

#### NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

#### PUBLIC BOARD MEETING

Wednesday 22 May 2019 at 1.30pm in the Medical Education Centre, Poole Hospital, Longfleet Road, Poole, BH15 2JB

#### AGENDA

19/038	Apologies for absence To receive apologies for absence	(Oral)
19/039	<b>Declarations of interests</b> To declare any new interests and consider any conflicts of interest specific to the meeting	(Item 1)
19/040	<b>Minutes of the last Board meeting</b> To approve the minutes of the Board meeting held on 20 March 2019	(Item 2)
19/041	<b>Matters arising</b> To consider matters arising from the minutes of the last meeting	(Oral)
19/042	Chief Executive's report To receive the Chief Executive's report Andrew Dillon, Chief Executive	(Item 3)
19/043	<b>Finance and workforce report</b> To receive the finance and workforce report <i>Ben Bennett, Director, Business Planning and Resources</i> <i>Directorate</i>	(Item 4)
19/044	Business plan 2019/20 To approve the business plan Andrew Dillon, Chief Executive	(Item 5)
19/045	Widening the evidence base: the use of broader data and applied analytics in NICE's work To approve the statement of intent for consultation <i>Professor Gillian Leng, Deputy Chief Executive and Director,</i> <i>Health and Social Care Directorate</i>	(Item 6)

19/046	<b>Digital health technologies evaluation pilot</b> To receive the report <i>Meindert Boysen, Director, Centre for Health Technology</i> <i>Evaluation</i>	(Item 7)
19/047	NICE impact: stroke To review the report Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate	(Item 8)
19/048	Audit and Risk Committee minutes To receive the unconfirmed minutes of the meeting held on 24 April 2019 Dr Rima Makarem, Chair, Audit and Risk Committee	(Item 9)
19/049	Audit and Risk Committee annual report and terms of reference To receive the annual report and approve the updated terms of reference Dr Rima Makarem, Chair, Audit and Risk Committee	(Item 10)
19/050	Revisions to Standing Orders, Standing Financial Instructions, and Scheme of Reservation and Delegation To agree the updated documents following annual review Ben Bennett, Director, Business Planning and Resources	(Item 11)
19/051	<b>Directors' reports for consideration</b> Evidence Resources	(Item 12)
19/052	<b>Directors' reports for information</b> Centre for Guidelines	(Item 13)
19/053	Centre for Health Technology Evaluation	(Item 14)
19/054	Communications Directorate	(Item 15)
19/055	Health and Social Care Directorate	(Item 16)
19/056	Any other business To consider any other business of an urgent nature	(Oral)

**Date of the next meeting** To note the next public Board meeting will be held on Wednesday 17 July 2019 at Northampton Guildhall, St Giles' Square, Northampton, NN1 1DE (annual general meeting).

Interests Register - Board and Senior Management Team				
Name	Role with NICE	Description of interest	Interest arose	Interest ceased
Board Members				I
Sir David Haslam	Chair	Patron of Cry-Sis	1986	
		Visiting Professor in Primary Health Care.de Montfort University, Leicester.	2000	
		Professor of General Practice, University of Nicosia.	2014	
		Contributor to Practitioner Medical Publishing, for writing a monthly column in The Practitioner.	1996	
		Chair - Kaleidoscope Health & Care Advisory Board.	2016	
		Adviser to Vopulus Ltd.	2016	
		Member of Faculty of Healthcare Leadership Academy	2016	
		Patron - The Louise Tebboth Foundation	2017	
		Member of Board of Directors, State Health Services Organisation, Nicosia, Cyprus	2018	
Prof Sheena Asthana	Non-Executive Director	Trustee of Change Grow Live (charity).	2017	
		Member of the Advisory Committee on Resource Allocation (NHS England).	2017	
Angela Coulter	Non-Executive	Director, Coulter & Coulter Ltd.	2009	
	Director	Member, Academy of Medical Royal Colleges Choosing Wisely steering group.	2015	
		Honorary Fellow, Royal College of General Practitioners.	2007	
		Honorary Professor, Institute of Regional Health Research, University of Southern Denmark.	2007	
		Member, Public Advisory Board of Health Data Research UK	2019	

#### **NICE** National Institute for Health and Care Excellence

Prof Martin R Cowie	Non-Executive Director	Consultancy payments for the membership of Steering committee/DSMBs/Endpoint committees related to Global Clinical Trials or Registries: XATOA, COMPASS, COMMANDER-HF (Bayer); SHIFT, QUALIFY, OPTIMIZE (Servier); RELAX-Region Europe, PARALLAX, VERIFY (Novartis); COAST (Abbott); COAST-AHF (Neurotronik); FIRE1 system (FIRE1); SERVE-HF (ResMed).	2016	
		Associate Editor honoraria from Heart (BMJ Publications) and Journal of the American College of Cardiology.	2016	
		Research grants to Imperial College London to support investigator-led research projects (ResMed; Bayer; Abbott; Boston Scientific; NIHR; British Heart Foundation).	2016	
		Fellowships of the Royal College of Physicians of London and Edinburgh, and of the European Society of Cardiology, the Heart Failure Association of the European Society of Cardiology, and the American College of Cardiology.	2016	
		Chair of the Digital Committee of the European Society of Cardiology, and Member of the Digital Committee of the British Cardiovascular Society.	2016	
		Member of the Advocacy Committee of the European Society of Cardiology.	2016	
		Member of the Medical Advisory Board of two patient charities: the Atrial Fibrillation Association, and the Pumping Marvellous Foundation.	2016	
		Adviser, BMJ Best Practice	2019	
Elaine Inglesby- Burke CBE	Non-Executive Director	Chief Nursing Officer, Northern Care Alliance NHS Group (Salford Royal NHS Foundation Trust and Pennine Acute NHS Trust).	2004	
		Board Member – AQuA (Advancing Quality Alliance).	2012	
		Professional Advisor (Secondary Care) Governing Body – St Helens CCG.	2014	
		Trustee – Willowbrook Hospice, Merseyside.	2007	
Prof Tim Irish	Non-Executive	Life science assets held in a blind trust and managed by an independent trustee	2015	
	Director and Senior Independent Director	Professor of Practice, King's College London's School of Management / Business and a paid consultant to King's Commercialisation Institute.	2017	
		Non-Executive Director, Life Sciences Hub Wales Ltd.	2017	2019
		Chairman and Non-Executive Director, Quirem Medical BV Supervisory Board.	2015	
		Non-Executive Director, Fiagon AG.	2017	

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		Non-Executive Director, eZono AG.	2018	
		Non-Executive Director, Feedback plc.	2017	
		Non-Executive Director, Styrene Systems Ltd.	2017	2019
		Board Member, Pistoia Alliance Advisory Board.	2017	2019
		Non-Executive Director, Pembrokeshire Retreats Ltd.	2006	
		Non-Executive Director, ImaginA b Inc.	2019	
Dr Rima Makarem	Non-Executive Director and Senior	Audit Chair & Non-Executive Director, University College London Hospitals NHS Foundation Trust (UCLH).	2012	
	Independent Director	Chair, National Travel Health Network & Centre (NaTHNaC).	2015	
		Trustee at UCLH Charity.	2013	
		Independent Council Member at St George's University of London.	2016	
		Non-Executive Director and Audit Committee Chair, House of Commons Commission	2018	
		Non-Executive Director, The Hillingdon Hospitals NHS Foundation Trust	2019	2019
		Lay Member, General Pharmaceutical Council	2019	
Tom Wright CBE	Non-Executive Director	Chief Executive, Guide Dogs.	2017	
Senior Management	Team			
Sir Andrew Dillon	Chief Executive	Trustee, Centre for Mental Health charity.	2011	
		Visiting Professor at Imperial College London.	2016	
Ben Bennett	Director Business Planning & Resources	None.		
Meindert Boysen	Director Centre for Health	Member of the Board of Directors for the International Society for Pharmacoeconomics and Outcomes Research.	2017	
	Technology Evaluation	Member of the International Advisory Panel for the Agency for Care Effectiveness (ACE) in Singapore.	2019	

#### **NICE** National Institute for Health and Care Excellence

Paul Chrisp	Director Centre for Guidelines	Spouse works in medical communications offering services to a range of pharmaceutical companies.	2009	
Jane Gizbert	Director Communications	Non-Executive Director Tavistock and Portman NHS Mental Health Trust.	2014	2019
Prof Gillian Leng	Deputy Chief Executive and Health and Social Care	Honorary Librarian and Trustee at the Royal Society of Medicine.	2013	
-		Editor of the Cochrane EPOC Group.	2012	
	Director	Visiting Professor at the King's College London.	2012	
		Association Member BUPA.	2013	
		Chair - Guidelines International Network (GIN).	2016	
		Spouse is an Executive Director at Public Health England.	2013	
Alexia Tonnel	Director Evidence Resources	None.		

#### NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

#### Public Board Meeting held on 20 March 2019 at Lancaster Town Hall, Dalton Square, Lancaster LA1 1PJ

#### 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.

#### Present

Sir David Haslam Professor Sheena Asthana Professor Angela Coulter Professor Martin Cowie Elaine Inglesby-Burke Professor Tim Irish Dr Rima Makarem Tom Wright	Chair Non-Executive Director Non-Executive Director Non-Executive Director Vice Chair and Non-Executive Director Non-Executive Director Non-Executive Director
Executive Directors	
Sir Andrew Dillon Professor Gillian Leng Alexia Tonnel	Chief Executive Health and Social Care Director and Deputy Chief Executive Evidence Resources Director
Directors in attendance	
Meindert Boysen Paul Chrisp Jane Gizbert Catherine Wilkinson	Centre for Health Technology Evaluation Director Centre for Guidelines Director Communications Director Acting Business Planning and Resources Director
In attendance	

## David Coombs

Associate Director – Corporate Office (minutes)

#### 19/021 APOLOGIES FOR ABSENCE

1. Apologies were received from Ben Bennett.

#### **19/022 DECLARATIONS OF INTEREST**

2. Rima Makarem stated that she had recently been appointed as a lay member of the General Pharmaceutical Council and Martin Cowie declared his role as an

adviser to BMJ Best Practice, both of which will be added to the register of interests.

#### **ACTION: David Coombs**

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

#### 19/023 MINUTES OF THE LAST MEETING

4. The minutes of the public Board meeting held on 30 January 2019 were agreed as a correct record.

#### 19/024 MATTERS ARISING

- 5. The Board reviewed the actions arising from the public Board meeting held on 30 January 2019 and noted that:
  - Alexia Tonnel will be undertaking training to become a mental health first aider.
  - Future impact reports will take account of the feedback from the Board's discussion.
  - The ABPI and ABHI are represented on the data analytics external reference group, and the next meeting, which Macmillan are attending to give a patient group perspective, will consider future representation from the data analytics industry.
  - Elaine Inglesby-Burke has been appointed to the Remuneration Committee.

#### 19/025 CHIEF EXECUTIVE'S REPORT

- 6. Andrew Dillon presented his report, which described the main programme activities to the end of February 2019 and summarised the financial position at the end of January 2019. He highlighted the update from the Science Advice and Research programme, including the range of science policy and research collaborations on various methodological issues, and the actions underway to address the shortfall in income from NICE's Scientific Advice services.
- 7. Martin Cowie highlighted the extensive communication he has received from colleagues who are concerned about the draft abdominal aortic aneurysm guideline, which they feel diverges from internationally recognised best practice. Paul Chrisp stated that following NICE's quality assurance process and the feedback received from stakeholders, the committee were asked to look again at the recommendations, including to ensure the link between these and the evidence considered is clear. The committee subsequently held a further meeting and agreed to maintain the proposed recommendations. NICE is therefore working with system partners to look at the approach to implementing the

guideline in the context of this feedback on the draft guideline. Andrew Dillon stated that the Senior Management Team will consider the outcome of these discussions and the proposed next steps, which may include escalation to the Board.

8. The Board received the report.

#### 19/026 FINANCE AND WORKFORCE REPORT

- 9. Catherine Wilkinson presented the report which outlined the financial position at 31 January 2019 and gave an update on workforce developments. Year to date, there is a financial underspend of £1.3m. This is forecast to increase to £1.9m by the year-end, which is £0.1m higher than the underspend forecast in the report to the January Board meeting. Catherine highlighted the update on the HR initiatives in the report, including the work to bring recruitment back in-house and to maximise staff potential including new leadership and management apprenticeships for existing staff.
- 10. The Board received the report, and thanked Catherine Wilkinson for her contribution as acting Business Planning and Resources Director.

#### 19/027 BUSINESS PLAN 2019/20

- 11. Andrew Dillon stated that the Board had been due to approve the 2019/20 business plan at this meeting. However, NICE was only recently informed by the Department of Health and Social Care (DHSC) that funding would not be provided to fully cover the increases in employer's pension contributions in 2019/20 and the cost of the second year of the Agenda for Change pay award. These create an unforeseen £1.1m cost pressure, in addition to the anticipated £1.6m deficit that is due to the timelag in realising income from the first year of introducing charging into the technology appraisal (TA) and highly specialised technologies (HST) programmes.
- 12. Andrew Dillon stated that it has therefore been necessary to withdraw the proposed business plan while options for addressing the £1.1m cost pressure are developed. It is hoped that proposals will be available for the Board in April, with a view to the Board approving a revised business plan in May. Andrew stated that he has set out his concerns to the DHSC about the timing for receiving this information, and to reconfirm expectations that the DHSC will provide funding to cover the shortfall in income in the first year of TA and HST charging, to the extent this is necessary.

#### 19/028 NICE IMPACT REPORT: MENTAL HEALTH

13. Gill Leng presented the report on how NICE's guidance can contribute to improvements in mental health. Gill noted the positive commentary in the report from the Chief Executive of Mind and highlighted the range of NICE's guidance on mental health that dates back to NICE's first clinical guideline, which was on schizophrenia. Gill acknowledged the areas for further improvements identified in

the report, which NICE will seek to feed into the work to deliver the NHS Long Term Plan.

14. The Board welcomed the report and discussed how it could be promoted and communicated to a range of audiences including service users and health care professionals. The importance of tailored communication for particular audiences was noted, including targeting the wider medical profession given the poor physical health often experienced by people with mental illness. The multiple social media activities to promote previous impact reports were welcomed, and it was suggested that it would be helpful to evaluate which had been most effective.

#### **ACTION: Jane Gizbert**

- 15. The Board received the report.
- 16. In response to a question from the audience, Gill Leng confirmed that NICE has published guidance covering both acute and community mental health services, and this report is focused on areas where data on uptake is available.

#### 19/029 NICE INDICATOR PROCESS GUIDE

- 17. Gill Leng presented the report that outlined the proposed updates to the process guide for developing NICE indicators. The most significant changes to the guide are to provide a more specific set of criteria to assess indicators, and a more flexible approach to indicator testing. Following Board approval, the updated guide will be sent out for a 12-week public consultation from mid-April 2019 to mid-July 2019. Gill paid tribute to Mark Minchin's contribution as the Associate Director responsible for the indicator programme.
- 18. Board members asked about the implications of the proposed changes for the Quality and Outcomes Framework (QOF), and also the extent data quality is included in the proposed indicator assessment criteria. In response, Gill Leng stated that the proposed changes will provide greater flexibility on the size of population to which an indicator will apply. The precise impact of the changes on the QOF will depend on the outcome of the contract negotiations between NHS England and the British Medical Association's General Practitioner Committee. NICE is not involved in these negotiations, nor in setting the target level for an indicator in the QOF. In relation to data quality, Mark Minchin highlighted this is inherent to all the proposed assessment criteria, and particularly relevant to the feasibility domain.
- 19. The Board noted and welcomed NICE's work on developing indicators to date, and approved the proposed updates to the process guide for public consultation.

#### **ACTION: Gill Leng**

#### **19/030 LONDON OFFICE ACCOMMODATION**

20. Andrew Dillon presented the update on the planning for when the lease on the current London office ends in December 2020. He highlighted that the British

Council are moving to Stratford, east London, in the summer of that year and NHS Property Services are seeking to secure space in this new office that could be leased to NICE and other DHSC Arm's Length Bodies. Andrew highlighted the quality of the proposed accommodation and the transport links to the area. Subject to the Board's agreement to include NICE in these negotiations, he stated that an internal working group will begin to meet to consider how to utilise the proposed space, and plan for the move, including working through the implications for staff.

21. The Board approved the proposed next steps including entering into negotiations to progress the proposed move to Stratford in the summer of 2020.

#### 19/031 AUDIT AND RISK COMMITTEE MINUTES

- 22. Tim Irish presented the unconfirmed minutes of the Audit and Risk Committee meeting held on 23 January 2019, which he chaired on behalf of Rima Makarem. He noted that the committee reviewed the arrangements for introducing charging for the TA and HST programmes and were assured these arrangements were robust. Catherine Wilkinson paid tribute to the staff who have developed these arrangements, notably Nicola Bodey, Lori Farrar and Danielle Lees. She noted the positive response to date from the companies who have received an invitation to participate in the TA and HST programmes in April and May and are therefore be the first to be subject to the charging regime.
- 23. The Board received the unconfirmed minutes.

#### 19/032 DIRECTOR'S REPORT FOR CONSIDERATION

- 24. Meindert Boysen presented the update from the Centre for Health Technology Evaluation (CHTE) and paid tribute to the staff across the Centre's work programmes. He highlighted the impact of multiple high profile policy initiatives on the Centre, including the NHS Long Term Plan, the Life Sciences Sector Deal, and the Voluntary Scheme for Branded Medicines Pricing and Access. While NICE is committed to delivering these, Meindert noted the need to ensure sufficient resources are in place and the timescales for implementation are appropriate.
- 25. Meindert highlighted the information in the report on the implementation of the budget impact test (BIT). Of the 31 topics that met the company evidence submission stage, nine have reached final guidance publication. Five of these have been recommended for routine commissioning, with the other four recommended for use in the cancer drugs fund (CDF). Only one of the topics that progressed to final guidance with a recommendation for routine commissioning was subject to a delay as a result of the BIT process. This was due to the need for a policy decision on whether the BIT applied to a topic going through the CDF review, and it did not affect patient access to the technology. Meindert highlighted the commitment to formally review the BIT next year.

- 26. The anticipated shortfall in published TA guidance against the business plan target was discussed, particularly in the context of the incoming charging regime. Meindert noted the range of factors that can affect the timescale for publishing TA guidance, and stated that work is underway to improve forecasting and scheduling, to ensure capacity is most effectively utilised. Catherine Wilkinson explained the charging arrangements and noted that the first payment is required at the start of the appraisal process.
- 27. The Board noted the report and thanked Meindert for the Centre's work.

#### 19/033 – 19/036 DIRECTORS' REPORTS FOR INFORMATION

28. The Board received the Directors' Reports.

#### 19/037 ANY OTHER BUSINESS

29. None.

#### NEXT MEETING

30. The next public meeting of the Board will be held at 1.30pm on 22 May 2019 at Poole Hospital, Longfleet Road, Poole, Dorset BH15 2JB.

# National Institute for Health and Care Excellence Chief Executive's report

This report provides information on the outputs from our main programmes for 12 months to the end of March 2019 and on our financial position for the same period, together with comment on other matters of interest to the Board.

The Board is asked to note the report.

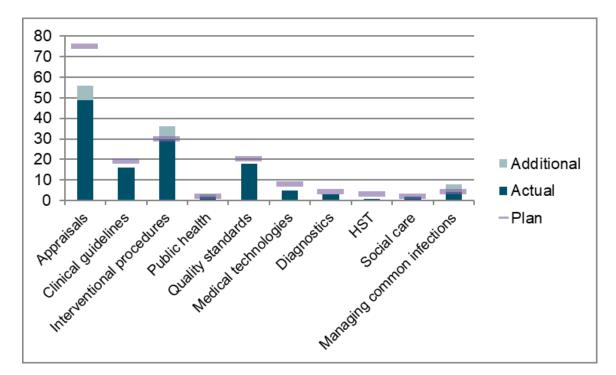
Andrew Dillon Chief Executive May 2019

# Introduction

- 1. This report sets out the performance of the Institute against its business plan objectives and other priorities, and for income and expenditure for the 12 months to the end of March 2019. This report notes the guidance published since the last public Board meeting in March and refers to business issues not covered elsewhere on the Board agenda.
- 2. The report also contains a report on the performance of the Science, Advice and Research programme in Appendix 5.
- 3. The balanced scorecard, reporting more detail on aspects of our performance for 2018-19 financial year, is set out at Appendix 6.

# Performance

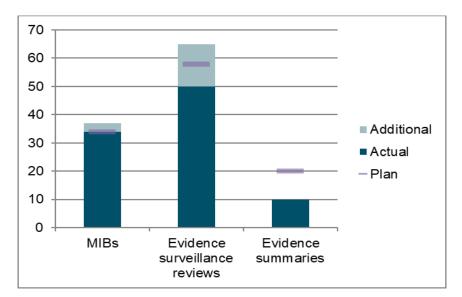
- 4. The current position against a consolidated list of objectives in our 2018-19 business plan, together with a list of priorities identified by the Department of Health and Social Care, is set out in Appendix 1.
- 5. Extracts from the Directors' reports, which refer to particular issues of interest, are set out at Appendix 2. The performance of the main programmes between April 2018 and March 2019 is set out in Charts 1 and 2, below.



#### Chart 1: Main programme outputs: April 2018 to March 2019

National Institute for Health and Care Excellence Chief Executive's report Date: 22 May 2019 Reference: 19/042 Notes to Chart 1:

- a) HST refers to the highly specialised technologies programme (drugs for very rare conditions)
- b) The variance is the difference between the target output for the reporting period, as set out in the business plan and the actual performance
- c) '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 3. Guidance, quality standards and other advice published since the last Board meeting in March is set out Appendix 4.
- 7. The explanation for the significant variation in the technology appraisal programme is reported in more detail in the Health Technology Evaluation Director's report elsewhere on the agenda. That report notes that the majority of the topics delayed (74%) fall into two categories: topics rescheduled due to regulatory approval timeline changes or suspended due to negative regulatory decisions, and topics delayed after draft guidance publication, to accommodate commercial discussion with NHS England. The remainder of the delayed topics are either the result of company requests for more time to submit data or analysis, or to non-submission of data by companies.
- 8. The performance of other Institute programmes is set out in Chart 2, below.



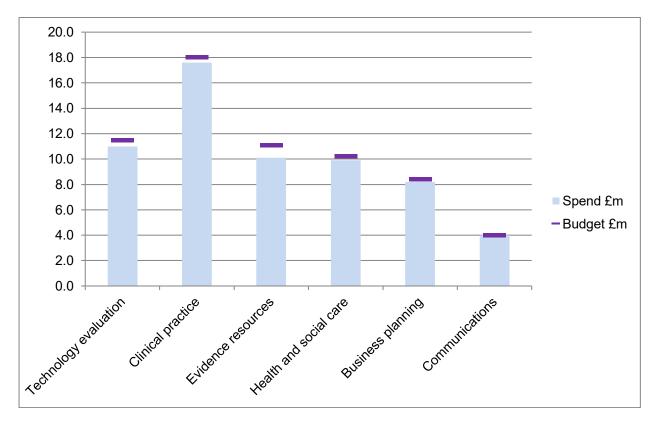
#### Chart 2: Advice programmes main outputs: April 2018 to March 2019

Notes to Chart 2:

MIBs (medtech innovation briefings) are reviews of new medical devices

# **Financial position (Month 12)**

9. The financial position for the 12 months from April 2018 to the end of March 2019 is an under spend of £3m (6%), against budget. This consists of under spend of £2m on pay and £1.1m on non-pay budgets, offset by income under recovery of £0.1m. The position of the main budgets is set out in Chart 3. Further information is available in the Business Planning and Resources Director's report.



#### Chart 3: Main programme spend: April 2018 to March 2019 (£m)

#### Appendix 1: Business objectives for 2018-19

In managing its business, NICE needs to take account of the objectives set out in its business plan, and the organisational and policy priorities for NICE set out by the Department of Health and Social Care. The table below consolidates and tracks progress with the main elements of these influences on our work in 2018-19.

Objective	Actions	Update
Guidance, standards	, indicators and evidence	
Publish guidance, standards and indicators, and provide evidence services against the targets set out in the Business Plan and in accordance with the metrics in the balanced scorecard	<ul> <li>Deliver guidance, standards, indicators and evidence products and services, in accordance with the schedule set out in the Business Plan</li> <li>Ensure performance meets the targets set out in the balanced scorecard</li> <li>In conjunction with national partners, develop a process for agreeing a joint narrative on the financial and workforce impact of our guidance</li> </ul>	<ul> <li>Details of the main programmes' performance against plan, including explanations for any variances are set out elsewhere in this report.</li> <li>We are meeting regularly with national partners to review guidelines with a potential resource impact, and to publish statements on implementation for the healthcare system where required.</li> </ul>
Implement changes to methods and processes in the technology appraisal (TA) and highly specialised technologies (HST) programmes	<ul> <li>Continue to implement changes to the TA and HST programmes: the TA fast track process, the budget impact test and value assessment in HST</li> <li>Subject to the outcome of consultation, implement the proposals for increasing capacity in the TA programme</li> <li>Make changes to the operation of the advisory committees, to improve the efficiency of the overall committee resource</li> </ul>	• The number of topics going through the new TA process is growing, with 6 topics dealt with at the first appraisal committee discussion in 2019. It is anticipated that by Summer 2019 the committee meetings will be dominated by topics running through the new process. We expect there to be very few topics using the old process by the start of 2020.
Refine and implement new methods and processes to	Review the methods and processes for efficient and timely guideline update outputs	Work to streamline chair recruitment is complete.

Objective	Actions	Update
accelerate the development of guidelines	<ul> <li>Revise and implement new methods and processes to support the development of guideline updates in-house</li> <li>Revise and implement new processes for the surveillance of guidelines</li> <li>Complete and publish a revised Guidelines Development Manual</li> </ul>	<ul> <li>Ongoing work is underway to streamline the recruitment of chairs and committee members.</li> </ul>
Maintain a suite of digital evidence services to meet the evidence information needs of health and social care users and partner agencies	<ul> <li>Maintain and monitor performance of NICE Evidence Services (CKS, HDAS, BNF microsites, Evidence Search), with investment in new features on a strictly needed basis</li> <li>Procure and implement the national core content in line with Health Education England (HEE) commissioning decisions</li> </ul>	• The BNF and BNFc microsites, and the CKS service, have performed strongly during 2018/19 (increase in sessions of +131%, +99%, + 38% respectively relative to the previous year). The Evidence Search and HDAS services have seen a decline in yearly sessions (-23% and -10% respectively).
Implement NICE-related aspects of the life sciences industries sector deal and the Accelerated Access Review	<ul> <li>Develop an implementation plan for those aspects of the Life Sciences Sector Deal that are relevant to NICE</li> <li>Operationalise the Accelerated Access Collaborative (AAC) programme office, developing mechanisms for effective engagement with all members of the Collaborative</li> <li>Establish the infrastructure for the MedTechScan horizon scanning programme (now HealthTech Connect)</li> <li>Establish a Commercial Liaison Team to provide input to NHS England to inform their negotiations with companies, based on the outputs of the Technology Appraisal and HST programme</li> </ul>	<ul> <li>The AAC Secretariat is supporting NHS England (NHSE) to deliver acceleration plans for the 12 rapid uptake products supported by the AAC partners. The Secretariat has also developed and trialled a formal AAC product identification process and has shared the learnings with the AAC board. The Secretariat is now working closely with partners to identifying high potential early stage products for selection by the AAC, and it is anticipated that the first products will be selected in Summer 2019.</li> <li>HealthTech Connect was successfully launched on 20 April 2019, receiving ever</li> </ul>

Objective	Actions	Update
	Engage with DHSC and MHRA to ensure operational readiness for the UK's departure from the European Union	<ul> <li>increasing interest from companies and other stakeholders.</li> <li>Members of the commercial liaison team have been working with NHSE on the development of a commercial framework in response to the voluntary scheme for branded medicines pricing and access.</li> <li>Regular meetings have been held with the MHRA to explore the impact of a potential no-deal exit from the European Union on technology appraisals.</li> </ul>
Review and remodel the approach to developing and delivering NICE guidance to take account of real-world data, machine learning and new digital platforms	<ul> <li>Develop a strategy for implementing changes to the development of NICE guidance to take account of new evidence sources, digitally-enabled authoring and machine learning</li> <li>Subject to SMT and Board agreement, and the availability of resources, develop and implement an action plan for 2018-19</li> </ul>	<ul> <li>A cross-Institute team has been established to support the use of data analytics across all NICE guidance programmes, with an associate director and technical adviser now in post. Additional posts will be filled over the next few months.</li> <li>The third meeting of the external expert group took place at the end of April, with a discussion about the future opportunities within the health system.</li> <li>A draft action plan has been developed, with a focus on developing a cross-Institute framework for data and analytics, and external relationships. This framework will be subject to open consultation over the summer, subject to approval by the Board in a later agenda item.</li> <li>Work continues with ONS on a project to capitalise on data science to make</li> </ul>

Objective	Actions	Update
		<ul> <li>efficiencies in the guidelines surveillance process.</li> <li>Data owners have been identified and the Centre for Guidelines are exploring opportunities for the use of complex data analytics to inform guideline development.</li> </ul>
Adoption and Impact Deliver a programme of national, regional and local strategic engagement to support alignment across the health and care system and the uptake of NICE guidance and standards	<ul> <li>Work with local health and care systems to promote the use of NICE guidance and quality standards, measured against the metrics in the 2018-19 strategic engagement plan</li> <li>Support the use of NICE guidance and standards through the work of other national organisations in health, public health and social care, measured against agreed metrics</li> <li>Work with key system partners, in particular NHSE and PHE, to deliver mutually supportive communication activities</li> <li>Use our membership of the Arm's Length Bodies CEO group to promote a compelling narrative about the value of our work to the health and care system</li> <li>Work with the devolution communities to ensure awareness of the NICE offer and help with system and service design</li> </ul>	<ul> <li>Progress against agreed metrics is reported to the Board on a 6-monthly basis.</li> <li>Engagement with other national organisations is on track, with detail included in the report from the Health and Social Care directorate.</li> <li>We are working with system partners in relation to the Long Term Plan and are providing supportive resources for Integrated Care Systems based on NICE guidance.</li> </ul>
Deliver a programme of support to encourage the adoption of drugs and	<ul> <li>Promote the innovation scorecard within the clinical community to encourage the uptake of recommended drugs and technologies</li> </ul>	• Stakeholders and users are being consulted on plans to develop the scorecard. The work of the Accelerated

Objective	Actions	Update
other medical technologies recommended by NICE	Deliver budget impact assessments to inform application of the budget impact test within the NICE TA and HST programmes	<ul> <li>Access Collaborative (see above) will complement this work.</li> <li>Budget impact assessments are being delivered as planned.</li> </ul>
Monitor the impact and uptake of Health and Social Care products and services and ensure that guidance and standards meet the needs of our audiences	<ul> <li>Produce 6 topic-based reports showing uptake and impact of NICE guidance and standards</li> <li>Deliver a rolling programme of audience research projects including an annual stakeholder reputation audit</li> </ul>	<ul> <li>Topic based reports are presented to the Board at each public meeting. The May 2019 report covers stroke.</li> <li>The field work for the reputation research project is complete. We received 602 stakeholder responses to the online survey and carried out 31 in-depth interviews and 2 focus groups with a total of 14 participants. This is in addition to the 129 responses to the MP survey and 2064 public survey responses reported previously.</li> <li>We are currently reviewing the findings and preparing a report for SMT.</li> </ul>
Promote NICE's work and help users make the most of our products by providing practical tools and support, using innovative and targeted marketing techniques. Contribute to demonstration of impact though regular evaluation	<ul> <li>Undertake a programme of enhancements to content on the website for different audiences including visual summaries and improving the 'user journey' on the NICE website to enable users to easily find the information they want</li> <li>Support shared decision making within NICE through delivery of commitments in the action plan of the Shared Decision-Making Collaborative</li> <li>Deliver a programme of quality assurance activities including endorsement, shared learning and the shared learning award</li> </ul>	<ul> <li>Work is continuing to identify and resolve accessibility issues on the NICE website. A dedicated role has been created on a fixed term basis to help move us closer to compliance.</li> <li>The introduction of more engaging content on the website is proving popular with our audiences. Evaluation of the new interactive data charts for our technology appraisal programme shows an increase in views of 53% for the new style pages. There has also been a significantly lower</li> </ul>

Objective	Actions	Update
		exit rate which indicates that more people are staying on the website to view other information.
		• A meeting of a core group of the Shared Decision Making (SDM) Collaborative took place in January to share updates on SDM activities across members and to agree the focus and priorities for the next full collaborative meeting in June.
		<ul> <li>NICE is now routinely developing shared decision aids. Development of the NICE SDM guideline is now underway. Recruitment of early committee members has taken place and the scoping workshop for the topic was held in December 2018.</li> </ul>
		• Quality assurance activities are progressing as planned. The shared learning award for 2019 was given to a project supporting the earlier diagnosis and surgical treatment of pancreatic cancer.
Promote collaboration on evidence management, system integration and data science initiatives across ALBs and with academic establishments and other external stakeholders	<ul> <li>Support NHS Digital to understand the domain model of NICE (and its broader evidence context), and explore the opportunities/value of introducing common interoperability standards (such as SNOMED) into the structure of NICE's content</li> <li>Support NHS England to deliver the digital IAPT pilot programme (Improving Access to Psychological Therapies)</li> </ul>	<ul> <li>Staff in the digital services team have continued conversations with NHS Digital and Kings College London regarding a collaborative research project further exploring the Learning Health System for the UK. A key aspect of this is the definition of a computable knowledge object which will need to inform and be informed by the structure of NICE's recommendations.</li> </ul>

Objective	Actions	Update
		<ul> <li>4 digital therapy technologies have been found to be eligible to enter the IAPT assessment programme and IAPT assessment briefings have been started, or are scheduled to start, later in this financial year. 3 briefings were complete in April 2019 rather than March, as originally planned.</li> </ul>
Create a structured and coordinated approach for working with and listening to stakeholders	<ul> <li>Implement agreed actions from the public involvement strategic review including introduction of the Expert Panel and pilot novel methods in relation to user-focused evidence</li> <li>Further develop a system to capture audience insights (including Twitter and Website analytics) and provide regular reports to senior management</li> <li>Develop metrics to measure the extent and impact of our engagement with social care audiences</li> </ul>	<ul> <li>Implementation of the actions from the strategic review is ongoing, and development of methods to allow lay people to submit their interest in working with NICE (outside of applying for specific committee recruitments) is in progress.</li> <li>A report bringing together insights from a number of audience research projects with responses from social care respondents was discussed with the Board in April, alongside an update on NICE's social care programme. The insight report is also being considered within the NICE Connect project.</li> </ul>
Deliver new digital service projects, maintain NICE's existing digital services and implement service improvements based on user insights and service performance and strategic priorities	<ul> <li>Deliver digital service projects that support NICE's strategic goals and transformation agenda. The projects will be prioritised and scoped throughout the year to support NICE in four key areas: evidence management, structured content development, process optimisation and dissemination/channels</li> <li>Maintain all live NICE Digital Services to agreed service levels (service availability and time to defect resolution)</li> </ul>	<ul> <li>A number of digital projects are underway across the portfolio, including:</li> <li>Since January 2019, all new NICE guidance is initiated using EPPI R5 which offers a consistent platform for managing evidence across NICE. Work is ongoing to put NICE's Guideline collaboration centres on the same platform.</li> </ul>

Objective	Actions	Update
	<ul> <li>Translate data and observations about the performance of NICE Digital Services into actionable improvement proposals and implement in line with business priorities</li> <li>Undertake continuous improvement of live services in response to user insights and service performance. For the NICE website, formally establish a new priority-led approach ('Journey Maps') to service improvement</li> </ul>	<ul> <li>The Comment Collection project (work to bring efficiencies to the external consultation process) continued during 2018/19 culminating in the service being successfully assessed by the Government Digital Service (GDS) Service in April 2019. Training has been completed across several teams and the service is being used across surveillance guidelines, public appraisal consultation documents (ACDs), diagnostics consultation documents (DCDs), medical technologies evaluation programme (MTEP) and quality standards (QS). Work to develop further features to support more complex consultations will continue in subsequent phases of development in 2019/20.</li> </ul>
Inform the review of the Pharmaceutical Price Regulation Scheme (PPRS)	Engage with the Department of Health and Social Care to inform the re-negotiation of the PPRS, focussing attention on those aspects of the Scheme which have an impact on the development of NICE guidance	<ul> <li>The voluntary scheme for branded medicines pricing and access was published in December 2018. Implementation plans for the activities related to NICE are being developed, including assessing the impact of the Voluntary Scheme on the Commissioning Support Programme in light of the undertaking for NICE to appraise all new active substances.</li> <li>Plans have been developed, and governance structures put in place, to support the review of the methods for the technology appraisal programme, and the</li> </ul>

Objective	Actions	Update
		process and methods for the highly specialised technologies evaluation programme.
Operating efficiently		
Operate within resource and cash limits in 2018-19	Deliver performance against plan for all budgets and achieve or exceed on non-Grant-in-Aid income targets	• The Institute is operated within its resource and cash limits in 2018/19.
Implement the third year of a three-year strategy to manage the reduction in the Department of Health and Social Care's Grant-In- Aid funding and deliver a balanced budget in 2018- 19	<ul> <li>Centres and directorates to continue to deliver the savings expected from them in order enable the Institute to manage within the reduced Grant in Aid funding received from DHSC, by April 2019</li> </ul>	<ul> <li>All savings targets for 2018-19 have been achieved.</li> <li>Cost recovery charging for technology appraisals and highly specialised</li> </ul>
	• Ensure that fully designed and tested financial and operational arrangements for cost recovery charging for technology appraisals and highly specialised technologies are in place in time for charging to begin	technologies evaluations commenced from 1 April 2019.
Further develop and grow NICE Scientific Advice	<ul> <li>Re-establish NICE Scientific Advice as a business unit with increased devolved autonomy within the NICE legal entity</li> <li>Work with relevant NICE corporate functions (HR, Finance and Communications) to define the scope of devolved autonomy and governance arrangements</li> <li>Drive the business unit as a market facing way to deliver increased revenue and influence</li> </ul>	leadership (with Director Jeanette Kusel joining the team in November), the acquisition of NICE's International Knowledge Transfer Service and discussions around the possibility of
		<ul> <li>At the start of the 18/19 financial year, NICE Scientific Advice adopted an invest- to-grow strategy which has resulted in greater diversity in the types of projects</li> </ul>

Objective	Actions	Update
		<ul> <li>delivered but the team has experienced lower-than-expected growth in demand for core services. This is partly attributable to changes in capacity of senior members of staff due to sickness/turnover, uncertainty in the market related to the UK's exit from the EU and other external factors. NSA has taken several steps to control spending, increase business development activities and better understand its customers in order to make service improvements and has seen a recent upturn in demand.</li> <li>NSA finished the year with a net deficit of £289,000 but made a full £350,000 contribution to NICE's overheads and still has a total reserve of £749,000.</li> </ul>
Actively pursue revenue generation opportunities associated with international interest in the expertise of NICE and the re-use of NICE content and quality assurance	<ul> <li>Articulate and promote NICE's value propositions associated with the re-use of NICE content outside of the UK, including permissions to use content overseas, adaptation of guidance, quality assurance services and syndication services</li> <li>Promote our capacity for knowledge sharing with international organisations interested in NICE's expertise and experience and take advantage of country-specific opportunities</li> </ul>	<ul> <li>During 2018/19, NICE issued 145 quotes to re-use NICE content. 54 content and 8 syndication licences were signed. The total income invoiced in 2018/19 for content re-use services amounts to £198,766 against an income target of £75,000.</li> <li>A review of the contextualisation process of NICE guidelines in Ireland has been conducted and will conclude that the process was a positive and valuable experience for all those involved. Additionally, the value for money analysis shows that it can be considered an efficient use of resources where there is no need to create a new evidence base.</li> </ul>

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Objective	Actions	Update
		<ul> <li>Since NSA took over the responsibility of the International Knowledge Transfer Services in September 2018, a total of 68 enquiries from 34 different countries have been received. Of these, the team has delivered 29 of the requests to date, the majority of which have been international delegations visiting NICE for short meetings (15) or more detailed tailored seminars or workshops (7). The team are working towards developing a future international service offering from NICE, with a commercial focus, which will be launched in 2019/20.</li> </ul>
Enthuse and enable staff to deliver on the Institute's objectives, ensuring that every member of staff has a clear set of personal objectives, a personal development plan and an annual appraisal	<ul> <li>Ensure that all staff have clear objectives supported by personal development plans</li> <li>Actively manage staff with the objective of ensuring that the global job satisfaction index in the annual staff survey is maintained or improved from its 2017 level</li> </ul>	<ul> <li>The Board approved an updated workforce strategy in November 2018.</li> <li>The results and the accompanying action plan from the completed 2018 survey were reported to the Board in September. The 2019 survey is currently underway.</li> </ul>
Develop an accommodation strategy, taking into account projected future demand and national policy	<ul> <li>Consider the options for future office space in London, taking account of current lease arrangements</li> <li>Prepare a strategy for Board approval by December 2018</li> </ul>	• We are engaged in the Department of Health and Social Care's London office accommodation strategy which is being facilitated by NHS property services. The option of moving with the British Council to Stratford before the end of the current lease in London in 2020 is being actively pursued as part of the strategy.

#### Section/ Director Featured section reference Health and social Para 8 NICE's engagement plan for 2019/20 builds on the success of 2018/19 and includes care engagement with the Accelerated Access Collaborative and the Office for Life Sciences. In social care, plans include a campaign to support social workers to use NICE guidance in their practice. In the health sector, there is a focus on supporting the NHS Long Term Plan, both at a national and local level, and builds on the Five Year Forward View activities during 2018/19. For public health, the plan includes supporting the implementation of the new Quality Framework and supporting building new relationships with the Department for Education. The Board will receive a focussed progress report in November 2019. Guidelines Para 16 On 28 March we published a summary of NICE guidance and other safety advice on valproate. The summary brings together NICE's recommendations for this drug across all of our guidelines, plus advice on safe prescribing from other sources (for example, Medicines and Healthcare products Regulatory Agency (MHRA) safety alerts, the BNF, summary of products data and information from the Driver and Vehicle Licensing Agency) in an easy to access visual summary. The summary was produced following the strengthening last year of restrictions on use of valproate by the MHRA. We continue to work closely with the MHRA to ensure our recommendations align with safety advice. Health technology Para 14 During 2018/19 a number of products recommended in diagnostics guidance were evaluation included in national adoption policy initiatives. For example, placental growth factor (PIGF) based testing for suspected preeclampsia (DG23), high sensitivity troponin tests for early rule out of myocardial infarction (DG15) and quantitative faecal immunochemical tests for colorectal cancer (DG30) were designated as Rapid Uptake Products by the Accelerated Access Collaborative. Molecular testing for Lynch syndrome in people with

#### **Appendix 2: Extracts from the Directors' reports**

	colorectal cancer (DG27) has been included in the testing directory of the Genomic Medicine Service which is directly funded by NHS England.	
Evidence resources	To support the NICE Connect project, two short focused pieces of consultancy work were undertaken in the last quarter of the year. These two pieces covered: first, advice on approaches and supporting technology to enable authoring and management of complex content and second, assessment of NICE's data management capability across NICE. Both pieces concluded in March with reports and final presentations. The conclusions will inform the development of the NICE Connect Project vision.	Para 12
Communications	In 2018-19 NICE published a suite of 7 impact reports, measuring the use of NICE guidance to improve outcomes in a range of areas including mental health, preventing falls, and delivering maternity services. To support the publication of these reports, we delivered a comprehensive programme of stakeholder communications to ensure that they were being viewed by frontline professionals, managers and commissioners in the relevant sectors. Typically, we were able to leverage our contacts at royal colleges, professional bodies, arm's length bodies and charities, to ensure each report was shared with hundreds of thousands of health/care professionals. For example, the mental health report published in March was shared with over 800,000 mental health practitioners, commissioners and service users, via our contacts' newsletters, member bulletins, and social media channels. We have also added the impact reports to the relevant topic pages on the website to improve their visibility.	Paras 4-6
Finance and workforce	In March and April, the HR team ran masterclasses on performance appraisals, with the aim of ensuring that line managers fully understand all stages in our appraisal cycle, can review and set SMART objectives and use coaching style conversations. These were attended by 165 managers. The next series of masterclasses will focus on Performance at Work, supporting managers in maximising the performance of their staff, increasing engagement and motivation, and addressing areas of underperformance with confidence. NICE has agreed to participate in the Workforce Race Equality Standard (WRES) this year, following a positive meeting with the senior managers responsible for this	Paras 36 and 37

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programme at NHS England. The data will be used to review our position against other	
organisations, including arm's length bodies.	

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### Appendix 3: Guidance development: variation against plan April 2018 - March 2019

Programme	Variation against plan	Reason for variation
Clinical Guidelines	3 topics delayed	Suspected neurological conditions: Delayed as ongoing discussions held with NHS England on the recommendations. Publication date is to be confirmed. Depression in adults: Publication moved to December 2019 (Q3 2019-20) as further work is required following stakeholder consultation. Abdominal aortic aneurysm: diagnosis and management: Publication delayed due to ongoing discussions with stakeholders. Publication date to be confirmed.
Interventional procedures	No variation against plan 2018-19	
Interventional procedures	6 additional topics published in 2018-19, that were not planned for this financial year	Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia: Published in January 2019 (Q4 2018-19).
		Electrically-stimulated intravesical chemotherapy for superficial bladder cancer: Published in January 2019 (Q4 2018-19).
		Laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth: Published in January 2019 (Q4 2018-19).
		Barnett Continent Intestinal Reservoir (continent ileostomy): Published in February 2019 (Q4 2018-19).
		High intensity focused ultrasound for symptomatic benign Thyroid nodules: Published February 2019 (Q4 2018-19).

Programme	Variation against plan	Reason for variation
		Radially emitting laser fibre treatment of an anal fistula: Published March 2019 (Q4 2018-19).
Medical technologies	3 topics delayed	IN.PACT: Delayed awaiting availability of new evidence. Topic paused. Endocuff Vision: Delayed due to the committee capacity issues. Due to publish in June 2019 (Q1 2019-20). PICO: Delayed due to the committee capacity issues. Due to publish in May 2019 (Q1 2019-20).
Public Health	No variation against plan 2018-19	
	1 additional topic published in 2018-19, that was not planned for this financial year	Flu vaccinations: Originally planned to publish in 2017-18. Published in August 2018 (Q2 2018-19).
Quality Standards	2 topics delayed	School based interventions: Delayed due to the Department of Health and Social Care's request to seek approval from the Department for Education minister(s). Publication now anticipated in June 2019 (Q1 2019-20). Influenza: Development of the Quality Standard delayed due to the underpinning
		guideline, NG103 Flu vaccination: increasing uptake, publishing later than planned. Quality Standard will now publish in January 2020 (Q4 2019-20).
Diagnostics	1 topic delayed	Lead-I electrocardiogram (ECG) devices for detecting atrial fibrillation using single-time point testing in primary care: The first committee meeting for this topic was rescheduled to allow additional work to be carried out by the External Assessment Group (EAG) developing the diagnostics assessment report. The earliest anticipated date for publication of the final guidance is now 8 May 2019 (Q1 2019-20).
Technology Appraisals	26 topics delayed	Blinatumomab for acute lymphoblastic leukaemia [ID1036]: Following on from advice received from the company the appraisal was rescheduled to align with latest regulatory expectations. Expected publication date is June 2019 (Q1 2019-20).

Programme	Variation against plan	Reason for variation
		Abiraterone for treating newly diagnosed metastatic hormone-naive prostate cancer: Topic suspended. NICE are awaiting confirmation from the company of the price abiraterone will be available to the NHS for this indication. Once this price is confirmed the appraisal will re-start. Expected publication date to be confirmed.
		Nivolumab with ipilimumab for untreated metastatic renal cell carcinoma: Topic suspended. On 27 July 2018, the CHMP adopted a negative opinion, recommending the refusal of the marketing authorisation for Opdivo with Yervoy (nivolumab with ipilimumab) in this indication. Following an update from the company, a re-examination of this opinion will be sought. This appraisal will therefore be rescheduled, and a further update will be issued in due course. Expected publication date to be confirmed.
		Ocrelizumab for treating primary progressive multiple sclerosis: Topic delayed. Originally due to publish 31 October 2018. The appraisal had been paused while commercial discussions between the company and NHS England take place. Expected publication is June 2019 (Q1 2019-20).
		Certolizumab pegol for treating chronic plaque psoriasis: Delayed following request from company. Expected publication date is April 2019 (Q1 2019-20).
		Brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma: Appraisal committee meeting was rescheduled due to a major conference taking place on the original date. Expected publication date is April 2019 (Q1 2019-20).
		Multiple myeloma (relapsed, refractory) - daratumumab (with bortezomib and dexamethasone): Company requested to revise the timelines in order to include important data within the submission. Expected publication date is April 2019 (Q1 2019-20).
		Breast cancer (HER2 negative, HR positive) - abemaciclib (with fulvestrant, after endocrine therapy): Publication delayed to allow time for development of Managed Access Agreement. Expected publication date is May 2019 (Q1 2019- 20).

Programme	Variation against plan	Reason for variation
		<ul> <li>Enzalutamide for treating non-metastatic hormone-relapsed prostate cancer: Topic was rescheduled following request from company for additional time to work on their submission. Expected publication date is May 2019 (Q1 2019-20).</li> <li>Durvalumab for maintenance treatment of unresectable non-small-cell lung cancer after platinum-based chemoradiation: The company requested more time to compile an evidence submission for this technology. Expected publication date is May 2019 (Q1 2019-20).</li> </ul>
		Sodium zirconium cyclosilicate for treating hyperkalaemia: Delayed due to appraisal committee meeting being rescheduled. Expected publication date is June 2019 (Q1 2019-20).
		Nusinersen for treating spinal muscular atrophy: Appraisal delayed to allow time for consultation on the provisional recommendations. Topic also delayed following the second committee meeting on 23 October 2018. The third committee meeting was held on 6 March 2019. Expected publication date is June 2019 (Q1 2019-20).
		Erenumab for preventing migraine: Following an update from the company, the appraisal was rescheduled. Expected publication date is July 2019 (Q2 2019-20).
		Letermovir prophylaxis for cytomegalovirus disease after allogeneic stem cell transplant: Following release of the ACD the company requested that NICE suspend this appraisal because it is considering its commercial arrangement for this product. Therefore, the basis for the decision making is likely to change and the appraisal committee meeting was rescheduled. Expected publication date is July 2019 (Q2 2019-20).
		Olaparib for maintenance treatment of recurrent, platinum-sensitive ovarian, fallopian tube and peritoneal cancer that has responded to platinum-based chemotherapy: Second appraisal committee meeting postponed to allow company to confirm commercial arrangements. Expected publication date to be confirmed.

Programme	Variation against plan	Reason for variation
		Nivolumab with ipilimumab for untreated non-small-cell lung cancer that has a high tumour mutational burden: The company requested that NICE suspend this appraisal because of a change to its regulatory timelines for this indication. Expected publication date to be confirmed.
		Dexamethasone intracanalicular insert for treating inflammation and pain after cataract surgery: Change to regulatory timelines. Expected publication date to be confirmed.
		Tezacaftor and ivacaftor combination therapy for treating cystic fibrosis with the F508del mutation: The company has not provided an evidence submission for this appraisal. Therefore, we have suspended the appraisal whilst we consider the next steps. Expected publication date to be confirmed.
		Mepolizumab for treating eosinophilic granulomatosis with polyangiitis: Suspended following on from advice received from the company, the dates for this appraisal will be confirmed once regulatory approval timelines are established. Expected publication date to be confirmed.
		Eculizumab for treating refractory myasthenia gravis: The company has not provided an evidence submission for this appraisal. Therefore, we have suspended the appraisal whilst we consider the next steps. Expected publication date to be confirmed.
		Patiromer for treating hyperkalaemia: Second committee meeting postponed and timelines to be confirmed. Expected publication date to be confirmed.
		Idelalisib for treating follicular lymphoma refractory to 2 treatments: Delayed after second committee meeting following request from company. Expected publication date to be confirmed.
		Masitinib for treating amyotrophic lateral sclerosis: On 18 April 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Alsitek (masitinib), intended for the treatment of amyotrophic lateral sclerosis (ALS). Consequently, this appreciael has been suspended
	d Caro Excellence	Iateral sclerosis (ALS). Consequently, this appraisal has been suspended.         Nivolumab for treating gastric or gastro-oesophageal junction cancer after 2 or more therapies: On 27 June 2018, the company notified the Committee of Medicinal Products for Human Use (CHMP) that it was withdrawing its

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Programme	Variation against plan	Reason for variation
		application to extend the license of nivolumab in the treatment of previously treated gastric or gastro-oesophageal junction cancer. Consequently, this appraisal has been suspended.
		MABp1 for previously treated metastatic colorectal cancer: The EMA's Committee for Medicinal Products for Human Use (CHMP) has adopted a negative opinion recommending the refusal of the marketing authorisation for this drug in this indication. This topic has been suspended.
		Betrixaban for preventing venous thromboembolism in people hospitalised for acute medical conditions: On 22 March 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Dexxience (betrixaban), intended for the prevention of venous thromboembolism in acutely ill medical patients. This topic has been suspended.
Technology Appraisals	7 additional topics published in 2018-19, that were not planned for this financial year	Lutetium (177Lu) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours: MTA was split into 2 appraisals in 2017/18, with one part published in June 2017 (TA449) and one part (TA539) in August 2018.
		Denosumab for preventing skeletal-related events in multiple myeloma: Published as a terminated appraisal in December 2018 (Q3 2018-19).
		Decitabine for untreated acute myeloid leukaemia: Published as a terminated appraisal in December 2018 (Q3 2018-19).
		Bevacizumab with carboplatin, gemcitabine and paclitaxel for treating the first recurrence of platinum-sensitive advanced ovarian cancer: Published as a terminated appraisal in February 2019 (Q4 2018-19).
		Lung cancer (non-small-cell, advanced, metastatic, BRAF V600E positive) - dabrafenib (with trametinib): Published as a terminated appraisal in February 2019 (Q4 2018-19).

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Programme	Variation against plan	Reason for variation
		Abatacept for treating psoriatic arthritis after DMARDs: Published as a
		terminated appraisal in March 2019 (Q4 2018-19).
		Pembrolizumab for treating recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based chemotherapy: Published as a terminated appraisal in March 2019 (Q4 2018-19).
Highly Specialised Technologies (HST)	2 topics delayed	Afamelanotide for treating erythropoietic protoporphyria: Following receipt of an appeal, which was upheld at the appeal hearing on 30 July 2018, the topic has been returned to the committee. Anticipated publication in June 2019 (Q1 2019-20).
		Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2: After the third appraisal committee meeting the topic was delayed while further discussions took place between NICE, the company and NHS England. Expected publication is now April 2019 (Q1 2019-20).
Social Care	No variation against plan 2018-19	
Managing Common Infections	No variation against plan 2018-19	
	4 additional topics published in 2018-19 that were not planned for this financial year	Urinary tract infection (catheter-associated): antimicrobial prescribing: Published in November 2018 (Q3 2018-19).
		Bronchiectasis (non-cystic fibrosis), acute exacerbation: antimicrobial prescribing: Published in December 2018 (Q3 2018-19).

Programme	Variation against plan	Reason for variation
		Chronic obstructive pulmonary disease (acute exacerbation): antimicrobial prescribing: Published in December 2018 (Q3 2018-19).
		Catheter associated urinary tract infections: Published in November 2018 (Q3 2018-19).

Programme	Торіс	Recommendation
Clinical Guidelines	Intrapartum care for high risk women	General guidance
	Lung cancer (update)	General guidance
Interventional procedures	Radially emitting laser fibre treatment of an anal fistula	Special
Medical	No publications	
technologies		
Diagnostics	No publications	
Public Health	No publications	
Managing	No publications	
Common		
Infections		
Social care	No publications	
Quality Standards	No publications	
Technology Appraisals	Benralizumab for treating severe eosinophilic asthma	Optimised
	Cochlear implants for children and adults with severe to profound deafness	Optimised
	Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies	Recommended for use within the CDF
	Abatacept for treating psoriatic arthritis after DMARDs	Terminated appraisal
	Pertuzumab for adjuvant treatment of HER2-positive early stage breast cancer	Optimised
	Pembrolizumab for treating recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based chemotherapy	Terminated appraisal
	Brigatinib for treating ALK-positive advanced non-small-cell lung cancer after crizotinib	Recommended
	Ertugliflozin as monotherapy or with metformin for treating type 2 diabetes	Optimised
Highly	No publications	
Highly Specialised		

# Appendix 4: Guidance published since the last Board meeting in March 2019

Programme	Торіс	Recommendation
Technologies (HST)		
Evidence summaries	No publications	
Medtech Innovation Briefings (MIB)	CADScor system for ruling out coronary artery disease in people with symptoms of stable coronary artery disease	Summary of best available evidence
• • •	IQoro for stroke-related dysphagia	Summary of best available evidence
	IQoro for hiatus hernia	Summary of best available evidence
	Kendall DL for ECG monitoring in people having cardiac surgery	Summary of best available evidence
	PredictSure-IBD for inflammatory bowel disease prognosis	Summary of best available evidence
	Narrow band imaging for Barrett's oesophagus	Summary of best available evidence
Evidence Surveillance Reviews	CG162 Stroke rehabilitation in adults	Surveillance review decision
	CG109 Transient loss of consciousness ('blackouts') in over 16s	Surveillance review decision
	CG89 Child maltreatment: when to suspect maltreatment in under 18s	Surveillance review decision
	MPG1 Developing and updating local formularies	Surveillance review decision
	NG5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes	Surveillance review decision
	CG178 Psychosis and schizophrenia in adults: prevention and management – exceptional surveillance review	Surveillance review decision
	PH49 Behaviour change: individual approaches – exceptional surveillance review	Surveillance review decision

Programme	Торіс	Recommendation
	CG76 Medicines adherence: involving patients in decisions about prescribed	Surveillance review decision
	medicines and supporting adherence	

#### Key to recommendation types

#### Guidelines (clinical, social care and public health):

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

#### **Interventional Procedures:**

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

#### Medical technologies:

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

#### **Diagnostics guidance:**

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

#### Management of common infections:

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

#### **Quality standards:**

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

#### Technology appraisals and highly specialised technologies:

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

#### Evidence summaries and medtech innovation briefings:

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

#### Surveillance reviews:

These reports bring our knowledge of current evidence on guidance we have already published up to date.

# Appendix 5: Science, Advice and Research Programme progress report

#### **NICE Scientific Advice**

- During the 2018/19 financial year, NICE Scientific Advice initiated 58 individual advisory projects. This includes 18 projects where companies have sought advice from NICE directly (including our first time advising on vaccines, patient preference studies and in conjunction with the Canadian agency CADTH), 23 where NICE has given advice through the European Network for HTA's Early Dialogue procedure, 4 PRIMA projects (quality checking economic models) and 13 META Tool consultations. The team has delivered 2 in-house seminars and 3 META Tool facilitator training days (including one with Health Technology Wales). In addition, the team spoke at 64 external engagements, including 12 site visits to companies within the life sciences industry.
- 2. Since NSA took over the responsibility of the International Knowledge Transfer Services in September 2018, a total of 68 enquiries from 34 different countries have been received. Of these, the team has delivered 29 of the requests to date, the majority of which have been international delegations visiting NICE for a short meeting (15) or a more detailed tailored seminar or workshop (7). Further 24 enquiries are currently in progress and are yet to be confirmed. The team has also been developing working relationships with a number of external stakeholders including Healthcare UK, The Department of International Trade, the Department of Health and Social Care, The Foreign Commonwealth Office (FCO), the NHS Consortium and the NHS Confederation. The team recently presented at the NHS International Health Group on the current international offer and are in discussions around how best to provide services to support the activities of the Better Health Programme and Prosperity Fund. The team are working towards developing an international strategy and met with Healthcare UK in March to discuss their ideas for the future international service offering from NICE with a cost recovery and commercial focus.
- 3. NICE Scientific Advice has had an eventful year which has seen a change in leadership (with Director Jeanette Kusel joining the team in November), and initial agreement on a range of exciting new initiatives. This includes a collaboration with the London School of Economics to run a co-branded Executive Masters of Science in Evaluation of Health Care Interventions and Outcomes. The course will be developed over the coming year with the first cohort of students beginning their studies in April 2020. Another important development is the agreement with Innovate UK to manage the offering, in

conjunction with the University of Manchester, for the winners of round 4 of the Digital Health Technology Catalyst. This involves helping companies with the development of their technologies to support future market access and will provide the team with valuable insight on the challenges faced by digital health technology (DHT) developers which, in turn, will help NSA refine its offer for the growing DHT market.

4. NICE Scientific Advice adopted an invest-to-grow strategy at the start of the 2018/19 financial year and experienced lower-than-expected growth in demand for services. This is partly attributed to uncertainty in the market related to the UK's exit from the EU and other external factors. Despite this, NSA has taken several steps to control spending, increase business development activities and better understand its customers in order to make service improvements and has seen a recent upturn in demand.

#### Science Policy and Research

- The Science Policy & Research (SP&R) team have continued to build on their portfolio of grant-funded projects in 2018/19, securing a further four new projects, totalling over £1.6M, funded by Horizon 2020 and Innovative Medicines Initiative (IMI). These are:
  - The "<u>GetReal Initiative</u>", where NICE has a leading role in establishing a real-world evidence think tank, which will gather international thought leaders and will discuss, assess and give recommendations on the opportunities and barriers to the generation, use and acceptability of real-world evidence in the context of European regulation and HTA.
  - "<u>EHDEN</u>" aims to build Europe's largest federated network of standardised data sources in Europe for the purpose of clinical research and pharmaceutical development. NICE co-leads work on outcomes standardisation, helping to ensure that the data collected will be suitable for both regulatory and HTA purposes.
  - "HTx" aims to create and test a framework for 'next generation' HTA and will provide solutions for a broad range of challenges such as personalised medicine, combination therapies, big data and artificial intelligence. NICE's main role is to provide insight on the acceptability and usefulness of proposed solutions from the European HTA perspective.
  - "Value Dx" has a remit to facilitate and accelerate the rigorous assessment and implementation of diagnostic technologies into healthcare settings. It will to this by establishing the methods, processes and approaches needed to understand, evaluate, and assess the value of diagnostics in the context of optimising antibiotic use. NICE will convene

an international advisory panel comprised of experts in regulatory-HTApayer systems.

- 6. To ensure NICE's research needs are recognised, and ensure relevant research is prioritised, SP&R representatives continue to advise funding panels at the Medical Research Council (MRC), the Department for Health and Social Care (DHSC) R&D Committee and DHSC's Policy Unit. As an example, SP&R worked with the MRC and the National Institute for Health Research (NIHR) to develop an 'opportunity' notice inviting research proposals on new methods for improving the use of observational data in effectiveness research. Around £1.3M funding was awarded to two research groups led by the <u>University of York</u> and <u>University College London</u> which are now live projects, ending in 2021. SP&R also developed a further 'opportunity' notice in the area of advanced diagnostics, which is now a <u>live call</u> for research proposals.
- 7. SP&R is leading on the work to update <u>NICE's policy statement</u> regarding the five-level EQ-5D health-related quality of life measure, and has worked with DHSC to commission four eminent experts to provide advice to guide our next steps; we expect to receive advice in August 2019. The work is being funded through an unrestricted grant from the EuroQol Research Foundation.
- 8. SP&R continues to liaise with the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC). NETSCC actively reviews all <u>NICE research recommendations</u> as a key source of relevant research topics and where appropriate commissions research to answer the research recommendations within the remit of its funding programmes. NETSCC staff may assist NICE advisory committees in formulating actionable research recommendations, taking account of research in progress and planned. NICE key priority research recommendations are fast tracked through the NETSCC processes. This has resulted in 87 projects being funded by NETSCC in response to NICE research recommendations, totalling £70 million as of March 2018
- 9. A memorandum of understanding (MoU) between NICE, Health Innovation Manchester and the University of Manchester was signed for a further three years. The MoU sets out a shared commitment to improving the overall health of the population through research and informing health policy and practice, as well as through the development and evaluation of health technologies and collaboration on teaching, training and education. The NICE steering group is in the process of identifying specific activity which will benefit from the objectives common to all MoU parties.

10. In February we launched the updated <u>Research governance policy</u>. The revised policy has been restructured, contains updated references relating to UK research governance law and includes clearer guidance on the approval steps to obtain senior sign off for research activity. SP&R have also delivered the Technical Forum - monthly presentations from NICE staff and external speakers, often on subjects related to NICE's priority areas for methods research, ensuring that the technical teams producing NICE guidance are upto-date with the latest methods research.

### EUnetHTA

- 11. The team set up a network to support implementation of EUnetHTA outputs among EUnetHTA partners. A group of 15 EUnetHTA partners acts as support leads for 71 agencies participating in the network. Each agency in the network has a named contact for implementation issues and queries, there is a feedback system to collect information about the experience of using EUnetHTA assessments, and webpages provide examples about how other partners are making use of EUnetHTA assessments and tools.
- 12. The team published 2 implementation reports available on the EUnetHTA website describing uptake of EUnetHTA assessments and feedback from using the assessments. Over the year the team collected over 150 examples of using the reports and obtained feedback from 14 interviews. Use in the current joint action is compared with the use reported in the previous EUnetHTA joint action and provides evidence of increasing use of EUnetHTA assessments. The team have presented their work at EUnetHTA internal and external events and at external conferences including ISPOR, HTAi, DIA and BioEurope. The data collection work now also includes Industry stakeholders and their experiences of using EUnetHTA assessments in their national submissions for reimbursement.
- 13. The team has started work supporting EUnetHTA to develop the scientific and technical mechanism of a permanent mechanism of HTA cooperation. At the end of September 2018, the team held focus groups at the NICE London office with 20 partners from agencies across Europe. In April 2019, NICE delivered a final report to EUnetHTA describing procedures for existing and proposed cooperative working in HTA and the elements that facilitate or challenge uptake. The report includes recommendations for EUnetHTA to take forward as it develops the technical and scientific elements of a permanent model of HTA cooperation.
- 14. In March 2019, NICE hosted our annual National Implementation and Impact Work Package meeting. 50 partners from HTA agencies across Europe

attended a two-day conference in Zagreb where partners shared their experiences of using EUnetHTA outputs and carried out small group workshops. The content of the workshops included discussions about how HTA cooperation might be carried out in the future, barriers and facilitators to using EUnetHTA tools and methods, methods to incorporate EUnetHTA assessments into decision making processes and indicators of successful uptake.

#### Office for Market Access

- 15. The Office for Market Access (OMA) has had a successful business year and achieved full cost-recovery in 2018/19. Over this period the team has delivered 14 engagements covering a broad range of themes across the whole life sciences industry; these include 4 Early Access to Medicine Scheme (EAMS) engagements, 1 knowledge transfer engagement, 3 focussed safe harbour engagements and 6 large multi-stakeholder safe harbour engagements. The team have also facilitated 27 CHTE speaking engagements.
- 16. There is a high level of interest going into 2019/20, with four further engagements already scheduled. The team will also explore how the current service offering can be developed and enhanced to provide more varied opportunities for the life sciences industry and system partners to engage.
- 17. In April 2019, OMA moved back to the Centre for Health Technology Evaluation (CHTE), hence future updates will be included in the CHTE board report.

#### Accelerated Access Collaborative Secretariat

- 18. During 2018/19 the Accelerated Access Collaborative Secretariat (AACS) has established strong working relationships with the Office for Life Sciences and other AAC partner organisations. The team have successfully delivered 3 AAC Board and 7 Steering Group meetings and established a calendar of business moving forwards.
- 19. The team have made good progress in supporting the AAC's identification and selection of products, with initial processes and methods being developed. During 2018 the AACS successfully carried out a pragmatic exercise with partners to identify the first late stage products for support by the AAC, and 12 rapid uptake products were selected in Autumn 2018. The AACS has continued to support NHSE to develop implementation plans which aim to improve the adoption of the 12 rapid uptake products. During early 2019, the AACS presented initial plans to the AAC board for selection of early

stage products, and an approach has been agreed which the team will implement with partners over the coming months. In April 2019, the AACS moved back to the Centre for Health Technology Evaluation (CHTE), hence future updates will be included in the CHTE board report.

# Appendix 5: Balanced Scorecard 2018-19: April 2018 – March 2019

#### Delivering services and improvements

Reference: 19/042

Outputs	Measure	Target	Planned YTD	Actual YTD	Cumulative performance	RAG
Development and publication of	of guidance and evidence outp	outs (as spe	cified in Busi	iness Plan)	)	
Publish 2 public health	Publication within stated	80%	2	3	150%	Green
guidelines	quarter					
Publish 19 clinical guidelines,	Publication within stated	80%	19	16	84%	Green
including updates	quarter					
Publish 4 management of	Publication within stated	80%	4	8	200%	Green
common infections	quarter				1000/	
Publish 2 social care guidelines	Publication within stated quarter	80%	2	2	100%	Green
Dublich 75 technology	Dublication within stated year	100%	75	56	75%	Amber
Publish 75 technology appraisals guidance Notes: 26 topics delayed: full details are report.	Publication within stated year		rther analysis	in the Healt	th Technology Eval	uation Director's
appraisals guidance Notes: 26 topics delayed: full details are report. Publish up to 30 interventional	set out in the Chief Executive's r Publication within stated		orther analysis	in the Healt	th Technology Evalu	uation Director's Green
appraisals guidance Notes: 26 topics delayed: full details are report. Publish up to 30 interventional procedures guidance	e set out in the Chief Executive's r Publication within stated quarter Publication within stated	report and fu				
appraisals guidance Notes: 26 topics delayed: full details are report. Publish up to 30 interventional procedures guidance Publish 4 diagnostics guidance	e set out in the Chief Executive's r Publication within stated quarter	report and fu	30	36	120%	Green
appraisals guidance Notes: 26 topics delayed: full details are report. Publish up to 30 interventional procedures guidance Publish 4 diagnostics guidance Notes:	e set out in the Chief Executive's r Publication within stated quarter Publication within stated	report and fu	30	36	120%	Green
appraisals guidance Notes: 26 topics delayed: full details are report. Publish up to 30 interventional procedures guidance Publish 4 diagnostics guidance Notes: 1 topic delayed: • Lead-I electrocardiogram (EC meeting for this topic was res	e set out in the Chief Executive's r Publication within stated quarter Publication within stated	report and fu 80% 80% vrillation usin	30 4 g single-time p d out by the E	36 3 point testing external Ass	120% 75% 75% n primary care: Thessment Group (EA	Green Amber ne first committee AG) developing ti
appraisals guidance Notes: 26 topics delayed: full details are report. Publish up to 30 interventional procedures guidance Publish 4 diagnostics guidance Notes: 1 topic delayed: • Lead-I electrocardiogram (EC meeting for this topic was res	<ul> <li>set out in the Chief Executive's r</li> <li>Publication within stated quarter</li> <li>Publication within stated quarter</li> <li>CG) devices for detecting atrial fib scheduled to allow additional work</li> </ul>	report and fu 80% 80% vrillation usin	30 4 g single-time p d out by the E	36 3 point testing external Ass	120% 75% 75% n primary care: Thessment Group (EA	Green Amber ne first committee AG) developing ti

	Measure	Target	Planned YTD	Actual YTD	Cumulative performance	RAG
Development and publication	of guidance and evidence outp	uts (as spe	cified in Busi	iness Plan	)	
Notes:		, i				
2 topics delayed:						
<ul> <li>Afamelanotide for treating ery</li> </ul>	ythropoietic protoporphyria: Follov	ving receipt	of an appeal, v	which was l	upheld at the appea	al hearing on 30
July 2018, the topic has been	n returned to the committee. Antic	ipated publi	cation date is .	June 2019 (	Q1 2019-20).	-
<ul> <li>Cerliponase alfa for treating r</li> </ul>	neuronal ceroid lipofuscinosis type	e 2: Delayed	d due to the red	ceipt of an a	appeal that was reje	ected during
, .	n is now May 2019 (Q1 2019-20).					0
Publish 8 medical technologies	Publication within stated year	80%	8	5	63%	Amber
guidance						
Notes:						
3 topics delayed:						
<ul> <li>IN.PACT: Delayed awaiting a</li> </ul>	availability of new evidence. Topic	paused.				
, , ,	e to the committee capacity issues		blish in June 2	2019 (Q1 20	)19-20).	
	mmittee capacity issues. Due to p	•		• •	/	
Publish 34 medtech innovation	Publication within stated year	000/				
		80%	34	37	109%	Green
briefinas (MIBs)		80%	34	37	109%	Green
	-		-			
briefings (MIBs) Submit advice to Ministers on up to 38 Patient Access	Publication within stated year	100%	34 38	37 39	109% 103%	Green Green
Submit advice to Ministers on up to 38 Patient Access	-		-			
Submit advice to Ministers on up to 38 Patient Access Schemes	Publication within stated year	100%	38	39	103%	Green
Submit advice to Ministers on up to 38 Patient Access Schemes Deliver up to 25 commissioning	Publication within stated year Submission to NHS England		-			
Submit advice to Ministers on up to 38 Patient Access Schemes Deliver up to 25 commissioning support programme topics to	Publication within stated year Submission to NHS England Clinical Panel within stated	100%	38	39	103%	Green
Submit advice to Ministers on up to 38 Patient Access Schemes Deliver up to 25 commissioning support programme topics to NHS England	Publication within stated year Submission to NHS England	100%	38	39	103%	Green
Submit advice to Ministers on up to 38 Patient Access Schemes Deliver up to 25 commissioning support programme topics to NHS England Notes:	Publication within stated year Submission to NHS England Clinical Panel within stated quarter	80%	38	39 12	103% 48%	Green Amber
Submit advice to Ministers on up to 38 Patient Access Schemes Deliver up to 25 commissioning support programme topics to NHS England Notes: The target for the commissioning	Publication within stated year Submission to NHS England Clinical Panel within stated quarter support programme is the deliver	100% 80% ry of 'up to 2	38 25 25 topics'. The	39 12 number of	103% 48% topics was agreed i	Green Amber before the outpu
Submit advice to Ministers on up to 38 Patient Access Schemes Deliver up to 25 commissioning support programme topics to NHS England Notes: The target for the commissioning of each topic were known and ba	Publication within stated year Submission to NHS England Clinical Panel within stated quarter support programme is the deliver ased on the production of one doc	100% 80% ry of 'up to 2 sument. NHS	38 25 25 topics'. The S England (NH	39 12 number of ISE) actuall	103% 48% topics was agreed i y required a suite of	Green Amber before the output
Submit advice to Ministers on up to 38 Patient Access Schemes Deliver up to 25 commissioning support programme topics to NHS England Notes: The target for the commissioning of each topic were known and ba each topic and the management	Publication within stated year Submission to NHS England Clinical Panel within stated quarter support programme is the deliver ased on the production of one doc of topics through the specialised	100% 80% ry of 'up to 2 sument. NHS services prio	38 25 25 topics'. The S England (NH oritisation proc	39 12 number of SE) actuall cess. A revie	103% 48% topics was agreed by required a suite of ew was undertaken,	Green Amber before the output f documents for , and it was
Submit advice to Ministers on up to 38 Patient Access Schemes Deliver up to 25 commissioning support programme topics to NHS England Notes: The target for the commissioning of each topic were known and ba each topic and the management	Publication within stated year Submission to NHS England Clinical Panel within stated quarter support programme is the deliver ased on the production of one doc	100% 80% ry of 'up to 2 sument. NHS services prio	38 25 25 topics'. The S England (NH oritisation proc	39 12 number of SE) actuall cess. A revie	103% 48% topics was agreed by required a suite of ew was undertaken,	Green Amber before the output f documents for , and it was

Outputs	Measure	Target	Planned YTD	Actual YTD	Cumulative performance	RAG
Development and publication	of guidance and evidence outpu	uts (as spe	cified in Busi	ness Plan)		
Publish 58 guidance surveillance reviews	Publication within stated quarter	80%	58	65	112%	Green
Publish up to 20 evidence summaries	Publication within year	80%	20	10	50%	Amber
NHSE and the Regional Medicin received and one evidence sum 2019. The delay was due to com required additional time to review	ce reviews (specialised commission es Optimisation Committees (RMC mary (doxylamine/pyridoxine – the ments received from the manufact w before taking the final product to iewed once the product has been o	DCs). The nu first RMOC turer on the guidance ex	umber delivere product) bein 'consideration (ccutive for ap	ed reflects th g delayed fro s for practic	e reduced numbe om 29 March 2019 e' section late in th	r of referrals ) until 11 April ne process that
Deliver 10 quick guides for social care	Publication within year	100%	10	10	100%	Green
Deliver 20 quality standards	Publication within stated quarter	80%	20	18	90%	Green
Deliver 1 indicator set	Publication within year	100%	1	1	100%	Green
Deliver 30 endorsement statements	Publication within stated quarter	80%	30	30	100%	Green
Deliver 50 shared learning examples	Publication within stated quarter	80%	50	50	100%	Green
Publish 12 monthly updates of the BNF and BNF C content	Publication within stated quarter	80%	12	12	100%	Green
Deliver a regular medicine awareness service (50 MAWs)	Publication to regular schedule	90%	50	50	100%	Green
Deliver 16 medicines optimisation key therapeutics topics	Publication within stated quarter	80%	16	14	88%	Green
Deliver 25 medicines evidence commentaries	Publication within stated quarter	80%	25	25	100%	Green

Outputs	Measure	Target	Planned	Actual	Cumulative	RAG
			YTD	YTD	performance	
Development and publication	n of guidance and evidence outp	uts (as spec	cified in Busi	ness Plan)		
Deliver 4 IAPT (Improving	Publication within stated	80%	4	1	25%	Red
Access to Psychological	quarter					
Therapies) assessment						
briefings						
Notes:			·	·		•
NHS England commissioned N	ICE to assess up to 14 selected, di	gitally enhan	ced therapies	for depressi	on and anxiety ov	er 3 years. Seven
	ate. Four IABs were planned for pu					
	meeting the selection criteria for IA					
this, 5 technologies previously f	tound ineligible were able to be ass	essea. 3 nev	v ellaible notit	ications were	e also received in	the last quarter of

## Adoption and impact

Outputs	Measure	Target	Planned YTD	Actual YTD	Cumulative performance	RAG
Provision of support products for	r the effective implementation of g	uidance				1
Provide adoption support products for up to 5 topics	Provide within year	80%	5	4	80%	Green
Publish up to 96 resource impact products to support guidance	Publication within year	80%	96	71	74%	Amber
Coverage of NICE in the media	% of positive coverage of NICE in the media resulting from active programme of media relations	80%	80%	80%	80%	Green

## **Operating efficiently**

Outputs	Measure	Target	Planned YTD	Cumulative performance	RAG
Delivering programmes and ac	tivities on budget				
Effective management of financial resources	Revenue spend	To operate within budget	2018/19 Annual budget was £52.9m	Net spend for 2018/19 was £49.9m. This was a net under spend of £3.0m	Green
Effective management of non- exchequer income	Net income received from non-exchequer income sources measured against business plan targets	90%	The business plan income target was to receive £3.3m income.	Total income from these sources was £2.6m in 2018/19 (90% of target).	Green
Produce the annual report and accounts within the statutory timeframe	Publications	100%	Lay before summer parliamentary recess.	2017-18 Annual accounts laid 10 July 2018 as planned.	Green

Outputs	Measure	Target	Cumulative performance	RAG
Maintaining and developing a sk	illed and motivated workforce			
Management of recruitment	Proportion of posts appointed to within 4 months of first advertisement	80%	94%	Green
Management of sickness absence	Quarterly sickness absence rate is lower than NHS average rate (3.7% Apr-Jun 2011) or general rate for all sectors (2.8%)	90%	100%	Green
Staff satisfaction	Proportion of staff reporting in staff survey that the Institute is a good, very good or excellent place to work (global job satisfaction index)	75%	95%	Green
Staff involvement	Hold monthly staff meetings	80%	83%	Green

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	Implementation of NICE's quality standard for healthy workplaces: improving employee mental and physical health and wellbeing in respect of own staff	80% of quality statements	83%	Green
Sustainable development				
Recycled waste	% of total waste recycled	50%	99%	Green
Improving stakeholder satisfac	tion			
Improved satisfaction	Complaints fully responded to in 20 working days	80%	100%	Green
Improved satisfaction	Enquiries fully responded to in 18 working days	90%	87%	Amber
Votes:	h 2019 capacity within the enquiry handling team was sigr			
measures to address the backlog	cholder groups (performance for these enquiries has been which is now reducing. Most vacancies are now filled, and	,		
	Improve steadily from Q2 2019-20.	100%	98%	Amber
Improved satisfaction	improve steadily from Q2 2019-20.           Number of Freedom of Information requests           responded to within 20 working days	100%	98%	Amber
Improved satisfaction Notes: 137 FOI requests were received k Q1, one was delayed due to the r was delayed due to senior staff ar enquiry about declarations of inte	Number of Freedom of Information requests	esponded to outsic ns and commercia se. In Q4, the third	le of the require I sensitivity. In was due to a c	ed timeframe. In Q2, the second omplicated
Improved satisfaction Notes: 137 FOI requests were received k Q1, one was delayed due to the r was delayed due to senior staff a enquiry about declarations of inte	Number of Freedom of Information requests responded to within 20 working days by the end of quarter 4 of 2018-19. Three requests were re need for 3rd party advice on technology appraisal redaction vailability, off-site storage retrieval and seeking legal advice rest for two historical guidelines. We required legal advice	esponded to outsic ns and commercia se. In Q4, the third	le of the require I sensitivity. In was due to a c	ed timeframe. In Q2, the second omplicated

Outputs	Measure	Target			Cumulative performance	RAG
Interest in opportunities for lay people to sit on our advisory reflected by ratio of applications to positions	2 to 1 (or greater) each quarter	100%	2 to 1	6:1	300%	Green

Outputs	Measure	Annual target	Cumulative performance	RAG
Improving efficiency and s	peed of outputs			
Speed of production	% STAs for all new drugs issuing an ACD or FAD within 6 months of the product being first licensed in the UK	90%	100%	Green
Speed of production	% of multiple technology appraisals from invitation to participate to ACD in 41 weeks, or where no ACD produced to FAD in 44 weeks	85%	N/A	N/A
Notes:				
No publications have been p	lanned.			
Speed of production	% of Appeal Panel decisions received within 3 weeks of the hearing	80%	100%	Green

#### **RAG Status - Key**

Green	Greater than or equal to annual target
Amber	Between 50 % and less than annual target
Red	Less than 50% of annual target

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May 2019

National Institute for Health and Care Excellence Chief Executive's Report Date: 22 May 2019 Reference: 19/042

# National Institute for Health and Care Excellence Finance and workforce report

This report gives details of the provisional financial position for the year ended 31 March 2019 and an update on the workforce.

The Board is asked to review the report.

Ben Bennett

Business Planning and Resources Director

May 2019

# **Financial Position as at 31 March 2019**

#### Summary

1. Table 1 summarises the provisional financial position for the year ended 31 March 2019. There is a full analysis in Appendix 1

#### Table 1 Financial Position at 31 March 2019

	Budget £m	Expenditure £m	Income £m	Variance £m
Guidance & Advice	51.1	53.2	(3.5)	(1.3)
Corporate	13.2	13.6	(0.9)	(0.6)
Other Income	(11.9)	0.0	(12.1)	(0.2)
Reserves	0.5	(0.3)	(0.1)	(0.9)
Grand Total	52.9	66.5	(16.6)	(3.0)

- 2. The table shows a total under spend against budget of £3.0m (6%) at the end of the financial year 2018/19. This is primarily attributable to vacant posts as well as under spends against the non-pay budget across the Directorates. This has partially been offset by income being lower than anticipated.
- 3. The 2018/19 under spend of £3.0m is £1.1m higher than forecast in the March 2019 Finance and Workforce board report. This change is mainly due to non-cash accounting adjustments relating to the unwinding of provisions for potential liabilities and depreciation charge adjustments.
- 4. The 2018/19 capital allocation was £0.5m. Of this allocation £0.17m was utilised on office improvements, software licenses and IT Hardware. Further information is provided in the capital section of this paper.
- 5. The 2019 staff survey was launched on 7 May 2019 and will remain open for 3 weeks.

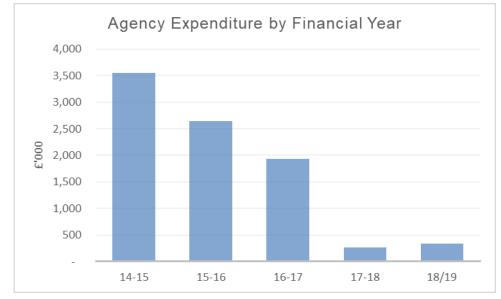
### Financial Position as at 31 March 2019

- 6. Work on the 2018/19 final accounts is close to complete. The statutory audit will take place throughout May 2019. The National Audit Office (NAO) has subcontracted the audit work to Ernst and Young (EY). This board report is based on the accounts pre-audit and may be subject to change as a result of audit adjustments. The accounts are due to be laid before parliament in July 2019.
- 7. Appendix B shows the unaudited 2018/19 key financial statements (comprising the Statement of Comprehensive Net Expenditure, Statement of Financial Position and Statement of Cash Flows).
- 8. Total expenditure for the year was £66.5m and income recognised from sources other than grant-in-aid (GIA) from the DHSC was £16.6m. Therefore the net expenditure funded from GIA was £49.9m, which was £3.0m (6%) lower than our initial GIA allocation of £52.9m. The under spend is primarily comprised of:
  - £2.0m pay arising from vacant posts across the Directorates.
  - £1.1m non-pay mainly due to an under spend on MedTech external assessment centre contracts, reserves not being utilised, lower than budgeted depreciation charges and unused provisions relating to potential liabilities included in the prior year (2017/18) annual accounts.
  - The above under spends are offset by income being £0.1m lower than anticipated, this is mainly attributable to the Science, Advice and Research Directorate.
- 9. The actual underspend of £3m is £1m greater than the forecast outturn reported to the Board in March. The difference is mainly due to year-end accounting adjustments relating to in-year provisions for potential liabilities, writing back of prior year provisions and adjustments to our depreciation charges.
- 10. Appendix 1 shows in detail the financial position by centre and directorate. Directors receive detailed monthly reports on the financial performance of their directorates and SMT receive a finance report detailing the summary position, forecast and issues on a bi monthly basis.

#### Pay and resourcing

11. Total pay expenditure to 31 March 2019 was £35.4m, which was a £2.0m (5%) under spend against the pay budget. This was distributed across the centres as follows:

- £0.45m (9%) in Evidence Resources
- £0.37m (4%) in the Centre for Health Technology Evaluation
- £0.32m (5%) in the Centre for Guidelines.
- £0.17m (6%) in the Science, Advice and Research Directorate
- At the beginning of 2018/19, we transferred £0.6m expected savings associated with vacant posts into reserves (known as the part-year effect adjustment). These reserves were not utilised.
- 12. The pay under spends are mainly attributable to the number of vacancies throughout the year. As at 31 March 2019 there were 612 whole time equivalent (wte) staff in post against a budget of 682 wte, with vacant budgeted posts totalling 70 wte (a 10% vacancy rate). In 2018/19 the vacancy rate against budget has been consistently around 10%. It should be noted that not all vacancies are "live" in terms of active recruitment as teams may be considering options or awaiting confirmation of continued funding.
- 13. The HR team are continuing to explore ways to enhance recruitment and improve staff retention. It should however be noted that analysis of recruitment data shows that approximately 50% of all vacancies are filled by internal candidates.
- 14. Spending on agency staff has fallen significantly in recent years. Chart 1 below details agency spend over the previous five financial years.



#### Chart 1 Agency Expenditure by Financial Year

15. Spending on agency staff in 2018/19 of £0.34m was an increase of £74,000 compared to 2017/18. This increase mainly relates to costs associated with the establishment of the NICE Connect project.

#### Non-pay Expenditure

- 16. Total non-pay expenditure to 31 March 2019 was £31.1m, which was a £1.1m (3%) under spend against budget. The under spend against budget was mainly attributable to:
  - An under spend on committee costs of £0.2m mainly due to reduced activity in NICE Scientific Advice and a lower number of committee meetings taking place to that budgeted across the Appraisals and Guidelines programmes.
  - An under spend on contracts of £0.2m mainly due to lower than anticipated activity on the new MedTech external assessment centre contracts.
  - An underspend of £0.1m on meeting expenses and room hire mainly due to a higher utilisation of existing meeting space in the Manchester and London offices.
  - Depreciation was £0.3m lower than budgeted mainly due to a revision of the London office depreciation calculation and the capital budget not being fully utilised in 2018/19. Further details are provided in the capital section of this paper.
  - Unused provisions mainly relating to legal fees and programme transition costs were £0.3m.
- 17. For this year end report Table 2 gives a comparison of the non-pay expenditure in 2018/19 compared to the previous year. There was an overall decrease of £2.38m. This decrease is associated with the culmination of the strategic savings programme where we have achieved better value in our use of external contractors and reduced some outputs.

Non-pay expenditure description	2018/19 £'000	2017/18 £'000
Guideline Development Centres	6,622	7,933
External contractors	5,893	5,416
British National Formulary	4,752	4,795
Healthcare Library Services	3,708	3,691
Premises and fixed plant	3,142	3,195
Rentals under operating leases	1,985	1,834
Travel expenditure	1,659	1,663
Medical Technology External Assessment Centres	1,296	2,200
Supplies and services - general	547	563
Depreciation and Amortisation	543	921
Education Training and Conferences	498	414
Establishment expenses	408	584
Chair and non-executive directors' costs	150	141
Legal fees	84	257
Auditor's remuneration: audit fees	50	50
Internal audit expenditure	42	34
Provisions	(287)	(223)
Total Non-pay expenditure	31,092	33,468

#### Table 2 Breakdown of non-pay expenditure for 2018/19 compared to 2017/18

- 18. The most significant category of expenditure (£6.6m) was payable to the Guideline Development Centres who support us with the development of clinical guidelines and quality standards. There was a decrease of £1.3m in expenditure mainly due to the end of the NCC for Social Care (SCIE) contract which formed part of the development of social care guidelines.
- 19. Expenditure on the medical technology external assessment centres is £0.9m lower. This is mainly due to reduced activity associated with the MedTech external assessment centre contracts that ended on 30 September 2018 and the new ones starting on 1 October 2018. In addition to this the call off element of the new contract was not utilised in 2018/19. The new contracts now have a flexible call off budget (40% of total contract value) in addition to the fixed monthly payments that is utilised in line with actual activity. Due to the phasing of activity across the life of the new contract this call off element of the contract was not fully utilised in 2018/19.
- 20. External contractor expenditure of £5.9m is an increase of £0.5m to 2018/19 mainly due to increased expenditure relating to the NE Quality Observation Services (NEQOS) contract (£0.2m) in the Health and Social Care Directorate and the increased use of Digital Services contractors (£0.1m) and clinical knowledge summaries (£0.1m) in the Evidence Resources Directorate.

- 21. Depreciation and amortisation charges of £0.54m is £0.38m lower. This is mainly due to a revision of the depreciation calculation for capitalised London office leasehold improvements in 2018/19 to reflect the expected office move in 2020. This amendment reduced the depreciation charge by £0.2m compared to the forecast charge for 2018/19. The remainder relates to not fully utilising the capital budget in 2018/19.
- 22. The cost of purchasing and distributing the BNF on behalf of the NHS was £4.8m. NICE received a contribution of £0.75m towards this total from the devolved administrations (Wales, Scotland and Northern Ireland) in 2018/19.
- 23. Legal fees are lower this year as there are fewer contractual and employment related issues compared to the 2017/18. The prior year figure also included a one-off provision of £140,000 relating to potential liabilities associated with one of these issues.
- 24. The provisions line in the table above relates to adjustments that are made in the annual accounts for liabilities of uncertain timing and amounts. Such adjustments included a provision for redundancy costs relating to the restructures taking place early in 2017, transition costs relating to ending the NCC social care contract and expected legal fees. Very little of these provisions were required during 2018/19, resulting in a write-back and the credit balance of £287,000.

#### Income

25. Total income recognised in 2018/19 was £16.6m. A summary extract of income sources compared with the previous year is shown in table 3 below:

#### Table 3 Breakdown of income sources for 2018/19

Income Sources 2018/19		
	<b>2018/19</b>	2017/18 £000
Income from related NDPBs and Special Health Authorities	2000	2000
NHS England	6,781	6,610
Health Education England	4,065	4,123
Income from devolved administrations	2,002	1,979
Office sublet income	938	879
Income from other sources		
Scientific Advice	1,575	1,802
Knowledge transfer and publications income	207	146
Office for Market Access	174	154
Research grant receipts	620	642
Income received for staff seconded out	58	61
Contribution to UK Pharmascan costs	12	20
Other income	73	64
Apprenticeship training grant	84	16
Total	16,589	16,496

- 26. NHS England funded several work programmes with a cumulative total of £6.8m for 2018/19. In 2018/19, this included activity to continue supporting the Cancer Drugs Fund (£2.3m), Evidence based treatment pathways for mental health (£1.4m), supporting the NHS England Evaluative Commissioning programme (£0.8m) and producing evidence summaries, commissioning support documents and Medtech innovation briefings (£1.3m), HealthTech Connect (£0.5m) and assessing digitally enhanced IAPT (Improving Access to Psychological Therapies) technologies (£0.3m).
- 27. Health Education England (HEE) provided £4.1m to fund the cost of core content (e.g. journals and databases) that is available on the NICE Evidence Search website.
- 28. In 2018/19 NICE Scientific Advice generated a net deficit of £0.29m after staff costs and other expenditure including a contribution to overheads. This deficit position was mainly attributable to lower than anticipated client demand in 2018/19, disruption associated with long term sickness absence and the

departure of the director. This deficit was underwritten through existing Scientific Advice reserves. The remaining reserves balance brought forward into 2019/20 is £0.75m.

- 29. Total research grant income in 2018/19 was £0.5m, mainly comprising IMI funding from the European Commission to support 6 ongoing projects in the Science Policy and Research Group. NICE also received £0.1m in 2018/19 from the European Health Technology Appraisal network (EUnetHTA) for work on the European HTA network.
- 30. The devolved administrations (Wales, Scotland and Northern Ireland) contributed £2.0m towards the cost of developing NICE guidance and products and procuring the BNF.
- 31. Charging arrangement for Technology Appraisals and Highly Specialised Technologies guidance began on 1 April 2019. Although the new process is in its infancy, we have already received 7 payments totalling £0.9m during April for appraisals starting in April and May 2019. This income will be recognised in the financial position over the lifetime that each appraisal is in development. The NICE Board will be provided with regular updates on income levels and issues in future finance papers.

#### **Capital Expenditure**

32. In 2018/19 NICE had a capital allocation of £0.5m, of this total £0.17m was utilised. Expenditure included £89,000 on IT software licences (antivirus and phish software), £50,000 on upgrading the office facilities (meeting pods, flooring and lighting) in Manchester and £35,000 on IT hardware (additional RAM and routers).

# Workforce

#### Resourcing

- 33. The project to bring recruitment in house is progressing and is on track. We are currently in the final stages of a procurement process and are expecting to purchase an applicant tracking system that will underpin the new internal recruitment service very soon.
- 34. A new initiative has been implemented to produce video content. It was developed in partnership with the Communications teams. This is helping us raise awareness of our employer brand and our employee value proposition before vacancies go live. We hope to have the data and analysis from these campaigns soon. This information will help drive more engagement and relevant high-quality applications during our recruitment campaigns.
- 35. We ran recruitment training combined with diversity and inclusion awareness for hiring managers, which has been well received. The course will continue to evolve in response to feedback and best-practice, and we will run the course periodically through the year.

#### Culture

- 36. In March and April, the HR team ran masterclasses on performance appraisals, with the aim of ensuring that line managers fully understand all stages in our appraisal cycle, can review and set SMART objectives and use coaching style conversations. These were attended by 165 managers. The next series of masterclasses will focus on Performance at Work, supporting managers in maximising the performance of their staff, increasing engagement and motivation, and addressing areas of underperformance with confidence.
- 37.NICE has agreed to participate in the Workforce Race Equality Standard (WRES) this year, following a positive meeting with the senior managers responsible for this programme at NHS England. The data will be used to review our position against other organisations, including arm's length bodies.
- 38. The Communications team has produced <u>an animation</u> showcasing NICE's workforce strategy. This is designed for both internal and external audiences and will support our recruitment activities.
- 39. The 2019 NICE staff survey was launched on 7 May 2019 and will remain open for 3 weeks. Follow-up work on the 2018 survey continues, with the HR team supporting directorates in implementing their action plans. The HR and Internal Communications teams have been working on "you said, we did" communications, including an intranet article from Andrew Dillon which

highlights many of the actions taken in response to last year's survey. The 2019 staff survey paper is expected to be presented at the July Board meeting.

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May 2019

# **Appendix A Summary of Financial Position**

The table below is a summary of the financial position per centre and directorate as at 31 March 2019.

		Budget £000s	Expenditure £000s	Variance £000s	Variance %
	Pay	6,377	6,057	(320)	(5%)
	Non pay	12,256	12,456	199	2%
Centre for Guidelines	Income	(624)	(751)	(127)	(20%)
	Total	18,010	17,762	(248)	(1%)
	Pay	8,297	7,932	(365)	(4%)
Centre for Health	Non pay	3,260	2,883	(377)	(12%)
Technology Evaluation	Income	0	(10)	(10)	
	Total	11,557	10,805	(752)	(7%)
	Рау	7,733	7,656	(77)	0
Health and Social Care	Non pay	2,481	2,293	(188)	(8%)
Health and Social Care	Income	0	(58)	(58)	
	Total	10,213	9,890	(323)	(3%)
	Рау	5,188	4,734	(454)	(9%)
Evidence Resources	Non pay	6,041	6,244	203	3%
	Income	(135)	(282)	(147)	(109%)
	Total	11,094	10,696	(398)	(4%)
	Pay	2,831	2,660	(171)	(6%)
Science Advice and	Non pay	572	323	(250)	(44%)
Research	Income	(3,183)	(2,354)	829	26%
	Total	220	629	408	n/a
Subtotal Guidance and		51,094	49,781	(1,313)	(3%)
	Pay	3,605	3,528	(77)	(2%)
Communications	Non pay	369	365	(3)	1%
	Income	0	0	0	
	Total	3,973	3,893	(80)	(2%)
Ducine of Discusion	Pay	2,944	2,904	(40)	(1%)
Business Planning and Resources	Non pay Income	6,345	6,217	(128)	(2%)
	Total	(879) <b>8,411</b>	(937) <b>8,185</b>	(58) ( <b>226</b> )	(7%) ( <b>3%</b> )
Subtotal Corporate	Total	12,384	12,078	(306)	(3%)
	Non pay	850	543	(307)	(36%)
Depreciation	Total	850	543	(307)	(36%)
	Income	(11,913)	(12,114)	(201)	0%
Other Income	Total	(11,913)	(12,114)	(201)	2%
	Pay	444	(71)	(516)	(116%)
Reserves	Non pay	61	(210)	(271)	(445%)
	Income	0	(84)	(84)	
	Total	505	(366)	(871)	(172%)
	Pay	37,419	35,399	(2,020)	(5%)
NICE Grand Total	Non pay	32,235	31,114	(1,121)	(3%)
NICE Grand Total	Income	(16,734)	(16,589)	145	1%
	Total	52,920	49,924	(2,996)	(6%)

# National Institute for Health and Care Excellence Business plan 2019/20

The business plan sets out our business objectives and performance measures for 2019/20. It has been updated to reflect the Board's review of earlier versions, and feedback from the Department of Health and Social Care.

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

Andrew Dillon

**Chief Executive** 

May 2019

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

**Business Plan: objectives and performance measures** 

2019/20

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# Introduction

- 1. This plan sets out our business objectives and performance measures for 2019/20.
- 2. Our purpose is to help improve the quality, sustainability and productivity of health and social care in England. We do this by producing guidance and information on effective practice and public health interventions, which enable people working in health and social care to make better decisions with and for those for whom they are providing services. We take account of value for money in developing our guidance, by recognising that new forms of practice need to demonstrate the benefits they bring against what they displace, and by recommending better targeting of interventions of limited value and opportunities for disinvesting from ineffective interventions. These are challenging decisions, and NICE plays an important role in supporting the health and care system to prioritise its investment. Our objectives support the wider system priorities, including delivering the NHS Long Term Plan, managing the risks and opportunities of EU Exit, and supporting the ambitions of the life sciences industrial strategy.
- 3. We promote our guidance and information using our own as well as a range of third party channels, including digital media and we help people to use it by providing practical support tools. NICE has a unique role in the health and care system given its remit across health care, public health and social care and is therefore well placed to adopt this system-wide perspective. To make sure our products are delivered efficiently and continue to meet the needs of our audiences, we have launched an ambitious project to review the way we produce and present our advice. Informed by user feedback, the NICE Connect project will understand and adapt to what our audiences and digital partners need from NICE in the future.
- 4. Established in April 1999 to reduce variation in the availability and quality of NHS treatments and care, our role was extended in 2005 to include advice on effective and cost effective public health practice. In 2009, we were asked to produce quality standards, derived largely from our clinical guidelines and to take responsibility for developing and maintaining clinical and public health indicators in the Quality and Outcomes Framework (QOF). At the same time, our technology evaluation programme was extended and we added more capacity to evaluate medical devices and diagnostics. Since 2013, our remit has included guidance and quality standards for adults' and children's social care, and highly specialised technologies for very rare conditions.
- 5. Our objectives for 2019/20 are framed around our six strategic ambitions:
  - Deliver and support the adoption of accessible, up to date and adaptable advice, fully aligned to the needs of our users
  - Play an active, influential role in the national stewardship of the health and care system

- Take advantage of new data sources and digital technologies in developing and delivering our advice
- Support the UK's ambition to enhance its position as a global life sciences destination
- Generate and manage effectively the resources needed to maintain our offer to the health and care system
- Within the organisation, maintain a motivated, well-led and adaptable workforce

#### NICE's unique offer

- 6. We will continue to produce guidance and standards that promote better integration between health, public health and social care services. Our work will be:
  - *Distinct:* delivering 'only from NICE' recommendations and services
  - *Aligned:* informing and enabling the ambitions and capacities of the health and care system
  - *Robust:* working with transparency, rigour, inclusiveness and contestability
  - *Efficient*: using our resources carefully, delivering our work when it is needed and responding to changes in the needs of the people and organisations we serve.
- 7. NICE is an England only body and has contractual arrangements with all three devolved administrations. Wales, Scotland and Northern Ireland have each developed their own approach to the organisation and management of their health and care services. They use different combinations of the guidance and advice we produce in ways which reflect their priorities, the needs of their staff and the local resources they have available to inform evidence-based practice. We tailor our relationship to the needs of each country and have effective working and contractual arrangements with the agencies which undertake complementary functions.

# The context in which we work

#### The health and care system

8. Demographics, constrained resources, public expectation and a wave of new technologies are combining to present the health and care system with both challenges and opportunities, as will the UK's exit from the EU. Much of what is needed can be delivered/driven by the NHS and local government, but much too will require collaboration with voluntary organisations, care providers and employers. This argues for a determined effort to do what we know will help to promote good health and prevent ill-health, support people to gain control of their care by supporting the Government's ambition to help people maintain as independent life as possible, and promote better integration of care between

hospitals and general practitioners and between the NHS, public health and social care. This ambition, for the NHS, is framed in the NHS Long Term Plan and in the forthcoming social care green paper.

#### Working with our system partners

- 9. We are committed to supporting the NHS, public health and social care, and organisations in the wider public and voluntary sector to help them achieve their objectives in challenging circumstances. From identifying specific recommendations that can save money, to advice on reconfiguration to support disinvestment from ineffective services, NICE has a range of products and services to help realise savings that can be reinvested.
- 10. We will continue to work collaboratively with the Department of Health and Social Care, NHS England, NHS Improvement, Public Health England, the Care Quality Commission and our other national partners and professional bodies, on their plans for a clear and compelling long-term vision for the future of health and care services. We will continue to ensure that our advice and guidance forms an integral part of their plans for change and supports a sustainable future, recognising the affordability challenge that the system can face in introducing new services and treatments.
- 11. We will ensure that our guidance is designed to work with a system that:
  - Is operating in a challenging funding environment
  - Is seeking significantly improved quality of care and value for money through a variety of means, including the emerging integrated care organisations and systems, and sharing of services and resources at local level
  - Is beginning to use diverse, previously unconnected data sets to better understand and respond to the needs of people who use services
  - Is collaborating with the life sciences industry to enhance the UK's position as a global industry destination
  - Is experimenting with a range of service delivery models
- 12. We need to ensure that our guidance and standards can be implemented as efficiently as possible, to improve the health and care of patients and the public. We work with system partners to support this in a number of ways, including through a variety of quality improvement initiatives. We track progress on engagement and uptake of our recommendations through a range of metrics, and through topic based impact reports, all routinely reported to the Board.
- 13. We track variation in uptake of our recommendations across the country in conjunction with partners, including working with NHS Digital to produce the Innovation Scorecard, and with NHS Improvement's Getting It Right First Time (GIRFT) initiative. Where possible we surface this unwarranted variation in our uptake reports, and work with local partners to increase adoption.

#### Helping the health and care system achieve financial balance

#### NHS

- 14. In the next 5 years, as the health and care system faces significant financial challenges, NICE will continue to help drive the optimal use of resources, in partnership with NHS England (NHSE) and NHS Improvement (NHSI). To do this, we will clearly identify cost saving guidance and its place in commissioning policy, demand management and coordinated reallocation of capacity. We will continue to support the optimal use of medicines and reducing inappropriate prescribing through the work of the Medicines and Technologies Programme, including focussed work on specific medicines. We will also assess budget impact of technology appraisal and highly specialised technologies guidance, and provide a forward planner that shows and categorises anticipated costs, by quarter, for all future guidance. This supports the commissioning process, particularly for specialised products. We will also work closely with NHSE and NHSI to support the roll out of new guidelines with a significant resource impact.
- 15. We will continue to actively engage with partner organisations to identify and improve uptake and disinvestment opportunities. In particular, we are working with NHS RightCare and NHS Improvement's Getting it Right First Time programmes and to coordinate and align medicines optimisation activities in order to support efforts to get the best value from medicines including improving patient outcomes. We also support the Regional Medicines Optimisation Committees (RMOCs), and we will provide these committees with relevant evidence reviews.
- 16. Another strand of our work to optimise NHS expenditure and improve patient outcomes relates to 'shared decision making', in which patients and clinicians work together to determine a test or treatment package that reflects patients' preferences. This approach has the benefit of improving patient satisfaction and, in many cases, of also reducing the use of more expensive, invasive technologies. NICE is working with NHS England to support this agenda, through a number of strands of work. This includes making the evidence base for NICE guidance more accessible, developing a guideline on shared decision making, curating a collection of quality standards on shared decision making, and providing a repository for a range of online tools.

#### Digital health and care services

17. Expectations regarding the potential of digital interventions and services to transform the delivery of care, improve people's outcomes and access, and save costs, remain high across the health and social care system. In practice however, while the evidence base for digital technologies is improving, it remains limited and the confidence of decision makers to recommend or fund these technologies continues to be low. In 2018, NICE developed evidence standards for digital health technologies, working in partnership with NHS England and Public Health England. These standards cover effectiveness and economic impact and will sit alongside other principles for the development and

commissioning of digital health technologies as described in the <u>Code of</u> <u>Conduct</u> published by the DHSC.

- 18. In line with the Life Sciences Sector Deal, NICE will build on the development of these standards to establish a programme of digital technology evaluation, working in partnership with agencies such as NHS Digital to provide a rounded assessment, subject to the release of the required funding.
- 19. NICE also continues to support NHS England to deliver the digital Improving Access to Psychological Therapies (IAPT) pilot programme which aims to provide evidence-based psychological therapies and widen access to therapy for people with anxiety disorders and depression.

#### Public expectations of NICE

- 20. As NICE guidance and quality standards continue to extend their reach beyond clinical and public health practice into social care, the expectations of people for whom NICE is working will continue to rise. We already know that investing in disease prevention and health promotion is good value for money. We will use our public health guidance and quality standards to support the arrangements for public health in England to promote that message.
- 21. The Government is committed to enabling the public to influence the development and delivery of health and social care services. NICE has, from its inception, actively encouraged and supported the involvement of patients, service users, carers and the public (both organisations and individuals) in the development and implementation of our guidance and advice, and in providing versions of this guidance and advice in accessible formats. We will continue to work closely with NHS England to improve support for shared decision making between patients and professionals. Over the years, NICE has broadened opportunities for public scrutiny of our decisions by providing access for the public to the meetings of our advisory bodies. In 2019/20 we will continue the implementation of the changes and improvements to our engagement with the public and those who speak on their behalf that were agreed following our strategic review of public involvement.

#### Public health

- 22. We continue to build on our existing relationship with Public Health England to support the delivery of many public health interventions and programmes. We also work closely with local authorities to ensure that guidance and related products are clear, relevant and accessible.
- 23. The partnership agreement between NICE and Public Health England (PHE) sets out how the two organisations will work together to share and develop knowledge and intelligence on healthcare, and on public health interventions and services at a national and local level. We will continue to work with PHE to optimise the national support for public health, including to jointly badge guidelines and other evidence based publications, and to actively support implementation of recommendations for public health at a local level.

24. NICE is leading and contributing to a number of work areas to support the fight against antimicrobial resistance. These include the publication of a series of short antimicrobial prescribing guidelines for managing common infections and antimicrobial evidence summaries, to support the stewardship of new antimicrobials coming to market. We are working with NHS England on the potential role for technology appraisal guidance for some antimicrobials and exploring how links to up-to-date information on resistance rates can be included in the British National Formulary (BNF).

#### Social care

- 25. NICE guidance and quality standards for social care are commissioned by the Secretary of State for Health and Social Care, and in the case of children's social care, work is commissioned by the Secretary of State for Education. They are intended for use in conjunction with the frameworks and regulation already in place, providing practical support to help drive up the quality of adult and children's care. They also support the work of local Health and Wellbeing Boards and help local people hold commissioners and providers to account.
- 26. We recognise that resource allocation decisions are a matter for local councils and we believe that using an evidence-based approach to cost-effectiveness can assist local commissioners make these decisions. This highlights the importance of ensuring that quality standards describe cost effective practice.
- 27. To ensure our products for social care are designed and presented in a way that meets the needs of the individuals who deliver social care and the organisations they work for, we began producing 'quick guides' in 2016. These have been very well received by the social care sector, and we will continue to develop these during 2019/20.
- 28. The social care community has long been an important audience for any NICE guidance and advice that impacts on broader health issues, particularly from our public health programme, in addition to our social care programme. NICE's role in this sector was consolidated in 2017 with the publication of 'Quality Matters', which set out NICE's role in supporting quality improvement for adult social care alongside other partners. In 2018, NICE played an active role in implementing Quality Matters, working closely with Skills for Care, the Social Care Institute for Excellence (SCIE) and other national partners.
- 29. For the first year of Quality Matters, NICE led the development of a new digital resource 'Unlocking capacity: better together' which promotes good quality, person-centred care through collaborative working across health and adult social care. The resource aims to inspire local system leaders to take the next step on their journey of collaborative working. We also developed NICE's Quality Improvement Resource for adult social care, mapping relevant quality standards to the CQC inspection framework.
- 30. We will continue to play a key role in year 2 of Quality Matters, leading on two action areas with other national partners including Skills for Care, CQC, SCIE

and NHS Digital: collecting and using data more effectively, and providing support for quality improvement.

#### Life sciences industry

- 31. NICE has an important relationship with the life sciences industry. Much of our guidance is based on data generated by pharmaceutical, biotechnology, medical devices and diagnostics companies, as they develop and prepare their products for market. Most of our programmes make recommendations about or provide information on new and existing health technologies. Our guidance has an impact on the commercial prospects of companies in the life sciences sector, in this country and internationally.
- 32. Our relationship with the industry is complex. Our primary responsibility is to help those who use the health and care services and those who care for them to get the best outcomes and to use the resources available effectively. However, because of the impact we have on the companies whose products we review, we also have a responsibility to consider the impact of our work on them. This requires a delicate balance but we can help the industry make it more likely that the products they bring to the NHS will address the needs of patients in an affordable and cost effective way and, as a result, enhance their prospects in the market.
- 33. We want to reduce the risk for companies introducing products to the UK market by helping them focus their value proposition on the most compelling data. We also want to work with companies and the NHS to design and manage novel evidence generation processes and new data-driven funding models for fast-track approval and reimbursement which provide benefits to patients and make the best use of NHS resources, and to support the UK in developing a world-leading approach to using data to track outcomes and manage early access to worthwhile new technologies. Our new Commercial and Managed Access Programme will support both industry and healthcare partners in their understanding of what could be done to facilitate patient access, especially where there is significant uncertainty about the benefits and costs of introducing a new technology. We are working closely in partnership with NHS England to achieve this, by co-creating operational processes and procedures to assist both our organisations to work more efficiently and effectively in this regard.
- 34. Building on the international value of a positive NICE appraisal, we continue to extend our support for companies by increasing the visibility and accessibility of the Office for Market Access and Scientific Advice Programme outside the UK.
- 35. Our vision for a thriving relationship between the industry regulators and the NHS is an environment which enables and promotes adaptive, integrated regulatory approval, followed by the fast, data-driven evaluation, reimbursement and adoption of compelling, affordable value propositions. In 2019, we will be working with the industry and our system partners, including NHS England, to implement key aspects of the new Voluntary Scheme for Branded Medicines Pricing and Access, the life sciences sector deal, the NHS Long Term Plan, and to continue our contribution to the work of the Accelerated Access Collaborative. These initiatives will benefit individuals by providing access to the

most effective and cost effective new treatments more efficiently, and will help the life sciences industry by increasing the opportunities for companies to help manage the introduction of their new technologies into the NHS.

- 36. The second sector deal relating to the Life Sciences strategy and the NHS Long Term Plan both call for NICE to increase its medtech programme, incorporating the evaluation of new digital health products. We are working with NHS England on the assessment of a small number of digital products and we stand ready to expand the wider medtech programme, once funding for it has been identified.
- 37. In 2019 we introduce charging arrangements for our technology appraisal and highly specialised technologies programmes. Charging will provide a more sustainable model, by reducing reliance on grant in aid and enabling us to flex capacity in future years in response to the pipeline of technologies, and be more responsive to developments in the life sciences sector. Charges have been set and will be reviewed in line with the principles of managing public money. A discount of 75% will be offered to small companies to minimise barriers to the participation. Over the past 20 years, we have developed a very good working relationship with companies in the life sciences sector, and one that we fully intend to maintain and build on as we put these cost recovery arrangements in place.

#### Exiting the European Union

- 38. As the UK leaves the EU, we will continue to work with DHSC and its arms' length bodies (ALBs) to manage the consequences of EU Exit on NICE and the wider health and care system. In particular, we will continue to coordinate the development and publication timeline for guidance on new medicines with the Medicines and Healthcare products Regulatory Agency (MHRA) to maintain timely patient access to effective new medicines and technologies. We will also need to consider the sustainability of the fee for service income we receive for our science advice programme, some of which is undertaken jointly with other EU countries, and the research income we currently receive from the EU.
- 39. NICE stores some personal data offshore in the EEA, and uses suppliers that do so. We are aware that if data protection legislation changes around data processor to data controller data transfers, these arrangements may need to be reviewed. We are working with our Data Protection Officer and colleagues at the Department of Health and Social Care to monitor the situation so that we are prepared to act quickly should we need to, to ensure continued access to our data.
- 40. We have risk assessed each of these issues and have completed or are actively progressing work to put in place mitigation arrangements. We will also continue to update our business continuity plans in line with the UK's future relationship with the EU. At the same time, we are contributing to the EU Exit planning and coordination work undertaken by the Department of Health and Social Care.

41. We are actively encouraging and supporting the people we employ from other EU countries to register for settled status.

# Developing a vision for the future: the NICE Connect project

- 42. NICE has a significant portfolio of guidelines for health and social care, guidance on new medicines and technologies, plus other advice and support products. This can be challenging for us to keep up to date, and for users to readily identify the information they need. We have therefore initiated the 'NICE Connect project' to consider how we should organise and prepare our advice in future.
- 43. Our vision for the future is that all our work will be driven by pathways that reflect the way prevention, treatment and care are organised and delivered. These pathways will become the way that we will prepare and present advice to our users on effectiveness, safety and value for money. The pathways will enable links to be made across topics and within topics, and allow users to access underpinning evidence and practical support.
- 44. We will consider ease of access to information directly through our website and, importantly, how third party IT providers can readily adopt our content to provide access to users through routine decision support systems linked to data collection.
- 45. The overall benefit of the proposed new approach will be improved care for people, with better outcomes, as a result of:
  - Maintaining up to date recommendations , so care is always based on the best available evidence
  - Rapid sequencing of new drugs and technologies, so they will be adopted more quickly
  - Integrating our recommendations into IT systems, so adherence to evidence-based practice is increased
  - More accessible recommendations, so access to NICE advice is quicker and easier.
- 46. This ambition will be explored during 2019/20 through the generation of new diabetes pathways, which we will test and refine with users, to help us build our understanding of how we can meet their needs, and validate the case for change. Exploring the future needs of digital systems across health and social care will also form a central part of this early work.
- 47. The findings from the NICE Connect project will inform much of our future work, and we anticipate moving into digital development and process redesign in the second half of the financial year. This represents an ambitious piece of work for NICE, ensuring we work efficiently and deliver an up to date product to all our audiences.

# **Objectives and programmes**

- 48. NICE has the potential to both drive and enable the design and the effective delivery of services provided by the health and care system. Our knowledge of the evidence for good quality care and outcomes and our ability to convert it into guidance and other forms of information which those working in both systems can use to improve their decisions, puts us in a unique position to influence the nature and shape of services into the future.
- 49. In the development of guidance and standards, NICE operates a set of core principles. These principles inform the development of any new work programmes as well as the delivery of existing programmes. These principles state that we will:
  - Prepare guidance and standards on topics that reflect national priorities for the population's health and care
  - Use evidence that is relevant, reliable and robust
  - Set out frameworks for interpreting the evidence in our process and methods manuals, and review them regularly
  - Use independent advisory committees to develop recommendations
  - Take into account the advice and experience of people using services, health and social care professionals, commissioners and providers
  - Base our recommendations on an assessment of population benefits and value for money
  - Give people interested in the topic area the opportunity to comment on and influence our recommendations
  - Lead work with partners in the health and care system to encourage and support the adoption of our recommendations
  - Assess the need to update our publications in line with new evidence
  - Propose new research questions and data collection to resolve uncertainties in the evidence.
- 50. The planned actions in 2019/20 to deliver the strategic ambitions are on pages 32 to 34. The 'balanced scorecard', which sets specific targets based on these actions, is presented in Appendix 1. Details of the publication outputs for each programme are provided in Appendix 2. Further information on our products and services is outlined below.

#### Guidance and advice

#### Quality standards

51. NICE **quality standards** provide clear, concise statements of high-priority areas for quality improvement, covering health, public health and social care. Audiences include: commissioners of health, public health and social care; staff working in primary care and local authorities; social care provider organisations; public health staff; people working in hospitals; people working in the community and the users of services and their carers.

- 52. Quality standards help commissioners and providers improve quality by providing measures of best practice to support ongoing performance improvement. Around 16 quality standard topics are in development at any one time, through a process that actively involves those with expertise and understanding of current services. Quality standards include content related to all three dimensions of quality safety, effectiveness and experience and take into account overall cost impact.
- 53. Although quality standards are not mandatory, they are an important driver for change within the arrangements for commissioning and service delivery in health and social care. Both the Secretary of State and NHS England must have regard to NICE quality standards. Quality standards are also identified as a key tool for bringing clarity to and measuring quality, as part of the National Quality Board's 'Shared commitment to quality'. In social care, their role is reflected in Quality Matters. In public health, NICE is working with Public Health England to support their use in local government.

#### Guidance on health technologies

- Technology appraisals develop recommendations for the NHS on drugs and 54. treatments based on their clinical and cost effectiveness. We currently appraise all new and significant licence extensions for cancer drugs, and we will be appraising all drugs and significant licence extensions in accordance with the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (2019VS), by April 2020. We currently aim to publish final guidance for cancer drugs within 90 days of granting of the marketing authorisation, and following the 2019VS we will begin to extend that to all drugs. Regulations provide for the mandatory funding of drugs and treatments which are recommended in a technology appraisal and that funding must normally be available within 3 months of a positive appraisal. Entitlement to these drugs is set out in the NHS Constitution. The 2019VS also provides the opportunity to NICE to work with companies and NHS England on structured approaches to confidential commercial agreements, to facilitate the introduction of cost effective treatments and to work with system partners on an integrated horizon scanning initiative.
- 55. NICE also has responsibility for evaluating and providing advice to NHS England on selected **highly specialised technologies** which have been developed for treating conditions which affect very small numbers of people in England. Regulations provide for the mandatory funding of drugs and treatments which are recommended in a highly specialised technologies evaluation and that funding must normally be available within 3 months of a positive evaluation. Entitlement to these drugs is also set out in the NHS Constitution.
- 56. In accordance with the commitments in the 2019VS we will undertake a review of the methods guides for our technology evaluation programmes, including the selection criteria, ensuring that they are robust and fit for purpose by end March 2020.

- 57. NICE will continue to lead on the topic selection programme for the technology appraisal and highly specialised technologies evaluation programmes for the Department of Health and Social Care, and continue to work with the National Institute for Health Research Innovation Observatory (NIHRIO) horizon scanning facility to ensure that we receive early intelligence on emerging new health technologies. In addition, we will continue our work with NHS England and other stakeholders to support **PharmaScan**, and increase early awareness of new and emerging medical technologies through the development of **HealthTech Connect** – a secure online system for identifying and supporting health technologies (including devices, diagnostics, apps, and wearables) as they move from inception to adoption in the UK health and care system. Medical technologies (devices and diagnostics) are currently notified directly to NICE, usually by commercial sponsors and sometimes by clinical leads. With the establishment of HealthTech Connect we are reviewing our topic selection process in order to align with NHS England's topic selection, increasing clarity in respective roles and decision points, in order to drive a clearer and more streamlined process that will benefit NICE, NHS England and the life sciences industry. This exploration is expected to further allow us to align the work across the various topic selection programmes for pharmaceuticals, medical devices, diagnostics, and in future, digital technologies.
- 58. Our **medical technologies guidance** aims to identify cost saving interventions and recommends them to the NHS when the sponsor's case for adoption is supported by the evidence. The guidance is based on advantages to people and to the NHS, compared with current practice, and it includes detailed consideration of costs, settings and of the whole pathway of care.
- 59. Our **diagnostics guidance** advises the NHS and people on the clinical and cost effectiveness of diagnostic technologies that have the potential to transform clinical diagnosis pathways to achieve better outcomes and in some cases promote efficiencies. The scope of technologies to provide a diagnosis at the 'point of care' and to avoid attendances in secondary care is often an important consideration. We will continue to work with NHS England and other national partners on the appropriate evaluation of genomic tests following the introduction of the NHS Genomic Medicine Service.
- 60. In 2014, NICE began to produce **Medtech Innovation Briefings (MIBs)** to provide the NHS and social care with objective information on promising medical technologies as an aid to local decision making by clinicians, commissioners and procurement professionals, and to inform people about new technologies. We will continue to work collaboratively, particularly with NHS England, to develop MIBs as a rapid responsive resource where the need for information has been identified directly from the NHS. We will also exploit the potential of MIBs to address technologies across the whole spectrum of NHS and social care settings.
- 61. Since July 2016, a team at NICE has been working with colleagues in NHS England to support the arrangements laid out for the revised Cancer Drugs Fund (CDF). We have appraised all of the licenced treatments that were made available via the original Cancer Drugs Fund, and continue to work actively with

NHS England to develop managed access agreements for drugs recommended for use in the reformed Cancer Drugs Fund. We continue to collaborate with Public Health England and NHS England to monitor data collection during the CDF period and the first 2 topics exited the reformed CDF following data collection in 2018.

- 62. Changes to the TA and HST programmes, such as the introduction of a technical engagement step and the HST cost/QALY limit, have substantially increased the need for NICE to ensure companies have meaningful opportunities to engage in commercial and managed access conversations with both ourselves and NHS England. The demand from companies for such interactions with NICE is already significant. In order for these conversations to take place both at scale, and within the formal framework of NICE guidance production, appropriately resourced structures and processes are required in both NICE and NHS England. Commercial negotiation and managed access activity is resource intensive, sensitive and highly complex and in 2018/19 NICE established a Commercial and Managed Access Programme to work alongside NHS England.
- 63. In 2019/20 we will also continue to provide advice to NHS England on the feasibility of operating commercial arrangements put forward by companies through the **Patient Access Schemes Liaison Unit (PASLU)**, and will explore with colleagues in NHS England how, through PASLU and our Commercial and Managed Access Programme, we can support NHS England in the consideration of commercial access agreements.

#### Advice on safety and effectiveness

- 64. Our **interventional procedures guidance** provides important advice on the safety and efficacy of new interventional procedures, including those used in hospital, in the community and in people's homes. An interventional procedure is one used for diagnosis or treatment that involves making a cut or hole in the body, entry into a body cavity or using electromagnetic radiation (including X-rays or lasers). Topics for this programme are referred by any source including: manufacturers, individuals, other programmes at NICE, and the health professionals who wish to use them.
- 65. We are working with strategic partners to ensure the outputs are applied with consistency in the NHS in the 4 UK countries and in the private health sector.
- 66. Since 2017, NICE has been developing outputs and undertaking activities to support NHS England's commissioning of specialised services through the Commissioning Support Programme (CSP) and the Observational Data Unit (ODU). CSP is used by NHS England to bring together the evidence base for medicines that are of interest to its clinical reference groups for consideration of national commissioning, but that have not been selected by NICE for technology appraisal or highly specialised technologies programmes. The ODU is responsible for delivering evaluative commissioning projects on behalf of NHS England. The ODU is responsible for overseeing all aspects of these projects, from the detailed specification of the evidence needed to its

collection and analysis, highlighting the appropriateness of further evaluation by NICE where required. NHS England intentions for the CSP programme in 2019/20 will reflect their requirements which are changing as a result of the Voluntary Scheme for Branded Medicines Pricing and Access.

#### Guidelines

- 67. **NICE guidelines** make evidence-based recommendations on a wide range of topics, from preventing and managing specific conditions, improving health, and managing medicines in different settings; to providing social care and support to adults and children, and planning broader services and interventions to improve the health of communities. Guidelines covering clinical and social care topics aim to promote individualised and integrated care, including for example transitions between children's and adult services, and between health and social care. NICE guidelines include, where appropriate, recommendations on the organisation and delivery of care in health and social care services. Though not covered by a funding requirement or the NHS Constitution, they are an important reference for health and social care professionals and commissioners in the NHS, who are expected to take them into account, and for people who use health and care services. Importantly, our guidelines are also the primary source for our quality standards.
- 68. Maintaining the currency of the guidelines portfolio is a vital element of its relevance to the NHS and its suitability as the principal source for quality standards. As the portfolio has grown, reviewing and updating guidelines has become a major activity in the programme.

#### Medicines and prescribing

- 69. In addition to the recommendations in our guidelines, and technology appraisal and highly specialised technologies guidance, we provide a comprehensive suite of guidance, advice and support for optimal use of medicines. These include evidence summaries, key therapeutic topics, decision aids, medicines awareness services and the NICE associates programme. Prescribing advice for the NHS is provided via the British National Formulary (BNF) and through NICE's digital evidence resource.
- 70. **Evidence summaries** provide information on the effectiveness, safety, resource impact and person-related factors for new medicines which are not the subject of a timely technology appraisal. These are commissioned by NHS England to support the Regional Medicines Optimisation Committees. We also produce evidence summaries on the use of unlicensed or off-label medicines in conditions where there is no licenced alternative, supporting cross-system initiatives to facilitate the adoption of repurposed medicines with a robust evidence base. These are commissioned by NHS England specialised commissioning and provide the evidence base to support NHS England commissioning policies. Evidence summaries do not constitute formal recommendations, but summarise the available evidence to inform commissioning policies and local decision-making.

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

#### Indicators

- 72. We provide a range of evidence-based **indicators** to support national and local measurement of quality improvement. NICE has a robust process in place for developing indicators, which was recognised in 2015 through two independent reviews carried out by the King's Fund and the Health Foundation.
- 73. Indicators developed by NICE are used in the Quality and Outcomes Framework (QOF) to reward general practice for the provision of high quality care and to standardise improvements. NICE worked closely with NHS England and other national stakeholders in the recent national review of the QOF, and we will continue to work with NHS England and others to ensure NICE indicators support future revisions of the QOF.
- 74. NICE also produces indicators to help Clinical Commissioning Groups identify areas for improvement, to enable them to compare their care processes and outcomes with other groups, locally and nationally. NICE will work closely with NHS England to ensure indicator development reflects their priorities.
- 75. NICE is working with the CQC and other colleagues to identify indicators and measures that reflect high quality social care. This is being taken forward as a workstream within Quality Matters, and will draw on measures that NICE has identified in quality standards for social care.

#### Evidence services

76. NICE Evidence Services are online evidence resources to help people working in the NHS and wider public health and social care sector make better decisions by providing them with access to clinical and non-clinical evidence-based information of the highest quality. The service draws on a comprehensive range of information sources (including local experience), providing easy access to information that has traditionally been hard to find. The system includes a 'simple search' built around a powerful search engine, as well as an advanced database search for researchers and information specialists who need to search content across a range of bibliographic databases. The BNF and BNFC are also available as part of this service, as well as the Clinical Knowledge Summaries, which summarise practice recommendations for over 330 topics typically presenting in primary care. Access to these multiple services is now fully integrated within the NICE website and signposted from any page of the website. This enables a seamless journey for our users, from one information source to another.

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

Improving Access to Psychological Therapies (IAPT) assessment briefings

78. To support NHS England's programme to improve access to psychological therapies, we evaluate selected, digitally assisted therapies for depression and anxiety using ongoing data collection to determine whether there are improvements in service efficiency, with outcomes that are at least as good as those achieved with NICE recommended non-digital therapy. We identify potential digital products, which are screened in line with NICE recommendations and address a condition currently managed by the IAPT programme, and produce an assessment briefing that is considered by an expert panel for inclusion in the IAPT programme. Suitable products are allocated to a set of local IAPT services, and evaluated in practice. Collected data is reviewed on a regular basis by the panel, who evaluate whether the products are suitable for use by mainstream IAPT services after 2 years if their performance is at least as good as NICE recommended non-digital therapy and there is a reduction in the unit cost allowing an increase in activity within current resources.

#### Data and analytics

- 79. Increases in the amount and breadth of data available, the development of new and efficient mechanisms for analysis, and advances in the way information is labelled, linked and shared, have the potential to significantly disrupt our traditional approaches to synthesising research evidence. At the same time they offer opportunities to improve timeliness, relevance and efficiency. Our work to exploit these opportunities will move forward at pace in 2019/20 as we develop a framework and strategy for data and analytics.
- 80. In addition to these activities we will formalise relationships with a range of external organisations with an interest in data and analytics, including Health Data Research UK and the Alan Turing Institute. We will also continue to work with the University of Manchester and the Connected Health Cities in the North of England to further explore, through practical examples, how big data can provide evidence relating to the effectiveness of new and existing treatments and produce new big-picture health insights.

#### Engagement

#### Communications

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

- 82. Work continues to improve the NICE website and we are developing ways to use new digital platforms, including social and multi-media, to communicate with existing and new audiences as people change the way they access information.
- 83. Through our audience insights programme we will regularly monitor and evaluate what our audiences think about NICE's products and services, how they use them, and what we can do to improve their interactions with us.
- 84. In all areas of communications work from writing and editing guidance, responding to enquiries about our work, developing and maintaining digital content, through to our public affairs work with government, and engagement with the press and other media as well as internal audiences we will ensure that guidance and advice is easily accessible, simple to use and readily understood. Our aim is to explain NICE's key role in delivering excellence in health and social care.

Involving people who use health and care services and the public

- 85. We have a service user and public-centred approach in our methodologies across all our programmes. Our processes are designed to enable organisations that represent patients, service users, carers and the wider public to submit evidence, alongside health professionals and others, and to influence the formulation of guidance and other products and services. Individual patients, service users, carers and community members are directly involved in the development of each piece of NICE guidance, and other products. We are committed to seeking improvements in how we can better incorporate the views of lay people into our work and in disseminating our recommendations to a public audience. We will continue to implement the recommendations from our public involvement strategic review, aligning these with broader changes across NICE's guidance development processes and methodologies, in particular the work being undertaken in the CHTE 2020 programme.
- 86. We are committed to working with networks of organisations that represent the interests of the public, patients, people who use services and their carers. Groups such as Patients Involved in NICE (PIN) and the Richmond Group<sup>1</sup> are crucial in the development of our methods, our guidance and the NHS Evidence service, and we will continue to develop our capacity and our methodologies to do so.
- 87. We are also committed to encouraging and supporting voluntary and community sector organisations to champion the use of NICE guidance and standards. We will continue our work to refer people to appropriate patient and voluntary sector organisations as part of our guidance to provide readers with additional sources of support. In particular, most quality standards have voluntary and community sector organisations included as supporting organisations. These organisations enter into a formal agreement with us about how they will promote individual quality standards. We will also continue to work with Healthwatch England to

<sup>&</sup>lt;sup>1</sup> The Richmond Group of Charities is a collaboration of 14 health and social care organisations in the voluntary sector

provide advice to local Healthwatch organisations on supporting the use of NICE guidance and standards.

Involving health and social care practitioners and organisations

- 88. NICE recognises the important role that health and care professionals play in driving change. This is clearly demonstrated in the evidence base for changing practice, and in numerous successful examples of implementing NICE guidance in the Local Practice collection. The effective engagement of professionals, as members of guidance-producing advisory bodies and as external experts in the development and implementation of NICE guidance and advice is therefore of key importance. Both their professional experience and their ability to interpret evidence is an essential contribution to our work. Given the demands made on their time in their routine work, we need to make sure that the opportunities we offer to become involved in our work are as attractive as possible.
- 89. Our Fellows and Scholars programmes are another way in which we can draw on the experience of health and social care professionals and managers from all disciplines. NICE's Student Champions programme continues to be an important mechanism for educating and informing students about NICE. The programme also helps students to understand the importance of using evidence and helps embed a culture of evidence based thinking and practice that they can take with them into their future educational and professional lives.
- 90. Organisations that commission and deliver services are important external partners in our work. We want to ensure that they are encouraged to become involved in the development of our guidance as well as its implementation.

Science Policy and Research

- The Science Policy and Research programme leads NICE corporate scientific 91. affairs, and develops and maintains NICE's research governance infrastructure. The programme collaborates with and influences external policy partners and the research community to define and develop research projects of strategic importance to NICE. The team works with NICE's Internal Research Advisory Group to develop NICE's methods and encourages partners to commission research relevant to our work. This includes membership of the DHSC Research and Development Committee and proactive involvement with national health research funders such as the Medical Research Council (MRC) and the National Institute for Health Research (NIHR). Through this influence, projects have been initiated in several areas relevant to our role including work on the HTA implications of histology-independent indications of cancer drugs and methods work on capturing the value of direct patient and public health benefits of new antimicrobials. In response to work with NICE, the MRC also issued a highlight notice to attract research applications to develop new methods and techniques for synthesising and assessing evidence for complex diagnostic technologies such as next-generation sequencing platforms.
- 92. The programme of scientific policy and research activities, which align to NICE's research priority areas, is increasingly delivered through grant funded research

projects. Building on a solid track record established over the past 5 years, NICE is regarded as an effective research partner and invited to participate in consortia to bid for key Horizon 2020 (H2020) and Innovative Medicines Initiative (IMI) project funding. The current portfolio includes 9 live IMI and H2020 projects. Outcomes from the projects are translated to practice through internal engagement with the guidance producing teams, and life sciences companies engaged in developments through the Office for Market Access and NICE Scientific Advice.

93. The Science Policy and Research programme also leads on key external engagement with a number of regulatory and policy bodies including the MHRA.

#### Adoption and impact

#### Implementation

- 94. NICE guidance and advice needs to be effectively implemented to have any impact on the health and wellbeing of the population and the quality of care provided. Our job is to produce what is needed, when it is needed and then do all we can to encourage and support those who are in a position to apply it. This is a complex, challenging task for which an understanding of the evidence for effective ways of overcoming obstacles is an essential prerequisite. There is a growing body of research evidence on not merely what change is desirable in health and care systems but how to achieve it. NICE needs to be both a user of, and contributor to, the evidence on how to effect large-scale transformational change in complex health systems. To facilitate this process, NICE has an ongoing programme of implementation support to encourage the uptake of guidance and quality standards, including tailored advice for the sustainability and transformation partnerships (STPs) and Integrated Care Systems (ICSs).
- 95. The implementation strategy has five specific objectives. To:
  - produce guidance and standards that are fit for the audience's needs
  - ensure relevant audiences know about the guidance recommendations
  - motivate and encourage improvement
  - highlight practical support to improve local capability and opportunity
  - evaluate impact and uptake.
- 96. NICE has an Implementation Strategy Group comprised of academic leaders in the field of health, care, social science, and public involvement who help us to achieve the aims of the implementation strategy. The group advises on new areas of implementation science and engaging with the research community to stimulate evaluation of significant areas of implementation and improvement science to inform our work.
- 97. NICE provides or endorses relevant implementation support products for a range of purposes, including support for commissioning, support for service improvement and audit, and support for education and learning, all with the aim of making implementation more straightforward at a local level. Some examples of support from NICE include

- the web based 'Into practice' guide for organisations on how to put evidence into practice
- a forward planner updated monthly to summarise our future work programme, provide indicative costs and highlight links with the tariff,
- a Local Practice Collection which includes Shared Learning examples and Quality and Productivity case studies on the NICE website.
- 98. We also have a regional field team that provides information about NICE and practical support and advice, particularly around the effective processes for implementation, to NHS trusts, Academic Health Science Networks, CCGs, local authorities, social care providers, sustainability and transformation partnerships, and accountable care organisations and systems. During 2019/20 we will continue to align the work of the field team where relevant with the regional structures of NHS England, NHS Improvement and Public Health England along with prioritised local engagement activities. This will continue to facilitate a strategic approach of working more closely with partner organisations, and of using new technologies such as webinars, to increase the team's impact. The team will also continue to work closely with NICE's medicines and prescribing associates to maximise our impact, support and advice to the service.
- 99. In addition to this local and regional activity, we also have an active programme of strategic engagement at a national level. The focus of the national level programme is to ensure that the evidence base as set out in NICE guidance and quality standards is embedded in activity with national partners and professional bodies. Progress in engagement and its effect on the use of NICE guidance and standards is reported against a series of measures.
- 100. We measure the use of NICE guidance and capture this in impact reports that look at how the health and care system uses our recommendations to improve outcomes in priority areas. The reports are based on data showing the uptake of our guidance and quality statement from national audits, reports, surveys and indicator frameworks. They are presented to our public Board meetings, published on our website and publicised through communications activities.

#### Adoption of health technologies

- 101. We support the uptake of new technologies in conjunction with the Academic Health Science Networks, the Office for Life Sciences, and NHS England, including providing the secretariat for the NICE Implementation Collaborative (NIC) Board and the Accelerated Access Collaborative. The vision is to coordinate and align identification of transformative technologies, identification of implementation barriers, and uptake data, with clinical engagement, to provide system learning and drive adoption and uptake. We facilitate the adoption of prioritised medical technologies across the NHS through engagement with clinical teams, commissioners and patient groups.
- 102. By applying NICE's skills, knowledge and experience in adoption, uptake and resource impact, we are supporting the realignment of the innovation scorecard

with key clinical areas, the work of the Getting It Right First Time initiative, the Accelerated Access Collaborative and the commitments made in the Voluntary Scheme for Branded Medicines Pricing and Access.

#### Endorsement and accreditation

103. To support users of NICE Evidence, we introduced a formal accreditation programme, enabling 'kite-marking' of high quality independent guidance producers. We now also have a process of formally endorsing externally produced implementation tools and resources, where these are in line with NICE recommendations. This process helps users of guidance to identify high quality resources, recognising the potential power of these channels and the lack of capacity to produce all that we might want to ourselves.

#### Digital team and services

- 104. Underpinning the work of all NICE's teams is a range of digital services, tools and applications. Some of these systems are internally facing to support the guidance producing teams. Others are externally facing to allow widespread access to our content through a range of channels and formats.
- 105. Existing services are being maintained and continuously improved by our internal team of digital professionals, in line with business priorities and user needs. Particularly, we strive to continually improve our website, to ease the navigation of NICE's complex portfolio of products and services, and facilitate access to relevant and related content for users. We also continue to improve mobile access to our services.
- 106. Alongside the maintenance of existing systems, our digital team supports the digital transformation of the organisation by co-developing systems that will improve the efficiency and productivity of NICE's content development processes starting at systems to improve evidence retrieval and analysis, all the way to systems enabling the capture, presentation and sharing of recommendations. The digital transformation programme will support the NICE Connect project during 2019/20, with the pilot's findings shaping the direction of NICE's ongoing digital transformation.
- 107. In delivering our digital offer, we are creating important links with digital teams across the Arms' Length Body sector as well as a number of specialist academic centres. We will continue to develop these connections and explore opportunities to inform, and where suitable, influence the design of system-wide digital information services and products. This will ensure that the effort invested by NICE in producing its information assets is not duplicated and that NICE material is used as source reference material in digital systems developed by the health and care sector wherever suitable.

### **Resource assumptions**

108. NICE receives most of its funding directly from the Department of Health and Social Care (DHSC). This funding is known as Grant-in-Aid (GIA) and is split

into two key components, administration and programme funding. Administration funding is applied to the DHSC's non-frontline activities and support activities such as the provision of policy advice, business support services and technical or scientific advice and support. Most of the DHSC's budget is categorised as programme funding and is applied in providing frontline NHS services.

- 109. The majority of NICE's funding (and DHSC's own funding) is classified as administration – the exceptions are funding for supplying the British National Formulary (BNF) publications to the NHS and some costs associated with the medical technologies evaluation programme. NICE also receives other income from Health Education England and NHS England which is also treated as programme funding.
- 110. During the final quarter of 2018/19 DHSC informed us that the cost pressures in relation to the increased NHS pensions scheme employer's contributions and the Agenda for Change pay deal would not be fully funded as had previously been assumed. This was unexpected and the impact is detailed below.
- 111. The table below shows the planned sources of funds for 2019/20 and how they will be applied. It also shows how these compare with the 2018/19 business plan.

#### Table 1: Sources and application of funds

	2018-19	2019-20
	£m	£m
Sources of Funding		
Grant-in-Aid (GIA) funding		
Administration	42.9	40.0
Programme	8.3	8.0
Agenda for change pay deal	0.5	0.5
Net contribution to NHS Pension Central Fund	-	(0.6)
Non-Cash Funding - Depreciation	0.9	1.0
Non-GIA funding		
Income from NHS England	6.9	4.3
Income from Health Education England	3.8	3.8
Income from Devolved Administrations	1.9	1.9
Income from TA and HST fees	-	3.2
Other operating income	4.6	4.6
Total Sources of Funding	69.8	66.7
Application of Funds		
Guidance and Advice	55.8	54.5
Corporate	13.1	13.9
Depreciation Charges	0.9	1.0
Total Applications of Funding	69.8	69.4
Budget deficit	0.0	(2.7)
Non-recurrent savings needed to fund pay and pension increases	-	1.1
Transition Funding relating to TA cost recovery	-	1.6
Total non-recurring savings and transition funding	0.0	2.7

- 112. The reduction in GIA funding over the spending review period has presented a significant challenge. The Senior Management Team and Board agreed a strategic savings programme to deliver these savings in the four financial years from April 2016. The Board also agreed a strategic vision for NICE that seeks to retain the broad scope of NICE's offer at the end of this period.
- 113. The savings programme included a plan to recover the costs of technology appraisals and highly specialised technologies programmes by charging industry. Proposals for the introduction of fees were suspended in 2017 but charging is expected to commence in 2019/20. The charges will only be made on appraisals that commence after 31 March 2019, which means a number of appraisals that will complete in 2019/20 will not be charged for. This leaves a potential shortfall of £1.6m against our savings programme in 2019/20. The

DHSC has agreed to underwrite this amount, shown as transition funding in Table 1 above.

#### Sources of funds

- 114. The 2019/20 administration funding will fall by 7% (£2.9m) in cash terms. This is the fourth and final year of an overall straight line phased real terms reduction of 30% in our baseline administration funding over the current Spending Review (SR) period to 2019/20. The programme budget will also reduce from £8.3m to £8.0m which gives a total in year reduction in GIA funding of £3.2m (6%) as part of a straight line 10% reduction to the programme element over the SR period.
- 115. The DHSC recently consulted on increasing the rate of employer's contributions to the NHS pension scheme from 14.3% to 20.6%. This increase will take effect from 1 April 2019. The additional pension contributions payable by NICE will total £1.6m in 2019/20, of which £1.0m is funded by DHSC. The cost pressure of £0.6m will be deducted from our GIA allocation as a net contribution to the NHS pension central budget.
- 116. In addition to the baseline administration GIA budget, we will receive £0.5m additional funding as a contribution to the costs of the Agenda for Change 2018-21 pay deal. The new pay deal increased our pay budget by approximately £0.5m per year cumulatively, however only the first year increase is being funded, creating a £0.5m cost pressure.
- 117. The unfunded pay and pension costs total £1.1m. This cost pressure was identified late during the business planning process. To balance the budget, we have assumed that we will release non-recurrent savings of £0.8m from vacant posts during the year and we will reduce our non-pay budget for external contracts by £0.3m.
- 118. DHSC's 2019/20 budgets have yet to be formally approved. Therefore, the above GIA figures should be considered as provisional until formal confirmation of 2019/20 budgets has been provided by the Department.
- 119. In addition to GIA funding there are a number of other sources of income. In total these are projected to be £17.8m (26% of total sources of funding), an increase of £0.6m from 2018/19. The increase is mainly due to the introduction of charges for technology appraisals (£3.2m), although this is offset by a reduction in NHS England funding due to our work on evidence based treatment pathways in mental health ending in March 2019.
- 120. We anticipate that we will continue to receive funding to support a number of existing programmes commissioned by NHS England, such as our work to support the Cancer Drugs Fund which included an expansion of the technology appraisal programme. Details are set out in the table below.

#### Table 2: NHS England funding

Funding from NHS England		2019-20
	£m	£m
Ongoing activity		
Cancer Drugs Fund	2.6	2.6
Evidence based treatment pathways in mental health		-
Commissioning Support Programme	0.8	0.2
Evaluative Commissioning	0.6	0.4
Develop and launch new HealthTech Connect database	0.5	0.3
MedTech Innovation Briefings	0.4	0.4
Evaluation of digital therapies within the IAPT programme	0.3	0.3
Rapid Evidence Summaries	0.1	0.1
Total confirmed activity	6.9	4.3

- 121. The reduction in funding from NHS England is primarily due to the end of the evidence based treatment pathways in mental health activity, which as noted above, is contractually due to end on 31 March 2019.
- 122. The funding for HealthTech Connect database was higher during 2018/19 due to upfront investment in building the tool, therefore the reduced funding in 2019/20 reflects the move to the operational phase of the project. The funding for evaluative commissioning which supports our observational data unit is reducing by £0.2m, as there are only 3 active research projects confirmed for 2019/20 compared to the 5-6 normally in place. If new projects commence in 2019/20 additional funding will be provided by NHS England.
- 123. Funding of £3.8m will come from Health Education England under the service arrangements in place whereby NICE procures and provides the national core content for the NHS.
- 124. Income from the devolved administrations in Wales, Scotland and Northern Ireland contributes to the cost of guidance production, producing the BNF and some supporting services. Service level agreements and contracts set out the level of funding that will be provided and which outputs can be used by each country or support to be provided. It is expected that this income will remain at £1.9m in 2019/20.
- 125. In a full year it is expected that £9.2m will be received in charges to industry for technology appraisals and highly specialised technologies evaluations. However, as charges will only be made for appraisals that commence in the year, a total of £3.2m will be received in 2019/20. Careful monitoring of cash flow will be required during this launch phase of charging to ensure financial balance is maintained throughout the financial year.
- 126. Income from other sources is expected to amount to £4.6m, this funding is mainly made up as follows:

- NICE Scientific Advice provides early advice to the pharmaceutical and medical technology industries. These activities are expected to generate £2.4m to cover direct costs and contribute to overheads where appropriate.
- Rental income will remain around £0.9m for 2019/20. Our London office will continue to host the Human Fertilisation and Embryology Authority (HFEA) and we will continue to generate income from the sub-lets in our Manchester office to Homes England (formerly the Homes and Communities Agency) and the Care Quality Commission.
- The Office for Life Sciences provides £0.3m funding for NICE to provide the Accelerated Access Collaborative Secretariat.
- There are also small amounts of income from other sources anticipated to contribute £1.0m for income generating activities within Science Policy and Research, the Office for Market Access (OMA) and Intellectual Property and Business Content Management. Science Policy and Research have secured a number of European research grants to help fund ongoing projects and staff resource spanning over a number of years.
- 127. In addition to the Grant-in-Aid funding that we receive from the Department of Health and Social Care, we also bid for capital funding on an annual basis. Although subject to confirmation, the assumed capital requirement for 2019/20 is £0.5m as per previous years. It is anticipated this will be used to maintain office facilities and IT hardware and software.
- 128. There is also a non-cash limit of £1m associated with depreciation of assets. These capital and depreciation budgets and resource limits are over and above the Grant-in-Aid funding set out above.

#### How we apply our resources

- 129. The pay budget for 2019/20 is currently £40.3m, including expected pay inflation cost pressures (see appendix 3.1 for full breakdown). This is an increase of £1.5m (4%) compared to 2018/19. This is mainly due to pay inflation, length of service increments awarded to staff and includes a 1% non-consolidated payment due in April 2019 to those employees at the top of their pay band, as agreed in the Agenda for Change pay deal.. Total budgeted headcount (682 whole time equivalents (wte)) is broadly the same as in 2018/19.
- 130. The non-pay budget for 2018/19 is £29.1m, a reduction of £2.0m (6%). Of this, £1.5m relates to a contract with the Royal College of Psychiatrists ending on 31 March 2019 due to the evidence based treatment pathways for mental health work funded by NHS England ending on 31 March 2019. A further £0.6m is being saved from the external NICE Guideline Development Centres as part of the NICE strategic savings programme. These savings are offset by non-pay cost pressures mainly on facilities (rent, business rates and service charges) and IT (notably licences and software).

131. A number of new activities launched during 2018/19 will continue into 2019/20 and beyond. These include the NICE Connect project to transform the way we develop and present guidance and advice products to meet the needs of people who want to use them, plus increasing the use and understanding of data and analytics to inform our work. This new activity is being funded by additional savings generated during budget setting for 2019/20, and there will be opportunity costs as teams within NICE offer their support by releasing staff to work on the projects in the short-term. In the long-term we are looking for external sponsors to help us with these projects.

## **Human Resources**

- 132. This year we refreshed the Workforce Strategy, which is a three year plan that sets out the strategic direction of the Human Resources (HR) department. It is supported by an annual HR business plan that sets out the specific projects and objectives to be undertaken that year to support the strategy.
- 133. Following a review of our recruitment strategy and the appointment of a recruitment manager we will be bringing recruitment in-house. This will not only enhance our recruitment service but improve the hiring manager and candidate experience. The HR team will work with each centre and directorate to formulate specific workforce plans to achieve more effective resourcing strategies. This will include more targeted recruitment campaigns and increased use of social media platforms to maximise our employer brand. We are also refreshing our approach to on-boarding following a review of our induction.
- 134. We will build links with key universities and identify opportunities to pilot a 'graduate programme' and/or placements for niche hard to fill roles while also continuing to drive our apprentice strategy and identify ways to maximise our use of the apprentice levy.
- 135. We are progressing our talent management activities by engaging with the DHSC, Civil Service and other leadership programmes, including attending steering groups and supporting assessment centres. This will be underpinned by a suite of internal management development initiatives, including 'practical' mini-master classes in soft skills and key HR policies for line managers.
- 136. We are committed to staff engagement and we will be involving our employees with the creation of NICE values and running a campaign of health and wellbeing initiatives with a particular focus on mental health. We will also refresh our equality and diversity policy and continue to develop strategies to increase diversity and inclusion at NICE, particularly in black, Asian and minority ethnic leaders at band 7 and above.
- 137. We will also be supporting the business with the people strands in a number of transformation programmes such as the NICE Connect project, CHTE 2020 and the proposed NICE Foundation.
- 138. Another key objective is to improve the efficiency of HR processes and systems. Following on from the implementation of 'employee' and 'supervisor

self-serve' on the Electronic Staff Record (ESR), phase two is the development of 'people dashboards' for managers with real time reporting, and e-appraisal. We will also move our Learning Management System (LMS) to ESR, creating one platform for all HR and learning systems.

## **Estates**

139. All of NICE's office facilities operate on a totally flexible working model. The Human Fertilisation and Embryology Authority is co-located in our London office, and the Care Quality Commission (CQC) and Homes England are co-located in our Manchester office. This provides income to offset against our savings targets and ensures that we are making best use of the space we lease. The lease on the London office runs through to the end of 2020 and will not be extendable beyond this. We are engaged in the DHSC London office accommodation strategy and as part of this we will relocate our London office during 2020, probably as part of a co-location arrangement with other DHSC ALBs. The lease on our Manchester office was renewed at the end of 2017 for a 10 year term with a break opportunity at year 7 for which we have negotiated favourable terms. In the longer term, but no earlier than 2024, the Government Property Unit is planning a North West hub, which currently aligns with the Manchester lease break.

## Procurement

140. We continue to comply with the Government's policy objectives in relation to procurement and efficiency controls. We use Government LEAN sourcing principles for all significant procurements and undertake to complete them within the 120 day target. We also comply with Government Commercial Operating Standards and use the central contract solutions where appropriate for procurement of common goods and services. We will also take part in aggregated procurements for common goods and services. We conform to the Efficiency Reform Group controls and procedures where applicable.

# Sustainable development

- 141. We are committed to supporting and promoting sustainability and climate change resilience issues.
- 142. We will continue to consider our own direct impact, focusing our efforts on areas where carbon impact is most significant. These include electricity use, staff and non-staff business travel, printing of guidance and the British National Formulary (BNF), office waste and recycling. We will continue our activities to support the Government's policy to remove consumer single use plastics from the central government estate.
- 143. In addition, we are continuing to explore ways in which the sustainability of health interventions might feature in the guidance we produce, to guide the decisions made by health and social care providers, and people who use health and care services. A sustainability steering group has been established that is considering how sustainability factors (social and environmental) can be

incorporated into shared decision aids, following an initial piece of work on asthma inhalers. We will do this in conjunction with the Centre for Sustainable Healthcare and the Sustainable Development Unit. Any future changes to our methods or for the presentation of guidance would need to be the subject of discussion and consultation.

# Equality

- 144. As part of NICE's compliance with the Public Sector Equality Duty there is an equality analysis process for each item of NICE guidance (which includes quality standards and indicators for the Quality and Outcomes Framework and Clinical Commissioning Group Outcomes Indicator Set). This seeks to ensure that, wherever there is sufficient evidence, NICE's recommendations support local and national efforts to advance equality of opportunity and narrow health inequalities.
- 145. NICE meets the Equality Act's specific duty on publication of information through its <u>annual equality report</u> on the impact of its equality programme. In March 2016 the Board agreed equality objectives for the period 2016 to 2020 in accordance with the Public Sector Equality Duty.
- 146. The NICE equality and diversity group meets quarterly and includes members from each centre/directorate. In addition to overseeing the delivery of the equality objectives and coordinating input to the annual equality report, the group seeks to share good practice across NICE and provide a forum for discussing and proposing solutions to cross-Institute equality issues.
- 147. We have produced data on the <u>gender pay gap</u>, in the format required by the Department of Health and Social Care. This information is available on our web site. To further support this area, the Senior Management Team has nominated an Executive Director sponsor for equality and diversity

## **Risk management**

- 148. We will continue to actively consider the risks associated with the achievement of our strategic and business objectives. The senior management team regularly review risks to ensure that appropriate mitigating action is being taken. The Audit and Risk Committee receives regular assurance on behalf of the Board concerning the identification and management of risks. The main vehicle for this assurance is the risk register but the Audit and Risk Committee is also briefed on significant incidents resulting from unforeseen or unmitigated risks.
- 149. The Board receives assurance on these from a number of sources but primarily through the Chief Executive's and the Directors' reports to the bi-monthly Public Board meetings, and also the risk register. The Department of Health and Social Care regularly assesses the extent to which NICE has met its statutory obligations and manages its risks at accountability meetings.

# **Principal business objectives 2019/20**

Deliver and support the adoption of accessible, up to date and adaptable advice, fully aligned to the needs of our users	Delivery date
<ul> <li>Deliver guidance, standards, indicators and evidence products and services, in accordance with the schedule set out in the business plan and the balanced scorecard, including the planned increases in the technology evaluation programmes</li> </ul>	Ongoing
<ul> <li>Subject to evaluation of the NICE Connect project pilot, develop a business case and programme plans for the next phase of the project</li> </ul>	End of Q3
<ul> <li>Undertake a review of the topic selection arrangements for the HST programme and methods guides for the technology evaluation programmes</li> </ul>	End of Q4
<ul> <li>Review and update the guidelines methods and process manual to determine the optimal development path and timeline for guideline development in the context of the NICE Connect project</li> </ul>	End of Q4
<ul> <li>Maintain and monitor performance of NICE Evidence Services (CKS, HDAS, BNF microsites, Evidence Search, Medicines Awareness Service), with investment in new features on a strictly needed basis</li> </ul>	Ongoing
<ul> <li>Enable access to the new national core content and procure any additional content in line with Health Education England's (HEE) commissioning decisions</li> </ul>	• Q1
<ul> <li>Support shared decision making within NICE through delivery of commitments in the action plan of the Shared Decision Making Collaborative</li> </ul>	Ongoing
<ul> <li>Deliver a range of tools and support for the uptake of NICE guidance and standards, including adoption support products, endorsement statements, and shared learning examples</li> </ul>	Ongoing
Evaluate the most effective social and multimedia channels currently used to promote NICE's work	Ongoing
Evaluate the scope to improve the recruitment and retention of advisory committee members	End of Q2
Play an active, influential role in the national stewardship of the health and care system	Delivery date
<ul> <li>Work with NHS England and other health and care system partners to support the implementation of the NHS long term plan</li> </ul>	Ongoing

<ul> <li>Explore with NHS England the options for a digital health technology evaluation workstream, building on the Evidence for Effectiveness standards</li> </ul>	End of Q2
<ul> <li>Subject to the UK's EU exit arrangements, design and put in place changes to our current technology appraisal process in order to secure consistency with UK regulatory arrangements</li> </ul>	End of Q2
<ul> <li>Commission a bi-annual NICE reputation research project to assess our key stakeholders' views of NICE and our work, and conduct specific and targeted audience research on key issues that contribute to meeting corporate business objectives and implementation of NICE guidance</li> </ul>	End of Q2
<ul> <li>Deliver a suite of activities to mark NICE's 20<sup>th</sup> anniversary</li> </ul>	End of Q1
Take advantage of new data sources and digital technologies in developing and delivering our advice	Delivery date
<ul> <li>Develop and establish a long term data analytics strategy for NICE together with a framework for the appropriate the use of data analytics across NICE's programmes, and facilitating a national leadership in the field</li> </ul>	End of Q3
<ul> <li>Identify digital investment priorities, and their sequencing, to align with the NICE Connect project transformation work, reviewing the roadmap quarterly</li> </ul>	Ongoing
<ul> <li>Manage and maintain the live digital services of NICE utilising user insight and strategic service goals to prioritise use of resource</li> </ul>	Ongoing
Generate and manage effectively the resources needed to maintain our offer to the health and care system	Delivery date
• Deliver performance against plan for all budgets and achieve or exceed on non-Grant-in-Aid income targets	End of March 2020
<ul> <li>Introduce charging for technology appraisal and highly specialised technologies and recover the target income for 2019/20</li> </ul>	From 1 April 2019
<ul> <li>Deliver existing grant funded research projects to plan and timetable and secure a pipeline of new projects for 2020-21</li> </ul>	End of March 2020
<ul> <li>Promote our capacity for knowledge sharing with international organisations interested in NICE's expertise and experience, including the re-use of NICE's published content outside of the UK</li> </ul>	Ongoing

Support the UK's ambition to enhance its position as a global life sciences destination	Delivery date
<ul> <li>Make preparations to implement the commitments of the 2019 Voluntary Scheme for Branded Medicines Prici and Access related to NICE so that (i) all new active substances and drugs with significant licence extensions will be appraised, except where there is a clear rationale not to do so, by April 2020; (ii) NICE is able to publis recommendations on non-cancer drugs within 90 days of licensing to match the timescales for cancer drugs (ongoing)</li> </ul>	going
<ul> <li>Deliver the actions set out for NICE in the Government's Life Sciences Sector Deals and significantly increase the number of evaluations of these health tech products conducted, giving greater scope for considering different types of innovation, including digital products.</li> </ul>	• Ongoing
<ul> <li>Prepare a final case for establishing a not for profit organisation delivering fee for service advisory and educational programmes, aligned to NICE's public task</li> </ul>	End of Q3
Maintain a motivated, well-led and adaptable workforce	Delivery date
<ul> <li>Ensure that all staff have clear objectives supported by personal development plans</li> </ul>	End of Q1
<ul> <li>Actively manage staff engagement and morale with the objective of ensuring that the global job satisfaction index in the annual staff survey is maintained or improved from its 2018 level</li> </ul>	End of Q1
<ul> <li>Implement the actions set out in the workforce strategy, including mapping out career paths for key roles, including increasing opportunities for apprenticeships, and defining the behaviours expected of a manager at NICE</li> </ul>	End of Q2
<ul> <li>Work with NHS Property Services to secure the future London office accommodation, and begin planning for move to take place in the summer of 2020</li> </ul>	the • End of Q3
<ul> <li>Develop and implement a programme of improvements for the Manchester office to ensure best use of the space available</li> </ul>	End of Q2
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## **APPENDICES**

- 1. Balanced scorecard for 2019/20
- 2. Activity analysis for 2019/20
- 3. Revenue budget allocations for 2019/20
- 4. Board and Senior Management Team
- 5. Organisational chart

# Appendix 1 - Balanced scorecard 2019/20

#### Guidance, standards, indicators and evidence

Success Criteria	Key Measures	Target <sup>2</sup>
Development and publication of guidance and evidence outputs		
<ul> <li>Publish 33 guidelines</li> <li>Clinical areas (23)</li> <li>Public health (3)</li> <li>Social care (1)</li> <li>Managing common infections (6)</li> </ul>	Publication within stated quarter	80%
Publish 78 technology appraisals or highly specialised technologies guidance	Publication within stated year	80%
Publish 32 interventional procedures guidance	Publication within stated year	80%
Publish 6 diagnostics guidance	Publication within stated year	80%
Publish 7 medical technologies guidance	Publication within stated year	80%
Publish up to 38 medtech innovation briefings (MIBs)	Publication within stated year	80%
Deliver up to 38 commercial and up to 17 managed access briefings for NHS England to support discussions with companies, including 'Patient Access Schemes'	Publication within stated year	80%
Deliver up to 4 commissioning support programme topics to NHS England	Submission to NHS England Clinical Panel within stated quarter	80%
Manage portfolio of up to 3 evaluative commissioning projects for NHS England	Submission to NHS England Clinical Panel within stated quarter	80%
Publish 52 guideline surveillance reviews	Publication within stated quarter	80%
Deliver up to 12 evidence summaries including resource impact template	Publication within year	80%
Deliver up to 4 evidence summaries – antimicrobial prescribing	Publication within year	80%

<sup>&</sup>lt;sup>2</sup> The targets have been set at a level to reflect there will factors outside of NICE's control that affect publication timelines May 2019 NICE Business plan 2019/20

Key Measures	Target <sup>2</sup>
Delivery to NHS England within year	80%
Publication within year	100%
Publication within stated quarter	80%
Publication within year	100%
Publication within stated quarter	80%
Publication within stated quarter	80%
Publication within stated quarter	80%
Publication to regular schedule	90%
Publication within stated guarter	80%
Publication within stated quarter	80%
Publication within stated quarter	80%
	Publication within stated quarter         Publication within year         Publication within stated quarter         Publication to regular schedule         Publication within stated quarter         Publication within stated quarter         Publication within stated quarter

# Adoption and impact

Success Criteria	Key Measures	Target
Provision of support products for the effective implementation of guid	lance	
Publish resource impact products to support all NICE guidelines, positively recommended technology appraisals, medical technologies and diagnostics guidance at the point of guidance publication	Publication within year	90%
Maintaining and developing recognition of the role of NICE		1
Coverage of NICE in the media	% of positive coverage of NICE in the media resulting from active programme of media relations	80%

Operating efficiently		
Critical Success Factors	Key Measures	Target
Delivering programmes and activities on budget		
Effective management of financial resources	Revenue spend	To operate within budget
Effective management of non-exchequer income	Net income received from non-exchequer income sources (including Scientific Advice, Office for Market Access, research grants, knowledge transfer) measured against business plan targets	90%
Maintaining and developing a skilled and motivated workfor	rce	
Management of recruitment	Proportion of posts appointed to within 4 months of first advertisement	80%
Management of sickness absence	Quarterly sickness absence rate is lower than the average rate (3.33% as at January 2018) across the Specialist Health Authorities and other Statutory Bodies	3.33%
Staff satisfaction	Proportion of staff reporting in staff survey that the Institute is a good, very good or excellent place to work (global job satisfaction index)	80%
Staff involvement	Hold monthly staff meetings	80%
Staff well-being	Implementation of NICE's quality standard for healthy workplaces: improving employee mental and physical health and wellbeing in respect of own staff	80% of quality statements
Sustainable Development		
Recycled waste	% of total waste recycled	90%

Improving stakeholder satisfaction		
Improved satisfaction	Complaints responded to in 20 working days	80%
	Enquiries fully responded to in 18 working days	90%
	Number of Freedom of Information requests responded to	100%
	within 20 working days	
	PQs contribution provided within requested time frame	90%
Ensuring stakeholders have access to our websites as the main	Percentage of planned availability, not including scheduled	98%
communication channel	out of hours maintenance	
Interest in lay committee vacancies reflected by ratio of applications to	2:1 (or greater) each quarter	100%
positions		

Improving efficiency and speed of out	S
Speed of production <sup>3</sup>	% TAs for all new cancer drugs referred to NICE issuing 90% guidance within 90 days of the product being first licenced in the UK
	% of multiple technology appraisals from invitation to 85% participate to ACD in 41 weeks, or where no ACD produced to FAD in 44 weeks
	% of Appeal Panel decisions received within 3 weeks of the 80% hearing

- The product has been identified and referred early enough to allow for guidance publication to be timely, 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' or EU exit)
- 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' or EU exit)

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<sup>&</sup>lt;sup>3</sup> The following caveats are taken into account when measuring performance:

<sup>1. %</sup> STAs for all new cancer drugs issuing final guidance within 90 days of the product being first licenced in the UK

# Appendix 2 - Activity analysis 2019/20

Programme	2018/19 published outputs	2019/20 planned outputs
Social care guidelines	2	1
Clinical guidelines	16	23
Public health guidelines	3	3
Antimicrobial prescribing guidelines	8	6
Social care quick guides	10	8
Quality standards	18	16
Indicator menu	1	1
Technology appraisals or highly specialised technologies guidance	57	78
Medical technologies guidance	5	7
Medtech innovation briefings	37	34 (+/-4 subject to discussions over MoU with NHS England)
Diagnostics guidance	3	6
Commissioning support programme topics	12	Up to 4
Evaluative commissioning support	6	Up to 3
Managed access arrangements		Up to 17
Commercial access arrangements, including patient access schemes	39	Up to 38
Interventional procedures guidance	36	32
Evidence summaries including resource impact template	1	12
Evidence summaries – antimicrobial prescribing	0	4
Evidence reviews – specialised commissioning	7	10
Medicines optimisation key therapeutic topics	14	16
Medicines evidence commentaries	25	24
Shared decision making products	6	8
Shared learning examples	60	50
Endorsement statements	30	30
Guideline surveillance reviews	65	52

IAPT assessment briefings	1	7
Medicine awareness service	50	50
Topic based 'impact reports'	7	6

\*These figures only show the publication outputs from each programme and are therefore not necessarily the full measure of the activity in each programme.

# Appendix 3.1 - Centre and directorate budget allocations 2019/20

	2019-20			
Application of funds (Indicative budgets)		Рау	Non-pay	Total
	wte	£m	£m	£m
Guidance and advice				
Centre for Guidelines	108.0	6.8	11.3	18.1
Centre for Health Technology Evaluation	167.2	9.7	2.9	12.6
Health and Social Care Directorate	135.5	8.5	0.8	9.3
Evidence Resources Directorate	94.5	5.5	5.5	11.0
Science, Advice and Research	38.8	2.6	0.5	3.1
Corporate				
Communications Directorate	70.9	3.9	0.4	4.3
Business Planning and Resources Directorate	66.9	3.3	6.7	10.0
Depreciation			1.0	1.0
Total Budget	681.8	40.3	29.1	69.4

# Appendix 3.2 - Revenue projections in financial statements format

Statement of comprehensive net expenditure	
	2019-20
	£m
Expenditure	
Staff costs	40.3
Depreciation & Amortisation	1.0
Other expenditure	28.1
	69.4
Income	
Income from sales of goods and services	(7.4)
Other operating income	(10.4)
Net Expenditure	51.6

# Appendix 3.3 - Balance sheet projection

Statement of Financial Position to 31 March 2020	
	Crea
	£m
Ion-current assets	
Property, plant and equipment	3.0
Intangible assets	0.1
Total non-current assets	3.1
urrent assets	
Trade and other receivables	2.0
Other current assets	2.4
Cash and cash equivalents	1.5
Total current assets	5.9
Total assets	9.0
urrent liabilities	
Trade and other payables	(2.5)
Provisions for liabilities and charges	(1.0)
Total current liabilites	(3.5)
on-current assets less net current liabilities	5.5
on-current liabilities	
Provisions for liabilities and charges	(1.0)
Total non-current liabilities	(1.0)
ssets less liabilitites	4.5
axpayers' equity	
Seneral fund	3.3
on-exchequer trading reserves	1.2

# Appendix 3.4 - Cash flow projection

rojected cash flow statement for year ending 31 March	2020
	£m
cash flows from operating activities	
Net surplus after cost of capital and interest	(51.6)
Adjustments for non-cash transactions	1.0
	(50.6)
ash flows from investing activities	
Purchase of property, plant and equipment	(0.4)
Purchase intangible assets	(0.1)
	(0.5)
ash flows from Financing Activities Net grant-in-aid from Department of Health	51.1
et Cash inflow/(outlow) before financing	0.0
et increase/(decrease) in cash equivalents	0.0
cash and cash equivalents at the beginning of the pe	1.5
Cash and cash equivalents at the end of the period	1.5

#### **Appendix 4 - Board and Senior Management Team**

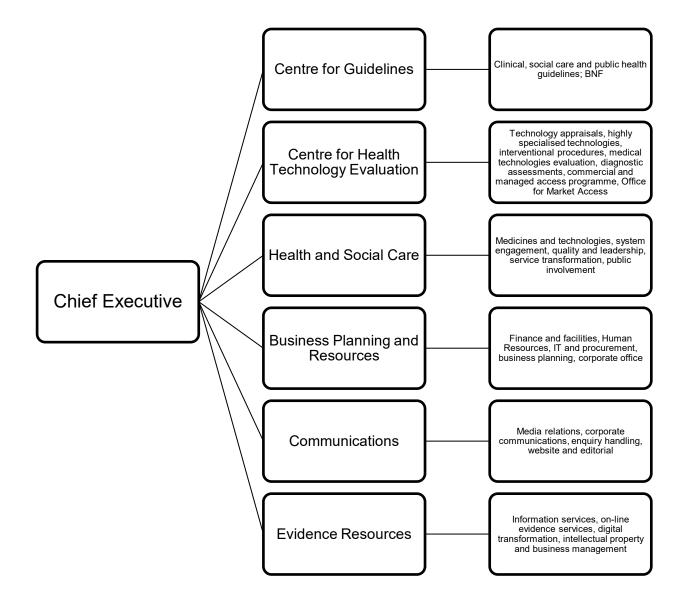
The members of the Board and the Senior Management Team are listed below.

Sir David Haslam CBE Professor Sheena Asthana Professor Angela Coulter Professor Martin Cowie Ms Elaine Inglesby-Burke CBE Professor Tim Irish Dr Rima Makarem Mr Tom Wright CBE Sir Andrew Dillon CBE\* Mr Meindert Boysen Mr Ben Bennett\* Dr Paul Chrisp Ms Jane Gizbert Professor Gillian Leng CBE\* Ms Alexia Tonnel\*

Note: \* Executive Directors

Chair Non-Executive Director Non-Executive Director Non-Executive Director Non-Executive Director Non-Executive Director Non-Executive Director Chief Executive Director: Centre for Health Technology Evaluation Director: Business Planning and Resources Director Centre for Guidelines Director: Communications Director: Health and Social Care Director: Evidence Resources

### Appendix 5 – Organisational Chart



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### National Institute for Health and Care Excellence

# Widening the evidence base: the use of broader data and applied analytics in NICE's work

This paper accompanies a statement of intent for the appropriate use of data analytics across NICE's programmes.

The Board is asked to discuss and agree the statement and the proposed open targeted engagement approach to external consultation.

Gillian Leng

Deputy Chief Executive and Director, Health and Social Care Director

May 2019

### Introduction

- 1. NICE helps the health and social care system to deliver the best outcomes within the resources available. We do this through a diverse range of programmes which share the same core process, including identification, assessment and interpretation of evidence, presented as guidance recommendations, advice or information.
- 2. The recommendations we make and the information we provide all need to be kept up to date, requiring a periodic repeat of the guidance development process, or a variation of it.
- 3. Increases in the amount and breadth of data available, the development of new and efficient mechanisms for analysis, and advances in the way information is labelled, linked and shared, have the potential to significantly disrupt our traditional approaches to synthesising research evidence. At the same time they offer opportunities to improve timeliness, relevance and efficiency.
- 4. This paper accompanies the 'statement of intent' that will signal our ambition for future use of data and analytics within NICE's guidance programmes and wider products.

### Background

- 5. Following Board discussions in March and May 2018, recurrent funding was ringfenced to support the establishment of a new Data and analytics (DA) team. A cross-NICE steering group, comprising senior representatives from all relevant internal programmes, has also been in place since early 2018. It is responsible for high level oversight of NICE's activities associated with data and analytics, and provides strategic support to the new team.
- 6. In January 2019 the Board considered a paper on the use of data analytics at NICE, which highlighted progress to date on how NICE is enhancing its capability to identify and use data and analytics in its work. This included the strategic focus to develop a framework for the appropriate use of data analytics across NICE's programmes.
- 7. Developing the framework, positioned as a 'statement of intent' for the use of data and analytics, was prioritised as a crucial part of both internal transformation and external communication. The statement built on internal advice to guideline developers produced to support the updated guidelines manual published in October 2018.
- 8. The statement of intent covers four key areas:

- What kind of evidence does NICE currently use to develop guidance
- What broader types of data are available
- When and why should broader types of data be considered
- Practical considerations associated with data analytics.
- 9. Technical detail on methodological considerations are not included in the statement, and future detailed documentation on this topic will be developed at a later stage, aimed at a technical audience and embedded within NICE's future methods guides.

#### Consultation approach

- 10. Following Board approval, it is proposed that the statement of intent will be publicly available on our website and open to consultation comments from stakeholders for a period of three months.
- 11. The statement of intent consultation will be framed to make it clear that we are seeking feedback on our ambition in relation to data and analytics, and not opening a wider debate on NICE's current methods.
- 12. The statement will also be discussed with existing groups with an interest in our developing work on data analytics:
  - NICE Data & Analytics Expert Reference Group
  - Innovation labs session (facilitated by Manchester University as part of the Datalab partnership)
  - Office for Strategic Coordination of Health Research (OSCHR) Health Informatics Sub-Group
  - NICE Centre for Health Technology Evaluation Methods Working Party
- 13. We also intend to hold a discrete workshop and accompanying webinars to engage both further participants within organisations of strategic position, and additional sector-wide stakeholders, during the period June to September 2019. These include:
  - NHS Digital
  - NHS X
  - NHS England

- Department for Health and Social Care
- HDR UK and emerging Digital Innovation Hubs
- Alan Turing Institute
- The Health Foundation
- Life Science Industry stakeholders
- Other wider data controllers (for example the ONS and HQIP)
- Patient groups and charities
- Other academic researchers in relevant fields.
- 14. We intend to structure both public feedback and targeted events against a series of questions. These are proposed as follows:
  - Is the overall approach set out in the statement of intent clear and understandable?
  - Does the statement of intent appropriately take account of current and future trends?
  - Are there any obvious gaps or omissions in the scope of ambition in the statement of intent?
  - Does NICE's ambition appropriately align with relevant external initiatives, and what opportunities for collaboration do these present?
  - Does the statement appropriately set out the scope of the data NICE should be considering, and are there any additional sources of data that should be captured for consideration which are not included in the categories listed in the statement of intent?
  - What steps should NICE take to maintain transparency and support validation and reproducibility in its use of applied analytics?
- 15. Responders will also have the opportunity to provide any other 'open text' commentary.

### **Risks and mitigation**

16. NICE will seek to mitigate key risks as we further develop our data and analytics work, and these are explored in appendix 1.

# Conclusion

Issues for decision

17. The Board is asked to:

- Approve the accompanying statement of intent for the appropriate use of data analytics across NICE's programmes.
- Approve the proposed consultation approach.
- Note the intention to present the final statement of intent to the Board in November 2019.

# Appendix 1: risks and mitigation

NICE will seek to mitigate key risks as we further develop our data and analytics work.

Category	Risk	Mitigation
Information governance	Risks of data breaches or misuse of sensitive data	We will ensure, through appropriate training and governance, that NICE and partner organisations are fully compliant with regulations and best practice in data handling, reporting and security. We will ensure that patient and public confidentiality is maintained.
Quality and validity	Risk that novel data analytic work conducted or commissioned by NICE may generate outputs where quality and validity is a concern	<ul> <li>We will engage with partners to develop a shared understanding of methods and processes before and during projects.</li> <li>We will clearly communicate our needs and standards, including: <ul> <li>a clear definition of questions to be addressed with data analytics</li> <li>a dvice on data cleaning and management</li> <li>ensuring that the most appropriate methods are used to address the question</li> <li>communicating uncertainties and limitations in any data or analysis</li> <li>demonstrating a strong commitment to transparency and reproducibility (for example by making data cleaning and analysis code available for review)</li> <li>supporting committees in interpreting results, to help them develop guidance.</li> </ul> </li> </ul>

Timely delivery	Risk of failing to deliver projects within the normal parameters of NICE's product development timelines	We will conduct feasibility assessment at the outset and during a project, to ensure that the proposed deadlines can be met. Feasibility assessments will include data access arrangements and the availability of supporting resources.
		We will work to reduce barriers to timely delivery, including by:
		<ul> <li>developing a clear project brief, with input from relevant stakeholders</li> </ul>
		<ul> <li>identifying factors that may affect the feasibility and timeliness of projects (such as the data quality of specific resources)</li> </ul>
		- streamlining processes as far as possible with respect to accessing data, and building relationships with relevant stakeholders and experts.
Reputational risks	Although NICE already carries out or commissions work in this area, this is not widely known. Health	We will promote our established work in this area. When new approaches to the use of data are introduced into specific products, the strengths and limitations will be made clear.
	and social care practitioners may have questions about the direct use of data in NICE's products and programmes.	We will explain to health and social care practitioners that we intend to use broader sources of data to supplement existing methods, rather than replace them. As with other types of evidence we consider, data analytic outputs will be used to aid decision-making but not to prescribe a particular decision.
Public trust	Risk that public perception of NICE's proposed expansion of its use of data and	We will engage in the wider public conversation around reuse of health and social care data, to develop and maintain public trust.
	analytics undermines public trust in the	We will ensure that patient and public data are used in an appropriate manner

National Institute for Health and Care Excellence Widening the evidence base: the use of broader data and applied analytics in NICE's work Date: 22 May 2019 Reference: 19/045

organisation or its	to deliver genuine benefit back to people
outputs	using health and social care services.

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May 2019

# Widening the evidence base: use of broader data and applied analytics in NICE's work

#### Purpose of this document

This document sets out how NICE intends to use broader sources of data and analytic methods to enhance our existing methods and processes. It does not give a detailed description of methodological processes and considerations, which will be covered in future papers.

#### Terminology

In this document the term 'data' refers to any source of quantitative or qualitative data that is suitable for use in NICE's work programmes, when examined using a range of analytic techniques. This definition includes (but is not limited to):

- electronic health record data
- 'real world data' looking at health and social care practice outside of trials (registries, for example)
- any other relevant data that has been made available for others to use.

The term 'data' does not, in this context, refer to published research findings and summary statistics. These will continue to form the core evidence for NICE recommendations and advice, and this paper sets out ways that other types of data may be used alongside these sources.

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#### Introduction

- 1. NICE helps the health and social care system to deliver the best outcomes for people using services with the resources available. We do this by developing recommendations, advice and information through a diverse range of programmes, which share the same core process of identification, assessment and interpretation of evidence.
- 2. The recommendations we make and the information we provide all need to be kept up to date, requiring periodic repeats of the guidance development process, or variations of it.
- 3. We want to embrace a range of technological advances and analyse a broader variety of data to develop evidence to inform our work. Fundamentally, the suitability of any particular data as evidence will be determined by the quality of the data and the nature of the question that we are trying to answer.
- 4. There are 5 key strategic areas that underpin the use of data analytics across NICE: data, tools, skills, collaboration and public trust. With an increasing emphasis on using data analytics across all our guidance, we will potentially be able to:
  - generate new evidence through data analytics, to help develop and update guidance more efficiently than is currently possible
  - answer questions that we cannot answer using our traditional approaches (for example, when systematic reviews identify gaps in the current literature, when considering questions for which trials are unlikely to be carried out, or when existing trials do not include populations of interest)
  - monitor and validate intermediate outcomes
  - measure the effectiveness and cost-effectiveness of interventions in realworld settings
  - improve our tracking of guidance implementation, uptake and impact, and our use of this information to inform the need to update guidance.
- 5. This will be achieved through:
  - unlocking and exploiting the full potential of data from a range of sources, including health and social care organisations, electronic patient records, research cohorts and patient surveys
  - developing partnerships with a range of expert organisations across the health and social care system and the wider data community
  - increasing capability to link live systems and unstructured data

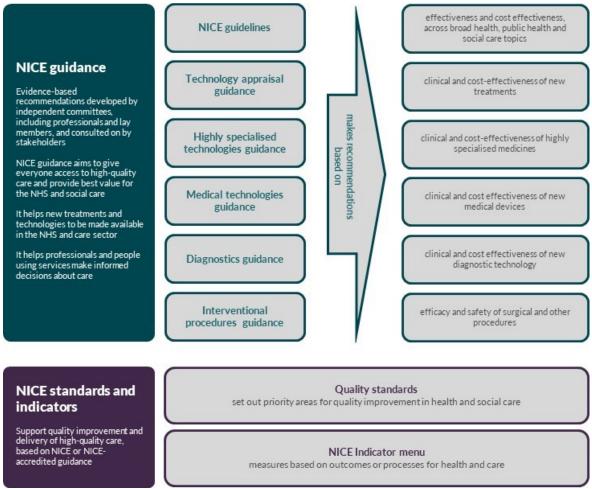
• translating data into evidence, recommendations and innovative interactive tools, which allow health and social care professionals and the public to put our analysis at the heart of decision-making.

#### The role of NICE

- 6. Since 1999, NICE has provided guidance and advice to the NHS. NICE was initially set up to reduce variation in the availability and quality of NHS treatments and care. However, over time our remit has expanded to include producing guidance to prevent ill health and promote healthier lifestyles, and developing guidance and advice for social care.
- 7. NICE guidance is officially for England only, but certain products and services are provided by agreement to Wales, Scotland and Northern Ireland.
- 8. NICE develops a range of different types of guidance and advice. This includes:
  - guidance for the NHS on health technologies (including procedures, diagnostic agents, devices and pharmaceutical and biopharmaceutical treatments) through our Health Technology Evaluation programmes, which ensures that people can access available treatments that are clinically and cost effective
  - advisory guidelines for health and social care professionals, which demonstrate best practice for diagnosing and managing a range of conditions, supporting people's social care needs, and encouraging better health
  - advice products that evaluate published evidence on a range of topics
  - standards and indicators to support delivery of high-quality care.

Key NICE guidance, standards and indicators are illustrated in figure 1.

#### Figure 1: NICE guidance, standards, and indicators



# What kind of evidence does NICE currently use to develop guidance?

- 10. Clinical, social care and public health guidelines have often been based on research findings published in academic journals. These findings may be quantitative or qualitative, and may come from a range of study types, including randomised controlled trials (RCTs), cohort studies, cross-sectional studies and surveys of the views and experiences of people using health and social care services.
- 11. Synthesis of published evidence may involve meta-analysis of quantitative findings or thematic analysis of qualitative data. All data sources contributing to evidence synthesis are quality appraised using standardised and validated tools.
- 12. When formal published evidence is not available, NICE has also used evidence from other sources, such as grey literature reports, and expert submissions from health and social care professionals and patients.

- 13. Guidance developed within our Technology Appraisals Programme includes reports from health technology manufacturers, which covers the evidence they consider relevant (such as particular RCTs). NICE guidance on the efficacy and safety of new interventional procedures also supports new data collection via NHS England's Commissioning through Evaluation programme. This programme supports the creation of new data sources, for example by creating new registries and commissioning analyses of hospital episode statistics. The technology appraisals programme also includes the Cancer Drugs Fund which supports early managed access to new cancer therapies.
- 14. We currently use a variety of other data sources, including patient registries, audits and electronic health records. <u>Case studies of our existing work using</u> these types of data can be found in the appendix. We recognise the value these data sources have for our work, and plan to amend our processes so that data analysis is considered in more of our programmes. To succeed in this, we will need to work closely with other organisations across the health and social care system and the wider data community.

#### What broader types of data are available?

- 15. A wide range of data sources are available. These include formal observational research datasets, as well as collections of data not originally collected for research purposes.
- 16. The selection of a data source will depend on the review question. Some questions are likely to need quantitative data that reflect the use of interventions in practice. These include questions about treatments and other interventions, or different approaches to delivering public health or social care programmes. On the other hand, questions about preferences of people using services may need to be addressed using text-based data that better capture people's experiences.
- 17. Sources that NICE has already used or could consider using in the future include:
  - primary care databases (for example, Primary Care Mortality Database [PCMD], Central Practice Research Datalink [CPRD], the Health Improvement Network [THIN], QResearch)
  - secondary care databases (for example, Hospital Episode Statistics [HES])
  - audits of clinical practice, and registries of the use of medicines, devices and other technologies
  - surveillance and monitoring data (for example, data on the uptake of public health preventive interventions, drug safety monitoring data)
  - datasets released by local authorities about public health and social care

- reports and outputs produced by health and social care organisations such as the Care Quality Commission and Healthwatch
- grey literature, that is, surveys, reports and datasets that have not been formally published or have limited distribution
- data that represent the views and experiences of people using services, whether captured formally (for example, via surveys) or informally (via online discussion forums and social media, or sites such as healthtalk.org).
- 18. If RCT data are available for broader use (for example when owners of the data are willing to share the data after the trial is complete), trial populations may act as cohorts for further analysis.
- 19. Some data sources may be publicly available (open access) and free to use, whereas other sources may only be available with permission from the data owner. In either case, use of data may be subject to specific terms and conditions. Depending on the nature of the project, we may work with external partners who already have access to these resources, or seek direct access to data ourselves.

#### When and why should broader types of data be considered?

- 20. There are a number of circumstances in which NICE could improve our methods and processes by making more extensive use of data.
- 21. For many of its products, NICE has used systematic reviews of published experimental or observational evidence, conducted in line with carefully developed protocols. There are also circumstances in which analysis of data has been used to inform decision-making. This section describes a range of situations in which analysis of data could be used in the context of NICE guidance and advice.

#### Where an evidence gap has been found

- 22. For some types of NICE guidance, the committee developing the guidance may make research recommendations if a systematic review has identified gaps in the evidence. These research recommendations offer structured questions that, if addressed, may produce evidence that can be used in updates of the guidance. NICE works with the National Institute for Health Research to promote research recommendations and encourage researchers to carry out work that addresses these questions.
- 23. Some evidence gaps could be addressed with data analysis. We could undertake or commission work that addresses specific evidence gaps, so that

recommendations can be made before the guidance is published. Alternatively, this work could inform future updates of the guidance.

# To measure the effectiveness and cost-effectiveness of interventions in real-world settings

- 24. The observed discrepancy between the effects of a health intervention in routine clinical practice (effectiveness) and the effects demonstrated in RCTs (efficacy) is known as the 'efficacy effectiveness gap'.
- 25. Contextual factors that interact with the effect of an intervention are known as drivers of effectiveness. These factors can contribute to an efficacy effectiveness gap. There are 3 levels of contextual factors:
  - the actual use of the intervention (for example, adherence, co-medication, dose/intensity, duration of use)
  - patient and disease (for example, age, gender, behavioural factors, baseline risk, genetics, severity of disease, comorbidities)
  - healthcare system (for example, implementation, medical practices, screening policies).
- 26. RCTs may not always reflect these contextual factors, and high-quality observational data may better indicate the expected effectiveness in routine clinical practice. For most decisions relevant to NICE guidance, the expectation is that the efficacy measured in trials will be greater than the effectiveness derived from analysis of broader types of data. This is because in routine practice characteristics such as age, comorbidities and adherence are more likely to reduce the effectiveness of the intervention compared with trial settings than enhance it. Qualitative data sources may also provide useful contextual information, for example by providing detail on any challenges in delivering an intervention or on the experiences of patients.

#### To demonstrate comparative effectiveness

27. NICE's assessments require an understanding of interventions in the context of alternative treatments (comparative effectiveness). RCTs remain the optimal design for assessing the comparative effectiveness of interventions. However, robust evidence of comparative effectiveness (either from direct comparisons or indirect/mixed-treatment comparisons) is often not available. This may be because the available evidence does not reflect practice, for example, because the use of an intervention has been optimised since the relevant RCT was conducted. When good-quality data sources are known to be accessible for interventions that lack sufficient comparative evidence to support decision-making, the developer may consider using data analytic techniques (for

example, propensity score matching) to explore the effectiveness of the intervention.

#### To monitor and evaluate intermediate outcomes of interventions

- 28. RCTs are often not long enough to demonstrate all the outcomes over the full time horizon of interest, especially for treatments for chronic conditions. In these situations, economic analyses often include extrapolation of outcomes over a longer time horizon. Committees considering review questions without economic analyses should still take into account the long-term effects of interventions when relevant. Analysis of data could be used to provide evidence of long-term effects as well as quantifying rare but serious adverse events that may not have been captured because of the limited time horizon or sample size.
- 29. Similarly, health economic models are often used to extrapolate the effects of interventions beyond the observed data. Examples of this include tying intermediate outcomes to other outcomes of interest, extrapolating the effectiveness of interventions further forward in time and making assumptions about downstream treatments and events. The developer could consider using analysis of data to directly inform or to validate these modelling assumptions.

#### To establish the characteristics of the population of interest in practice

30. RCTs are often a poor source of information about the characteristics of the true population to which the decision applies because their populations can be highly selective. Broader sources of data can provide more accurate information on the true population of interest, including demographics, disease severity and comorbidities. This may be particularly important when an economic model is being constructed and the composition of the simulated population is an important determinant of expected costs, benefits and harms. For example, trials often provide the best estimates of relative effectiveness, but these estimates should be combined with the most appropriate baseline population/risk in order to estimate absolute effectiveness, which is often the information of interest in economic evaluation.

#### To improve tracking of guidance implementation, uptake and impact

31. Analysis of data can be useful during the surveillance and update of guidance. Evidence generated from data, such as patient registries, can provide valuable insight into use of healthcare resources and implementation of interventions. This may be particularly valuable for recommendations that require a change in service provision, to feed into a 'Learning Health and Social Care System'.

#### To update guidance more efficiently than we do currently

32. We are currently investigating the automation of some of our horizon-scanning processes, to identify updated sources of evidence more quickly and cost-effectively.

- 33. Using a broader range of sources of data may enable us to identify when guidance needs a review sooner than scheduled. For example, guidance updates may be triggered by 'early warning signals' relating to the safety of devices and implants, and using a wider range of data sources may help us detect these signals. Data reported by the public via reporting systems (or more informally via online forums and social media) may provide signals that are not identified through other channels, though the reliability of these data sources will require further evaluation.
- 34. The use of broader data sources will not provide any operational efficiency compared with systematic reviews of published evidence. However, new analyses or data collection may improve efficiency when compared with waiting for this information to appear in the published literature.

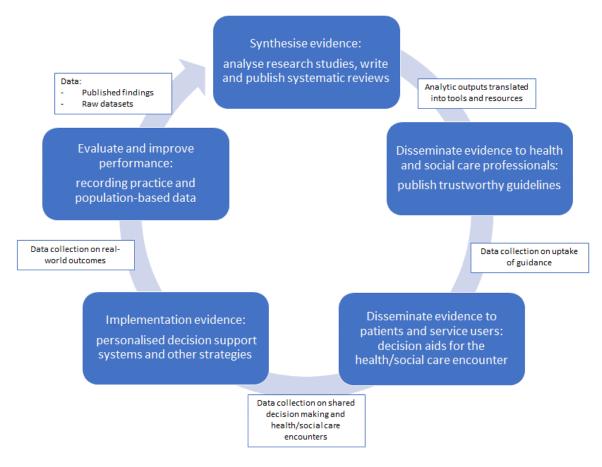
#### To better understand the experiences of people using services

35. Published studies do not necessarily capture the experiences of individuals when assessing the efficacy of an intervention or the organisation of a care pathway. Understanding the needs and experiences of people using services is particularly important for social care guidelines, which also often lack other sources of evidence to inform recommendations.

# Analytical work in the context of a 'Learning Health and Social Care System'

36. The model of the Learning Health System is based on a continuous loop between practice and evaluation.<sup>1</sup> This loop generates feedback, which can help improve standards of care (figure 2). NICE is interested in how this approach could be used in both the health and social care systems.

<sup>&</sup>lt;sup>1</sup> The Learning Healthcare System: Workshop Summary. Institute of Medicine (US) Roundtable on Evidence-Based Medicine; Olsen LA, Aisner D, McGinnis JM, editors. Washington (DC): National Academies Press (US); 2007. https://www.ncbi.nlm.nih.gov/books/NBK53483/



# Figure 2: How insights from data can support a Learning Health and Social Care System

- 37. It is currently challenging to ensure efficient and reliable flows of data and information throughout the system. This requires both a supporting infrastructure and people who are invested in the process at all stages of the cycle.
- 38. However, there is great potential for NICE's work using broader sources of data to contribute to the learning system, in particular using audit and registry data and long-term intervention follow-up from cohort studies. There are also opportunities in the commissioning and collection of new data, and in the use of novel ways to monitor the uptake and implementation of NICE guidance. Social media data may also be of value, for example in producing early warning signals for harmful drugs or devices.
- 39. Just as NICE's systematic review work identifies evidence gaps in the scientific literature, it is likely that work involving broader sources of data will highlight areas where data collection is lacking, or where the existing data are of poor quality.

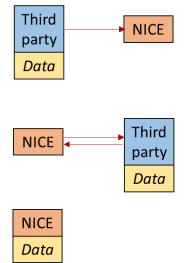
#### Practical considerations associated with data analytics

#### **Operational considerations**

40. There are a number of different operational models NICE could use for projects involving data, whether the data are being used to enhance existing products and services or to develop new ones. In many cases, work involving data will require involvement from third-party developers. Figure 3 outlines three different possible delivery models.

#### Figure 3: Potential delivery models for NICE projects involving data

- NICE receives an analysis carried out by a third party, based on data, and checks it for quality. This might be informed by a standard quality framework.
- NICE identifies the need for a piece of analysis using data and commissions a third party organisation to carry out the work. NICE checks the work for quality.
- NICE identifies the need for a piece of analysis using data and carries out the work in-house.



- 41. The nature of specific projects may determine the choice of delivery model. Factors to consider include:
  - whether data are publicly available or require access to be granted
  - whether or not NICE has sufficient technical and topic expertise to carry out the project internally
  - project delivery timelines
  - cost.

#### Feasibility and impact

42. Developers (whether they are teams within NICE or other organisations) should consider the practicalities of accessing data, including access costs and the possibility of changes to data ownership. This will need to be done in a timescale that meets the needs of the product under development. Developers will also need to consider whether the data needs processing so that it can be used to answer a review question. This can be a time-intensive part of analysis

and require collaboration with subject experts who have knowledge and understanding of the data.

- 43. Regardless of how the project is organised or where it is done, the same key steps will apply for most larger projects involving anything more complex than descriptive statistics and/or using open access data sources. These steps include:
  - defining the project or research question
  - obtaining access to the data, fulfilling information governance requirements
  - conducting analysis
  - quality assurance of data handling and analysis
  - reporting findings.

While we are currently streamlining our processes, not all of these steps are under our control or that of our partners, so developers must investigate the likely timelines for a project as early as possible.

44. The potential impact of the analysis on decision-making, including the likely robustness of the results, should also be considered alongside the cost and time needed. Proposals to undertake data analysis will be considered by NICE staff with responsibility for quality assurance and the NICE data and analytics team.

#### Governance requirements

- 45. Collection of new data involving people will usually require ethical approval.
- 46. When data already exist, formal approval is often still needed to use the data for a new purpose (such as research). In such cases a less complex process is followed, but approval is still needed from a research ethics committee.
- 47. Project development timelines need to factor in this process as a key step in delivery.
- 48. In addition to the above, NICE will need to ensure that all our data handling and processing complies with the requirements of GDPR legislation.

#### Methodological considerations

- 49. The recommended processes and methods for incorporating data analytics into NICE products and programmes will be embedded in future methods manuals. Issues include:
  - defining questions that address questions relevant to NICE's remit

- identifying appropriate sources of data to address these questions
- evaluating data quality
- selecting appropriate analytical methods
- acknowledging the issues of bias and confounding present in observational data sources.
- 50. We will actively engage with external partners to ensure that the methods used reflect best practice in data analytics and make use of new innovations as appropriate.
- 51. Quality assurance approaches will be applied both to data sources and the analysis carried out using the data.
- 52. Data quality should be addressed at both the resource and at the question level:
  - The general quality, validity and trustworthiness of a data source should be assessed
  - Additional quality assessment of data is needed for the specific question being considered, and the data items needed to address that question.

For example, a generally well-validated data source may not be suitable for addressing a specific question because of high levels of missing data in key variables, inconsistency of coding, or other issues.

- 53. NICE is working with EUnetHTA to develop a tool to assess the quality of registry data. This and continued collaboration with strategic data controllers across UK health bodies will be essential to the control and continued improvement of data quality.
- 54. Quality assurance processes will be included in future NICE methods manuals and aligned to the principles stemming from the MacPherson review in the 'Aqua Book: guidance on producing quality analysis. The following requirements will be included:
  - ensuring that a well-designed analytical protocol has been agreed
  - checking whether the analysis reflects what was agreed in the protocol
  - assessing whether data handling and cleaning decisions were acceptable, and whether populations, interventions, comparators and outcomes have been correctly defined from the available data
  - verifying the code used to perform data cleaning and analysis
  - statistical validation of findings as appropriate
  - communication of any uncertainty around the outputs of analysis,

# Supporting committees and stakeholders to make use of data analytics in developing NICE products

- 55. We intend to use broader types of data and evidence to supplement existing types of evidence, and to help guidance committees make recommendations. As with other evidence types, data analytic outputs are intended to aid committee decision-making rather than to prescribe a particular decision.
- 56. While some committees and stakeholders already have experience of using outputs from unpublished research or newly commissioned data, others may need additional support to consider broader types of evidence.

#### Transparency and reproducibility

- 57. NICE guidance and advice are produced with a high level of transparency, and new work using broader data sources must maintain these standards.
- 58. There are some additional challenges to consider:
  - Access to certain types of data may restrict how NICE can share specific aspects of a piece of analytical work (for example, it may not be possible to make the raw datasets available).
  - Ethical and privacy considerations may prohibit the sharing of some data or outputs because of the need to avoid the risk of identifying individuals. This risk increases as the number of data sources linked together increases.
- 59. As well as sharing of review question protocols and quality assessment of data sources, the sharing of the code used to identify study populations and carry out analysis would be considered best practice for transparency and reproducibility.

#### Summary

- 60. NICE welcomes the opportunity to continue our well-established practice of translating evidence into practical guidance and advice, and to expand our methods and processes to enable more extensive and effective use of broader sources of data.
- 61. We acknowledge that there are challenges in expanding our use of data and analytics, but we believe that the potential benefits to health and social care providers and users of their services outweigh the risks. We look forward to engaging with other organisations that have expertise in data analytics, to explore areas of shared interest and work together to improve health and social care. We will seek to reduce barriers and set up frameworks to enable this work to succeed.

#### Appendix: Case studies of work at NICE

NICE currently uses broader sources of data in several ways. The following are examples of what we have already done.

#### 1. Supporting health economic modelling

We often rely on economic modelling to aid decision-making. To build economic models, good-quality evidence from large patient record databases is commonly used to bridge the gap between efficacy data from trials and the potential application of the technology to NHS practice. For example, in the <u>type 2 diabetes guideline</u> the THIN database (which collates demographic and clinical data in primary care from over 200,000 people with diabetes) was used to establish the baseline characteristics of the population being simulated in the economic model.

In the <u>Parkinson's disease guideline</u>, we used data from the Parkinsonism incidence in north-east Scotland study (PINE). This is a rich dataset describing an incident community cohort with up to 10 years' follow-up. The data was used to estimate the long-term prognosis of people with Parkinson's disease and the ways that different treatments could be expected to influence the natural history of the disease.

#### 2. Monitoring how NICE guidance is being used in practice

We want to understand how the recommendations in our guidance are used in health and social care. There are various sources of data that can help with this. Our Adoption and Impact team routinely searches data sources such as THIN (primary care), Hospital Episode Statistics (secondary care) and prescribing data sources such as ePACT2 (primary care) and HPAI (secondary care).

In a recent example, the Adoption and Impact team were asked to look at Hospital Episode Statistics activity data on people admitted to hospital who have a risk assessment for venous thromboembolism or bleeding. Diagnosis, age, sex and length of hospital stay were considered, and the team found that length of hospital stay made a difference to the cost to the NHS of using different risk assessment tools. In the next guideline update, we made a recommendation to address this.

#### 3. Ensuring that guidelines are updated when new evidence emerges

Our Surveillance team checks that our published guidelines are up to date. This is done by searching for new evidence that could contradict, reinforce or clarify guideline recommendations. In addition to evidence, 'intelligence gathering' plays an important part in surveillance decision-making. Data sources that the surveillance team use include:

• antimicrobial prescribing data collected by Public Health England, to evaluate the impact on our antimicrobial prescribing guidelines

- data indicating how guidelines are being used in practice, for example uptake data for our <u>osteoporosis guideline</u> collected by a Royal College of Physicians audit
- MHRA drug safety monitoring data, which can be incorporated into surveillance reviews of guidelines with recommendations on medicines
- prescribing data for medicines recommended in our guidelines.

#### 4. Providing new data collection to support NHS England Specialised Commissioning policy decisions where trial data are not yet available or are not generalisable

NHS England's Commissioning through Evaluation programme gives selected groups of patients access to promising treatments that are not yet funded by the NHS. We work with external partner organisations who collect data on clinical outcomes and patient experiences. Analyses based on these data then contribute to a formal evaluation programme.

To date, 3 treatments provided through Commissioning through Evaluation schemes are now routinely commissioned in the NHS in England:

- left atrial appendage occlusion to prevent stroke in patients with atrial fibrillation
- selective dorsal rhizotomy to reduce spasticity in children with cerebral palsy
- selective internal radiation therapy for unresectable colorectal cancer metastases

A further 2 treatments have decisions pending (patent foramen ovale closure to prevent recurrent stroke, and MitraClip for mitral regurgitation)

# 5. Involving the public in our work by collecting data on the experiences of people using health and social care services

Our Public Involvement Programme (PIP) has a number of ways to support the use of data covering the experiences of people using health and social care services.

Our Interventional Procedures and Medical Technologies programmes sometimes collect new data on patient experiences through surveys of people using health and social care services. People are invited to participate by the professionals involved in their care, or by collaborating patient organisations. The data collected in these surveys are processed and collated by the PIP and passed on to the committees that develop NICE guidance.

Patient organisations are sometimes invited to submit information about the experiences of their members, to support our Technology Appraisals, Highly Specialised Technologies and Interventional Procedures Programmes. In some cases, submissions from patient experts will also be sought.

Our health and social care guidelines use grey literature for some guideline topics, to inform scoping or guideline development. This may include surveys conducted by organisations representing users of health and social care services (or their carers), data from online forums, and websites such as healthtalk.org.

#### 6. Providing evidence for health technology appraisal reviews

The committees that advise NICE on technology appraisals and highly specialised technologies are able to recommend that technologies are used subject to a managed access agreement (MAA). These typically include a specified period of data collection to inform a review of the guidance. Data collection usually includes elements of observational data. There are currently 30 MAAs collecting observational data across the Technologies that are recommended as part of the Cancer Drugs Fund, we work in partnership with NHS England and Public Health England to collect observational data via the Systemic Anti-Cancer Therapy Dataset to inform reviews of the guidance.

In 2018, NICE recommended one of the first <u>CAR-T cell therapies for use in the</u> <u>CDF</u>. As part of the <u>managed access agreement</u>, observational data are being collected using the Systemic Anti-Cancer Therapy Dataset, Hospital Episode Statistics and the UK bone marrow transplant registry. We expect that these data will help resolve uncertainty identified by the NICE committee developing the guidance, when it is reviewed in 2022.

### National Institute for Health and Care Excellence

# Digital health technologies (DHT) evaluation pilot

This report provides information on a pilot in the Centre for Health Technology Evaluation to evaluate a number of digital health technologies (DHTs). The pilot is being commissioned by NHS England following NICE's work on developing an Evidence Standards Framework for Digital Health Technologies during 2018/19. The pilot was approved by the NICE Senior Management Team on 16 April 2019. In addition to the evaluation pilot, the project team will also deliver Phase II of the Evidence Standards Framework for Digital Health Technologies project.

Evaluating DHTs is challenging for organisations such as NICE because there are a very large number of products available, with a variety of potential uses and settings, complex regulation pathways and rapidly iterating versions of the technologies. They also often come to market with low levels of evidence.

The Board is asked to note the report and the considerations specific to the evaluation of Digital Health Technologies.

Meindert Boysen

Director, Centre for Health Technology Evaluation

May 2019

### Introduction

 This paper describes the digital health technologies (DHTs) evaluation pilot which will be established during 2019/20, in the Medical Technologies Evaluation Programme (MTEP) in the Centre for Heath Technology Evaluation. The Medical Technologies Advisory Committee (MTAC) will develop the guidance in the pilot. The process will include an approach to data collection that is agile and interactive with the companies. The pilot will produce national guidance on cost saving technologies, consistent with the policy aims of the forthcoming NHS England funding mandate for medtech. The pilot project team will also work on Phase II of the evidence standards framework for digital health technologies project, to maximise the usefulness of the framework to a wide range of stakeholders.

### Background

2. DHTs are apps, programmes and software used in the health and care system. They may be standalone or combined with other products such as medical devices or diagnostic tests. DHTs have the potential to empower people, allow more convenient care, reduce numbers of appointments, and help people who may be isolated from standard care. They are often highly scalable with marginal cost.

#### Work to date by NICE on DHTs

- 3. NICE published the <u>evidence standards framework for digital health</u> <u>technologies</u>, with supporting case studies and educational materials, in March 2019. The project was commissioned by NHS England in May 2018 with the objective to produce a trusted and respected source of advice on what levels of evidence to produce for different types of DHTs and, where applicable, to turn this advice into standards to inform future assessments of digital health technologies.
- 4. The standards cover evidence of clinical effectiveness and economic impact and provide a common reference standard for discussions between innovators, investors and commissioners. They are designed to allow innovators to produce better evidence, faster, at lower cost to them and in turn, allow the NHS, over time, to commission and efficiently deploy, at scale, digital health tools that meet patient/NHS need.
- 5. NICE (including NICE Scientific Advice) and our partners are currently working to develop awareness and encourage adoption and use of the standards across the health system and with DHT developers.

# **DHT** evaluation pilot

## Why some DHTs need to be evaluated by NICE

- 6. DHTs and other medical technologies often claim to improve the efficiency of services, and save NHS resources, but differ significantly in their characteristics and the amount of scrutiny needed to substantiate their claims. Scrutiny is needed even where acquisition costs are relatively low, because the value delivered by DHTs often depends on money being saved from the care pathway. Evidence is needed to demonstrate that the product benefits patients and that claimed savings can be realised, to ensure cost-effective investment of NHS resources.
- 7. Claims made for the benefits of DHTs, medical technologies and diagnostic products that need a higher degree of scrutiny include:
  - A degree of novelty suggesting a step change in management options.
  - Proposed pathways in multiple benefitting populations, with different comparators and levels of evidence.
  - Diagnostics, where evidence on test accuracy cannot be relied upon to predict the consequences of testing.
  - Technical or scientific complexity including training, quality assurance, necessary infrastructure or other factors which might influence clinical utility.
  - A shift in setting or claims to reduce health care utilisation such as bed days or consultations.
- 8. This means that to be more certain about the risks and benefits of adoption to the system, DHT products that fulfil the above criteria are likely to need a systematic evaluation. Specific capacity to evaluate DHTs has not been formally commissioned by NHS England from NICE previously, although some DHT type products have appeared in NICE guidance (list available at Appendix 1).

## **Pilot topics**

9. A number of evaluation pilot topics have been proposed by NHS England. They all have some data in place, and companies being chosen to engage with the pilot are those that already have their products in use in NHS settings such as Academic Health Science Network areas. To lessen the risk of delays to the pilot from a product not being ready to proceed, a reserve list of topics is being developed. 10. It is expected that the products evaluated in the pilot will mainly be Tier 3b DHTs as defined in the NICE standards framework. These are technologies that have measurable user benefits, including tools used for treatment and diagnosis, as well as those influencing clinical management through active monitoring or calculation. Some DHTs in this tier will qualify as medical devices.<sup>1</sup> It may also be beneficial to gain experience during the pilot of evaluating Tier 3a products. Tier 3a DHTs are those which are designed for preventative behaviour change, or which allow self-management of a diagnosed condition.

Topic selection considerations for DHTs

- 11. Topic identification. The new HealthTech Connect tool for topic identification was built with digital technologies in mind. In future, DHTs may therefore be identified through this channel although it is likely that suitable future topic identification is going to require us to draw on intelligence from a wide range of sources in addition to HealthTech Connect.
- 12. Topic selection governance. Guidance and advice selection decisions for medtech and diagnostics topics are made by the Medical Technologies Topic Oversight Group which includes voting membership from NHS England. It is assumed that similar oversight would be needed for DHT selection decisions particularly where the new NHS England funding mandate will apply.
- 13. The evaluation pilot will focus on types of DHT that are commissioned in the UK, rather than being self-funded.
- 14. The purpose of the technology. Many DHTs are used for diagnosis or monitoring, rather than for therapeutic purposes. Although the pilot is being established under the medical technologies guidance process, in future, diagnostic assessment capability within NICE will be applied where needed for diagnostic or monitoring DHTs. The products in the pilot have a mix of therapeutic and diagnostic purposes.
- 15. Existing NICE guidance forms the background to the use of digital products including the NICE guideline on Behaviour change: digital and mobile health interventions (in development, expected August 2020).
- 16. Impact of updated European Union Medical Device and In Vitro Diagnostics Regulations from 2017, in which most DHTs are uprated from their current class 1 designation. These changes will be important in the development of topic selection criteria and routing considerations because more digital

<sup>&</sup>lt;sup>1</sup> EVIDENCE STANDARDS FRAMEWORK FOR DIGITAL HEALTH TECHNOLOGIES, NICE 2019

products will be regulated as medical devices than currently, and the evidence requirements for regulation will increase.

- 17. Selected technologies will need to have successfully completed the Digital Assessment Questionnaire (DAQ) and process, as a prerequisite for selection for NICE guidance development.
- 18. Timing of the evaluation. Guidance can only be produced as a snapshot in time on the development pathway for any particular technology so the maturity of the product and the timing and likelihood of any further significant planned developments would need to be considered. This rapid turnover means that it is unlikely to be appropriate for NICE to produce updated guidance in the future on the same version of the product.
- 19. Working with the innovation and integrated care landscape. The pilot will enable NICE to understand how better to support local partners in the innovation landscape, putting evidence generation on the front-foot and enabling scale of tools that work nationally.

### Pre-evaluation assurance infrastructure

20. Evaluation by NICE will take place after appropriate or equivalent regulatory approval. As some DHTs are not classified as medical devices, they cannot apply for a CE mark. Equivalent regulatory approval for apps can be from a wide variety of sources including IT industry standards (such as ISO9000), information governance standards, engagement with NHS digital bodies, data protection standards, accessibility standards. The <u>Digital Assessment</u> <u>Questions (DAQ)</u> cover a series of clinical and technical standards, questions and best practice aimed to enhance digital products to the required and recommended level. The DAQ, which is led by NHS Digital, is the de facto standard by which standalone apps are included in the <u>NHS apps library</u>. As part of the topic selection process NICE will be looking to ensure that an appropriate level of safety, technical and information governance assurance has been obtained.

## Evaluation pilot process

- 21. DHTs can be challenging for HTA bodies to evaluate because they often have a low level of evidence. On the other hand, their capability for real-time data collection as they are used, potentially accelerates the development of further evidence to confirm early promise. DHTs typically have a short life-span and undergo frequent iterations. The evaluation pilot process is designed for these features of DHTs.
- 22. The evaluation pilot process will be based on the process for developing Medical Technologies Guidance, but with a significant amendment tailored to National Institute for Health and Care Excellence Digital health technologies (DHT) evaluation pilots Date: 22 May 2019 Reference: 19/046

23. Where additional data collection is identified as being necessary for a product during the process, this would be funded by the company but with advice on data collection design from the NICE External Assessment Centre. Data collection where needed will take place in NHS settings where these technologies are already being rolled out, in order to support a speedy process.

Evaluation stage	Activities
Scope developed	Done by NICE team based on claimed benefits of technology, with input of expert advisers and local health and social care teams using or testing products.
Clinical evidence submitted	Company makes submission to NICE based on scope, using a template and guidance notes, including all relevant clinical evidence.
Technical engagement	External Assessment Centre reviews company's evidence using Evidence standards framework for digital health technologies. Topic lead team comprising committee representatives and NICE team discuss results with clinical and patient experts and company to establish if clinical evidence is sufficient for MTAC to make an adoption decision.
Economic modelling	If clinical evidence is adequate, company submits its economic evidence including a cost model using a template.
Assessment report	External Assessment Centre prepares assessment report critiquing company's clinical evidence and economic modelling.
Medical Technologies Advisory Committee (MTAC) meeting	MTAC considers clinical evidence, cost modelling, including resource impact of product on care pathway, expert and patient advice and any information on adoption and budget impact.
Committee decision	<ul> <li>If MTAC considers case for adoption of the DHT is made, recommendation made on use of the DHT. Guidance published following standard pre-</li> </ul>

Overview of product evaluation process

	<ul> <li>publication checks. NHS England funding mandate applies.<sup>2</sup></li> <li>If MTAC considers case for adoption of the DHT is NOT made, recommendation reflects this. Guidance publicly consulted on, then published, following standard pre-publication checks.</li> </ul>
Data collection	<ul> <li>If technical engagement stage establishes clinical evidence is insufficient for committee to make adoption decision, NICE commissions External Assessment Centre to advise company on data collection design to address evidence gaps.</li> </ul>
	<ul> <li>Duration of data collection varies by product, determined by External Assessment Centre, depending on factors such as degree of uncertainty, frequency of outcomes of interest in real world settings and duration of patient follow-up. May vary between products.</li> </ul>
	<ul> <li>Once additional evidence is available, process for presenting to MTAC is followed as above, MTAC prepares recommendations.</li> </ul>

- 24. NHS England will be asked to advise at the start of the project on suitable service delivery settings and commissioning arrangements to enable the data collection to happen without delay. We will look to take advantage of NHS sites currently involved in rollout of that technology and existing data collection mechanisms and activities.
- 25. The shortest timeline possible for guidance to be developed under this process would be 19 weeks from scope to publication, for a technology that has sufficient clinical and economic data, where MTAC makes a positive adoption recommendation.

## Data collection considerations

26. Where data collection is needed, Appendix 2 summarises steps to be taken with companies and the NHS to ensure that data collection for DHTs is systematically considered and carried out. This is based on learning from NICE's Commissioning through Evaluation projects and our work on Improving Access to Psychological Therapies, which involve data collection for products in NHS use to inform subsequent commissioning decisions.

<sup>&</sup>lt;sup>2</sup> Subject to it being in place by the time of the recommendations.

# **Evidence Standards Framework-DHTs Phase II**

- 27. In addition to the pilot evaluation project, the project team will deliver Phase II of the <u>ESF-DHT project</u>. This will address further evolution of the standards developed at Phase I, and may be modified depending on feedback from stakeholders. This second phase will help enable the EFS-DHTs to be operationalised, offering practical support to users in industry and other public sector bodies and enabling robust approaches to assessment that will help derisk adoption of new products. This was highlighted as a gap at the end of Phase I when the ESF-DHTs were published.
- 28. An overarching <u>initial code of conduct for data-driven technologies</u> has been published by the Department of Health and Social Care. The Code sets out 10 principles designed to help enable the development and adoption of safe, ethical and effective data driven technologies and describes what is expected from suppliers and users. <u>NICE's evidence standards framework</u> supports principle 9 of the code of conduct, where it is directly referenced. A range of toolkits are being developed by a range of national organisations to further support implementation of the Code. We continue to liaise with other organisations that are developing other parts of an integrated Code of Conduct/regulatory framework, addressing other aspect of DHT adoption, such as standards for providers when deploying the technologies.
- 29. A survey/workshop will establish user needs for the ESF-DHTs to determine the most helpful areas of support for stakeholders.
- 30. Supporting materials will be developed to facilitate an assessment of the evidence for economic impact for Tier 3b DHTs.
- 31. Additional resources will be developed to facilitate assessment of effectiveness evidence considering issues such as critical appraisal tools and the generalisability of evidence between different technology versions.

# **Pilot oversight and evaluation**

- 32. A Steering Group will be set up to ensure system stakeholders oversee the project appropriately and maximise its benefits across the whole system. Membership will be drawn from NICE, NHS England, Public Health England, social care system partners, AHSNs, NHS Digital and the regulators.
- 33. The pilot will be evaluated to ensure that it meets NHS England's objectives and can rapidly feed lessons learned into substantive evidence advice and DHT evaluation capability within NICE for the future. The Steering Group will set the parameters of the evaluation.

# Conclusion

34. The evaluation of DHTs is challenging because of their varied nature, the many ways they can be used and the iterations they frequently undergo. In addition, they often become available with a low evidence base. They have already become integral to many aspects of health and social care, and in the future they will be involved in an ever-larger proportion of NICE's guidance. We will use the pilot to explore the most effective process and methods for determining their benefits, to ensure that adoption decisions for DHTs are based on the best available evidence. Patients and the health and social care systems will benefit from a robust national evaluation process for those DHTs which would otherwise be risky to adopt because of uncertainties about their evidence or cost case.

35. The Board is asked to:

• note the report and the considerations specific to the evaluation of Digital Health Technologies.

National Institute for Health and Care Excellence

May 2019

# **Appendix 1**

List of NICE guidance featuring digital health technologies:

## Medical technologies guidance (MTG)

[MTG13] <u>WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis</u> and monitoring of hypertension; Published date: January 2013

[MTG32] <u>HeartFlow FFRCT for estimating fractional flow reserve from coronary CT</u> <u>angiography</u>; Published date: February 2017

## **Diagnostics guidance (DG)**

[DG1] The EOS 2D/3D imaging system; Published date: October 2011

[DG6] <u>Depth of anaesthesia monitors – Bispectral Index (BIS), E-Entropy and Narcotrend-Compact M</u>; Published date: November 2012

[DG21] Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system); Published date: February 2016

## Technology appraisals (TA)

[TA97] <u>Computerised cognitive behaviour therapy for depression and anxiety;</u> Published date: February 2006

# Appendix 2

Data collection issues for DHTs

Data collection components	Lead	Considerations/comments
Advice on data collection design	NICE External Assessment Centre	Carried out following Technical Engagement stage in pilot process. Studies will need appropriate approvals as outlined by <u>the Health Research Authority</u> .
Data collection	Company	Potential for real-time data collection may reduce costs to company compared with standard trials. Standard data collection modality may still be needed for important outcomes not automatically collected by the device.
Service delivery during data collection period	NHS clinical leads	May be rolled out in limited area eg AHSN/STP, rather than nationally, to enable speedy data collection. Duration of data collection period is methodologically determined. Costs of patient treatment (including Excess Treatment Costs if applicable) will need to be met, as will costs of any service changes needed to deliver DHT-enabled service during data collection period. Costs to NHS may be reduced if company loans DHT during data collection period.
Patient consent for data collection	NHS clinical leads	Data should be appropriately consented including for third party analysis.
Data analysis	Company OR NICE External Assessment Centre	Currently for medtech and diagnostics where NICE recommends further research, this is carried out by the NICE External Assessment Centre. Some DHT data may be enhanced by linkage to other standard sources such as HES, CPRD or ONS, to provide longer-term outcome data. Approval processes should be planned to avoid delay to data analysis.
Data publication	Company OR	High quality peer reviewed journal would be the standard.

	NICE External Assessment Centre	Report only, without publication may be appropriate for NICE External Assessment Centre reports.
Present new data to Committee	Company and NICE	Clinical data from data collection period are used to update the economic model.

# National Institute for Health and Care Excellence NICE impact: stroke

This report gives details of how NICE's evidence-based guidance contributes to improvements in stroke care.

It also highlights the activities of the system support for implementation team to address implementation issues identified in the NICE impact report and provides information about NICE's communications activity in relation to the previous impact report on mental health

The Board is asked to review the NICE impact stroke report, provide feedback about how information on variation has been presented and note the actions proposed by the system support for implementation team and the communications activity.

Professor Gill Leng

Deputy Chief Executive and Director, Health and Social Care Directorate

May 2019

# Introduction

- The attached NICE impact report focuses on stroke and reviews the uptake of NICE guidance, guided by the recently published NHS Long Term Plan and the NHS RightCare pathway. It looks at stroke prevention, acute care, rehabilitation and includes a spotlight on thrombectomy. A commentary is provided by Juliet Bouverie, Chief Executive of the Stroke Association
- 2. The Board has requested that additional information on variation is presented in the impact reports. This report includes a variation bar chart on page 5 and a heatmap on page 9 to illustrate variation in prescribing and rehabilitation across England.

# System support for implementation

3. The System Support for Implementation team is currently scoping options to provide support to national partners in 2019/2020, to address the implementation issues highlighted in the NICE impact report on stroke, and the stroke and transient ischaemic attack in over 16s: diagnosis and initial management guideline update. A paper will be presented to the Health and Social Care Senior Leadership Team in late 2019 to outline any proposed activities.

# **Promoting NICE impact reports**

4. The System Support for Implementation team is currently scoping options to provide support to national partners in 2019/2020, to address the implementation issues highlighted in the NICE impact report on stroke, and the stroke and transient ischaemic attack in over 16s: diagnosis and initial management guideline update. A paper will be presented to the Health and Social Care Senior Leadership Team in Working with partners and key stakeholder organisations.

Working with partners and key stakeholder organisations

- 5. We worked closely with our stakeholders to encourage them to spread the word about the mental health impact report through their networks and communication channels. In total we have leveraged our relationships with professional bodies to share and circulate the report to more than 889,000 health care professionals. Below are some examples of the communication activities carried out:
  - Anxiety UK shared our report via Twitter to its 123,000 followers and included it within its news bulletin, which went out to 350 approved UK therapists. Anxiety UK also posted a summary of Gill Leng's NHE blog on its blog channel.

- The Association of Directors of Public Health (ADPH) confirmed that the report was circulated via its weekly newsletters: BriePH (which goes out to 300 ADPH members) and eDPH (which goes out to 87 external ADPH stakeholders).
- The British Association for Behavioural and Cognitive Psychotherapies (BABCP) shared our report with 7,621 followers on Twitter and included it in its monthly newsletter to 11,000 BABCP members (these include nurses, counsellors, psychologists, psychiatrists and other health professionals, as well as students and trainees).
- The British Psychological Society promoted the report via Twitter to its 67,500 followers.
- Public Health England shared our report via Twitter to its 183,000 followers and included an announcement in the March edition of its news bulletin, which goes out to just under 7000 people.
- The Royal College of Nursing disseminated the impact report to members of its mental health forum.
- Rethink Mental Illness shared the report via Twitter to its 208,000 followers.
- The Royal College of Psychiatrists promoted the impact report to its 77,000 followers on Twitter.
- The Social Care Institute for Excellence (SCIE) retweeted our report to SCIE's 35,000 followers. SCIE will also include an item about it in an upcoming edition of SCIEline, its e-bulletin which goes out to 104,000 stakeholders.
- Together for Mental Wellbeing promoted the impact report via Twitter to its 65,500 followers and disseminated the report internally to senior staff.
- The National Health Executive (NHE), published a blog by Gill Leng: <u>What</u> <u>progress are we making to transform our population's mental health?</u> This forms part of a series of blogs that NHE is publishing on all of our impact reports. NHE confirmed that the blog received 372 page views and 321 unique views. Users spent an average of 4 minutes, 5 seconds on the blog page.

## Newsletters

6. We highlighted the mental health impact report, as well as <u>a National Health</u> <u>Executive blog</u> by Gill Leng on the report, in the March editions of our <u>newsletters</u> to stakeholders: NICE News (25,213 subscribers) and Update for Primary Care (12,405 Subscribers). <u>NICE News</u> subscribers demonstrated the most interest in the report, downloading it 739 times (17% of the traffic). The news item in <u>Update</u> <u>for Primary Care</u> generated 67 downloads (5% of the traffic). Both click-through rates are good by industry standards.

### Social media

7. On publication, we promoted the mental health impact report via all our social media channels - Twitter, Facebook and LinkedIn - with each one receiving very good engagement rates.

Twitter

8. When the report was published in March, we immediately shared a link to it on Twitter. This initial tweet received 24,876 impressions (number of times the post had been viewed) and 135 clicks through to the report.

LinkedIn

 We also shared a link to the report on LinkedIn. As of the 25th April, we had received 2,944 impressions, 58 clicks to the report and an engagement rate of 3.36%. Anything above 2% is excellent by industry standards.

Infographic - Twitter

- 10. In addition, we created an infographic to highlight key statistics within the report and encourage more users to access it (see figure 1). We shared this a few weeks later, in April. This was well received by our Twitter followers, achieving a 1.8% engagement rate, which is very good by industry standards.
- 11. As of the 25th April, the infographic had 11,277 impressions and 46 clicks on Twitter (see figure 2), which is good considering we had previously promoted the report on Twitter a month earlier. Most of those who engaged with our initial tweet linking to the report, and to the infographic, were people working in the mental health field, including nurses, academics, GP's and students. We also had retweets and likes from people with more of a general interest such as mental health bloggers and members of the public.
- 12. Additionally, we had engagement with the infographic from corporate Twitter accounts including SCIE, various NHS library services and CCGs.

Infographic - Facebook

13. We shared the same infographic on Facebook, where it achieved a 1.9% engagement rate. As of 25 April, our Facebook infographic post had been viewed by 5,214 people and generated 94 reactions (see figure 2). There were 21 link-clicks, which demonstrates that users are viewing the impact report after seeing the social post. Given the positive engagement generated by the infographic, our media team will continue to create infographics for each new impact report and promote these via our social media channels.

### Figure 1

# NICEImpact **Mental Health** NICE plays a key role in setting high standards for the care of people with mental health conditions. 1 in 4 Mental health conditions are the largest single cause of disability in the UK, with 1 in 4 adults experiencing a mental health condition in any given year. When left untreated, poor mental health can cause physical health problems as well. 33 guidelines and 18 quality standards We've been publishing resources since 2002 in order to support the identification and management of common and severe mental health conditions in children, young people and adults. Improving Access to Psychological Therapies (IAPT) programme The number of people who accessed NICE-recommended psychological therapies through IAPT has more than doubled from 435,000 in 2012/13 to over 1 million in 2017/18 The Eating Disorders Pathway Eating disorders are serious mental health conditions which most commonly start in adolescence. In just over 2 years, from 2016, the percentage of children and young people who started treatment for their eating disorder within the recommended 4 weeks, increased from 65% to 80%.

## Figure 2

weet Activ	vity			
NICE @NICEComms     Our NICE impact report reviews how     NICE recommendations are being	Impressions	11,278		
	Total engagements	247		
and the second second	used in the health and care system. Take a look at our infographic on	Detail expands	113	
And and a	mental health which summarises some of the key outcomes @Read	Link clicks	46 37	
	the report here: http://bit.ly/2CEai2T	Media engagements	37	
	Click on the image below to expand	Retweets Likes	22	
Pic.twitter.com/LWNrdEKYIm	Profile clicks	4		
Promote your Tweet Your Tweet has 11,277 total impressions so far. Get more impressions on this Tweet! Promote your Tweet				

Performance	for your post	
5,214 People Re	ached	
94 Reactions, com	ments & shares (1)	
56 Like	37 On post	19 On shares
4 O Love	3 On post	1 On shares
5 Comments	4 On Post	1 On Shares
29 Shares	27 On Post	2 On Shares
221 Post Clicks		
122 Photo views	21 Link clicks	78 Other Clicks (1)
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### **Events**

- 14. Our events team continues to promote our impact reports at all relevant events, exhibitions and speaking engagements. For example, this summer, our impact reports will be promoted to delegates on the NICE stand at exhibitions including The Royal College of Nursing Congress, Public Health England's Annual Conference and NHS England's 'NHS Expo'.
- 15. In addition, printed versions of our impact reports will be available at our own annual conference in May and at our parliamentary reception in June.

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May 2019

# NICEimpact stroke

This report highlights progress made by the health and care system in implementing NICE guidance. We recognise that change can sometimes be challenging and may require pathway reconfiguration. Additional resources such as training and new equipment may also be required.

We work with partners including NHS England, Public Health England and NHS Improvement to support these changes, and we also look for opportunities to make savings by reducing ineffective practice.

# NICE impact stroke

There are more than <u>100,000 strokes</u> in the UK each year causing 38,000 deaths, making it a leading cause of death and disability. This report focuses on how NICE's evidence-based guidance contributes to improvements in care for people who are at risk of or who have had a stroke.



# Stroke prevention in atrial fibrillation p4

People with atrial fibrillation are 5 times more likely to have a stroke. We look at how NICE-recommended stroke risk assessment and anticoagulation for people with atrial fibrillation can help reduce the number of strokes.



## Acute care p7

People who have had a stroke need access to high quality acute care as quickly as possible. We review how NICE's recommendations are contributing to people receiving quality acute care, which improves their outcomes.



# Rehabilitation p11

As more people survive stroke there is a greater focus on rehabilitation. We consider how NICE's recommendations on therapies, early supported discharge and vocational rehabilitation are used to help people return to their homes and to work if they wish to do so. We also look at how reviewing rehabilitation goals and health and social care needs can improve the support people and their carers receive.



# Spotlight on thrombectomy p15

Thrombectomy is a new development in ischaemic stroke treatment. It has been shown to improve outcomes in some stroke patients if it is performed promptly.



## **Commentary** p16

Juliet Bouverie, Chief Executive of the Stroke Association, reviews recent achievements and considers NICE's role in contributing to improvements in stroke care.

# Why focus on stroke?

NICE impact reports review how NICE recommendations for evidence-based and cost-effective care are being used in priority areas of the health and care system, helping to improve outcomes where this is needed most.

NICE provides evidence-based guidance and advice to help improve health and social care services. The uptake of NICE guidance is influenced by close relationships with partners in the system, such as NHS England, NHS Improvement and Public Health England (PHE).

In the UK there are over 1.2 million stroke survivors with two thirds of survivors leaving hospital with a disability. This leads to an estimated cost of £26 billion a year. Public Health England data suggest that the average age for someone having a stroke is decreasing, with over a third of strokes in adults between 40 and 69.

Survival rates have improved and the national focus is now on how stroke can be prevented, treated quickly, and how people can be supported after a stroke. To support this an <u>NHS</u> <u>RightCare stroke pathway</u>, underpinned by NICE guidance, has been developed by NHS England, the Royal College of Physicians Intercollegiate Stroke Working Party, the Stroke Association and a range of other stakeholders. The <u>National</u> <u>Stroke Programme</u> has also been developed jointly by NHS England and the Stroke Association, to help deliver better prevention, treatment and care for people who have a stroke and meets the ambitions set out in the <u>NHS Long Term Plan</u>.

NICE published its first guideline on the <u>diagnosis and initial</u> <u>management of stroke</u> in 2008, which was updated in May 2019. A <u>quality standard</u> has also been published and updated, indicators have been developed and a guideline has been published on <u>stroke rehabilitation</u>, which is also planned for an update.

NICE routinely collects data which provide information about the uptake of its guidance. To produce this report, we have worked with national partners to select those data which tell us about how NICE guidance might be making a difference in priority areas of stroke care. They also highlight areas where there is still room for improvement.

Stroke is a life-threatening medical condition that occurs when there is a blocked artery (ischaemic stroke) or burst blood vessel (haemorrhagic stroke). The damage this causes can affect the way your body works, as well as how you think, feel and communicate.



interventional procedure guidance

# Stroke prevention in atrial fibrillation

It is estimated that 7,000 strokes could be prevented and over 2,000 lives saved every year in England if people with atrial fibrillation were adequately treated.

People with atrial fibrillation are 5 times more likely to have a stroke, and more than **1.1 million people** have a diagnosis of atrial fibrillation in England. In 2014 NICE updated its recommendations for the prevention of stroke in people with atrial fibrillation, which required a change in practice.

The updated recommendations included the assessment of the risk of stroke using the  $CHA_2DS_2$ -VAS<sub>c</sub> tool. These recommendations led to the development of <u>NICE menu</u> <u>indicators</u>, which were adopted into the Quality and Outcomes Framework (QOF). Data from the QOF show that, in 2017/18, 94% of people with atrial fibrillation were risk assessed using this tool.



94% of people with atrial fibrillation were risk assessed using the NICE recommended CHA<sub>2</sub>DS<sub>2</sub>-VAS<sub>c</sub> tool

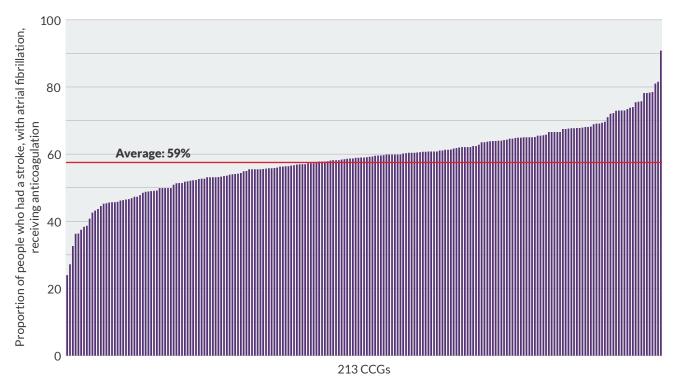
For those who are assessed at being at risk of stroke (a  $CHA_2DS_2$ -VAS<sub>c</sub> score of 2 or more) NICE guidance on **atrial fibrillation** recommends offering anticoagulants. While there has been an increase in the use of the  $CHA_2DS_2$ -VAS<sub>c</sub> tool, around 15% of people assessed as being at higher risk of stroke are still not receiving anticoagulants in primary care. This may be due to patient choice with some people choosing not to take anticoagulants.

Anticoagulant prescribing rates in primary care for people with atrial fibrillation at risk of stroke

2015/16	78%
2016/17	81%
2017/18	84%

Anticoagulants are medicines which prevent blood from clotting. This reduces the risk of stroke. The term covers warfarin (vitamin K antagonist) along with anticoagulants referred to as direct oral anticoagulants (DOACs), which are also known as non-vitamin k oral anticoagulants (NOACs).

DOACs recommended by NICE are apixaban, dabigatran etexilate, edoxaban and rivaroxaban. In secondary care the <u>Sentinel Stroke National Audit</u> <u>Programme</u> (SSNAP) found that the proportion of people presenting to hospital with a stroke, who had atrial fibrillation, and were receiving anticoagulation before they had a stroke increased, from 38% in 2013/14 to 59% in 2017/18. However this varied from 24% to 91% across CCGs in England. This wide variation means that some people at risk of stroke are not receiving treatment as recommended by NICE.

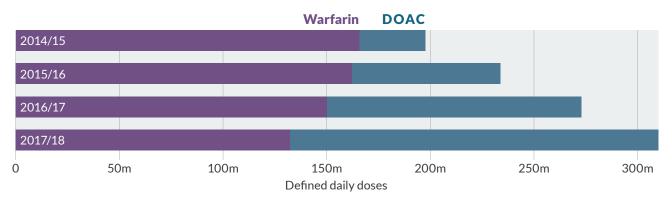


NICE has produced a <u>patient</u> <u>decision aid</u> to help people with atrial fibrillation reach a decision about whether to take an anticoagulant to reduce their risk of stroke, and which one to take if they decide to do so. As well as helping to increase the use of anticoagulation NICE no longer recommends the use of antiplatelet medication (aspirin, clopidogrel, ticagrelor and prasugrel) as a single treatment for stroke prevention. SSNAP data show a decrease in antiplatelet prescribing in people who had atrial fibrillation before a stroke, from 42% before the NICE guidance in 2013/14 to 18% in 2017/18. To support this 'do not do' recommendation, antiplatelet use was removed as a treatment option from the QOF in 2015.

In order to improve adherence to anticoagulation, NICE guidance on atrial fibrillation recommends that people should have a choice of which anticoagulation to take. This includes direct oral anticoagulants (DOACs) or warfarin (vitamin K antagonist). Primary care prescribing data show that overall anticoagulation prescribing has increased over the last 4 years and the proportion of prescribing of DOACs has also increased.

Proportion of people who had a stroke, with atrial fibrillation, receiving anticoagulation by CCG 2017/18

# Increase in DOAC prescribing and a decrease in warfarin prescribing over time



A decrease in the use of warfarin may allow for a reduction in the clinics needed to monitor dosage, since DOACs do not require therapeutic monitoring. Such monitoring is estimated to cost the NHS in England, Wales and Northern Ireland  $\underline{\pounds90}$ <u>million</u> annually and represents a large proportion of the overall cost of warfarin use.



# DOAC prescribing has increased 6 fold between 2014/15 and 2017/18

Following the updated NICE recommendations, NHS England and Public Health England launched several improvement initiatives to implement NICE guidance. These include:

- updates to the QOF
- setting Academic Health Science Networks atrial fibrillation as a priority to 'detect, protect and perfect'
- publishing <u>Health matters: preventing cardiovascular</u> <u>disease</u> to improve the detection and management of high risk conditions including atrial fibrillation.

Between 2011 and 2016 hospitalised atrial fibrillation related strokes reduced from 98 per 100,000 patients per week to 86 per week. <u>Research</u> carried out by Cowan et al. (2018) reported that this was linked to identifying more people with atrial fibrillation and increasing uptake of anticoagulation therapy. While it was not possible to attribute this increase to a single cause, guideline changes, quality improvement initiatives, and the advent of DOACs may have contributed.

#### The NICE Implementation

**Collaborative** produced a report on supporting local implementation of NICE guidance on the use of DOACs for reducing stroke risk in non-valvular atrial fibrillation. It focuses on how barriers might be overcome locally to facilitate appropriate use of the drugs. NICE recommends for people with sudden onset of neurological symptoms a validated tool, such as FAST (Face Arm Speech Test), should be used outside hospital to screen for a diagnosis of stroke or TIA.

Urgent care needs to be provided in an acute stroke unit with the right facilities and specialist staff available around the clock. This needs to be followed by rehabilitation and specialist support.

# Acute care

In the first 48 hours after the start of stroke symptoms, people need urgent access to high quality acute care to help improve their outcomes.

## **Brain imaging**

How quickly people receive a brain scan after arriving at hospital is a key part of acute care and helps to determine which treatment will be most effective. All people with symptoms of acute stroke should have brain imaging as soon as possible to assess:

- if the stroke has been caused by a blocked artery (ischaemic stroke) or burst blood vessel (haemorrhagic stroke)
- which part of the brain has been affected
- how severe the stroke is.

'My wife recognised it immediately when I was having a stroke. She called an ambulance which arrived really quickly. I got to hospital and I was scanned straight away. They found a clot in my brain and gave me thrombolysis. The care I got in hospital was quick and efficient, but there are long waiting lists for rehab services. Getting physio and speech therapy has been an uphill struggle. I had my stroke more than six months ago and I'm still waiting to get a speech therapy appointment. But I am determined not to let my stroke stop me from getting back into my workshop.' Leslie, Gosport The NICE guideline on the diagnosis and initial management of stroke recommends brain imaging should be performed immediately (defined as within 1 hour) for people with acute stroke if indicated. The Sentinel Stroke National Audit Programme (SSNAP) data show the proportion of people scanned within 1 hour is steadily improving, from 42% in 2013/14 to 53% in 2017/18. The proportion of people scanned

within 12 hours of arriving at hospital increased from 85% in 2013/14 to 94% in 2017/18.

# Thrombolysis

Thrombolysis is administered to people who have had an ischaemic stroke to break down and disperse a clot that is preventing blood from reaching the brain. Breaking down a blood clot can restore blood flow to the brain, saving brain cells from damage and reducing disability after stroke. Receiving thrombolysis as quickly as possible is crucial to improving outcomes after an ischaemic stroke. NICE recommends thrombolysis using the medicine alteplase within 4.5 hours for people who have had a stroke. SSNAP shows good uptake of this recommendation with 88% of eligible patients receiving thrombolysis in 2017/18; an improvement from 74% in 2013/14. Sixty four percent of patients received thrombolysis within 1 hour of arriving at hospital, which is encouraging that many people are receiving this treatment so quickly.

# Stroke care pathway from the emergency department to CT scan and from CT scan to thrombolysis

Plymouth Hospitals NHS Trust reviewed their own SSNAP data on brain imaging within 1 hour, with the aim of improving target times.

The trust made these changes to their stroke service:

- implemented a 'thrombolysis bag' to reduce delays in patients receiving thrombolysis on the CT scanner
- routine tasks such as ECG and changing patients' clothes postponed until after thrombolysis
- weekly meetings to maximise review and feedback to all departments through clinical leads
- employment of 3 specialist stroke nurses (in-hours)

- stroke nurse presence extended to out-of-hours
- education and awareness of the urgency of strokes (treated as urgently as trauma patients, among the imaging and emergency team).

The trust has improved their brain imaging times, from a median time of 1 hour and 43 minutes in July to September 2013 to a reduced median time of 35 minutes between December 2016 and March 2017.

The trust has submitted more details on their improvements in a **NICE shared learning example**.

## Admission to a specialist acute stroke unit

Specialist acute stroke units are a discrete area in the hospital. Early admission to a stroke unit ensures that people who have had a stroke are cared for by a specialist stroke team, and are more likely to receive the necessary assessments and treatments they need.

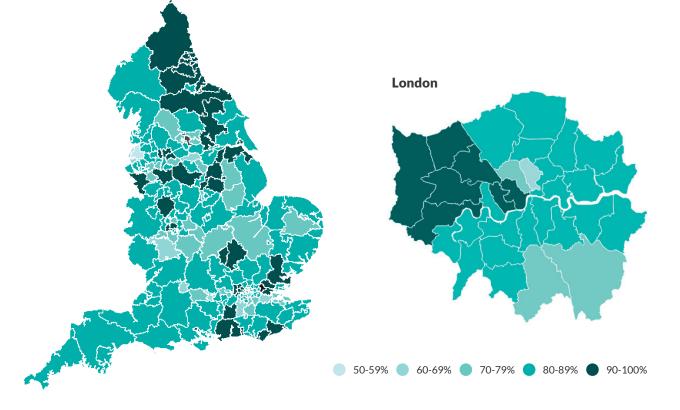


Admission to a stroke unit within 4 hours has been around 58% for the last 5 years

NICE recommends admission to specialist acute stroke units within 4 hours, so that treatment can begin as quickly as possible, and to help prevent complications. This is also highlighted in the <u>NHS RightCare stroke pathway</u> which includes admission to specialist acute stroke units within 4 hours as a key national priority for improving stroke care. SSNAP collects data from all stroke units, specialist acute stroke units and hyper-acute stroke units and refers to them all together as 'stroke units'.

Proportion of people achieving the SSNAP target of spending at least 90% of their inpatient stay on a stroke unit, by CCG 2017/18 SSNAP data show that admission to a stroke unit within 4 hours still requires improvement. The data has remained stable at around 58% for the last 5 years. These results vary geographically and across the 7 day week. SSNAP suggest this may be due to waiting times in A&E and bed availability.

In addition to early treatment, stroke units offer the best quality of stroke care during the rest of a person's stay in hospital. The <u>CCG outcomes indicator set</u> records the proportion of people who have had an acute stroke who spend 90% or more of their stay on a stroke unit. The data ranges from 57% to 98% across CCGs, which suggests there is wide variation and there remains room for improvement in many areas.



The **NHS Long Term Plan** highlights the importance of centralising hyper-acute stroke care into a smaller number of well-equipped and staffed hospitals, which have seen the greatest improvements.

This builds on the **NHS Five Year Forward View** which highlighted the London stroke service reconfiguration. This consolidated 32 stroke units into 8 hyper-acute units and a further 24 units providing care after the first 72 hours. Patients are assessed immediately by specialised stroke staff equipped to instantly perform brain imaging and give clot busting treatment where appropriate. The report highlights that this has achieved a 17% reduction in 30-day mortality and a 7% reduction in patient length of stay along with savings to the NHS of £5.2 million per year.

## **Swallow screening**

After a stroke many people are unable to swallow safely as the risk of inhaling food or drink is more common. These people may require food and fluids to be given by other methods.

NICE recommends that people with acute stroke have their swallowing screened by a specially trained healthcare professional within 4 hours of admission to hospital. This should happen before they are given any oral food, fluid or medication. If needed an ongoing management plan should be put in place for providing adequate nutrition. SSNAP data show swallow screening within 4 hours of admission has improved from 64% in 2013/14 to 75% in 2017/18.

NICE recommends that if the admission screen indicates problems with swallowing, the person should have a specialist assessment of swallowing, preferably within 24 hours of admission and not more than 72 hours afterwards. SSNAP data show specialist assessment of swallowing within 72 hours of admission has increased from 78% in 2013/14 to 88% in 2017/18.



Following a change to the evidence base and limited implementation of some of the recommendations, NICE has decided to <u>update</u> the guideline on stroke rehabilitation in adults.

# Rehabilitation

A greater focus on rehabilitation can improve the lives of people living with stroke by enabling them to return to their usual place of residence and to work if they wish to do so. NICE makes recommendations on speech and language therapy, physiotherapy and occupational therapy.

The NHS Long Term Plan suggests that the number of stroke survivors living with disability will increase by a third by 2035. In 2013 NICE produced guidance on stroke

'After my stroke I felt like I lost my independence, I was so much more reliant on others. I needed help washing and dressing and I could no longer do the things I used to with my grandchildren. I feel fortunate there is access to a lot of support in my area. I was supported by the Community Stroke Team and got physiotherapy, occupational therapy and psychological support. Then I was referred to the Stroke Association's reablement Service in Sheffield. Having that long-term help has been essential in rebuilding my life.' Donna, Sheffield rehabilitation in adults. It aims to improve rehabilitation for people who have had a stroke by specifying how stroke units and multidisciplinary stroke teams are organised. It makes detailed recommendations on assessments and interventions for the functional difficulties caused by stroke. When the quality standard on stroke was updated in 2016, it shifted focus from acute care to rehabilitation, reflecting an increasing number of people surviving a stroke.

## Therapies

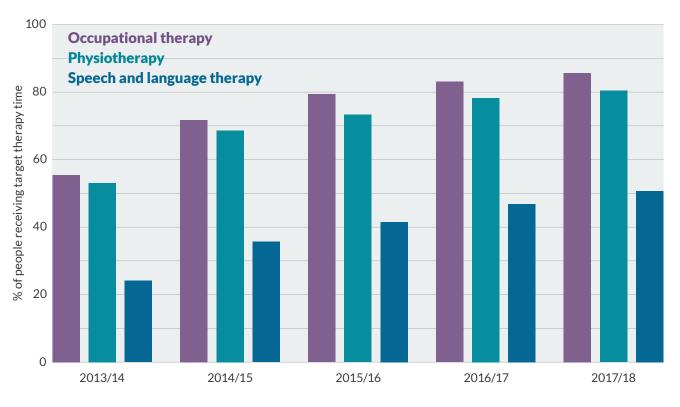
The NICE quality standard states that adults having stroke rehabilitation in hospital or in the community should be offered at least 45 minutes of each relevant therapy for a minimum of 5 days a week.



People receiving occupational therapy target times increased from 56% in 2013/14 to 86% in 2017/18

The percentage of people receiving NICE-recommended therapy has improved over the last 5 years. However there are still many people who do not receive the amount of rehabilitation therapy that they need, particularly speech and language therapy. The <u>Sentinel Stroke National Audit</u> <u>Programme</u> (SSNAP) calculates target therapy times for people who have had a stroke. These are based on estimates for the number of people who will require a particular therapy, so the target time is different for each.

#### Improvements in people receiving SSNAP calculated target therapy time



# Improving patient activity on the Stroke unit and efficiency of the workforce

Mid Cheshire NHS Foundation Trust assessed the implementation and perceived benefit of group therapy sessions on their stroke rehabilitation unit. The stroke rehabilitation therapy team introduced group therapy sessions in September 2017 and audited the results for 1 month against the NICE stroke rehabilitation guideline.

The team were able to successfully provide therapy over 5 days, improving from 4 days previously. All of the sessions ran for 45 minutes or longer, therefore adhering to NICE guidance, and all patients saw benefit in group work. Improvements were made in patient contacts, a 24 hour approach to rehabilitation, and patients becoming more active. Additional and unexpected benefits were the importance of the groups on patients' moods and staff morale.

The trust have submitted more details on their improvements in a **NICE shared learning example.** 

## **Early supported discharge**

Early supported discharge is an intervention that allows people's care to be transferred from a hospital environment to a community setting. It enables people to continue their rehabilitation therapy at home, with the same intensity and expertise that they would receive in hospital. NICE recommends that adults who have had a stroke are offered early supported discharge if the core multidisciplinary stroke team assess that it is suitable for them.

SSNAP estimates that 34% of people who have had a stroke will be suitable for early supported discharge. In the last 5 years there has been an increase in the proportion of all people who have had a stroke receiving this intervention, from 25% in 2013/14 to 36% in 2017/18.

## Vocational rehabilitation

After a stroke, adults may have significant disabilities that prevent them from returning to work. Working can contribute to a person's identity and perceived status, has financial benefits, and can improve their quality of life and reduce ill health. NICE recommends that adults who have had a stroke are offered active management to return to work if they wish to do so.

SSNAP carried out an organisational audit of post-acute stroke service providers in 2015. Only 27% of CCGs commissioned vocational rehabilitation services, which help someone with a health problem to return to or remain in work or volunteering.

## Improving support for vocational rehabilitation

Greater Manchester Stroke Operational Delivery Network is working with Greater Manchester Neuro Rehabilitation Operational Delivery Network to improve support for vocational rehabilitation. An audit of clinical teams in 2017 highlighted a number of issues including the need for further training for professionals, new pathways and assessment tools, resource and time limitations and lack of resources for the voluntary sector.

The networks therefore aim to upskill local healthcare professionals in supporting people with neurological conditions in vocational rehabilitation, develop a pathway of best practice with access to specialist vocational rehabilitation support, and encourage better links and working with other agencies including the voluntary sector and job centres.

Return to work has been identified as an area for quality improvement in the updated **NICE quality standard** on stroke, published in 2016.

### **Review**

Regular review allows a person with stroke to discuss with a trained professional how they are recovering, whether they need to make changes to their lifestyle or whether further therapy is needed. At this assessment patient outcomes should be measured to help improve stroke services.

NICE recommends that adults who have had a stroke have their rehabilitation goals reviewed at regular intervals and have a structured health and social care review at 6 months and 1 year after the stroke, and then annually. This review can help identify problems or difficulties the person who had the stroke and their family or carers may be experiencing.

Data from SSNAP show that, in 2017/18, 92% of people had their rehabilitation goals agreed within 5 days of arrival in hospital. However it does not record whether these goals were reviewed. The audit does record whether people had an assessment 6 months after a stroke. While the proportion of people having an assessment has increased, from 20% in 2013/14 to 30% in 2017/18, there is still room for improvement.

# Developing and implementing outcome measures incorporating NICE guidance and quality standards

The Greater Manchester Stroke Operational Delivery Network collaboratively developed a single set of outcome measures for the whole stroke care pathway. The measures selected reflect NICE guidance on stroke and stroke rehabilitation, and include the updated NICE quality standard on stroke.

Final measures were agreed and approved in August 2016 and were provided to commissioners to incorporate into acute and community contracts for 2017/18. The project has been successful in terms of reaching a collaborative agreement on a set of outcome measures involving two care settings that include all NICE quality standards for stroke. There was considerable involvement from NHS stakeholders, as well as the voluntary sector who helped ensure the measures selected focused on areas that mattered to patients and carers.

The network have submitted more details on their improvements in a **NICE shared learning example**.

# Spotlight on thrombectomy

Thrombectomy (intra-arterial intervention) is a new development in the care of ischaemic stroke (clots). It involves direct removal of a clot using a device passed into the blocked artery, usually from the femoral artery in the groin, to restore normal blood flow.

In 2016 NICE produced thrombectomy interventional procedure guidance on mechanical clot retrieval for treating acute ischaemic stroke. Evidence on its safety and efficacy is adequate to support the use of the procedure by clinicians experienced in the use of thrombolysis for stroke and in interpretation of relevant imaging. The procedure should only be carried out by appropriately trained specialists with regular experience in intracranial endovascular interventions, with appropriate facilities and neuroscience support.

The Sentinel Stroke National Audit Programme (SSNAP) says the procedure has been shown in trials to improve outcomes in eligible patients if it is performed within a few hours of stroke. However, facilities for thrombectomy are only available in a small number of centres, and there is a shortage of trained staff to perform the procedure. In 2017/18, SSNAP reported that 781 thrombectomies took place in England, Wales and Northern Ireland across 26 centres; an increase from 594 in 2016/17.

The updated NICE stroke guideline, published in May 2019, includes recommendations on the use of thrombectomy.

## Mechanical thrombectomy for large vessel occlusion stroke

University Hospitals of North Midlands NHS Trust has implemented a pathway to offer mechanical thrombectomy to treat large vessel occlusive strokes in suitable people. After implementing the pathway 94% of people with severe strokes due to large vessel occlusion, who received mechanical thrombectomy, were discharged to their own homes rather than to a nursing home; 23% were discharged home within 1 week. Before implementing the treatment pathway, when only intravenous tissue alteplase was used, 70% of patients were discharged to inpatient rehabilitation, with significant annual costs. There has been £0.8 million savings from a reduction in the length of stay in hospital and £1.6 million savings from a reduction in social care costs. The trust have submitted more details on their improvements in a **NICE quality and productivity example.** 

The NHS Long Term Plan aims to expand mechanical thrombectomy treatments from 1% to 10% of stroke patients, which will allow 1,600 more people to be independent after their stroke each year. During 2019 the plan commits to working with royal colleges to pilot a new programme for hospital consultants to be trained to offer mechanical thrombectomy.

In March 2018 NHS England commissioned mechanical thrombectomy for acute ischaemic stroke.

# Commentary

Juliet Bouverie, March 2019

The scale and impact of stroke is enormous and growing-if we do nothing, the cost of stroke to the health and care system is estimated to rise from £26bn to between £61bn and £91bn by 2035. Importantly, 90% of all strokes are preventable, and by working together, clinicians and decision-makers can lead the way in both reducing strokes and improving outcomes. Robust, well-observed clinical guidance right across the pathway is crucial to stroke survivors' recoveries.

As this report highlights, acute stroke care has seen some much needed improvements and developments in recent years. But there is still more to be done, especially in eradicating the 'postcode lottery' in access to recovery services, and providing support for people once they leave hospital. The number of stroke survivors who receive the recommended amount of rehabilitation, including speech and language therapy and vocational therapy, continues to lag behind improvements elsewhere in the pathway, while only one in three people have a follow-up review six months on from their stroke. It is no wonder that 45% of stroke survivors reported to us that they feel abandoned after they leave hospital. Behind these statistics there are countless personal stories. These are the stories that we hear every day at the Stroke Association, the real driving factors for improvement.

In addition to rehabilitation, large hyperacute stroke units are more likely to provide world class, evidence-based stroke treatment, and we want this to be the case across as much of the country as possible. Progress in reconfiguring acute services will save lives, improve outcomes, and reduce the overall cost of stroke, both to society and economically.

Improved outcomes are also linked to thrombectomy, a gamechanging procedure that we want all eligible patients to have access to. Progress in rolling out this treatment has been limited. We welcome its inclusion in the recent draft NICE stroke and TIA guidance, as well as the procedure's inclusion in the NHS Long Term Plan for England.

Of course, key to reducing the burden of stroke is improving the way key risk factors such as hypertension and atrial fibrillation (AF) are identified and managed. The NHS Long Term Plan places prevention at the heart of the public health agenda.



Juliet Bouverie is the Chief Executive of the Stroke Association

However, more remains to be done to identify those with AF and take away reliance on GPs by supporting other health care professionals, such as pharmacists, to lead this work. NICE's guidance is an important driver in preventing strokes happening in the first place, alongside public health initiatives such as the One You campaign from Public Health England.

The Stroke Association has been working in partnership with NHS England and key Arm's Length Bodies, to develop the National Stroke Programme which is underpinned by the Long Term Plan. Part of the programme's work will be to work with health leaders to better embed clinical guidance such as the NICE-accredited National Clinical Guideline for Stroke into service delivery. Stroke remains one of the greatest health challenges of our time, but we have a real opportunity to transform people's outcomes and experiences. We know that with the right specialist support and a whole load of courage and determination, the brain can adapt, people can recover. We welcome the updates of the NICE guidelines on stroke and stroke rehabilitation and look forward to working together to support their implementation.

We would like to thank Professor Tony Rudd, National Clinical Director for Stroke. We would also like to thank the Stroke Association for their contributions to this report.

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### AUDIT & RISK COMMITTEE

## Unconfirmed minutes of the meeting held on 24 April 2019 at the NICE London Office

#### Present

Dr Rima Makarem Elaine Inglesby-Burke Professor Sheena Asthana Tom Wright	Non-Executive Director (chair) Non-Executive Director Non-Executive Director Non-Executive Director (by telephone)
In attendance	
Andrew Dillon	Chief Executive
Ben Bennett	Business Planning and Resources Director
David Coombs	Associate Director - Corporate Office
Barney Wilkinson	Associate Director - Procurement and IT
Catherine Wilkinson	Deputy Director – Business Planning and
	Resources
Jane Lynn	Head of Financial Accounts
Elaine Repton	Corporate Governance & Risk Manager (minutes)
Gill Leng	Health & Social Care Director and Deputy Chief
	Executive (for item 4.2)
Sarah Cumbers	Programme Director - Transformation (for item 4.2)
Niki Parker	Government Internal Audit Agency
Andrew Jackson	National Audit Office (NAO)
Andrew Ferguson	National Audit Office (NAO)
Hassan Rohimun	Ernst & Young (EY)
David Wright	NICE Sponsor Team, DHSC

### Apologies for absence

- 1. Apologies for absence were received from Jane Newton.
- 2. The chair reported that Tim Irish had stepped down from the committee following his appointment as vice chair of the NICE board. Tom Wright had been appointed to the committee.

### **Declaration of interest**

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

### Minutes of the last meeting

4. The minutes of the meeting held on 23 January 2019 were agreed as a correct record.

## Action Log

- 5. The committee reviewed the action log noting that Andrew Dillon had received confirmation that the DHSC will underwrite any financial shortfall resulting from the transition to technology appraisal (TA) and highly specialised technologies (HST) cost recovery in 2019/20.
- 6. David Wright advised that the DHSC sponsor team had raised the ongoing issue of NHS England's (NHSE) late payment of invoices with the NHSE finance business partner and offered to escalate the matter further if no improvement was seen. NICE was content for the time being that the matter had been highlighted across the sponsor teams.
- 7. Barney Wilkinson reported that software had now been purchased to allow 'phishing' exercises to take place in 2019, with the aim of raising staff awareness about such emails. A report upon its use will be brought to the September meeting.

#### **RISK MANAGEMENT**

#### Risk register 2019/20

- 8. The committee reviewed the 2019/20 risk register and welcomed the revised presentation of grouping the principal business risks under the relevant strategic ambition.
- 9. Within risk 07/19, it was queried whether NICE's involvement was limited to the evaluation of digital health apps, or was it anticipated to have a wider role for the NHS. It was confirmed that the pilot study related to the evaluation of four specific apps at this stage.
- 10. The committee noted the 2019/20 risk register.

### **Risk discussion – NICE Connect**

- 11. Gill Leng and Sarah Cumbers presented an overview of the NICE Connect transformation project, describing its aim and intended benefits of presenting NICE's advice as pathways that reflect the way prevention, treatment and care are organised and delivered. A pathway committee has been established looking at diabetes as a test topic.
- 12. The committee discussed the activities within the current exploratory phase and the objectives to be achieved by September 2019, at which time a report will be presented to the Board with the findings from phase one and recommendations for the next steps.
- 13. The key risks to the transformation programme were discussed, notably the risk of insufficient resources. This includes financial resources to support the significant digital investment required, and staff resources with the necessary skills to lead the digital transformation and cultural change programmes that will need to take place. Gill Leng reported that the risks of doing the work off-set

the risks of not doing it, as it will ensure NICE's outputs remain relevant to users. Reference was made to the external consultancy work that was commissioned to look at NICE's future approach to data and content management. The outcome of work has reinforced the changes required as a priority to current processes and methods and the digital architecture.

14. The committee noted the progress of the NICE connect project and thanked Gill and Sarah for their attendance.

### **INTERNAL AUDIT**

#### Whistleblowing arrangements

- 15. Niki Parker presented the findings of a review of whistleblowing arrangements which had concluded that overall good practice was being followed with an up to date policy in place. Detailed guidance was available for investigating officers (in line with ACAS advice) and there was a clear reporting route for concerns to be raised. The review received a moderate assurance rating with four recommendations for improvement.
- 16. The committee asked whether a low number of whistleblowing referrals was positive. Niki Parker advised the work had looked at the arrangements in place for staff to make referrals and the findings had pointed towards there being a culture which allowed concerns to be raised with no fear of victimisation.
- 17. The report was noted.

#### Workforce planning

- 18. The committee noted the findings of the NICE workforce planning review of arrangements in place to identify and address the future workforce needs of the organisation. The review received a moderate assurance rating with five medium priority recommendations for improvement.
- 19. The internal audit report was noted.

#### Cyber review

- 20. The committee welcomed the findings of the internal audit review of arrangements for managing cyber security. A substantial assurance level was given with two medium and one low level recommendations being made. The committee commented that the positive report reflected the amount of cyber security improvement work undertaken last year.
- 21. The chair asked what the business continuity planning exercise in March had involved and what the outcome was. Barney Wilkinson explained the scenario the senior management team worked through and summarised the findings which will be used to update processes in readiness for any future incidents.
- 22. The internal audit report was noted.

# Controls over confidential (non-personal) information in the Centre for Health Technology Evaluation

- 23. The review of controls over confidential (non-personal) information in the Centre for Health Technology Evaluation received a moderate assurance level with four recommendations.
- 24. The committee noted that there is a comprehensive set of internal procedures, guides and policy documents covering the processes in place within the Centre and queried whether this report could be shared with other teams to check their own arrangements. It was confirmed that the senior management team had agreed that the report should be taken to the Information Governance Steering Group to be cascaded to all teams.
- 25. The report was noted.

### Annual report and audit opinion 2018/19

- 26. Niki Parker presented the GIAA's annual audit opinion giving a moderate assurance level for 2018/19 based on a sufficiently wide range of audits and the three key compliance areas of risk management, governance and control. Niki confirmed that her conversations with management during the year had been good and that the positive report reflected the improved relationships.
- 27. The report was noted and welcomed.

### Internal audit progress report 2019/20

- 28. The report detailed the audits planned for 2019/20 and requested approval of an amendment to the GDPR review that was being carried forward from 2018/19. Scoping for the planned GDPR audit had identified duplication with an external review recently completed, but highlighted the benefit of seeking assurance that responsibilities for GDPR within contract management are being appropriately fulfilled.
- 29. The committee noted the progress report and supported the proposal to allocate the days from the GDPR audit to the contract management audit, in order to review the arrangements in place to ensure GDPR compliance in contracts.

### **EXTERNAL AUDIT**

#### Audit progress report on 2018/19 financial statements

30. Hassan Rohimun presented the audit progress report on preparation of the 2018/19 financial statements outlining the areas tested during the interim audit. The committee queried why exit packages in particular had been reviewed. Hassan advised that this work was part of the wider payroll checks. Ben Bennett stated that there had not been any compromise agreements.

31. The year end audit will begin on 6 May 2019. The external auditor's interim report was noted.

#### Committee effectiveness review 2018/19

- 32. Andrew Ferguson presented the outcome of the committee's effectiveness review in 2018/19. The survey used the same questions as the previous year to allow comparison. Overall the responses were more positive than in 2017/18 with three specific areas identified for improvement: communication and relationships with the DHSC's Audit Committee; reviewing counter-fraud arrangements; and assurance mapping.
- 33. It was noted that the Chair attends regular meetings with other ALB audit chairs and DHSC's Audit Chair. The DHSC sponsor team attend NICE's Audit Committee on a regular basis. It was not felt at this point that more communication was needed, but a watching brief will be kept.
- 34. It was noted that work was underway to ensure NICE complies with the Cabinet Office's counter fraud functional standards. The committee will review an updated counter fraud, corruption and bribery policy, and the submission to the Cabinet Office on the functional standards. The chair agreed to speak separately with the Corporate governance and risk manager to discuss an assurance mapping exercise.

#### ACTION: RM/ER

- 35. The issue of induction and training was raised. An induction was being organised for Tom Wright and the chair asked other non-executives if they needed any other specific training, to get in touch. The NAO will be able to offer advice and support.
- 36. The committee effectiveness review was noted.

#### NAO wider work in the health and care sector

37. Andrew Jackson advised the committee of the NAO's recent publications within the wider health and care sector. Reference was made to new guidance for audit committees on cloud services, which was soon to be published.

#### Non-audit work notification

- 38. Hassan Rohimun reported that EY had been approached to undertake VAT compliance work for NICE, as well as delivering the external audit in partnership with the NAO. The committee received assurance that there will be complete independence of the two teams, and that EY had satisfied itself that any potential risks had been considered and mitigated. EY had liaised with the NAO, who were also satisfied with the independence.
- 39. The committee was satisfied with the assurances given by EY to allow them to undertake the VAT compliance work.



### FINANCE

### Financial accounting performance

- 40. Catherine Wilkinson presented the financial accounting performance report as at 31 March 2019. The report demonstrated a positive year end position.
- 41. Catherine was asked to explain the increase in overpayments to ex-employees. She advised that the leavers process had not been followed by some line managers. As a result of this, an internal audit review of the staff starters, leavers and movers process had been requested. Following the audit new forms are being piloted with the HR team to improve the process. Consideration is also being given to improving induction training for new line managers.
- 42. The financial accounting performance report was noted.

#### Report on the M9 financial position 2018/19

43. The committee received the 2018/19 month 9 interim annual accounts. The report was positive and no issues of concern raised.

#### Forecast outturn

44. Ben Bennett summarised the year end forecast outturn position in the item above. The committee received assurance that the year end financial position was positive, with no significant findings expected.

### **CONTRACTS & IT**

#### Annual waivers analysis 2018/19

- 45. The committee reviewed the analysis of waivers from the Standing Orders and Standing Financial Instructions which have been approved in 2018/19. It was noted that the number of waivers had increased compared with last year (from 16 to 24), but the total value of waivers had decreased by over £1.6m. This was mainly due to high value health data projects (for example journal databases) being procured through a contract framework. The committee was satisfied there were no trends to be concerned about in the supporting detail.
- 46. The annual waiver analysis for 2018/19 was noted.

#### Waiver report – January to March 2019

47. The waivers report to the end of March was reviewed. The report was noted.

### **CORPORATE OFFICE**

#### Internal audit recommendations log

48. Progress in addressing the outstanding audit actions was reviewed. It was noted that one action remained outstanding from the 2017/18 internal audit

plan, relating to improved financial reporting on the British National Formulary (BNF) contract spend.

- 49. Within the 2018/19 plan, the counter-fraud actions are being addressed in line with the requirements to meet the Cabinet Office functional standards. The committee noted the rationale for the revised due dates for the non-staff travel and subsistence actions.
- 50. The progress update was noted.

### Review of internal audit effectiveness in 2018/19

- 51. The committee received the feedback from the review of internal audit effectiveness in 2018/19. The survey had used the same questions as last year for comparison. Overall the feedback was much more positive. The committee could identify from the scores that the relationship with management was significantly improved.
- 52. The report was noted.

# Revisions to Standing Orders, Standing Financial Instructions and Reservation of Powers to the Board

- 53. The committee was asked to review proposed amendments to the Standing Orders, Standing Financial Instructions and Reservation of Powers to the Board following an annual review.
- 54. The proposed change to formal competitive tendering and quotation arrangements was queried in terms of the rationale for costs being given at least a 50% assessment weighting in regard to other selection criteria being applied. After some debate, it was agreed to replace the proposed text of "at least 50%" with "costs should normally be given a 50% weighting". This would reflect the importance of quality when assessing bids and provide the scope to vary the weighting where justified.
- 55. The generic description of "employees" to include the non-executive directors was also queried. It was agreed to amend the documents to clarify that the reference was for the purpose of these documents only and did not affect the legal status of non-executives.
- 56. Subject to the two amendments raised, the proposed changes to the Standing Orders, Standing Financial Instructions and Reservation of Powers to the Board were agreed for submission to the public Board meeting in May.

### ACTION: ER

### Review of the committee's terms of reference

57. The committee reviewed the proposed amendments to its terms of reference, following the scheduled annual review.

- 58. The proposal to reduce the quorum from three to two prompted a discussion about the importance of IT capability to hold virtual meetings. Alterative web conferencing software was highlighted, and it was confirmed that attendance by web or teleconferencing counted towards the quorum. However, it was noted that current technical issues impaired the quality of interaction via teleconferencing at the moment.
- 59. The proposed amendments to the terms of reference were agreed for submission to the Board.

### ACTION: ER

#### Breaches of the declarations of interest policy

- 60. The committee was asked to review an annual report on breaches of the policy on declaring and managing interests in 2018/19. This was the first report of its type following introduction of two new policies applicable to advisory committee members and board members and employees in April and May 2018.
- 61. The committee noted three breaches had been identified, the details of which were given in the report. It was noted that one committee member had resigned from their role, but one had remained a member of their committee. David Coombs updated the committee on the current review of the advisory committee policy, which will reinforce the risk-based approach to dealing with interests.
- 62. The annual report on breaches was noted.

#### Use of the NICE Seal

63. The NICE seal had not been used since the last meeting.

#### Audit & risk committee draft annual report 2018/19

64. The committee reviewed a draft annual report to the Board summarising its activities in 2018/19. The report was agreed subject to minor amendments to the formatting.

### ACTION: ER

#### Draft annual governance statement 2018/19

65. Elaine Repton presented the draft governance statement which will form part of the accountability report within the annual report and accounts. The committee was asked to provide any comments on this section. The draft annual governance statement was agreed.

### Committee annual plan 2019

66. The committee noted its annual work plan for 2019. It was agreed the September meeting should receive a report on TA and HST cost recovery.

## **OTHER BUSINESS**

67. There were no further items of business raised.

### FUTURE MEETING DATES

68. The Committee confirmed its meetings in 2019 would take place at 2.00pm on:

- 19 June 2019 (at 9.30am)
- 4 September 2019
- 28 November 2019 (Thursday)
- 22 January 2020

The meeting closed at 4.30pm.

## Audit and risk committee annual report 2018/19 and terms of reference

This report summarises the work of the Audit and risk committee during the 2018/19 financial year. The Board is asked to note in particular the committee's assessment of the work undertaken in 2018/19 (paragraphs 5 - 25) and the anticipated challenges for the coming year (paragraph 35).

The committee has undertaken an annual review of its terms of reference and proposes a number of changes set out in appendix 2.

The Board is asked to:

- receive the annual report from the committee
- approve the proposed changes to the committee's terms of reference.

Dr Rima Makarem

Chair, Audit and Risk Committee

May 2019

## Introduction

- 1. The committee's primary function is to provide the board with an independent and objective view of the adequacy and effectiveness of NICE's governance arrangements, system of internal controls, financial control and management of risk.
- 2. In order to discharge this function the audit and risk committee prepares an annual report for the board and Accounting Officer. This report includes information provided by internal audit, external audit and other sources of assurance, such as reports from management.

## Background

- 3. The composition of the committee has been unchanged in the year which has enabled continuity of the committee's work with experienced members who have a sound understanding of NICE and the challenges it faces. The committee chair is also the audit committee chair in two other public bodies, and therefore brings the added benefit of experience, insight and a wider perspective from outside of NICE.
- 4. The committee has continued to have close links with the Department of Health & Social Care (DHSC) through the attendance of the NICE sponsor team at its meetings. The committee chair also attended an event for Arm's Length Body (ALB) chairs hosted by the DHSC in February 2019.

## Audit and risk committee's assessment

- 5. The assessment of the committee, based on the totality of the work presented to it, including but not exclusively the internal and external audit work, is that control and governance processes are well designed and managed. They provide reasonable assurance to the board.
- 6. Members of the board should acknowledge that the assurances given can never be absolute. The highest level of assurance that can be provided to the board is a reasonable assurance that no major weaknesses have been identified in NICE's risk management arrangements, internal and financial controls and governance processes.

## Information supporting the committee's opinion

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

Internal Audit

- 8. NICE's internal audit service is provided by auditors from the Government Internal Audit Agency (GIAA). As in prior years, should the need arise, private or specialist firms may be contracted to perform discrete audits. There was no requirement for this during 2018/19; all the work was performed by GIAA.
- 9. NICE's head of internal audit changed during the year, with the committee pleased to welcome Niki Parker to the role in May 2018.
- 10. The committee agreed an annual work programme for internal audit at the start of the year and reviewed the findings from these audits throughout the year.
- 11. These audits informed the head of internal audit's opinion, which the committee reviewed in draft at its meeting on 24 April 2019 covering the financial year ended 31 March 2019. An opinion of moderate assurance was issued. The final report will be presented in June when the committee will review the annual report and accounts for 2018/19.
- 12. The moderate opinion is the same as the assessment for last year. We consider the current assessment as 'usual', and not a cause for concern. The table below sets out the full range of audit work in the year, with conclusions discussed later in the report:

Assignment	Final report issued	Opinion
Non-staff expenses and allowances	Sept 2018	Moderate
Financial control environment – starters and leavers process	Sept 2018	Moderate
Counter-fraud arrangements	Nov 2018	Moderate
Preparations for NICE Foundation	December 2018	Substantial
Whistleblowing arrangements	March 2019	Moderate
Workforce planning	April 2019	Moderate
Confidential information in the Centre for Health Technology Evaluation	April 2019	Moderate
Cyber security arrangements	April 2019	Substantial

### Table 1 - Internal audit reviews

(See appendix 1 for the explanation of assurance opinion levels)

External audit

13. The National Audit Office (NAO) took a decision to contract out the detailed work of the 2018/19 financial audit of the NICE accounts to Ernst & Young (EY). The

NAO's Engagement Director and Engagement Manager continued to support the committee and attend meetings, in addition to the Associate Partner from EY.

14. The responsibility for recommending the audit opinion to the Comptroller and Auditor General (C&AG) is retained by the NAO. They give their opinion on whether the accounts give a true and fair view of the financial affairs of NICE and also whether its funds have been applied to the purposes intended by Parliament. This opinion will follow their audit starting on 6 May 2019, and a clean unqualified opinion is again anticipated following a positive interim audit at the end of month 9.

Fraud and corruption

- 15. As a Non-Departmental Public Body there has been no requirement for NICE to purchase a specific range of proactive and preventative counter fraud work. NICE would instead be given support from the DHSC Anti-Fraud Unit as required.
- 16. During the course of the year, counter fraud has become an area of greater focus across the DHSC and in November 2018 the DHSC's Anti-Fraud Unit organised a risk event for ALBs and their Sponsor Teams, which involved a risk management workshop and a counter-fraud presentation from the DHSC.
- 17. In March 2019 NICE and other ALBs were informed they would in future have to meet new obligations under the Cabinet Office's counter-fraud functional standards by 2 September 2019 (previously this only applied to larger organisations). This will involve completion of an assurance checklist to the Cabinet Office, development of an action plan and a fraud risk register. As part of these requirements NICE's counter-fraud, bribery and corruption policy is being updated and will be presented to the committee for review, as will the submission to the Cabinet Office.
- 18. There were no incidents of fraud, bribery or corruption detected during the 2018/19 financial year.

Assurance framework

- 19. The audit and risk committee has oversight of NICE's internal control and assurance arrangements. The arrangements include the:
  - identification of corporate risks linked to business objectives
  - assessment and management of significant risks
  - monitoring of the effectiveness of the internal controls
  - monitoring of financial controls and exception reporting

- review of independent assurance reports.
- 20. NICE's Risk Management Policy emphasises the directors' ownership of the risk identification and management process and requires that the senior management team (SMT) reviews the register quarterly. The next review of the policy is scheduled for May 2020, subject to any issues arising that necessitate an earlier review.
- 21. Identification of risks NICE's assurance arrangements involve an annual business planning cycle that establishes clear business objectives for the organisation and individual centres and directorates. Directors and their management teams identify potential risks that could adversely affect delivery of these objectives and develop strategies to manage them. These are included in a business risk register which is reported to the NICE senior management team and the audit & risk committee at the beginning of the financial year setting out the key business objectives of the organisation and listing controls and assurances for the management of those risks.
- 22. **Management of risks** Each quarter the audit and risk committee reviews the high and medium level risks in the business risk register, and the low risks annually. The SMT reviews the full corporate register bi-monthly. In doing so, the SMT and audit & risk committee assess whether the management strategies are likely to be effective in mitigating the risk level, and additional actions are agreed where necessary. They also consider whether any new risks have emerged that should be added to the register, and whether any risks have been mitigated to an extent they can be removed from the corporate register and monitored as part of local business management.
- 23. In addition to reviewing the risk register annually, the board also undertakes an annual review of strategic risks. The board and this committee reviews a strategic risk register (covering a three year period), currently 2018 21, which details the wider risk environment within which NICE is operating, and focuses on the external influences which could potentially have a significant impact on NICE.
- 24. **Corporate governance arrangements** Different elements of NICE's corporate governance framework have been reviewed within the annual internal audit plan. In 2018/19 arrangements for whistleblowing, counter-fraud and payment of non-staff expenses were reviewed. This continual programme of review ensures that NICE has in place processes and procedures that are appropriate to the risk profile and take account of best practice.

### Management

**25.** The committee received a range of assurance reports from management throughout the year. These are summarised in the table below.

Management assurance	Description
Losses and compensation register	As required by DHSC, NICE maintains a register of such payments. This is reported at each audit and risk committee. For 2018/19 the total value of these payments was £34,783 (£34,172 2017/18).
	Of this amount £26,668 relates to train cancellation or amendment fees, £756 relates to flight cancellation costs and £625 relates to meeting cancellation costs. The remaining value relates to bad debts written-off (£6,734).
Contract waiver report	The committee receives a report at every meeting of the tender waivers that have been authorised since the last meeting. Details are provided of the reason for the waiver, the value and the person that authorised it. The committee also receives an annual summary of all waivers granted during the year. In 2018/19 there were a total of 100 contracts awarded of which 24 were subject to waivers, with a total value of £403,517. The committee scrutinises waivers granted and requests specific assurance from management if it has any concern.
Technical accounting issues	The committee receives reports where there are significant changes to accounting policies or practices. Two new accounting standards (IFRS 9 & 15) to be adopted within the Financial Reporting Manual were reported to the committee in November, with details of their anticipated impact on the NICE accounts.
Specific Incident reports	Where there is an incident particularly relating to a loss suffered by NICE, the committee receives a report as part of its risk management duties. There were no incidents relating to accidental disclosure of confidential information, of a material enough nature that required escalation to the committee. The committee received a report on a whistleblowing case detailing the investigation, the findings and follow up action taken.
Approval of redundancy payments	Redundancies within contractual terms are approved by the Senior Management Team. Significant severance payments which go beyond the contractual terms are subject to approval of the DHSC. There were 3 redundancies during 2018/19. The costs had been accrued in the year.

## Table 2 - summary of sources of management assurance

Management assurance	Description
Annual assurance reports	There are a range of reports that the committee receives to provide additional assurance. During 2018/19 the committee received reports on contract management, information governance and compliance with the new Data Security & Protection toolkit, IT security and cyber security, and the management of complaints.

## Key messages from the year's work

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

- The committee was able to review an early draft of the annual report and accounts in April to provide an opportunity to comment on its content ahead of the approval in June. The executives were requested to bring forward the timetable for the production of the annual report and accounts to build this into the annual plan.
- We were pleased to receive in April 2018, a clean set of accounts for the financial year 2017/18 and a positive audit opinion. The work is done to very tight timetables but continues to present a positive picture of the accuracy and control of our core financial systems. This continues to be reinforced by internal audit assessments. It is pleasing that our internal auditors gave a 'moderate' rating to our key financial controls.
- We continue to focus part of our meetings on risk management. We receive at each meeting a statement of the main risks facing NICE and the mitigating actions taken by the executive. We receive once each year the full register (i.e. to include the low risks) to provide visibility of risks that could potentially escalate to medium and gain assurance on the management of these. We also receive the strategic risks twice yearly.
- We invite a senior manager to present to us at each committee meeting to hear their perspective on the challenges and risks in a specific area of responsibility. We have looked at the risks around cyber security within the Digital Services team, whistleblowing, the recruitment and retention of staff and the introduction of charging for technical appraisals and highly specialised appraisals.
- We reviewed the committee's terms of reference in April 2018 and again in 2019 as part of the annual review cycle. We take advice from our auditors to ensure they reflect best practice.
- There have been eight internal audit reports published (listed in table 1 above). We were assured that the audit plan covered a good spread of

NICE's work. In total there were 34 recommendations for improvement (1 high, 23 medium and 10 low). The committee is satisfied that good progress has been made to implement recommendations from audit reviews and is satisfied that any revised timescales for implementation are appropriate.

- No new incidents of fraud had been detected within NICE in 2018/19 but we will need to continue to assure ourselves of the effectiveness of controls recognising the issue of proportionality of controls to risks. An internal audit review of counter-fraud arrangements gave a moderate assurance rating and made four recommendations for improvement.
- During 2019/20 we will be undertaking a self-assessment of NICE's current arrangements for preventing fraud, against the Cabinet Office's 'functional standards for counter fraud'. These standards are the basic components that an organisation should have in place to effectively deal with fraud. A report will come to committee in September 2019.
- In November 2018 we received a comprehensive annual review of NICE's IT security arrangements which provided the committee with assurance regarding the overall design of the network's security systems and multi layers of protection internally and externally. The committee noted that the report also included the systems, software tools and external hosting environment overseen by the Digital Services team within the Evidence Resources Directorate. The Evidence Resources Director had also attended the April 2018 meeting to give a presentation of the security arrangements in place to protect the range of services supported by her directorate.
- Controls over information security are equally important. The committee received an annual information governance (IG) assurance report in November 2018 which detailed arrangements in place to ensure the effective management of information. Key achievements in the year were the successful implementation of the General Data Protection Regulation (GDPR), the launch of a new mandatory IG training module, identification of Information Asset Owners across all teams, co-ordination of an Information Governance Steering Group and formal appointment of a Data Protection Officer for NICE.
- A follow-up report in January 2019 detailed how NICE was transitioning from the Cabinet Office's security policy framework (SPF) and the National Cyber Security Centre's '10 Steps to cyber security', to the new Data Security & Protection (DSP) toolkit. The committee was presented with an interim report on NICE's compliance with the DSP toolkit which highlighted two areas requiring further work (business continuity planning and IT protection). The committee was assured that the senior

management team had agreed actions to ensure these areas were addressed ahead of the deadline for the final submission of 31 March 2019.

- We reviewed an updated whistleblowing policy and were pleased to note the training sessions for managers were being delivered. An internal audit review of whistleblowing arrangements had also taken place providing assurance that lessons learned from the recent case had been addressed.
- We received our first annual report on breaches of the policies on declaring and managing interests. We noted the detail of three breaches reported during 2018/19 (two involved advisory committee members and one employee) and were pleased to note in all three cases the breach was handled without any negative impact on guidance development. We discussed the lessons learnt, including to ensure interests are rigorously probed when shortlisting applications for positions on our committees.

## **Review of the committee's effectiveness in 2018/19**

27. The committee's terms of reference require that periodically, the committee shall review its own effectiveness and report the results to the board. The NAO facilitated a review of the committee's performance using the NAO's audit and risk committee effectiveness checklist. In March 2019 all the regular attendees at the committee's meetings were asked to complete the checklist. Andrew Ferguson presented the highlights from the review to the committee in April 2019 which showed improvements compared with last year's review specifically around the role and scope of the committee. There are three broad areas where there is opportunity for further development, and the committee will address these in 2019/20: relationship and communication with the DHSC and the DHSC Audit & Risk Assurance Committee; terms of engagement and induction training for new audit & risk committee members; and using assurance mapping to target the areas of greatest risk in NICE.

## Training

28. Last year, as in the previous year, the committee chair agreed with the NICE chair to utilise the NEDs' December meeting as a training opportunity. A session on cyber assurance was presented by Templar executives on behalf of the DHSC and NHS Digital.

## **Review of internal and external audit services**

- 29. In line with governance best practice, the committee's annual work programme includes a review of the performance and effectiveness of the internal and external auditors.
- 30. In terms of the management of the internal audit service provided by the Government Internal Audit Agency, progress in implementing the annual audit plan is reviewed at each meeting. The committee has received and reviewed the GIAA's annual opinion report.
- 31. All those who regularly attend audit & risk committee meetings were invited to complete a survey to review the performance of external audit (in December 2018) and internal audit (in March 2019). The views expressed in each were summarised for discussion by the committee.
- 32. This year's review of internal audit showed a significant improvement in the relationships between NICE and the GIAA team, and a greater satisfaction level in the quality of reports produced. A new Head of Internal Audit (and deputy) was allocated to NICE in 2018/19. The committee welcomed the positive working relationships that have been established, which are essential to gaining the maximum benefit from the contract and to ensure the work of internal audit assists NICE in improving performance and adding value to NICE's activities.
- 33. The NAO is NICE's external auditor appointed by Parliament. The report on the effectiveness of their performance was positive with no areas of concern regarding their work. The issue of the NAO contracting out NICE's audit to EY prompted comments around a potential loss of knowledge about NICE by those undertaking the audit, and the committee were therefore assured that the NAO would as is routine, retain oversight and attend the committee's meetings.

## Challenges and risks for 2019/20

- 34. In the coming year we will continue to review the range of risks facing NICE, consider the controls in place and assess their effective management. In terms of our focus, we are conscious of the following issues and risks facing NICE which will guide our work:
  - **Financial pressures** In last year's report we mentioned the continuing financial pressure that NICE, like other public bodies, faces and we feel it appropriate to include this again. NICE does have a cautious approach to spend commitments which has enabled it to manage pressures so far. The DHSC's approval to charge companies for Technology Appraisal and Highly Specialised Technologies on a full cost recovery basis will generate income from 1 April 2019. There is still a significant risk within

this process which the committee explored at its meeting in January, namely the risk of non-payment by companies and the 75% discount for small companies which will have to be funded by NICE through grant-inaid.

- NICE Connect NICE needs to embrace new digital technologies to support its NICE Connect transformation programme otherwise it risks its products becoming inaccessible and no longer fit for purpose for health and care professionals. The challenge of investing in the right digital technologies whilst also taking account of the resource constraints under which NICE operates will be a difficult balance in 2019/20.
- **Review of TA and HST methods and process guides** We recognise NICE's desire to work with the DHSC, NHS England and other ALB partners to gain stakeholder agreement to the remit, process and outcome of the review.
- Workforce planning The committee recognises the challenges of recruiting and retaining a motivated workforce. The specialised nature of many technical roles within NICE present added difficulties. This coupled with the re-location of the London office, most likely to Stratford, could potentially increase the risk of staff choosing to leave NICE and have an impact on the ability to deliver the guidance set out in the business plan. Plans to bring the recruitment process in-house will provide the opportunity to have a flexible recruitment approach better suited to meet NICE's needs.
- 35. Finally, we should record our appreciation of the excellent work and support from those in the business planning and resources directorate whose work we most scrutinise and rely on. We are assured that management take governance issues seriously and we have particularly valued the discussions about risks with senior managers at our meetings. We also note with pleasure the effective working relationships that continue to operate with our external auditors and internal auditors.

## The role and operation of the Audit and Risk Committee

36. The members of the committee during the period of the report were:

Rima Makarem (chair)	from 01/01/2017
Sheena Asthana	from 24/11/2016
Elaine Inglesby-Burke	from 16/11/2016

Tim Irish

- 37. No members declared any conflicts of interest in any agenda items during the year.
- 38. The following managers attend the committee meetings regularly to support it, present reports, respond to audit reports and answer queries from the committee:

Andrew Dillon	Chief executive
Ben Bennett	Business planning and resources director
Catherine Wilkinson	Associate director - Finance and facilities
Barney Wilkinson	Associate director - procurement and IT
David Coombs	Associate director - corporate office
Jane Lynn	Senior financial accountant
Elaine Repton	Corporate governance and risk manager (committee secretary)

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

39. Representatives also attend from:

Internal audit	The Government internal audit agency
External audit	National audit office and Ernst & Young
DHSC	NICE Sponsor team

- 40. It has been the committee's normal practice to hold a private discussion at the start of each meeting, between the auditors and members of the committee without the management present. This is to give the auditors an opportunity to raise any matters of concern without the presence of the management. The committee members find this session really helpful and propose to continue this in 2019/20.
- 41. The committee is required to meet at least 4 times a year. Meetings took place during the period and were attended as follows:

Member	25-Apr-18	20-Jun-18	26-Sept- 18	28-Nov-18	23-Jan-19
Rima Makarem	Р	Р	Р	Р	А
Tim Irish	Р	Р	Р	Р	Р
Elaine Inglesby- Burke	A	Ρ	A	Ρ	Ρ
Sheena Asthana	Р	Р	Р	Р	Р

## Table 3 - attendance at meetings in 2018/19

42. The quorum for meetings of the committee is three. The table above shows all meetings of the committee during the period were quorate.

## Conclusion

43. Putting all of the above into context, we concluded that NICE is well managed with effective processes and controls, strong financial, procurement, HR, information, and digital service management, and a skilled and committed workforce, that provides a resilient and strong base for the challenges ahead.

## Appendix 1

## Table 4 - Explanation of internal assurance levels

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

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May 2019

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Audit and Risk Committee

## Terms of reference and standing orders

## Terms of Reference

- 1. The purpose of the audit and risk committee is to provide an independent and objective view of governance and internal control at NICE and to advise the board accordingly.
- 2. The committee's duties and responsibilities are to:
  - Review the adequacy and effectiveness of NICE's corporate governance arrangements, in particular those relating to:
    - o risk management
    - o information governance and <u>cyber</u> security
    - o the use of resources and internal financial controls
    - o the safeguards against fraud, corruption and bribery
    - o the raising and investigation of concerns (whistle-blowing)
    - the declaration and management of interests by those working for NICE as an as an employee or through contributing to the advisory committees.
  - Review the annual report and accounts, together with any accompanying internal audit opinion and external audit opinion, with particular focus on the annual governance statement, consideration of key accounting policies and practices, estimates and judgements and the quality of the year-end financial statements, unadjusted mis-statements, major judgemental areas, and significant adjustments arising from the audit.
  - Ensure there is an effective internal audit and external audit function in place which meets mandatory standards and provides independent assurance to the committee, chief executive and the board.
  - Review the findings of internal and external audit, and review management's responses to recommendations made.
  - Periodically review its own effectiveness and report the results to the board.
- 3. To meet these responsibilities, the committee will:
  - review the risk register each quarter
  - review NICE's information governance and IT security arrangements
  - receive an annual report on breaches of NICE's policies on declaring and managing interests
  - review the standing financial instructions, standing orders, and reservation of powers to the board and scheme of delegation
  - approve the internal and external audit work plans annually and review

performance against those plans

- consider the appointment and dismissal of the internal auditor within the authority delegated to NICE.
- 4. The committee will recommend to the board approval of NICE's annual report and accounts.
- 5. The committee will formally report annually to the board on the outcome of its work on the effectiveness of NICE's governance and internal control arrangements.
- 6. In order to meet its duties and responsibilities the committee is authorised by the board to:
  - seek any information it requires from any employee
  - obtain outside legal or other independent professional advice
  - invite any non-NICE staff members with relevant experience and expertise to its meetings if it considers this necessary.

## **Standing Orders**

### General

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

### Membership

- 8. The committee will comprise a minimum of three and a maximum of five non-executive directors of NICE, one of whom will be appointed as chair of the committee. The composition of the committee will be given in NICE's annual report and accounts.
- 9. The chair of NICE shall not be a member of the committee.

### Other attendees

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

### Quorum

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

## Voting

12. The decisions of the audit and risk committee will normally be arrived at by a consensus of those members present. Before a decision to move to a vote is made, the chair will, in

all cases, consider whether continuing the discussion at a subsequent meeting is likely to lead to a consensus.

- 13. Voting, where required, will be by show of hands and decisions determined by a simple majority of those members present at a quorate meeting.
- 14. The chair of the meeting will be included in the vote and in the event of a tie, the chair will have a second, casting vote.

### Arrangements for meetings

- 15. All members must make a declaration of any potential conflicts of interest that may require their withdrawal in advance of each meeting.
- 16. The audit and risk committee shall meet a minimum of four times a year in January, April, September and November. There will be an additional meeting in June solely for the purpose of reviewing the annual report and accounts.
- 17. The committee shall meet in private session with the internal and external auditors respectively, <u>and together, as the chair requests</u>, to consider matters of internal control or any other matter within its terms of reference.
- 18. No other business shall be discussed at the meeting except at the discretion of the chair.

### Minutes

- 19. The minutes of audit and risk committee meetings shall be formally recorded by the corporate governance & risk manager and submitted to the next meeting for approval.
- 20. The minutes of audit and risk committee meetings shall be submitted to the board. The chair of the committee shall draw to the attention of the board any issues that require disclosure to the full board, or that require executive action.
- 21. Minutes will be published on the NICE website, subject to the redaction of any confidential or otherwise exempt material.

### Other matters

- 22. The corporate office will provide support to the meetings.
- 23. The internal and external auditors shall have direct access to the chair.

### Interpretation or suspension of standing orders

- 24. During the course of a meeting, the chair of the audit and risk committee shall be the final authority on the interpretation of the standing orders.
- 25. Except where this would contravene any statutory provision, any one or more of the standing orders may be suspended at any meeting provided that a simple majority of those present and eligible to participate vote in favour of the suspension.
- 26. Any decision to suspend standing orders will be recorded in the minutes of the meeting and no formal business may be transacted while standing orders are suspended.

## Review of terms of reference and standing orders

27. These terms of reference and standing orders will be reviewed annually. The next review date is April 2020.

National Institute for Health and Care Excellence Audit and Risk Committee terms of reference and standing orders April 2019

## Revisions to Standing Orders, Standing Financial Instructions, and Reservation of Powers to the Board and Scheme of Delegation

This report details proposed changes to NICE's Standing Orders, Standing Financial Instructions and Reservation of Powers to the Board and Scheme of Delegation, following an annual review.

The Board is asked to approve the amendments to the governance documents.

Ben Bennett

Director, Business Planning and Resources

May 2019

## Introduction

 The Board is asked to review and approve proposed changes to NICE's Standing Orders (SOs), Standing Financial Instructions (SFI) and Reservation of Powers to the Board and Scheme of Delegation, following an annual review and approval by the audit and risk committee.

## Background

2. NICE is required to review its SOs, SFIs and Reservation of Powers to the Board and Scheme of Delegation annually. This review has taken place and a number of updates are proposed below.

## Key issues and changes

3. The suggested updates are summarised in the tables below. The full documents have been circulated to the Board electronically.

Section	Proposed change	Rationale
Failure to comply with Standing Orders (SO 10 & 11)	Text has been added to state that a failure to comply with SOs may be regarded as a disciplinary matter which following investigation under the disciplinary policy and procedure, could result in dismissal. Details of non-compliance will be reported to the audit and risk committee.	Included for clarification and to bring the SOs in line with the SFIs
Record of attendance (SO 65)	Moved into the 'meetings' section as more logical position than 'variations to SOs'.	Presentational purposes
Appointment of committees and joint committees (SO 87)	Re-wording of the text.	For simplification
Counter-fraud and anti-bribery and corruption (SO 95 and 96)	Inclusion of corruption.	Recommended by the DHSC Anti-Fraud Unit
Formal competitive tendering (SO 109)	Amended to confirm when seeking tenders, costs should normally be given a 50% assessment weighting in regard to the other selection criteria which are being applied.	In response to recommendations from the investigation of a whistleblowing case

## Table 1 Standing orders (SOs)

Section	Proposed change	Rationale
Formal competitive tendering (SO 114 - 117)	Updated text to replace NICE's 'buying and purchasing guide' with procurement team's internet pages.	General updating
Quotations and tenders (SO 121)	Additional text added to confirm cost should normally be given a 50% assessment weighting in comparison to other factors being evaluated.	In response to recommendations from the investigation of a whistleblowing case
Contracts (SO 127)	New SO added to require the senior management team to receive regular updates on contract management performance, new supplier procurement and contract performance for all significant contracts.	Recommendation following whistleblowing case and internal audit of the revised policy

## Table 2 Standing financials instructions (SFIs)

Section	Proposed change	Rationale
General (SFI 3)	Updated text to replace NICE's 'buying and purchasing guide' with procurement team's internet pages.	General updating
General (SFI 5)	Text has been added to state that a failure to comply with SFIs may be regarded as a disciplinary matter which following investigation under the disciplinary policy and procedure, could result in dismissal.	To align with Standing Orders
Terminology (SFI 9)	Amend description of "employee" in line with other NICE policies.	To align with other policies
Responsibilities and delegation (SFI 15 (d))	Extending the responsibilities of the BP&R director to cover all statutory obligations.	For completeness
Responsibilities and delegation (SFI 16 (e))	Added the requirement for all directors and employees to comply with procurement advice.	General updating
Internal audit (SFI 24)	Role of internal audit updated to reflect risk- based approach to auditing.	General updating
Budget control and reporting (SFI 39)	Added statement that breaches of SFIs may result in removal of budget delegations.	For completeness

Section	Proposed change	Rationale
Budget control and reporting (SFI 40 (c))	Clarification that underspends on allocated budgets cannot be redirected to other activities without prior approval.	For clarification
Bank accounts – general (SFI 45)	PayPal accounts amended to online merchant accounts.	General updating
Bank and online accounts (SFI 45 (d))	Added direction for the BP&R director to only draw down the amount required to pay liabilities associated with allocated funding.	For clarification
Bank accounts - tendering and review	Deleted responsibility of the BP&R director to regularly review NICE's banking arrangements to ensure best value for money and seeking competitive tenders every five years.	NICE's banking arrangements are directed by the DHSC
Remuneration and terms of service (SFI 60)	Remuneration committee responsibilities updated to reflect the committee's current terms of reference.	For consistency
Funded establishment	Text deleted as repeats the section on business plan, budgets and control.	General updating
Employee appointments (SFI 64)	Text amended to state that any regrading of a post must be approved by the chief executive, unless otherwise delegated to the business planning and resources director via the star chamber approval process. Previously the text referred to approval by the chief executive unless delegated to a director.	To reflect current process
Processing of payroll (SFI 66)	Additional text noting that NICE's payroll is provided externally and the BP&R director's responsibilities for controls and VFM.	For completeness
Processing of payroll (SFI 68 (h) & (i))	Deleted reference to salary payments being made to employees by cheque.	General updating
Processing of payroll (SFI 70 & 71)	Additional text to reinforce the importance of line managers informing the BP&R director of staff leavers and completing the correct forms to cease salary payments.	General updating
Delegation of authority (SFI 75)	Additional text to confirm that the finance team will maintain a list of authorised signatories, agreed by the chief executive.	For completeness
Requisitioning, order of goods (SFI 78)	Additional text requiring requisitioners to raise a purchase order or obtain a contract number.	For completeness
Requisitioning, order of goods (SFI 83 (c))	Relevant HM Treasury guidance updated.	General updating

National Institute for Health and Care Excellence Revisions to Standing Orders, Standing Financial Instructions, and Reservation of Powers to the Board Date: 22 May 2019 Reference: 19/050

Section	Proposed change	Rationale
Requisitioning, order of goods (SFI 83 (d))	Reference added to NICE's policy on acceptable gifts and hospitality.	For completeness
Requisitioning, order of goods (SFI 83 (I) & (m))	Text added to clarify that corporate credit cards should only be used when usual payment methods are not applicable and that records should be completed and returned to the finance team.	For completeness
Asset registers (SFI 95 (a))	Removal of 'architect's' certificates and replaced with 'professional' certificates of quality assurance.	General updating
Asset registers (SFI 95 (b))	Text replaced with new SFI 95(b) updated to include reference to IFRS 16.	General updating
Disposals and condemnations (SFI 116 (a) & (c))	Text added to clarify asset disposals will be carried out by the IT or facilities team and immediately reported to finance for updating the fixed asset register.	General updating
Losses and special payments (SFI 118 & 119)	Inclusion of statement that any action to be taken in response to a suspected fraud is outlined in NICE's counter-fraud and anti- bribery and corruption policy. Clarification that any individual suspecting or identifying a loss has a duty to report this to a line manager or other senior manager, who will immediately inform the business planning and resources director, who will assess whether a criminal offence has been committed and if so, inform the DHSC Anti-Fraud Unit and the chair of the audit and risk committee.	Following updates to the counter-fraud and anti-bribery and corruption policy.
Information technology (SFI 126 (a))	Inclusion of the General Data Protection Regulation and updating the text to refer to the Data Protection Act 2018	Updating legislation
Information technology (SFI 129 - 130)	Replaced computer services and systems with IT/digital services and systems.	General updating

Section	Proposed change	Rationale
Regulation and control (para 24)	Replaced executive powers with decision making powers.	Simplification
Strategy, business plans and budgets (para 31)	Replaced 'defining' the strategic objectives with the Board's role being to 'approve' NICE's strategic objectives.	General updating
Direct operational decisions (para 40)	The Board's authority limit to approve extra contractual individual staff compensation payments reduced from £50,000 to £20,000 in line with the DHSC and HM Treasury permissions.	Correction
Financial reporting arrangements (para 43)	Removal of text relating to banking arrangements as NICE is directed by the DHSC and therefore this is not a decision reserved to the Board.	Clarification

## Table 3 Reservation of powers to the board and scheme of delegation

## Conclusion

- 4. The Board is asked to:
  - approve the amendments to the governance documents.

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May 2019

# National Institute for Health and Care Excellence Directors' progress reports

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

Alexia Tonnel, Director, Evidence Resources Directorate (Item 12)

Dr Paul Chrisp, Centre for Guidelines (Item 13)

Meindert Boysen, Director, Centre for Health Technology Evaluation (Item 14)

Jane Gizbert, Director, Communications (Item 15)

Professor Gillian Leng, Director, Health and Social Care Directorate (Item 16)

May 2019

## **Evidence Resources progress report**

- 1. This report sets out the performance of the Evidence Resources directorate against our business plan objectives as the end the 2018/19 financial year. It also highlights the usage performance of the NICE Evidence suite of on-line services as the end of March 2019.
- 2. The Evidence Resources Directorate comprises three teams which provide a range of functions to NICE:
  - The Information Resources team provides access to high quality evidence and information to support guidance development. It also commissions key items of content made available to the NHS via the NICE Evidence Services.
  - The Intellectual Property (IP) and Content Business Management team manages the range of activities involved in granting permissions to use NICE's IP and content.
  - The Digital Services team delivers NICE's digital transformation activities and maintains all the live digital services of NICE.

## Performance

 Performance against the Evidence Resources objectives for 2018/19 is summarised for each team of the directorate. We also provide an update on our work pertaining to the assessment of Digital Health Tools. Finally, we provide some usage statistics about NICE Evidence Services.

## Information Resources update

- 4. A key objective of the Information Resources team in 2018/19 was to support and undertake the re-procurement of the National Core Content (NCC) on behalf of Health Education England (HEE). This was completed as planned and the new NCC collection has been available since 1 April 2019.
- 5. In March 2019, our team of information specialists adopted the new Evidence Management platform of NICE. The team had supported the development of the new platform through the year and this was a key milestone for the joined team.
- 6. In the context of the objective to explore new methods and approaches, a new process for identifying primary data and primary data sources has been established by the team and data are being routinely identified for guidelines; the

approach will evolve as NICE's methods and processes to data analytics develop. In addition, two members of the information services team have published a book – <u>Systematic searching: practical ideas for improving results</u> – which captures current best practice in searching for evidence and looks to the future in terms of challenges and opportunities for the profession.

## Intellectual Property (IP) and Content Business Management update

7. During 2018/19, the team has responded to numerous requests to re-use NICE content. 145 quotes to re-use NICE content were issued and 54 content and 8 syndication licences were signed. The total income invoiced in 2018/19 for content re-use services amounts to £198,766 against an income target of £75,000. Of this total, £7,500 relates to Knowledge Transfer Services prior to its transfer to Scientific Advice in September 2018 and £4,800 to work carried out by the Publishing Team under the Content Assurance Service.

## **Digital Services update**

8. There are 4 principal objectives underpinning the work of the Digital Services team in 2018/19. Key achievements during 2018/19 are set out against these objectives are addressed in turn.

## Delivery of strategic digital services projects:

- 9. The Evidence Management platform (delivering web tools for searching evidence, systematic review needs and building an evidence surveillance capability) was further developed in a new cloud infrastructure throughout the year. Since January 2019, all new guidance should be started using the EPPI R5 software, offering a consistent platform across NICE. Work is on-going to put NICE's Guideline collaboration centres on the same platform.
- 10. The Comment Collection project (work to bring efficiencies to the external consultation process) continued during 2018/19 culminating in the service being successfully assessed by the Government Digital Service (GDS) Service in April 2019. Training has been completed across several teams and the service is being used across surveillance guidelines, public appraisal consultation documents (ACDs), diagnostics consultation documents (DCDs), medical technologies evaluation programme (MTEP) and quality standards (QS). Work to develop further features to support more complex consultations will continue in subsequent phases of development in 2019/20.
- 11. Work to support configuration of a new identity management solution to replace our current in-house 'NICE Accounts' solution is well underway. We appointed an external consultancy to collaborate and accelerate this work in close partnership with an internal digital services team. This partnership was completed in March 2019 with significant progress to the overall solution having

been made. Over the course of 2019/20 each digital service of NICE will be sequentially migrated onto this new cloud-based authentication solution.

- 12. To support the NICE Connect project, two short focused pieces of consultancy work were undertaken in the last quarter of the year. These two pieces covered: first, advice on approaches and supporting technology to enable authoring and management of complex content and second, assessment of NICE's data management capability across NICE. Both pieces concluded in March with reports and final presentations. The conclusions will inform the development of the NICE Connect Project vision.
- 13. In September 2018, the NICE Digital Services team took over the management of the Contact Database and Planning Tools previously managed by NICE IT. The transition was complex but managed successfully. A 'discovery phase' to look at the longer-term solution to support stakeholder management at NICE commenced before the end of March 2019. In line with the recommendations of the external data management consultancy, the development of an Institute-wide stakeholder management capability should be a priority for 2019/20 and beyond.

### Live services maintenance and improvements:

- 14. NICE Digital Services operated within the service levels (99.70%) agreed with DHSC for availability (uptime) with 99.94% average performance throughout the year.
- 15. Across the 12 months of 2018/19, 378 defects were closed. In the same period, 89 Change Control Requests were completed.
- 16. A strategic review of live services, designed to support prioritisation of capacity and resource to maintain live services, was completed during the year. To date, the retirement of two services has been agreed by SMT: first, the retirement of the NICE guidance app in September 2018 and then the retirement of the ROI (Return on Investment) tools in February 2019.
- 17. During 2018/19, the Digital Services team, through better communication with their business owners, and better prioritisation of business needs, have significantly reduced investment in the maintenance of existing life services. This has allowed more resources to be invested in new development. The % of 'chargeable' resources allocated to ongoing live services maintenance dropped from 60% in 2017/18 to just 34% in 2018/19. This reduction has been delivered despite the transition of the Planning tools and Contacts Database live tools from the NICE IT team to the Digital Services team in September 2018. These services have required significant levels of ongoing maintenance including to support the new technology appraisal charging processes.

#### Team productivity improvement:

- 18. Recruitment update: 10 vacant roles were advertised during the year, 7 of which were recruited to by the end of March 2019. 5 members of staff resigned during the year. A new recruitment campaign is on-going to fill in 5 more roles in the first quarter of 2019/20. The use of external contractors has very significantly reduced over the last 2 years. As of 1 April 2019, only one contractor was providing specialist services to NICE.
- 19. Talent management update: A new online training package with high coverage in specialist digital training courses was procured in partnership with the HR team. It will support staff development across our range of digital disciplines from April 2019.

#### Promoting external collaborations:

- 20. Our current provider of cloud hosting services has continued to share information with our Digital Services team to promote their suite of artificial intelligence cloud services. We have identified use cases to undertake rapid testing of some of these capabilities and assess their potential to support process improvements.
- 21. Our joint research project with Kings College London to research and develop provenance models for guidance has progressed through planning stages. Work to identify key use cases relating to updating NICE guidance are underway.
- 22. Alongside the GIN conference in 2018 NICE facilitated a related event to bring together key people involved in the development of technology and standards relating to guideline development. This was jointly organised with the GIN-Tech Working Group and enabled us to bring together international guideline development tool providers and researchers with NHS Digital and NIHR. The meeting identified the need to formally define 4 levels of guidance structure (ranging from text to computable guidelines).
- 23. NICE Digital services staff have continued conversations with NHS Digital, Kings College London and Charles Friedman regarding a collaborative research project further exploring the Learning Health System for the UK. A key aspect of this is the definition of a computable knowledge object which will need to inform and be informed by the structure of NICE's recommendations.

# 'Evidence for Effectiveness' standards for digital health technologies update

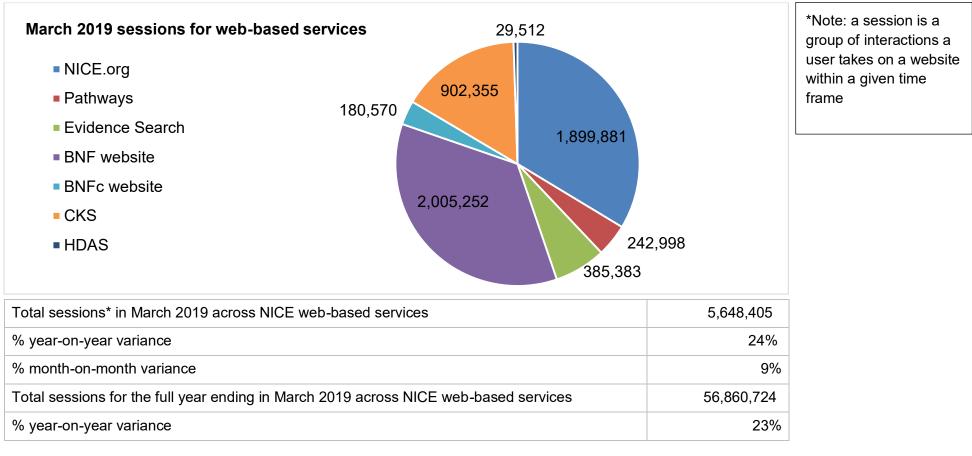
24. An important objective of the directorate, in partnership with the Centre for Health Technology Evaluation, was to work with NHS England, Public Health England, MedCity and Digital Health London to develop standards for assessing the effectiveness and economic impact of Digital Health Technologies (DHTs). Following an extensive period of engagement with industry, academics and clinicians an initial version of the evidence standards framework was published on 10 December 2018 along with a questionnaire for users to offer feedback. The framework was generally well received across the system and an updated version reflecting the feedback received was published on 4 March 2019. This included a supporting information pack consisting of case studies, a guide to conducting an economic assessment, a budget impact tool and links to relevant data sources and educational resources. The updated version of the framework was published to coincide with the publication of the updated version of code of conduct for data driven health and care technologies published by the Department for Health and Social Care in February 2019, which refers directly to the evidence standards framework published by NICE. Work is ongoing to ensure the framework is taken up and used by national agencies, manufacturers and innovators, commissioners and investors.

25. In 2019/20 NICE has been commissioned to undertake a pilot to develop medtech guidance for digital health technologies and to further develop the evidence standards framework to ensure its wider system use.

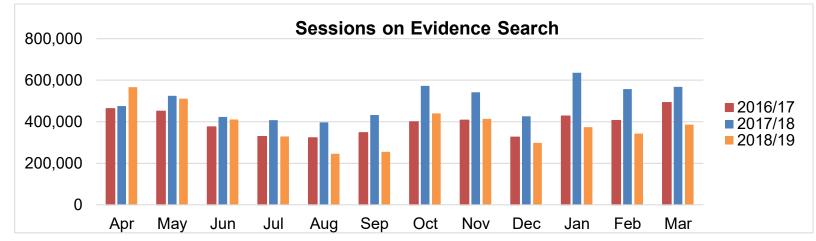
## **Performance statistics for NICE Evidence Services**

26. Figure 1 and table 1 below summarise the position of all NICE's digital services at the end of March 2019, contrasting the relative size of the externally facing services of NICE, measured in number of 'sessions'. This financial year NICE digital services have received almost 57 million sessions; this represents a 23% increase in comparison with 2017/18.

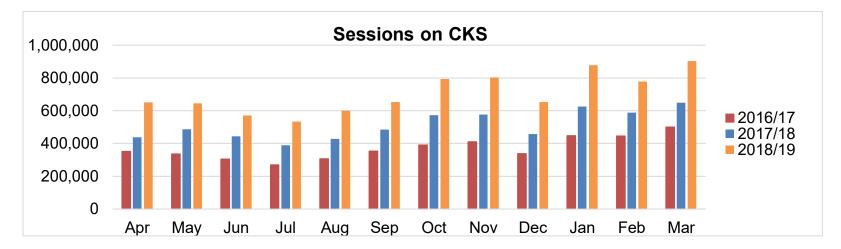
#### Figure 1 and table 1: Overview of NICE's digital services performance as of March 2019

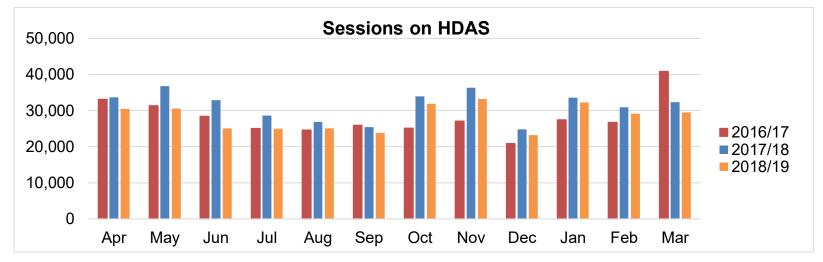


- 27. Figures 2-4 below detail the performance of the 3 services which provide access to evidence beyond that produced by NICE: Evidence Search, Clinical Knowledge Summaries (CKS) and HDAS.
  - CKS continues to grow year-on-year and in this financial year it has received 38% greater sessions than in 2017/18.
  - Evidence Search ends the financial year with a decrease of 23% in sessions in comparison with the previous year.
  - HDAS has also remained behind last year's traffic with 10% fewer sessions.

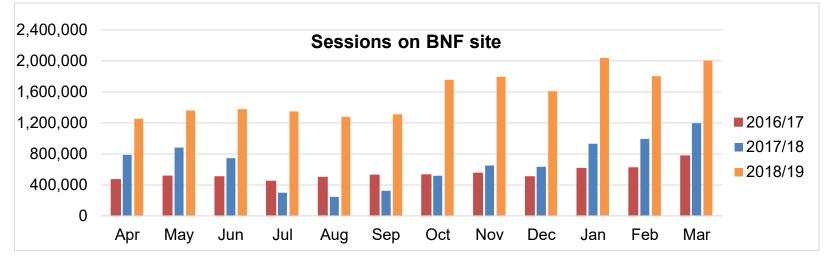


#### Figures 2-4: Performance of services providing access to 'other evidence' as of March 2019

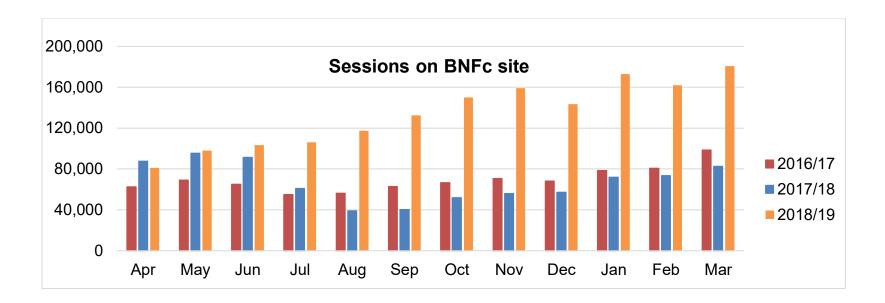




28. Figures 5-6 illustrate the performance of our BNF microsites. BNF and BNFc microsites have experienced a major growth this financial year (+131% and +99% of sessions respectively) and their trends suggest that they could carry on growing.



#### Figures 5-6: Performance of services providing access to BNF content as of March 2019



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## National Institute for Health and Care Excellence

### **Centre for Guidelines progress report**

1. This report sets out the performance of the Centre for Guidelines against our business plan objectives during March 2019. It also highlights areas of work and specific guidelines that are felt to be of particular note for the Board.

## Performance

- Two clinical guidelines were published during March 2019, no public health, social care or antimicrobial prescribing guidelines were scheduled for publication during March 2019. A total number of 29 guidelines were published in 2018-19, 16 clinical, 3 public health, 2 social care and 8 antimicrobial prescribing guidelines. All other deliverables are on track.
- 3. Eight surveillance reviews were published during this reporting period, of which 7 were exceptional reviews. A total of 66 surveillance reviews were completed in 2018-19. All other deliverables are on track.
- 4. The Surveillance review team has been actively testing the new comments collection system and engaging with digital developers about its use and ongoing development.
- 5. An evaluation of the impact of National Institute for Health Research (NIHR) reports on surveillance reviews has been completed and shared with colleagues at NIHR. The evaluation provides useful feedback on how we use NIHR reports, including such detail as the number of NIHR reports prompting an exceptional surveillance review and the number of subsequent guideline updates. The report will also help inform the ongoing working relationship with the NIHR.
- 6. The methods and processes for the scoping and post consultation/validation phases for partial updates were completed and implemented in Q1. Taken together, these phases are 6 months shorter than a standard full guideline and the development phase is half the standard length.
- 7. The development of social care guidelines transitioned to the National Guideline Alliance (NGA) in April 2018. Two social care guidelines published in 2018/19 and 3 were underway at year end. Quality assurance processes are in place throughout development of each social care guideline.
- 8. Business plans for all external contractors, including funding details and measurable objectives, were agreed and finalised for the 2019/20 business year.

- 9. Quarterly review meetings were held throughout 2018/19 with both internal and external guidance developers and suppliers. All contractors were within budget and delivered their key objectives by year end. Risk ratings were low and medium. Documentation for the 2019/20 business year was sent to contractors, for them to report against at quarterly review meetings.
- 10. A new contractor has been appointed to package and distribute the BNF and BNFC. The transition from the previous contractor is now complete. The subcontract to print the BNF and BNFC is based in Germany. We have documented the risks and mitigations that the sub-contractor has in place to reduce the impact of the UK's plans to exit the EU. An ongoing review of the risks will be maintained.
- 11. We continue to evaluate the Discretely Integrated Condition Event (DICE) simulation package, as part of the Improved Methods and Actionable Tools for enhancing Health Technology Assessment (IMPACT HTA) EU project by rebuilding existing guideline models. The aim is to assess whether using a standard modelling framework will bring efficiencies to building and quality assuring health economic models developed for guidelines.
- 12. The Methods and Economics team was represented at the MIRROR annual meeting in Barcelona in March 2019.
- 13. A meeting with DHSC Policy Research Unit in Quality Safety and Outcomes took place in March 2019 to agree a project plan on exploring core outcome sets and core indicators in public health and social care.
- 14. The Methods and Economics team is leading two cross-organisational methods projects that will inform the work of NICE Connect on strength of recommendations and treatment sequencing. The steering group for the first of these projects met in March 2019.

## Notable issues and developments

- 15. The draft updated guideline on management of hypertension, which recommends a lower threshold for treatment to prevent strokes and heart attacks, was published for consultation on 8 March. The draft recommendations were generally well received, representing a balance between improving treatment but not as aggressively as in some other countries.
- 16. On 28 March we published a summary of NICE guidance and other safety advice on valproate. The summary brings together NICE's recommendations for this drug across all of our guidelines, plus advice on safe prescribing from other sources (for example, MHRA safety alerts, the BNF, summary of products data and information from the Driver and Vehicle Licensing Agency) in an easy to

access <u>visual summary</u>. The summary was produced following the strengthening last year of restrictions on use of valproate by the Medicines and Healthcare products Regulatory Agency (MHRA). We continue to work closely with the MHRA to ensure our recommendations align with safety advice.

17. Dialogue continued in March with members of the British Thoracic Society (BTS) and the Scottish Intercollegiate Guidelines Network (SIGN) to discuss a collaborative approach to developing guidance on asthma, building on a constructive meeting in February.

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May 2019

## National Institute for Health and Care Excellence

### **Centre for Health Technology Evaluation progress report**

1. This report sets out the performance of the Centre for Heath Technology Evaluation (CHTE) against our objectives during the 2018/19 business year. It also highlights key developments in the centre during that period.

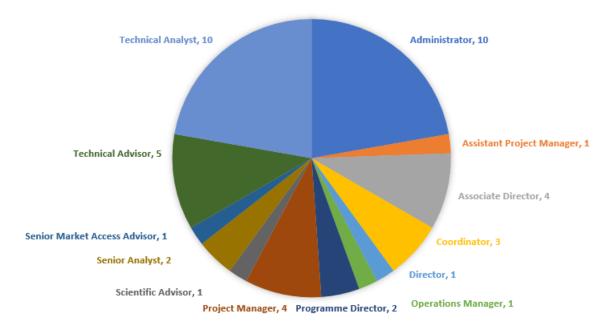
## Notable developments

- During 2018/19 CHTE prepared for the launch of two key initiatives: charging for technology appraisals and highly specialised technologies evaluations, and HealthTech Connect. Charging has been implemented on 1 April 2019, and HealthTech Connect had its initial "soft" launch in February and full launch in April 2019.
- The publication of the Long Term Plan, the second Life Sciences Sector Deal, and the 2019 Voluntary Scheme for Branded Medicines Pricing and Access in reinforced the value of NICE's offer to the life sciences sector. CHTE provided a very significant contribution to the development of these policy documents in 2018/19.
- 4. Interest from members of parliament in CHTE's work remains significant, culminating in the team responding to 44 parliamentary questions (PQs), participation in events organised by various All Part Parliamentary Groups (APPGs), including on access to medicines and medical devices, by providing evidence to the Health and Social Care Select Committee, and to the Independent Medicines and Medical Devices Safety Review (IMMDSR).

## Performance

**Centre Coordination Team** 

5. During the business year 2018/19, CCT engaged in recruitment activities for 45 positions within CHTE, and the Science, Advice and Research Programme. The type of roles can be seen below.



6. In 2018/19, 15 recruitment campaigns for membership across 8 committees were completed; 5 lay representatives and 27 professional members were recruited, while 2 campaigns are still in progress.

### Commercial and Managed Access Programme

- 7. The Commercial and Managed Access Programme (CMAP), established during 2018/19, includes the Cancer Drugs Fund (CDF) team and the Commercial Liaison Team (CLT). The current focus of the CLT, working in close collaboration with colleagues in the NICE TA and RIA teams, and the NHSE commercial medicines directorate, is to establish the working processes needed to deliver a seamless interface for all commercially related conversations between companies, NHSE and NICE.
- 8. The CDF team had 15 ongoing or completed managed access agreements in the work programme for the 2018/19 business year, which exceeds the current target of up to 14 managed access agreements.
- 9. In 2018/19 PASLU issued 38 pieces of advice to NHS England against a target of 30.

### **Commissioning Support Programme**

- 10. To the end of March 2019, work continued on the remaining 11 topics within the programme, with 3 of these expected to be considered at NHS England's CPAG prioritisation meeting in May and the remainder at CPAG's November 2019 meeting.
- 11. Following publication of the <u>2019 Voluntary Scheme</u> for branded medicines pricing and access, we reflected on the impact on the Commissioning Support

Programme which is that there will be an expected increase in the number of technology appraisals and highly specialised technology evaluations carried out by NICE.

#### **Diagnostics Assessment Programme**

- 12. In 2018/19, the Diagnostics Assessment Programme published 3 pieces of diagnostics guidance and supported the development of 3 pieces of technology appraisal guidance and 1 piece of highly specialised technologies guidance. The team also supported the review and sign off of Medtech innovation briefings.
- 13. The programme is continuing to work with key system partners in developing evaluations for the Genomic Medicine Service, supporting the work of the Accelerated Access Collaborative to facilitate the rapid uptake of technologies included in diagnostics guidance and the UK AMR Diagnostics Collaborative. The work of the Collaborative is currently postponed while NHS England review the programme of work and align with the future requirements of the AMR National Action Plan.
- 14. During 2018/19 a number of products recommended in diagnostics guidance were included in national adoption policy initiatives. For example, placental growth factor (PIGF) based testing for suspected preeclampsia (DG23), high sensitivity troponin tests for early rule out of myocardial infarction (DG15) and quantitative faecal immunochemical tests for colorectal cancer (DG30) were designated as Rapid Uptake Products by the Accelerated Access Collaborative. Molecular testing for Lynch syndrome in people with colorectal cancer (DG27) has been included in the testing directory of the Genomic Medicine Service which is directly funded by NHS England.

#### Interventional Procedures Programme

15. The Interventional Procedures Programme has exceeded its target publication for 2018/19 to 36 guidance publications, where the target was 30. This has been achieved with the same level of staffing by redesigning and streamlining the processes whereby newly notified procedures are progressed more efficiently and by ensuring that IPAC meets 12, rather than 11, times a year.

#### Medical Technologies Evaluation Programme

- 16. In 2018/19, the Medical Technologies Evaluation Programme published 5 pieces of medical technologies guidance and 38 Medtech innovation briefings.
- 17. The programme selected 3 new topics for evaluation in March. This represents an increase in the number of topics identified and selected for evaluation by the programme following closer working with NHS England on identifying topics

which the NHS would benefit from guidance on. All are due to publish the 2019/20 financial year.

- 18. During 2018/19 a number of products which feature in medical technologies guidance were included in national adoption policy initiatives. For example, NHS England selected Heartflow (MTG32) and SecurAcath (MTG34) for inclusion in the Innovation and Technology Payment 2018/19 and HeartFlow and Urolift (MTG26) were designated as Rapid Uptake Products by the Accelerated Access Collaborative.
- 19. Fourteen research commissioning projects were active during 2018/19 including initial feasibility studies, ongoing audits and primary clinical research, and analysis and reporting of completed studies prior to publication. Two research protocols were published during 2018/19 based on research recommendations in <u>DG19</u> and <u>DG22</u>.
- 20. An updated version of the Evidence Standards Framework for Digital Heath Technologies was published early March following stakeholder comments and feedback. There was generally a warm welcome for the content and methods, with a range of future priorities identified. This version will publish with planned supporting resources, including case studies, a budget impact analysis tool and a guide to budget impact analysis and cost consequences analysis.

### HealthTech Connect

21. HealthTech Connect, the secure online system for identifying and supporting health technologies as they move from inception to adoption in the UK health and care system, was subject to a soft launch in late February 2019. Since then, over 100 companies have registered to use it to support adoption of their medical technologies, devices and diagnostics, via outputs from NICE and NHS England commissioning policies.

### **Observational Data Unit**

22. The Observational Data Unit has submitted 4 Commissioning though Evaluation reports to NHS England in 2018/19 (5 in total since the work began). Three procedures have received positive routine commissioning decisions already, the other 2 have positive draft recommendations.

### Highly Specialised Technologies

23. In the 2018/19 business year the highly specialised technologies programme published 1 piece of guidance; burosumab for treating X-linked hypophosphataemia in children and young people (HST 8). This is lower than the expected 3 due to the receipt of an appeal which was upheld for ID927 afamelanotide for treating erythropoietic protoporphyria and a third committee

meeting and delays to ID943 cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2. The programme currently has 8 ongoing topics which are expected to publish in the 2019/20 business year.

### **Technology Appraisals**

- 24. In the 2018/19 business year the technology appraisals programme published a total of 56 pieces of guidance. This number is lower than anticipated in the business plan as 21 scheduled topics were suspended or delayed during the business year for a variety of reasons:
  - 38% rescheduled due to regulatory approval timeline changes or suspended due to negative regulatory decisions
  - 38% delayed after draft guidance publication to accommodate on-going discussions with NHS England regarding commercial opportunities
  - 14% delayed for a short period of time at company request (resulting in publication in the 2019/2020 business year)
  - 10% suspended due to non-submission of evidence from the company.
- 25. Delays to the appraisal process are often outside of the control of NICE (i.e. delays to the regulatory approval process) and present a level of risk for the planning of the work programme. Delays have impacted individual appraisals in previous business years and by utilising effective planning and risk mitigation techniques, the TA programme has been able to deliver a high level of agility in order to meet the planned output. The 2018/19 business year demonstrates an unprecedented level of delay and impact on the work plan that could not be predicted and mitigated against. It remains a challenge to predict the individual appraisal topics that will be subject to a delay. The introduction of the new process in April 2018 is expected to minimise delays incurred due to the requirement for additional commercial discussions, by allowing opportunity for these conversations to occur before the first appraisal committee meeting. The impact of this should be seen in 2019/20 as more topics go through the new process. Even though the total figure for publication of final guidance is lower than anticipated, it is important to note that the programme worked on over 80 individual topics within the business year.
- 26. The first topic to be appraised using the new STA process, ID1175 durvalumab for maintenance treatment of unresectable non-small-cell lung cancer after platinum-based chemoradiation, was considered by the appraisal committee on 14 February 2019. This resulted in a recommendation for use within the CDF and the topic is expected to publish on 1 May 2019. The introduction of the technical engagement step prior to appraisal committee was key to achieving a

straight to FAD decision from the first meeting. A further 4 topics have been considered by committee under the new process since February, two of which have also received a positive recommendation from the first committee meeting.

27. In the 2018/19 business year 56 budget impact tests were completed. Of the 23 topics that met the BIT at the company evidence submission stage, 6 have reached final guidance publication; 3 technologies were recommended for use in the CDF, and 3 have been recommended for routine commissioning. NHS England have not needed to formally request a variation to the funding requirements for the routinely commissioned topics, as they have successfully addressed any affordability issues via commercial agreements with the companies involved.

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May 2019

## National Institute for Health and Care Excellence

## **Communications directorate progress report**

- This report sets out the performance of the Communications directorate against the directorate's business plan objectives over the course of the financial year 2018-19. The business plan objectives are listed on page 10.
- 2. These Communications Directorate business objectives are closely aligned to the NICE strategic objectives.
- 3. The Communications Directorate is responsible for ensuring NICE's stakeholders know about how NICE's work can help to improve quality and change practice in health and social care. We help to protect and enhance the reputation of NICE through daily contact with the public, media, parliamentarians and other key groups. And we contribute to ensuring NICE content meets users' needs and is easily accessible through our website and other channels.

## Performance

Communications support and strategic advice

- 4. In 2018-19 NICE published a suite of 7 impact reports, measuring the use of NICE guidance to improve outcomes in a range of areas including mental health, preventing falls, and delivering maternity services. To support the publication of these reports, we delivered a comprehensive programme of stakeholder communications to ensure that they were being viewed by frontline professionals, managers and commissioners in the relevant sectors.
- 5. Typically, we were able to leverage our contacts at royal colleges, professional bodies, arm's length bodies and charities, to ensure each report was shared with hundreds of thousands of health/care professionals. For example, the mental health report published in March was shared with over 800,000 mental health practitioners, commissioners and service users, via our contacts' newsletters, member bulletins, and social media channels.
- 6. We have also added the impact reports to the relevant topic pages on the website to improve their visibility.
- 7. Over the course of the year our stakeholder communications team worked with digital services colleagues to secure a platform to host webinars at NICE. We selected and tested a platform called Zoom, which can be used to host small interactive online meetings and large webinar events for up to 500 people. We

will be looking to trial this new technology to deliver interactive, online, corporate events in 2019-20.

- 8. Over the past 12 months we have successfully extended the range of publishing software we use to create more engaging and interactive content on the website. We have developed new ways to display data for example our new pages on technology appraisal statistics and has resulted in over 50% more views.
- 9. We worked with colleagues in HR to pilot a new approach to our recruitment communications. Through a series of engaging case studies and videos we achieved a 600 per cent increase in page views of our <u>recruitment pages</u> during the pilot campaign period and all roles were filled.
- 10. We developed a new bespoke area of our website to present our <u>guidance</u> <u>information on key topics</u> to sustainability and transformation partnerships which has received a lot of positive feedback.
- 11. Our corporate web pages aimed at the public were redeveloped. This included the creation of a new landing page <u>'NICE and the public'</u> to bring together the information about Public involvement at NICE and information about how NICE can help the public with their health/care. The new pages have resulted in a 26% increase in views.
- 12. We've created a number of videos and animations over the year to support our proactive communications work. Our video on lay committee members was played in the opening session at G-I-N to highlight our best practice in this area, and Health Education England are using our video on the Fellows and Scholars scheme in their own communications. We have provided advice to a number of ALBs who want to use our animations as a model for creating their own.
- 13. We developed <u>an interactive resource</u> to support the Quality Matters programme in social care which has been promoted by the Secretary of State for Health and Social Care and has proved popular with our audiences.
- 14. Over the past 12 months we have implemented a new multi-media marketing strategy for NICE Scientific Advice. We have extended the range of communication channels to include LinkedIn and a regular newsletter. We are achieving an average engagement rate of 4% on Scientific Advice LinkedIn posts which is above the industry average of 1%. The newsletter was launched in January and had an open rate of 50% and a click through rate of 20% which is also well above the industry average for this type of communication. Scientific Advice is achieving higher attendance at their events, an increase in visits to its web pages and more enquiries are being made about their services.

### Media

- 15. Sentiment percentages for media coverage over the course of the year were as follows:
  - Positive 80%
  - Neutral 11%
  - Negative 9%
- 16. Positive coverage was driven by our activity on the launch of the <u>antimicrobial</u> <u>prescribing guideline for acute cough</u>, the approval of dinutuximab beta to treat high-risk neuroblastoma, ruling <u>bronchial thermoplasty for severe asthma</u> is safe and effective, and approving the breakthrough CAR-T therapy tisagenlecleucel for treating young people with acute lymphoblastic leukaemia.
- 17. Other high-profile national news stories for NICE in 2018-19 included our new advice in April to help doctors quickly spot Lyme disease, so they can offer people NHS treatment as soon as possible, which was covered heavily on BBC outlets. We also received coverage in the Daily Express and Lancet for our antimicrobial prescribing guidelines, and the Daily Mail ran a positive story about a new NICE-recommended procedure to treat men with symptoms of an enlarged prostate.

### Social media and podcasts

- 18. Between April 2018 and March 2019 we have seen a 142% increase in followers on Instagram which now stands at 1,721. We have seen impressive engagement with our Facebook and LinkedIn posts, overall receiving 89,940 likes, shares or comments on Facebook and 16,194 likes, shares or comments on LinkedIn.
- 19. On Twitter our top tweet of the year was on our draft guidelines recommending a non-invasive MRI scan as a first-line investigation for people with suspected prostate cancer. It received 784 engagements (clicks, likes, shares, comments) and 37,967 impressions (number of times users saw the tweet). Our posts on Twitter are getting wide coverage overall receiving 11,326,301 impressions (number of times posts are seen) in 2018-19. Our YouTube page has continued to be popular among our following, with 43,377 views on our videos in the reporting period.
- 20. It has been over a year since we launched our podcast series, 'NICE Talks' and they continue to attract new listeners. During the financial year 2018-19 we received a total of 18,756 plays bringing our total plays on SoundCloud up to 28,350 plays.

### Audience insights

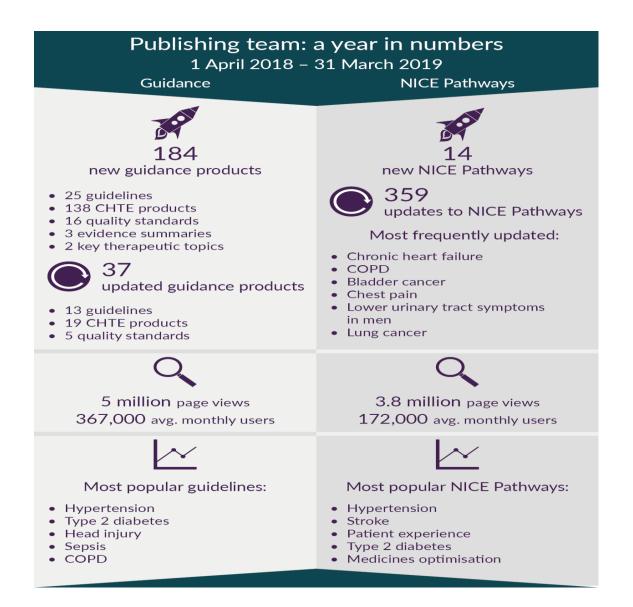
- 21. We have completed 8 in-depth audience research projects this year which included a review of our social care audiences and internal insights on our recommendation development process.
- 22. Five projects are currently underway which include NICE connect, NICE reputation research, and an evaluation of the involvement of people with learning disabilities in our quality standard process.
- 23. Over the past year we have also supported other teams to conduct 7 research projects including the NICE Principles consultation, HealthtechConnect user research, and a Public Involvement Programme consultation on health technology assessments.
- 24. We have delivered a strong mix of qualitative and quantitative insights with a total of 81 interviews, 3 focus groups, 4 observation sessions, and 143 surveys generating over 5000 responses.
- 25. In addition to research projects we carried out an audit of survey software that resulted in the approval of SNAP surveys being approved for organisational use. We have started to move all teams over to this to improve consistency and data management.
- 26. We also developed an insight hub on our intranet to support the dissemination of key findings and to provide advice to staff needing to carry out their own audience feedback work.

### Editorial and publishing

- 27. During 2018-19 we provided expertise and training to enable teams across NICE to produce quality content. As well as providing 'writing for NICE' training courses, this year we also devised and delivered tailored sessions on using and formatting templates.
- 28. We created and published a range of visually appealing materials to help explain guidance and related products. For example, we produced an accessible 'information for the public' page with icons and images, as well as an 'easy read' version and a video for learning disability guidelines.
- 29. We also developed new online summaries for other forms of guidance that are short, concise and use infographics and multimedia techniques, such as that produced for the Lyme disease guideline. <u>https://www.nice.org.uk/guidance/ng95/resources/visual-summary-pdf-</u> 4792272301. Other examples are the visual summaries on brain cancers and

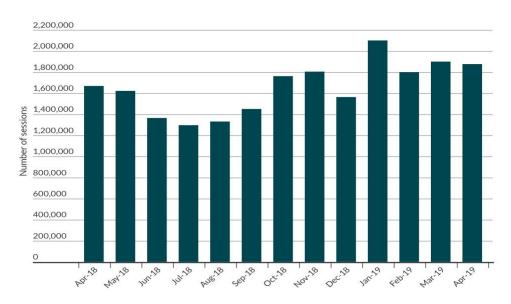
chronic heart failure. Our work on visual summaries was presented as a poster at the GIN conference.

- 30. Working with the system engagement team we developed a set of new online resources on a range of topic areas for sustainability and transformation partnerships (STP) and integrated care systems (ICS). These pull together NICE guidance, advice and tools that will help STPs meet the priorities they have identified for improving health and care in their areas.
- 31. Over the course of the year we continued to support NICE's work on shared decision making, providing editorial input on specific decisions aids (for example, <u>intrabeam radiotherapy for early breast cancer</u>), and helping develop a process guide on when to produce decisions aids as well as exploring options for presentation.
- 32. We also supported guideline developers on how to produce and present tables that summarise the pros and cons of different care options to help practitioners discuss these with people facing the decision. The first guidelines to include these were <u>brain tumours</u> and <u>early and locally advanced breast cancer</u>.
- 33. Working with colleagues in the Health and Social Care team, we helped to improve the currency of implementation tools and resources on the NICE website. We introduced a process where all resources are reviewed after 4 years and are either retained or withdrawn if they are no longer current.
- 34. We edited and published the updated <u>guidelines manual</u>. Alongside this, we produced a short summary document to show when and how people and organisations can get involved in the process.
- 35. Together with Public Health England and the NICE 'managing common infections' team we produced and published a <u>summary table</u> containing all the NICE and PHE guidance on managing common infections. This will be updated with new NICE antimicrobial prescribing guidelines as they are publish.
- 36. We worked with the digital services team on a web development project to change the presentation of <u>rationales</u>, which explain why committees made their guideline recommendations. They are now presented in an expandable box next to the recommendations they apply to, meaning viewers aren't taken away from the recommendations section when they want to find out why decisions were taken.



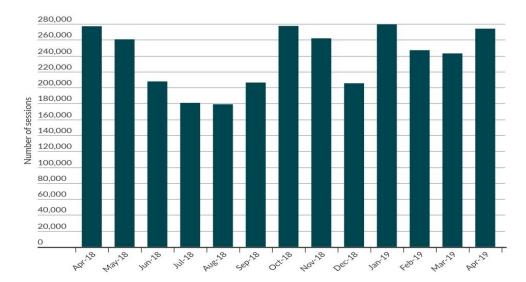
### Website performance

- 37. In the financial year 2018/19 we had 628,346 views of news stories on our website, a 28% increase on the previous year and the first time we have had more than 500,000 views in a 12 month period. Top news stories were a new treatment for men with an <u>enlarged prostate</u> with 42,507 views and new advice to help doctors spot Lyme disease with 33,607 views.
- 38. There were a total number of 19,645,618 sessions on the NICE website which represents a 9% increase on the previous year.



#### Number of sessions on nice.org April 2018 to April 2019

#### Number of sessions on Pathways April 2018 to April 2019



### Enquiries

- 39. We responded to a total of 12,048 enquiries during 2018/19. A combination of vacancies in the team and high demand on the service led to a significant backlog which reached 1,000 enquiries earlier this year. The backlog of enquires awaiting a response is now below 650 and reducing on a weekly basis.
- 40. The topic we answered most enquiries about was our ME/CFS guideline. Enquires mostly came from patients and carers concerned about our recommendations and the committee appointed to update the guideline.
- 41. Other high volume topics were:
  - Nusinersen for treating spinal muscular atrophy this was the most enquired about technology appraisal. Enquiries were mostly from patient group and individuals living with the condition asking for a positive outcome and also, a number questioning the appraisal route.
  - Lyme disease enquirers expressed concerned about diagnostic testing and treatment options for chronic Lyme.
  - Fertility problems: assessment and treatment enquirers asked about access to cycles of IVF as our guidance recommends 3 cycles but most CCGs have now limited the number of cycles they will fund.
  - Depression in adults: treatment and management enquirers expressed concerns about the ongoing update of the guideline.
  - Venous thromboembolism in over 16s: reducing the risk of hospitalacquired deep vein thrombosis - clarification questions on the recommendations and evidence base.
  - Managing medicines in care homes questions mainly from care home staff asking for advice, particularly on the use of monitored dosage systems.
- 42. Work is nearing completion on our CRM upgrade project. There have been delays due to the volume and complexity of data to be migrated to the new system but we now expect to be using the new system from the beginning of June 2019. Lessons learnt from this project are being fed into the discovery phase for the organisation-wide contact management project.

#### **Events**

43. We delivered a comprehensive programme of conferences, exhibitions and speaking engagements in 2018-19, including the NICE Annual Conference, which returned to Manchester for the first time in over a decade in June 2018,

and the Guidelines International Network (G-I-N) annual conference which we co-hosted with the Scottish Intercollegiate Guidelines Network (SIGN) in September.

- 44. The Annual Conference 2018 took place on 26 June at the Hilton Manchester Deansgate. The event was sold out to capacity (459 people, 45% private sector, 55% public/third sector) and more than 40 speakers from the NHS, ALBs and industry delivering a packed programme of high quality content. We had 9 exhibitors and 2 sponsors who delivered lunchtime fringe workshops.
- 45. The G-I-N 2018 Conference was delivered by NICE and SIGN's events teams on 11-14 September in Manchester. The event was a success, attracting 449 delegates from guideline-developing organisations and academia in 39 countries. The theme of the event was: "Why we do what we do: the purpose and impact of guidelines", and NICE's work/expertise was profiled prominently in both the plenary and parallel programme.
- 46. Our exhibitions programme in 2018-19 saw NICE representatives staffing information stands at 19 conferences, where they had the chance to meet hundreds of NHS, social care and public health professionals. On our stands at these events, we presented updates on new products and helped delegates troubleshoot issues they were having with implementing guidance locally. Of these 19 exhibitions, 12 were aimed at healthcare professionals, 1 for the public health sector, and 6 for social care.
- 47. Over the course of the year NICE staff spoke at over 50 conferences and external events, ranging from small, topic-specific seminars to the main stage at the World Healthcare Congress Europe.
- 48. The communications team also promoted the bi-monthly public board meetings and question time sessions. We developed productive relationships with communications team counterparts at the NHS Trusts, local authorities, and other health and care organisations in each host town, to cascade information about the forthcoming meetings to their staff, service users and patients.
- 49. Over the course of the 6 public meetings that took place in 2018-19, our communications efforts secured 373 (question time) and 205 (public board meeting) attendees in total. The best attended event was Oxford in July, with 75 people attending the question time session, and 36 the public board meeting.

#### Directorate resources

50. Capacity across a number of teams in the directorate is reduced as a result of a higher than usual turnover. Recruitment is underway for a number of posts and

we are reviewing workloads and priorities to maintain continuity in our support to the business.

## **Communication directorate objectives 2018-2019:**

Ensure guidance and related products from NICE are of the highest quality.

To be relevant and authoritative - engaging the media, digital audiences, key partners and stakeholders in NICE's work.

To encourage and enable our key audiences to discover and implement NICE's work.

To offer a creative and productive work environment by prioritising team engagement and personal development.

Inform and engage everyone at NICE including Board members in order to embed a shared understanding of NICE's work.

Shape and manage our resources in order to support NICE and its strategic objectives effectively and efficiently.

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May 2019

## National Institute for Health and Care Excellence

## Health and Social Care Directorate progress report

- 1. This report sets out the performance of the Health and Social Care Directorate against our business plan objectives for the financial year April 2018 March 2019. It also highlights notable developments that have occurred during the year.
- 2. The Chief Executive's Report details delivery of quality standards and evidence summaries.
- 3. The Board received the Social Care Update and Social Care Insight reports in April 2019. The Social Care Impact Report is due for submission to Board in July 2019.

## Performance

4. The directorate has delivered a number of products alongside strategic engagement and implementation support activities during 2018/19. Achievements include:

#### Summary of outputs

- Delivery of a number of products including the following balanced scorecard deliverables: 60 shared learning examples; 30 endorsement statements; 10 quick guides for social care; 50 medicines awareness services bulletins; 14 medicines optimisation key therapeutic topics; 25 medicines evidence commentaries; 4 adoption support products; 4 quarterly innovation scorecards and 1 indicator menu.
- Resource impact products were produced for all positive NICE guidance recommendations alongside published guidance. The difference in the number of products planned (96) and the number produced (71) was due to changes in the planned publication of technology appraisals, medical technologies and diagnostics guidance.

#### Engagement with the national, regional and local system

- 7. The key metrics and achievements for engagement with the external system are set out in Appendix 1, with some added detail below:
  - Following the success of the checklists developed to support Care Quality Commission (CQC) inspectors in using NICE guidance in mental health

inspections, discussions are taking place to support the sustainability of references to NICE guidance in CQC work.

- NICE was a member of the working and implementation groups which developed the new national clinical audit programme (CVDPrevent) for general practice on cardiovascular disease (CVD) prevention. The audit aligns with NICE guidance and provides data on the care provided for people with hypertension, hypercholesterolaemia and atrial fibrillation.
- The London Association of Directors of Adult Social Services (ADASS), NICE and a group of commissioners have produced shared standards and metrics based on NICE quality standards. Standards for care homes have been rolled out across all 33 London local authorities. Standards and metrics for home care services are being developed with input from NICE and will be followed up by standards for extra care provision. NICE has also been supporting work by London ADASS on a cost modelling template for commissioners and supported a resource on developing a learning culture.
- 8. The strategic engagement plan for 2019/20, available in Appendix 2, builds on the success of 2018/19 and includes engagement with the Accelerated Access Collaborative and the Office for Life Sciences. In social care, plans include a campaign to support social workers to use NICE guidance in their practice. In the health sector, there is a focus on supporting the NHS Long Term Plan, both at a national and local level, and builds on the Five Year Forward View activities during 2018/19. For public health, the plan includes supporting the implementation of the new Quality Framework and supporting building new relationships with the Department for Education. The Board will receive a focussed progress report in November 2019.

### Support for Implementation

- NICE worked closely with NHS RightCare to develop toolkits that encourage best practice in commissioning, underpinned by NICE's evidence-based recommendations. The first toolkit was published in March [link to the <u>NHS</u> <u>RightCare Toolkit on Improving Physical Health & Cardiovascular (CVD)</u> <u>Prevention in People with Severe Mental Illness</u>].
- 10. The Guideline Resource and Implementation Panel (GRIP) considered 14 topics over the year. Four implementation statements have been published on hearing loss, chronic obstructive pulmonary disorder, cerebral palsy and renal stones, and we are working with national partners to develop a statement for the stroke update.
- 11.NICE is a member of a clinical working group that has produced commissioning guidance on low value medicines for NHSE and NHS Clinical Commissioners.

The group developed <u>commissioning guidance on 18 medicines which should no</u> <u>longer be routinely prescribed in primary care</u> and will enable the NHS to save up to £141 million a year. The group also published <u>guidance on conditions for</u> <u>which over the counter items should not routinely be prescribed in primary care</u>.

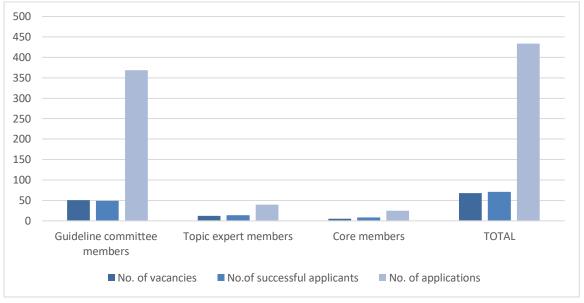
12. The Implementation Facilitator for Wales is now in post. This is the first time that NICE has had a formal remit to support health and social care in Wales.

### Supporting shared decision making

- 13. Our guidelines now feature more information to support shared decision-making and we have created patient decision aids to help people be more informed when they make choices about their care. In 2018/2019 we published a process that guides development of decision aids.
- 14. Of 9 decision aids developed throughout the year, three focussed on decisions relating to surgery for stress urinary incontinence or pelvic organ prolapse in women including the option of surgical mesh. These were co-badged with NHS England and endorsed by professional organisations including the Royal College of Obstetrics and Gynaecology. Another decision aid to help people choose which asthma inhaler is best for them and for the environment was highlighted by the media, including the BBC. We actively identify potential topics for decision aids, and we will review our approach to identifying and producing decision support tools in 2019/20.

#### NICE Public Involvement Programme (PIP)

- 15. Figure 1 shows the patient and public committee member recruitment for the period April 2018 to March 2019.
- 16. Overall, the ratio of applications to vacancies was 6:1; the target being 2:1 or greater, with 434 applications for 71 vacancies. More people were recruited than planned due to additional populations being identified during scoping and recruitment.
- 17. In addition, 107 patient experts were identified to give testimony at advisory committee and scientific advice meetings and 23 people were co-opted as specialist committee members onto Quality Standards Advisory Committees.
- 18. Where topics are very specialised or there is little voluntary and community sector organisation presence, alternative ways of capturing patient views and experiences are being explored.



# Figure 1 Patient and public committee member recruitment for the period April 2018 to March 2019.

## **Notable Developments**

19. This section includes significant developments or issues that occurred during 2018/19.

### NHS Long Term Plan

- 20.NICE has been invited to join the Research and Innovation and Mental Health working groups for the NHS Long Term Plan.
- 21. NICE continues to work with most of the Sustainability and Transformation Partnerships (STPs) across the country to ensure that plans for local reconfigured services are informed by relevant NICE guidance and quality standards. NICE has worked with STP programme leads to map guidance and supporting resources for maternity and children, mental health and learning disabilities, long term conditions, planned care and urgent and emergency care.
- 22. Intelligence gathered during the year suggests that NICE could simplify access to our recommendations. Resources on topics which align with STP priorities have been collated and can now be found in the same place. Nine themed resource packs have also been produced that describe how NICE products support closer working and integration.

### The Quality Outcomes Framework

23. Working with NHS England, the Royal College of General Practitioners (RCGP) and the Health Foundation, NICE is developing quality improvement modules to be considered for inclusion in the Quality Outcomes Framework (QOF). The first

two modules covering end of life care and prescribing safety have been included in the 2019/20 QOF in England and a further 8 modules will be developed in 2019/20.

#### Improving Access to Psychological Therapies

24. NICE continues to work with NHS England (NHSE) to assess digitally enabled Improving Access to Psychological Therapies (IAPT). In 2018/19, the second year of a 3-year programme, 1 IAPT assessment briefing was published and work commenced on 6 more. Four technologies will be evaluated in practice, supporting the collection of real-world activity data for clinical outcomes and resource use. NHSE has agreed a process and methods statement for the final NICE output which will be known as IAPT evaluation in practice reports. The reports will be categorised as NICE advice.

#### Quality Improvement Round Table Event

25. A Quality Improvement Round Table event was jointly hosted in June by NICE, NHSE and NHS Improvement (NHSI). It was attended by a range of national organisations with a role in supporting quality improvement and included examples of local quality initiatives. Outcomes of the meeting included a commitment to a shared approach, and to working together to provide greater system support to develop capability and capacity in the system with quality improvement efforts. A follow up meeting is planned for June 2019 to progress this work in collaboration with the new Chief Improvement Officer of NHSI, Hugh McCaughey, and the National Medical Director of NHSE, Steve Powis.

#### Adult Social Care: Quality Matters

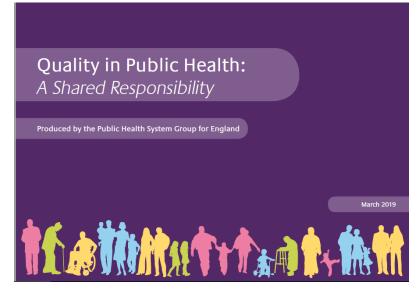
26. NICE, together with a group of national organisations, led the development of a digital resource "<u>Unlocking capacity: smarter together</u>". The resource, aimed at system leaders with the power to work differently, supports the Adult Social Care: Quality Matters priority of developing shared focus areas for improvement across health and social care. The NICE <u>quality improvement resource</u> for adult social care was also launched under the Quality Matters banner. Both outputs were praised by the Minister of State for Care, Caroline Dineage, in her summary of year 1 successes.

#### Quality in Public Health: A Shared Responsibility

27. NICE was a key partner in the development of the national quality improvement framework <u>Quality in Public Health: A Shared Responsibility</u> which published in March 2019. The framework sets out a system-wide commitment to high-quality public health functions and services and aligns to the existing quality frameworks

for the NHS (Shared Commitment to Quality) and adult social care (Quality Matters).

Figure 2 - Front cover of Quality in Public Health: A Shared Responsibility



28. The What Good Looks Like programme, a collaboration between PHE and the Association of Directors of Public Health, supports the public health quality framework. A series of practical guides for leaders and practitioners in the public health system in England is being developed that will set out the guiding principles of 'what good quality looks like' for population health programmes in any defined place. NICE has representation on the coordinating group and on five thematic groups to ensure that its guidance is embedded in the programme.

#### NICE Public Involvement Programme

29. An event, 'Successes, challenges and new developments', was held for standing lay members of NICE advisory committees in March. The agenda was coproduced by the lay members, 15 of whom attended the event. NICE's Deputy Chief Executive and Non-executive Director, Angela Coulter, shared their perspectives, alongside speakers from the technology appraisals and adoption and impact teams who spoke about the role of patient evidence and what happens to their guidance after publication. The event concluded with a celebration of the impact that lay members have had at NICE over the past 20 years and plans to improve public involvement by offering annual performance reviews for lay members and establishing a buddying scheme.

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May 2019

## Appendix 1: Strategic Engagement Metrics 2018-19 - performance summary

National Metrics

Organisation(s)	Strategic Metric	Progress Against Target	Progress Update
NHS England (NHSE) NHS Improvement (NHSI)	A set of tangible outcomes for delivery during 2018/19 is approved at the NICE, NHSE and NHSI, NQB quality improvement round table event	Complete	Event took place 28 June 2018 action plan developed. Small round table event in January 2019 formalised the action plan with wider follow-up planned for Spring 2019. the small round table discussion was held in January and a progress update on QI activity in the system provided to the NQB meeting in February 2019 at which Hugh McCaughey, Director of Quality Improvement attended. Follow up meeting with the wider stakeholder community planned for Summer 2019
NHS Improvement	100% alignment of 2018/19 GIRFT reports with NICE guidance, standards and indicators	Complete	6 reports to date (100% compliance): April - GIRFT cranial neurosurgery report May - GIRFT urology surgery report Aug - GIRFT oral and maxillofacial surgery report Oct - GIRFT national spinal report Dec - GIRFT opthalmology report Jan - GIRFT ENT report
NHS England NHS Improvement Health Education England (HEE)	Where available, NICE guidance and advice is embedded in policies and incentives to decommission low value interventions	Complete	Consultation ended 28/09/18. This is now in the implementation phase, NHSE presented to the Indicators Advisory Committee (IAC) to seek advice for the evidence based intervention programme.
Care Quality Commission (CQC)	NICE Quality Standard statements are in the checklists developed by CQC in their 12 mental health care areas	Complete	Checklists completed for the 12 CQC mental health core service frameworks and uploaded onto the CQC intranet site for Inspectors.
Public Health England	Maintain references to NICE guidance and quality standards in 80% of Public Health England publications where relevant	Complete	A review of all PHE publications completed for quarter 1 and quarter 3 with over 90% of relevant publications referencing NICE.

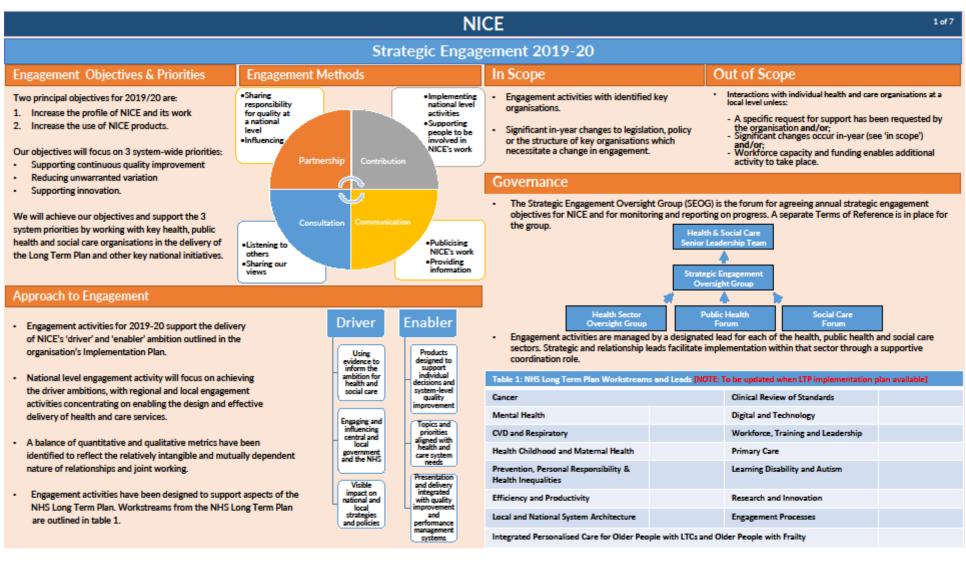
#### National Metrics

Organisation(s)	Strategic Metric	Progress Against Target	Progress Update
NHS England	NHS England embed relevant NICE guidance and standards in their framework for NHS Employers around health and wellbeing in the workplace	Complete	Review of the NHS Workforce Health and Weilbeing Framework underfaken May 2018,
British Heart Foundation NHS England Public Health England	The [British Heart Foundation's] draft UK CVD prevention audit and decision making tool published during 2018/19 includes NICE's CVD related indicators, guidelines and quality standards	Complete	Work on identitying potential indicators for inclusion in the audit has taken place; all of the areas for audit are underpinned by NICE guidance and where available make use of existing NICE indicators.
Local Government Association	3 themed publications issued by the Local Government Association reference NICE	Complete	October 2018: "Sector-led Improvement in public health: progress and potential" December 2018: 'Fit for and during pregnancy - A key role for local government" February 2019: 'Improving the publics health - local government delivers'
Department of Health and Social Care (DHSC)	Inclusion of 3 quality standard measures within the Quality Matters data framework (priority 2)	Ŧ	This metric will not be achieved in 2018/19 and will roll over into 2019/20. To adress this we are continuing to hold a series of meetings with core project group. Plans are in place to discuss progress with the QM board in May 2019.
Care Quality Commission (CQC)	10% of 'outstanding' social care inspection reports published in 2018/19 to reference NICE	Complete	36 'outstanding' reports published in the last month, 8 of these refer to NICE (22%). Since April 319 reports published of which 59 mention NICE, i.e. 18.5% over the whole period.
Department for Education (DfE)	1 piece of NICE guidance referenced within a DfE policy document	ŧ	NICE has submitted evidence to 2 DFE reviews - Children in Need enquiry and SEND and disability enquiry. The outcome of these reviews is still not complete and so it is unclear whether NICE evidence will be used/referenced
Key	Below target		

#### Regional / Local Metrics

Organisation(s)	Strategic Metric	Progress Against Target	Progress Update
Academic Health Science Networks (AHSNs)	NICE guidance, quality standards or indicators are shown to have supported quality improvements in 4 AHSNs	Complete	10 examples identified. Target exceeded.
Sustainability & Transformation Partnerships (STPs)	NICE guidance and quality standards are shown to have supported 11 STP programmes of work	Complete	31 examples identified. Target exceeded.
Mental Health Networks (Sustainability & Transformation Partnerships)	Four mental health STP networks/ mental health networks are supported to increase their use of NICE guidance and quality standards to improve commissioning and provision of mental health services	Complete	13 networks supported. Target exceeded.
Public Health England	7 examples of the NICE field team (and NICE Medicines Implementation Consultants as appropriate) working jointly with PHE regions/centres and other system partners to support Local Authority and STP/ICS use of NICE guidance and quality standards in meeting public health priorities		16 examples were identified. Target exceeded.
ADASS	Evidence of NICE guidance or quality standards being referenced in commissioning policies and contracts in 30 local authorities (20%)	Complete	Evidence in commissioning policies and contracts in 40 local authorities. Target exceeded.
Skills for Care	NICE features in 11 provider forum network events for social care providers (3 each region, 2 London) - joint delivery with Medicines Implementation Consultants, as appropriate	Complete	NICE featured in 43 events. Target exceeded.

## Appendix 2: NICE Strategic Engagement Plan 2019-20



			Health Sector Eng	agemen	t 2019-20			2 of 7
Sector Lead: Nicol	a Bent							
Focus Organisation	s			Key Challenges Key Opport			inities	
Care Quality Commiss     NHS Digital     Department of Health	National       Regional & Loca         • NHS England and NHS Improvement (NHSE & NHSI)       • NHS England and including NHS         • Care Quality Commission (CQC)       • NHS Digital         • Department of Health and Social Care (DHSC)       • Sustainability a Integrated Care         • Office for Life Sciences (OLS)       • Integrated Care		al Ind NHS Improvement (regional teams RightCare and GIRFT) England (regional teams and centres) Ind Transformation Partnerships (STPs) / e Systems (ICSs)	es)		<ul> <li>Strategic</li> <li>NHS Long Term Plan</li> <li>National Quality Board</li> <li>NHSE &amp; NHSI - increasing integration and alignm national programmes and activities and integratio regional teams</li> <li>Academic Health Science Networks (increasing ro Getting It Right First Time (GIRFT)</li> <li>STPs / ICSs</li> </ul>		activities and integration of Networks (increasing role)
Organisations	Priority Rationale		Key Metric/ Evaluation Criteria		Key Workstreams	Rela	itionship d(s)	Key Strategic Meeting
NHS England and NHS Improvement	<ul> <li>Long Term Plan national ambitic Improvement capacity and capa system</li> </ul>		References to NICE guidance and standards included in 80% of relevant Long Term Plan publications to support quality improvement		National Quality Board (NQB) Shared Comm to Quality     National Improvement and Leadership Deve (NILD) work stream     Long Term Plan activity on Quality Improvement	elopment	licola Bent	National Quality Board     National Improvement     Leadership and Development     Board
NHS England and NHS Improvement	<ul> <li>National ambition to improve the care through better outcomes an unwarranted variation</li> </ul>		100% alignment of 2019/20 GIRFT reports guidance, standards and indicators	with NICE	Getting It Right First Time (GIRFT)	N	licola Bent	CEO Board     National Clinical Directors     RightCare / GIRFT alignment     meeting     Rightcare Clinical Advisory     Group
Care Quality     Commission	<ul> <li>National ambition to improve the care through better outcomes as unwarranted variation</li> <li>Increased use of NICE guidance within the quality improvement</li> </ul>	nd reducing and standards	10% of 'outstanding' primary care inspectio published in 2019/20 reference NICE within inspection evidence table		<ul> <li>Regulation of General Practice Programme I Shared View of Quality in Primary Care</li> </ul>	Board Judit	th Richardson	CQC/NICE Biannual Oversight Meeting
NHS Digital	<ul> <li>Influencing and encouraging fut digital health evaluation</li> </ul>	ure partnership for	partnership for Integration of evidence standards framewoo health technologies into NHS Digital's Digit Applications Assessment Questionnaire (D/ the application process for DHTs to be plac NHS.UK by end of Q2		tal development of digital applications AQ) as part of		ark Salmon	<ul> <li>Regular meetings between NICE and the NHSD apps team</li> </ul>
Office for Life Sciences	Long term plan commitments to industry	life sciences	OLS accept the business case for funding th of the medtech work, including digital evalu NICE support an expanded and aligned hori functionality between health care partners i the AAC	ations. zon scanning	Expansion of medical technologies, includin, evaluation, within CHTE     Support for Accelerated Access Collaborativ	e digital	rella Mariow	Life Science Strategy Group

Health Sector Engagement 2019-20								
Sector Lead: Nicola Bent								
Engagement Prioritie	es – Regional / Local							
Organisations	Priority Rationale	Key Metric/ Evaluation Criteria	Key Workstreams	Relationship Lead(s)	Key Strategic Meeting			
<ul> <li>Sustainability &amp;Transformation partnerships (STPs) / Integrated Care Systems (ICSs)</li> </ul>	<ul> <li>National ambition to improve the quality of health care through better outcomes and reducing unwarranted variation</li> <li>Supports implementation of NHS Long Term Plan</li> </ul>	Engagement with work programme leads in 70% (30) STP/ICS to support use of NICE guidance, standards and resources, and to seek feedback and examples of their use to support delivery of NHS Long Term Plan priorities	<ul> <li>Production, promotion and implementation of resources within STPs/ICSs</li> </ul>	Nicola Bent (field team)				
<ul> <li>NHS provider organisations</li> </ul>	<ul> <li>Increased use of NICE guidance and standards within the quality improvement arena</li> </ul>	Engage with and support 12 NICE Manager/Leads Networks to raise awareness of new resources, support implementation and seek feedback on new initiatives (1 London, 1 NI, 1 Wales, 3 North, 3 Mids and East, 3 South)	<ul> <li>Building relationships at local level with NICE manager networks in NHS provider organisations</li> </ul>	Nicola Bent (field team)				
<ul> <li>Strategic Clinical Networks for Mental health</li> </ul>	<ul> <li>Supporting focus organisations to deliver their priorities</li> <li>Supports implementation of NHS Long Term Plan</li> </ul>	12 mental health strategic clinical networks are supported to understand and use NICE guidance and standards to deliver NHS Long Term Plan / SYFV mental health priorities	<ul> <li>Engage with commissioners and providers of mental health services to support the use NICE guidance</li> </ul>	Nicola Bent (field team)				

	Public Health Sector Engagement 2019-20 4 of 7								
Sector Lead: Judith Richardson									
Focus Organisations				Key Challenges			Key Opportuniti	ies	
National       Regional & Local         • Public Health England (PHE)       • Public Health England (regional teams)         • Association of Directors of Public Health (ADPH)       • Sustainability and Transformation Part Integrated Care Systems (ICSs)         • Department for Education (DfE)       • Local Authorities         • NHS England and NHS Improvement       • Engagement Priorities - National		alth England (regional teams) lity and Transformation Partnerships (STPs) / I Care Systems (ICSs)	- Poten level	tial changes in public health remit at a natio	onal	<ul> <li>quality for the p</li> <li>National focus or</li> </ul>	of a national shared commitment to ublic health sector n cardiovascular disease prevention common infections (MoCl)		
Organisations	Priority Ration	ale	Key Metric/Evaluation Criteria		Key Workstreams	Relatio	nship Lead(s)	Key Strategic Meeting	
Public Health England	<ul> <li>Shared, sys commitmer quality pub functions a</li> </ul>	ent to high implementation plans agreed for the Qualit			<ul> <li>Implementation of the Quality Framework for the Public Health System, Quality in Public Health: A Shared Responsibility</li> </ul>	Ju	idith Richardson	Public Health System Group	
<ul> <li>Public Health England</li> <li>Association of Directors of Public Health</li> <li>Local Government Association</li> </ul>	<ul> <li>Coordinate approach</li> </ul>	d system wide	NICE guidance and quality standards embedd of 10 'What Good Looks Like' themed public		<ul> <li>'What Good Looks Like' working groups</li> </ul>	Ju	dith Richardson		
NHS England and NHS Improvement	<ul> <li>Support the implementa Long Term</li> </ul>	ation of NHS	NICE guidance and quality standards are inclu NHS Long Term Plan action plans relating to on prevention (alcohol, obesity and smoking)	key areas	Long Term Plan workstreams	Ju	idith Richardson		
Department for Education	<ul> <li>Coordinate approach</li> </ul>	d system wide	Two meetings take place with key contacts in early years and schools directorate	the DfE		Ju	dith Richardson		

5 of 7

	Public Health Sector Engagement 2019-20 5 of 7								
Sector Lead: Judith Richar	rdson								
Engagement Priorities – Reg	zional / Local								
Organisations	Priority Rationale	Key Metric/Evaluation Criteria	Key Workstreams	Relationship Lead(s)	Key Strategic Meeting				
<ul> <li>Sustainability &amp; Transformation partnerships (STPs) / Integrated ( Systems (ICSs)</li> </ul>	Supports implementation of NHS Care Long Term Plan	Engagement with work programme leads in 70% (30) STP/ICS to support use of NICE guidance, standards and resources, and to seek feedback and examples of their use to support delivery of NHS Long Term Plan priorities	<ul> <li>Production, promotion and implementation of resources within STPs/ICSs</li> </ul>	Nicola Bent (field team)					
Public Health England (regional to	earns) - Supports implementation of NHS Long Term Plan	8 examples (2 per Field Team region) of NICE Field Team (and Medicines Implementation Consultants as appropriate) working jointly with PHE regions/ Centres and other system partners to support local delivery of the NHS Long Term Plan and ongoing CVD prevention work	<ul> <li>Engage with system partners to support the use of NICE guidance</li> </ul>	Nicola Bent (field team)					

	Social Care Engagement 2019-20 604								
Sector Lead: Jane Silv	ester								
Focus Organisations				Key Challenges K			tunities		
National       Regional & Local         • Department of Health and Social Care       • STPs/ Accountable Care Organisations / Integrate         • Care Quality Commission (central teams)       • Stills for Care (SfC)         • Association of Directors of Adult Social Services (ADASS)       • Care Quality Commission (regional teams)         • Social Work England       • Local authorities (Adult Social Care)		Accountable Care Organisations / Integrated Systems Quality Commission (regional teams) for Care (regional teams)	recent role in producing social care guidance     standards as an improvement t     Reduction in social care funding     Internal knowledge and confidence to engage     strategically across the sector     Regional		th CQC to promote NICE guidance and s as an improvement tool for SC providers				
Engagement Priorities -	National								
Organisations	Priority Rationale		Key Metric/Evaluation Criteria	Key Workstreams	Relation	nship Lead(s)	Key Strategic Meeting		
<ul> <li>Department of Health and Social Care</li> </ul>	<ul> <li>Cross-sector initiative to quality</li> </ul>	improving	Promotion of collaborative working (Unlocking capacity: smarter together) between health and adult social care at 4 events	QM Providing support for quality improvement	Jan	ne Silvester	Quality Matters Board		
<ul> <li>Department of Health and Social Care / NHS Digital</li> </ul>	<ul> <li>Cross-sector initiative to quality</li> </ul>	improving	Inclusion of 3 quality standards measures within the QM data framework	QM Collecting & using data more effectively	Jan	ne Silvester	Quality Matters Board		
Care Quality Commission	<ul> <li>Improve the quality of ad care</li> </ul>	ult social	20% of 'outstanding' social care inspection reports published in 2019/20 to reference NICE	Quality improvement resource (QIR)	Jan	ne Silvester	CQC/NICE Biannual oversight meeting		
Social Work England	<ul> <li>Improve the quality of ad care</li> </ul>	ult social	Reference to NICE in the guidance supporting new professional standards for social work, developed by Social Work England	Social work engagement campaign	Jar	ne Silvester	<ul> <li>NICE Social work advisory group</li> </ul>		

Social Care Engagement 2019-20									
Sector Lead: Jane Silv	Sector Lead: Jane Silvester								
Engagement Priorities -	- Regional/Local								
Organisations	Priority Rationale	Key Metric/Evaluation Criteria	Key Workstreams	Relationship Lead(s)	Key Strategic Meeting				
ADASS	<ul> <li>Improve the quality of adult social care</li> </ul>	Continue to support the use of NICE guidance and quality standards in social care commissioning organisations for adult social care through work with regional branch networks of ADASS in England and Wales (5 examples, 1 per Field Team region)	Influence quality through commissioning	Nicola Bent (Local/regional teams)	Regional ADASS meetings				
Skills for Care	<ul> <li>Improve the quality of adult social care</li> </ul>	Work with Skills for Care to engage with and support 10 regional networks of principal social workers in England, Wales and Northern Ireland for adult services, identifying 6 examples (1 per FT region) of NICE guidance and standards being used to inform their work	<ul> <li>Influence quality through key professionals</li> <li>Social work engagement campaign</li> </ul>	Jane Silvester Nicola Bent (Local/regional teams)	Skills for Care Workforce Development Forum				