opportunity to discuss their own individualised care plan in the last days of life, and further work is needed to ensure patients have the opportunity to discuss their preferences and wishes.

We are not surprised to see a slight reduction in focus on the preferred place of death, which can be difficult to achieve. Our preference is that the end of life experience is made as good as it can be, in whatever care setting, and that it should include 'what matters most' to the dying person. For example, it might be to see their dog for the last time, to hear their favourite music, or to know that someone will be with them when they are dying.

Support for carers

Carers often have an important role in ensuring that their loved one receives a good standard of care. Carers who provide unpaid care and support to a family member, partner or friend are often anxious and physically and emotionally tired when the person they care for reaches the end of their life.

The NICE guideline on supporting adult carers recommends that carers should be identified in line with the Care Act 2014 to ensure they receive information and support to enable them to carry out their caring roles.

Hospice UK's organisational survey of carer assessment and support found that 99% of hospices surveyed routinely identified the next of kin when people first accessed their services. A process or protocol for identifying main carers was reported in 87% of hospices, and 64% had a process for identifying additional carers.

There have been recent improvements in the emotional and practical support provided by hospital staff, as well as sensitive communication.
(National Audit of Care at the End of Life, 2019/20)

Opportunities for discussion

Our guideline on supporting adult carers says that carers should be offered frequent opportunities for discussion and help to understand information about the diagnosis and prognosis of the person they care for (with the person's consent), and that these should be carried out in a sensitive manner.

Almost 70% of people close to a dying person felt they had enough opportunities to ask questions and discuss the dying person's condition, according to the 2018 National Audit of Care at the End of Life, and 78% felt they were communicated with in a sensitive and compassionate way. Results of the 2019 survey suggest rates of sensitive communication have improved, with 84% saying staff communicated sensitively.

Practical and emotional support

NICE's guideline on end of life care for adults: service delivery says that people managing and delivering services should think about what practical and emotional support can be provided to carers of adults approaching the end of their life and review this when needed.

According to the National Audit of Care at the End of Life there has been a slight increase in the proportion of people close to the dying person who felt they had enough practical support from staff, from almost 58% in 2018 to 62% in 2019.

Support after the person dies

NICE's quality standard on end of life care for adults says that people closely affected by a death should be communicated with in a sensitive way and offered immediate and ongoing bereavement, emotional and spiritual support appropriate to their needs and preferences.

Staff communicate sensitively, but availability of bereavement services can be poor.
(National Survey of Bereaved People [VOICES], 2016)

Results of the 2018 National Audit of Care at the End of Life show that 82% of people who were close to the dying person felt supported by staff after the person's death. However, results of the National Survey of Bereaved People (VOICES) in 2016 showed that only 13% of people had the opportunity to talk to someone from health and social services or from a bereavement service about their feelings. Almost 21% said that they did not get an opportunity to talk to someone, but they would have liked to.

Insight from Marie Curie

There is a need to understand the opportunities for assessing and meeting carers needs in all care settings, and in particular the needs of young carers. We suggest that a formal carer's assessment is fundamental. Many people don't recognise themselves as carers and miss out on opportunities to access support.

The emotional and physical burden on carers is immense and can impact on their own health and wellbeing. There is growing evidence of a long-lasting impact and legacy for carers after the person has died. Inadequate support and pre-bereavement care can have a serious impact on other aspects of their lives such as employment and social isolation.

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Marie Curie provide free resources for professionals and the public.

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