

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

PUBLIC BOARD MEETING AND ANNUAL GENERAL MEETING

Wednesday 17 July 2019 at 1.30pm in Northampton Guildhall, St Giles' Square, Northampton, NN1 1DE

AGENDA

19/057	Apologies for absence To receive apologies for absence	(Oral)
19/058	Declarations of interests To declare any new interests and consider any conflicts of interest specific to the meeting	(Item 1)
19/059	Minutes of the last Board meeting To approve the minutes of the Board meetings held on 22 May 2019 and 19 June 2019	(Item 2)
19/060	Matters arising To consider matters arising from the minutes of the last meeting	(Oral)
19/061	Chief Executive's report To receive the Chief Executive's report Andrew Dillon, Chief Executive	(Item 3)
19/062	Annual report and accounts 2018/19 To receive the annual report and accounts Andrew Dillon, Chief Executive	(Item 4)
19/063	Finance and workforce report To receive the finance and workforce report Ben Bennett, Director, Business Planning and Resources	(Item 5)
19/064	Annual workforce report To receive the annual workforce report Ben Bennett, Director, Business Planning and Resources	(Item 6)
19/065	Annual revalidation report To receive the annual revalidation report and approve the statement of compliance Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate	(Item 7)
19/066	NICE impact: adult social care To review the report Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate	(Item 8)

TITLE: BOARD AGENDA DATE: 17 July 2019

19/067	Review of methods for health technology evaluation programmes To consider and approve the proposals Meindert Boysen, Director, Centre for Health Technology Evaluation	(Item 9)
19/068	Policy on declaring and managing interests for advisory committees To approve the updated policy Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate	(Item 10)
19/069	Public involvement programme annual review To receive the annual review Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate	(Item 11)
19/070	Audit and Risk Committee To receive the unconfirmed minutes of the meeting held on 19 June 2019 Dr Rima Makarem, Chair, Audit and Risk Committee	(Item 12)
40/074	Directors' reports for information	(14 40)
19/071	Centre for Guidelines	(Item 13)
19/072	Centre for Health Technology Evaluation	(Item 14)
19/073	Communications Directorate	(Item 15)
19/074	Evidence Resources Directorate	(Item 16)
19/075	Health and Social Care Directorate	(Item 17)
19/076	Any other business To consider any other business of an urgent nature	(Oral)

Date of the next meetingTo note the next public Board meeting will be held on Wednesday 18 September 2019 at Sheffield Town Hall, Pinstone Street, Sheffield S1 2HH

TITLE: BOARD AGENDA DATE: 17 July 2019

Interests Register – Board and Senior Management Team

Board Members

Name	Role with NICE	Description of interest	Interest arose	Interest ceased
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	
		Professor of Health Policy, University of Plymouth	2004	
Angela Coulter	Non-Executive Director	Director, Coulter & Coulter Ltd.	2009	
		Member, Academy of Medical Royal Colleges Choosing Wisely steering group.	2015	

Name	Role with NICE	Description of interest	Interest arose	Interest ceased
		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	
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	

Name	Role with NICE	Description of interest	Interest arose	Interest ceased
		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 Director and Vice Chair	Life science assets held in a blind trust and managed by an independent trustee	2015	
		Professor of Practice, King's College London's School of Management / Business and a paid consultant to King's Commercialisation Institute.	2017	
		Non-Executive Director, Life Sciences Hub Wales Ltd.	2017	2019
		Chairman and Non-Executive Director, Quirem Medical BV Supervisory Board.	2015	
		Non-Executive Director, Fiagon AG.	2017	
		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

Name	Role with NICE	Description of interest	Interest arose	Interest ceased
		Non-Executive Director, Pembrokeshire Retreats Ltd.	2006	
		Non-Executive Director, ImaginAb Inc.	2019	
Dr Rima Makarem	rem Non-Executive Director and Senior Independent Director Non-Executive Audit Chair & Non-Executive Director, University College London Hospitals NHS Foundation Trust (UCLH).		2012	
	·	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	
		Trustee, Doteveryone Charity	2017	

Senior management team

Name	Name Role with NICE Description of interest		Interest arose	Interest ceased
Sir Andrew Dillon	Chief Executive	Trustee, Centre for Mental Health charity.	2011	
		Visiting Professor at Imperial College London.	2016	
Ben Bennett	Ben Bennett Director Business Planning and 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	
Paul Chrisp	Director Centre for Guidelines			
Jane Gizbert Director Communications Non-Executive Director Tavistock and Portman NHS Mental Health Trust.		Non-Executive Director Tavistock and Portman NHS Mental Health Trust.	2014	2019
Prof Gillian Leng	Deputy Chief Executive and Health and Social Care Director	Honorary Librarian and Trustee at the Royal Society of Medicine.	2013	
		Editor of the Cochrane EPOC Group.	2012	
		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	

Name	Role with NICE	Description of interest	Interest arose	Interest ceased
Alexia Tonnel	Director Evidence Resources	None.		



NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Public Board Meeting held on 22 May 2019 at Poole Hospital, Longfield Road, Poole, BH15 2JB

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 Chair

Professor Sheena Asthana
Professor Angela Coulter
Professor Martin Cowie
Tom Wright
Non-Executive Director
Non-Executive Director
Non-Executive Director

Executive Directors

Sir Andrew Dillon Chief Executive

Ben Bennett Business Planning and Resources Director

Alexia Tonnel Evidence Resources Director

Directors in attendance

Paul Chrisp Centre for Guidelines Director
Jane Gizbert Communications Director

In attendance

Nicola Bent Deputy Health and Social Care Director

Mirella Marlow Deputy Centre for Health Technology Evaluation

Director

David Coombs Associate Director – Corporate Office (minutes)

19/038 APOLOGIES FOR ABSENCE

 Apologies were received from Elaine Inglesby-Burke, Professor Tim Irish, Dr Rima Makarem, Professor Gillian Leng and Meindert Boysen.

19/039 DECLARATIONS OF INTEREST

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

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19/040 MINUTES OF THE LAST MEETING

3. The minutes of the public Board meeting held on 20 March 2019 were agreed as a correct record.

19/041 MATTERS ARISING

4. The Board reviewed the actions arising from the public Board meeting held on 20 March 2019 and noted these were complete.

19/042 CHIEF EXECUTIVE'S REPORT

- 5. Andrew Dillon presented his report which outlined the 2018/19 year-end position against the business plan objectives and the performance measures in the balanced scorecard, together with a summary of the financial out-turn. He reflected on another year of positive performance and thanked directors and their teams for their work over the year. Due to factors outside of NICE's control, the number of technology appraisals (TAs) published was significantly below plan. Just under 75% of the delays were due to regulatory approval timeline changes, negative regulatory decisions, or to accommodate commercial discussion between the company and NHS England. The remainder of the delayed topics were either the result of company requests for more time to submit data or analysis, or non-submission of data by companies.
- 6. The Board discussed the increased number of delayed TAs, particularly in the context of the new cost recovery arrangements. Andrew Dillon and Mirella Marlow highlighted the ongoing work with NHS England to refine both organisations' respective processes to seek to ensure that commercial discussions with companies conclude within the TA timeline. Andrew stated that the causes for the increased number of delays due to the regulatory process could be explored.

ACTION: Meindert Boysen

7. The Board received the report.

19/043 FINANCE AND WORKFORCE REPORT

- 8. Ben Bennett presented the report which outlined the provisional position of a £3m underspend for the financial year ending 31 March 2019. The underspend is £1.1m higher than that forecast in the March Board report, mainly due to non-cash accounting adjustments relating to the unwinding of provisions for potential liabilities and depreciation charge adjustments. Ben noted that the staff survey is currently underway and he highlighted the workforce update in the report, including the animation produced to showcase the workforce strategy.
- 9. Board members noted the underspend and asked whether NICE should adopt a less risk averse position. As £2m of the underspend was due to vacant posts, it was suggested that a vacancy rate should be factored into the financial plan in order to reduce the likelihood of a similar underspend in future. In response, Andrew Dillon stated that he felt it was appropriate to adopt a prudent approach

National Institute for Health and Care Excellence Minutes of the last public Board meeting Date: 17 July 2019 Reference: 19/059 and not plan for posts remaining vacant throughout the year, as NICE cannot overspend its financial allocation. He explained that the underspend from vacant posts provides a reserve to mitigate in-year cost pressures and headroom for non-recurrent investment in new activities.

10. The Board received the report.

19/044 BUSINESS PLAN 2019/20

- 11. Andrew Dillon presented the business plan for the Board's approval. It has been updated to reflect the Board's review of earlier versions, and feedback from the Department of Health and Social Care. Andrew referred to the earlier discussion on the variation in the planned TA outputs in 2018/19 and stated that a more sophisticated method of tracking delivery of the TA workplan will be considered when developing the 2020/21 business plan, particularly in the context of TA cost recovery.
- 12. Ben Bennett reminded the Board of the challenging financial position in 2019/20, and the £3m reduction in funding from the Department for Health and Social Care (DHSC). Further to the discussions at the last Board meeting, the DHSC has now confirmed that it will provide additional funding to mitigate the £1.6m shortfall in the first year of TA cost recovery to the extent this is necessary.
- 13. The Board approved the business plan and delegated approval of any final amendments to the Chief Executive.

19/045 WIDENING THE EVIDENCE BASE: THE USE OF BROADER DATA AND APPLIED ANALYTICS IN NICE'S WORK

- 14. Nicola Bent presented the proposed statement of intent for the use of broader data and applied analytics in NICE's work, and was joined by Sarah Cumbers, Programme Director for Transformation, who outlined further background to the statement and the proposed consultation. Sarah noted that the statement does not include technical detail on methodological considerations, as this will be developed in further detail and embedded in future methods guides.
- 15. The Board discussed the proposals and the broader sources of data that could be used to support NICE's work. It was agreed that paragraph 17 in the statement which referred to current and potential sources of data should be broadened to include data gathered by apps and mobile devices, and health and care charities. The importance of continuing to work closely with organisations such as Health Data Research-UK was highlighted, and it was agreed that figure 3 in the statement that outlined potential delivery models for data projects should include a fourth option of working in partnership with a third party.
- 16. The Board strongly endorsed the proposals, and subject to the above amendments approved the statement of intent for consultation in line with the approach outlined in the report.

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ACTION: Gill Leng

19/046 DIGITAL HEALTH TECHNOLOGIES EVALUATION PILOT

- 17. Mirella Marlow presented the report on the pilot to evaluate four digital health technologies (DHTs), following NICE's work to develop an Evidence Standards Framework for DHTs in 2018/19. Mirella noted the challenges in evaluating DHTs, including the large number of technologies which may each rapidly update, the variety of potential uses and settings, complex regulation pathways, and low levels of evidence.
- 18. The Board discussed the pilot and highlighted the need to raise awareness of the Evidence Standards Framework and ensure the aims of this pilot are clear, both in terms of the nature of the output from the evaluation of the DHT and the audience for this work. Board members highlighted the range of DHTs and queried whether NICE has the resources to evaluate a sufficient number of DHTs, and if the output will remain relevant given the rapidly changing nature of these technologies. In response, it was clarified that NHS England is the customer for this work and has asked NICE to provide advice on whether the NHS should commission these DHTs. In relation to any future role in evaluating DHTs beyond the pilot, Andrew Dillon stated that NICE will need to focus on technologies which offer material improvements to processes and outcomes. He stated that as with non-digital technologies, it will be important to ensure that the health and care system has assurance on the safety, effectiveness and value for money of a digital product before it is routinely commissioned. Within this context, it was noted that it may be necessary to re-evaluate a DHT if it is substantially updated.
- 19. The Board noted the report. It was agreed that it would be helpful to explain the scope and rationale for the pilot on the relevant part of the NICE website.

ACTION: Meindert Boysen/Jane Gizbert

19/047 NICE IMPACT REPORT: STROKE

- 20. Nicola Bent presented the report on how NICE's guidance contributes to improvements in stroke care, and highlighted that in response to feedback from the Board, the report includes information on variation across clinical commissioning groups (CCGs) for two indicators. The system support for implementation team will continue to use these impact reports to guide work with national partners on issues affecting implementation of NICE guidance.
- 21. The Board welcomed the report and the additional information on variation by CCG. It was agreed that it would be helpful to disseminate the variation information to CCGs, and for future reports to identify the CCGs shown in such charts.

ACTION: Gill Leng

- 22. The Board received the report.
- 23. A member of the audience highlighted that while the report is focused on adults, children can also experience a stroke.

19/048 AUDIT AND RISK COMMITTEE MINUTES

- 24. Sheena Asthana, on behalf of Rima Makarem, presented the unconfirmed minutes of the Audit and Risk Committee meeting held on 24 April 2019. The committee received a series of positive internal audit reports and had an extensive discussion about NICE Connect and the associated risks to the project, notably of insufficient resources. Noting the recent changes in the committee's membership, Sheena thanked Tim Irish for his contribution and welcomed Tom Wright to the committee.
- 25. The Board received the unconfirmed minutes.

19/049 AUDIT AND RISK COMMITTEE ANNUAL REPORT 2018/19 AND TERMS OF REFERENCE

- 26. Sheena Asthana, on behalf of Rima Makarem, presented the report that summarised the work of the Audit and Risk Committee during the 2018/19 financial year. The committee has continued to reflect on its effectiveness and undertook an annual review of its terms of reference, following which amendments are presented for the Board's approval.
- 27. The Board received the annual report and approved the proposed changes to the committee's terms of reference.

19/050 REVISIONS TO STANDING ORDERS, STANDING FINANCIAL INSTRUCTIONS, AND RESERVATION OF POWERS TO THE BOARD AND SCHEME OF DELEGATION

- 28. Ben Bennett presented the proposed amendments to the governance documents following an annual review. He noted that the Audit and Risk Committee reviewed and supported the proposed amendments. In particular, the Committee discussed the proposed amendment to the standing orders in response to a whistle-blowing investigation and agreed that cost should normally be given a 50% assessment weighting when evaluating tenders and quotations.
- 29. The Board discussed its role in relation to NICE's strategic objectives and agreed that the scheme of reservation should refer to the Board setting NICE's strategic objectives to make clear it is has a key role in developing, and not simply agreeing, these. Subject to this change, the Board approved the amended standing orders, standing financial instructions, and scheme of reservation of powers to the board and scheme of delegation.

ACTION: Ben Bennett

19/051 DIRECTOR'S REPORT FOR CONSIDERATION

- 30. Alexia Tonnel presented the update from the Evidence Resources Directorate, and highlighted the diverse range of activities undertaken across the Directorate. It provides access to high quality evidence and information to support guidance development, commissions key items of content made available to the NHS via the NICE Evidence Services, grants permissions to use NICE's intellectual property and content, delivers NICE's digital transformation activities and maintains NICE's digital services. Alexia highlighted the changes that have enabled reduced investment in maintaining existing digital services and therefore more resources to be invested in developing new services. She noted the 23% increase in the use of the externally facing digital services compared to last year, with the British National Formulary (BNF) microsite seeing a 131% increase. Alexia highlighted the work undertaken with the Centre for Health Technology Evaluation (CHTE) to develop the Evidence for Effectiveness standards for digital health technologies, which were discussed earlier in the meeting.
- 31. The relatively low number of sessions on NICE Pathways compared to the main NICE website was noted, and there was a question as to whether this affects the case for the NICE Connect project which proposes that pathways will be the primary method for developing and presenting NICE guidance in future. In response, it was noted that the current Pathways do not contain all of NICE's products and are not promoted as the primary route for accessing NICE's guidance. It was agreed that it would though be helpful as part of the NICE Connect project to better understand the current use of the Pathways on the NICE website, and how these are accessed.

ACTION: Alexia Tonnel

32. The Board noted the report and thanked Alexia for the Directorate's work.

19/052 - 19/055 DIRECTORS' REPORTS FOR INFORMATION

33. The Board received the Directors' Reports.

19/056 ANY OTHER BUSINESS

34. None.

NEXT MEETING

35. The next public meeting of the Board will be held at 1.30pm on 17 July 2019 at Northampton Guildhall, St Giles' Square, Northampton, NN1 1DE (annual general meeting).

National Institute for Health and Care Excellence Minutes of the last public Board meeting Date: 17 July 2019 Reference: 19/059

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

This report provides information on the outputs from our main programmes for 3 months to the end of June 2019 and on our financial position to the end of May, together with comment on other matters of interest to the Board.

The Board is asked to note the report.

Andrew Dillon Chief Executive July 2019

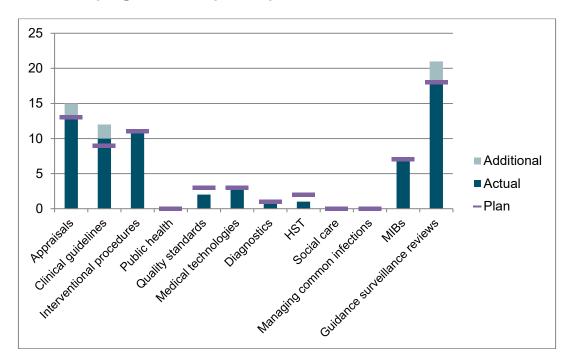
Introduction

- 1. This report sets out the performance of the Institute against its business plan objectives and other priorities for the 3 months to the end of June 2019 and for income and expenditure to the end of May 2019. This report notes the guidance published since the last public Board meeting in May 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 2019-20 financial year, is set out at Appendix 6. There are no material variations to note on this report.

Performance

- 4. The current position against a consolidated list of objectives in our 2019-20 business plan 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 and June 2019 is set out in Chart 1.

Chart 1: Main programme outputs: April 2019 to June 2019



download the data set for this chart

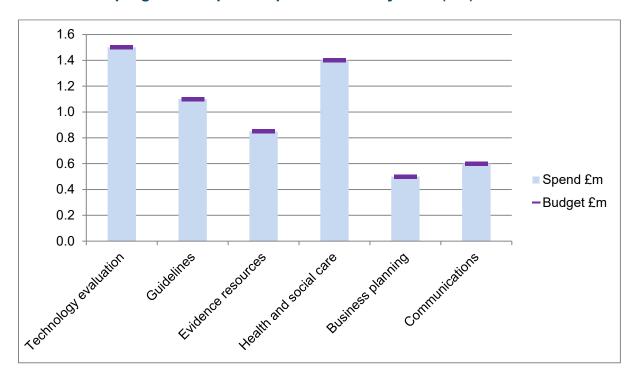
Notes to Chart 1:

- a) HST refers to the highly specialised technologies programme (drugs for very rare conditions)
- b) MIBs (medtech innovation briefings) are reviews of new medical devices
- c) Guidance surveillance reviews provide the basis for decisions about whether to update current NICE guidance
- d) The variance is the difference between the target output for the reporting period, as set out in the business plan and the actual performance
- e) 'Additional' topics are either those which should have published in the previous financial year, or that have been added since the publication of the business plan
- 6. Details of the variance against plan are set out at Appendix 3. Guidance, quality standards and other advice published since the last Board meeting in May is set out Appendix 4.

Financial position (Month 2)

- 7. The financial position for the 2 months from April 2019 to the end of May is an under spend of £0.3m (3%), against budget. This consists of under spend of £0.07m on pay and £0.084m on non-pay budgets, and an over-recovery on income of £0.099m. The position of the main budgets is set out in Chart 2. Further information is available in the Business Planning and Resources Director's report.
- 8. From the beginning of April, the cost of the technology appraisal and highly specialised technologies programmes is being recovered through income received from companies whose products are being appraised. Because individual appraisals can begin in one financial year and complete in a subsequent year, only part of the full cost of both programmes will be recovered in the first year of operation of the new arrangement (2019-20). The business plan anticipates that the deficit will be £1.6m.
- 9. At the end of month 2, income of £0.247m has been recognised against a target of £0.188, revealing higher than anticipated appraisal starts. Income is recognised in the year in which the work takes place. Appraisals are scheduled to take around 11 months. As appraisals are initiated further into the financial year, a decreasing proportion of income will be recognised in the current year. The Department of Health and Social Care has confirmed that it will cover an under recovery in technology appraisals income, up to a maximum of £1.6m, subject the Institute taking all reasonable compensating steps in over recovering other income sources and through savings in in other budgets.

Chart 2: Main programme spend: April 2019 to May 2019 (£m)



download the data set for this chart

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 2019-20.

	liver and support the adoption of accessible, up to date and aptable advice, fully aligned to the needs of our users	Delivery date	Progress update
•	Deliver guidance, standards, indicators and evidence products and services, in accordance with the schedule set out in the business plan and the balanced scorecard, including the planned increases in the technology evaluation programmes	Ongoing	Details of the main programmes' performance against plan, including explanations for any variances are set out elsewhere in this report.
•	Subject to evaluation of the NICE Connect project pilot, develop a business case and programme plans for the next phase of the project	End of Q3	Plans are in hand to develop a report for the Board in September with a business case and detailed plans for the next phase of work.
•	Undertake a review of the topic selection arrangements for the HST programme and methods guides for the technology evaluation programmes	End of Q4	The programme of work for the review has been launched, with internal and external planning meetings held, and a dedicated page on the NICE website created.
•	Review and update the guidelines methods and process manual to determine the optimal development path and timeline for guideline development in the context of the NICE Connect project	End of Q4	Work is ongoing to collate data that will feed into the update of the methods and process manual.
			Plans are being developed to optimise timelines for guideline development to support the NICE Connect project.
•	Maintain and monitor performance of NICE Evidence Services (CKS, HDAS, BNF microsites, Evidence Search, Medicines Awareness Service), with investment in new features on a strictly needed basis	Ongoing	All systems are performing in line with recent trends. Continued strong performance of the BNF microsites and the CKS service.

Date: 17 July 2019 Reference: 19/061

Enable access to the new national core content and procure any additional content in line with Health Education England's (HEE) commissioning decisions	• Q1	 There was no request to procure new content in Q1. A dialogue with NHS Digital is ongoing about their future plans for an identity management solution.
Support shared decision making within NICE through delivery of commitments in the action plan of the Shared Decision-Making Collaborative	Ongoing	A meeting of the Shared Decision-Making Collaborative was held in June, and was well attended. A revised action plan is being developed following on from this meeting.
Deliver a range of tools and support for the uptake of NICE guidance and standards, including adoption support products, endorsement statements, and shared learning examples	Ongoing	Tools and support have been delivered as planned. Further information is available in the Health and Social Care Director's report. The need for adoption support products is being reviewed as part of the NICE Connect project.
Evaluate the most effective social and multimedia channels currently used to promote NICE's work	Ongoing	An evaluation of media channels is underway and will be completed by mid- August. A report will be prepared by mid- September
Evaluate the scope to improve the recruitment and retention of advisory committee members	• End of Q2	New digital platforms have been used to promote opportunities for committee members, and ways of being more proactive about recruitment are being explored in CHTE.

	ay an active, influential role in the national stewardship of the alth and care system	Delivery date	Progress update
•	Work with NHS England and other health and care system partners to support the implementation of the NHS long term plan	Ongoing	We have mapped areas of NICE's work to the implementation arrangements for the Long Term Plan and are working with NHS England to ensure NICE guidance is appropriately reflected.
•	Explore with NHS England the options for a digital health technology evaluation workstream, building on the Evidence for Effectiveness standards	End of Q2	 An internal project team has been established and a stakeholder Steering Group, chaired by the Programme Director, Evidence Resources.
			 An outline process has been developed for the evaluation pilot.
			 Four apps have been identified as pilot topics.
•	Subject to the UK's EU exit arrangements, design and put in place changes to our current technology appraisal process in order to secure consistency with UK regulatory arrangements	End of Q2	 Planning for EU Exit has resumed, including consideration of adjustments required to the technology appraisal process.
•	Commission a bi-annual NICE reputation research project to assess our key stakeholders' views of NICE and our work, and conduct specific and targeted audience research on key issues that contribute to meeting corporate business objectives and implementation of NICE guidance	End of Q2	The final report on the findings of the research project findings is being worked on and will be presented to the Board in August.
•	Deliver a suite of activities to mark NICE's 20 th anniversary	End of Q1	A range of activities have taken place to mark NICE's 20 th anniversary including a staff event, parliamentary reception, and digital and multimedia presentations

Take advantage of new data sources and digital technologies in developing and delivering our advice	Delivery date	Progress update
Develop and establish a long term data analytics strategy for NICE together with a framework for the appropriate the use of data analytics across NICE's programmes, and facilitating a national leadership in the field	• End of Q3	A 'Statement of Intent' has been developed, which sets out how we aim to use data analytics in our future work. This is now the subject of a 3-month consultation and a series of workshops to gain further feedback.
Identify digital investment priorities, and their sequencing, to align with the NICE Connect project transformation work, reviewing the roadmap quarterly	Ongoing	A proposed roadmap of digital activities for 2019/20 was presented to SMT in June 2019. This will be updated quarterly, to reflect live services and NICE Connect priorities.
		To support the integration of plans and activities with the rest of NICE, the Digital Services team will present at each directorate's senior team meetings.
Manage and maintain the live digital services of NICE utilising user insight and strategic service goals to prioritise use of resource	Ongoing	Usual activity of defect resolution and responding to change requests continues.
Generate and manage effectively the resources needed to maintain our offer to the health and care system	Delivery date	Progress update
Deliver performance against plan for all budgets and achieve or exceed on non-Grant-in-Aid income targets	• End of March 2020	Projections at end of quarter 2 show that we expect to remain comfortably within the tolerance agreed with DHSC for the transition year to the full cost recovery for TA and HST.
		NICE Scientific Advice has initiated 18 individual advisory projects over the 1st

			quarter and is on-track to achieve the 2019/20 budget.
•	Introduce charging for technology appraisal and highly specialised technologies and recover the target income for 2019/20	• From 1 April 2019	Charging systems are now fully operational and income slightly ahead of target for Qtr1.
•	Deliver existing grant funded research projects to plan and timetable and secure a pipeline of new projects for 2020-21	• End of March 2020	Existing projects are being delivered to plan. Several projects extend to future years (some to 2023), with funding for the next 2 years secured at comparable levels to this year. Further projects are currently at the bid stage.
•	Promote our capacity for knowledge sharing with international organisations interested in NICE's expertise and experience, including the re-use of NICE's published content outside of the UK	Ongoing	 The International Knowledge Transfer Service has delivered 13 international engagements over quarter 1 and continues to build connections with external stakeholders and delivery partners. The team has been working on a strategy paper for international services at NICE which will be discussed at SMT in Q2. Revenue generated from content re-use services in Q1 was approximately £43,000, which is ahead of target for the year.
Support the UK's ambition to enhance its position as a global life sciences destination		Delivery date	Progress update
•	Make preparations to implement the commitments of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access related to NICE so that (i) all new active substances and drugs with significant licence extensions will be appraised, except where there is a clear rationale not to do so, by April 2020; (ii) NICE is able to publish recommendations on non-cancer drugs within 90 days of licensing to match the timescales for cancer drugs (ongoing)	• End of Q4/on-going	Planning meetings have been held with NHS England and NHS Improvement, and with the Department of Health and Social Care, to consider the timing of the expansion of the technology appraisal programme, and the ability to publish

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			guidance for non-oncology drugs against the same 90 day target as oncology drugs.
•	Deliver the actions set out for NICE in the Government's Life Sciences Sector Deals and significantly increase the number of evaluations of these health tech products conducted, giving greater scope for considering different types of innovation, including digital products.	Ongoing	 Work is ongoing with NHS England and NHS Improvement on the development of a new Medtech funding mandate, with NICE as a key partner. Discussions are ongoing with NHS England and NHS Improvement about the timing of a potential expansion of the Medtech programmes, and with the Department of Health and Social Care on how the expansion could be funded. The expansion of NICE's Medtech and diagnostics guidance capacity is signalled in the NHS Long Term Plan, but the source of funding for this is currently unclear.
•	Prepare a final case for establishing a not for profit organisation delivering fee for service advisory and educational programmes, aligned to NICE's public task	• End of Q3	The Board agreed in June that the original proposal was not viable and to stand down planning for the proposed entity.
Ma	aintain a motivated, well-led and adaptable workforce	Delivery date	Progress update
•	Ensure that all staff have clear objectives supported by personal development plans	End of Q1	Each directorate has an individual business plan and that is cascaded into individual objectives which links to the annual appraisal and informs personal development plans.
•	Actively manage staff engagement and morale with the objective of ensuring that the global job satisfaction index in the annual staff survey is maintained or improved from its 2018 level	End of Q1	The annual staff survey achieved our highest-ever completion rate of 85%. The results are being used to form organisational and directorate action plans, supported by

		HR. The results and action plan will be reported to the Board in September.
 Implement the actions set out in the workforce strategy, including mapping out career paths for key roles, including increasing opportunities for apprenticeships, and defining the behaviours expected of a manager at NICE 	End of Q2	We have introduced leadership and management apprenticeships at levels 3, 5 and 7 (MBA level) and are developing graduate opportunities in a range of areas.
		We will be introducing organisational values and behaviours for managers in the coming months.
Work with NHS Property Services to secure the future London office accommodation, and begin planning for the move to take place in the summer of 2020	End of Q3	Planning for the move to Stratford in Summer 2020 is progressing, with key decisions on contractual issues considered by SMT.
		Engagement with the leaseholder and other tenants on space configuration are well-advanced.
Develop and implement a programme of improvements for the Manchester office to ensure best use of the space available	End of Q2	A paper is being prepared for SMT which will seek approval for a range of enhancements to the Manchester estate.

Appendix 2: Extracts from the Directors' reports

Director	Featured section	Section/ reference
Health and social care	The ratio of applications, for patient and public member vacancies on NICE's advisory committees during the reporting period was 4.6:1, with the target being 2:1 or greater. 74 applications were received for 16 vacancies. Of note, there were no suitable applicants for the fever in under 5's guideline committee on the first round of recruitment, and the second round generated one application. The management of common infections committee looking at impetigo received one application that did not meet the required criteria. A decision was made not to undertake further recruitment, therefore discussions are taking place with the guideline development teams to explore ways of attracting appropriate lay representatives for committees. Eight patient experts have been identified to give testimony at committee meetings and at NICE's Scientific Advice meetings, and 6 people have been co-opted as specialist committee members onto Quality Standards Advisory Committees.	Paras 10-12
Recommendations relating to the use of synthetic polypropylene or biological mesh insertion for women with recurrent anterior vaginal wall prolapse have been withdrawn from the guideline on urinary incontinence and pelvic organ prolapse in women. The guideline provides a link and refers instead to the NICE interventional procedures guidance 599 on transvaginal mesh repair of anterior or posterior vaginal wall prolapse. The change was made to provide clarity regarding the relationship between the guideline and interventional procedures guidance, and to take account of a material change since publication in the availability of products CE-marked for the indication which was referred to in the guideline recommendations.		Para 13
Health technology evaluation The Commercial and Managed Access Programme (CMAP), established during 2018/19, includes the Managed Access team (previously the Cancer Drugs Fund team), the Commercial Liaison Team (CLT), the NICE Office for Market Access (OMA) and the		Paras 5 and 6

	Accelerated Access Collaborative Secretariat (AACS). These programmes focus on facilitating and supporting guidance production and market access during formal guidance processes. The CLT is working directly with colleagues at NHS England and NHS Improvement (referred to as NHSE in the rest of this report) to inform the development of the commercial framework and assess its potential impact. A detailed programme of work has been agreed to develop and implement the working processes needed to deliver a seamless interface for all relevant commercially related conversations between companies, NHSE and NICE. Recruitment to the team continues, with new staff joining in June 2019, and all roles expected to be filled by early September 2019. Completion of 38 commercial access agreements is anticipated in 2019-2020 with 11 PAS advice reports issued to NHS England in the first quarter.	
Evidence resources	 The directorate is supporting CHTE to explore with NHS England the options for a digital health technology evaluation workstream, building on the Evidence Standards for Digital Health Technologies published in 2018/19. Over the last three months, we have focused on supporting the following activities: development of NHS England's business case, contributing to Senior Management Team (SMT) and Board papers and project plans outlining the pilot work programme, as part of the internal project team; setting up and Chairing the external Steering Group for the pilot; promoting the use of NICE's Evidence Standards for Digital Health Technologies at a wide range of events and conferences and liaising with a broad range of external 	Para 6
Communications	partners and influencers. Significant new decision aids have been published, including 3 patient decision aids on surgery for stress urinary incontinence, uterine prolapse and vaginal fault prolapse (published in April); and 2 patient decision aids on decompressive hemicraniotomy surgery, which were published with the stroke and transient ischaemic attack update in May. Three algorithms have been published on lung cancer: systemic treatment options	Paras 22 and 23

	for advanced squamous NSCLC, systemic treatment options for advanced non-squamous NSCLC, and intrathoracic staging before radical treatment.	
Finance and workforce	The full-year forecast position is for an overspend of £0.8m (2% variance), wholly attributable to an under recovery of Technology Appraisal income in this first year of charging for these services. This is an estimate based on the number of appraisals that commenced during quarter 1 and the forecast position could change significantly as we progress through the year.	Para 3

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

Programme	Delayed Topic	Reason for variation
Clinical Guidelines	No variation against plan 2019-20	
	1 topic planned for 2019-20 published early	Hypertension in pregnancy: diagnosis and management: Originally planned to publish in July 2019. Guideline published in June 2019 (Q1 2019-20).
	2 additional topics published that were not planned for this financial year	Surgical site infections: prevention and treatment: Originally planned for 2018-Published April 2019 (Q1 2019-20).
		Suspected neurological conditions: Originally planned for 2018-19. Published May 2019 (Q1 2019-20).
Interventional procedures	No variation against plan 2019-20	
Medical technologies	No variation against plan 2019-20	
Public Health	No variation against plan 2019-20	
Quality Standards	1 topic delayed	School based interventions: The Department for Education is considering their formal endorsement of the product, but capacity issues are holding up their decision.
Diagnostics	No variation against plan 2019-20	
Technology Appraisals	No variation against plan 2019-20	
	2 additional topics published that were not planned for this financial year	Cabozantinib for previously treated advanced hepatocellular carcinoma: Published as a terminated appraisal in May 2019 (Q1 2019-20).

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Item 3

Programme	Delayed Topic	Reason for variation
		Bosutinib for untreated chronic myeloid leukaemia: Published as a terminated appraisal in April 2019 (Q1 2019-20).
Highly Specialised Technologies (HST)	1 topic delayed	Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2: Appeal received following release of FAD. Appeal was rejected. Subsequent timelines are to be confirmed.
Social Care	No variation against plan 2019-20	
Managing Common Infections	No variation against plan 2019-20	

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

Programme	Topic	Recommendation
Clinical Guidelines	Ectopic pregnancy and miscarriage: diagnosis and initial management	General guidance
	Surgical site infections: prevention and treatment	General guidance
	Specialist neonatal respiratory care for babies born preterm	General guidance
	Hyperparathyroidism (primary): diagnosis, assessment and initial management	General guidance
	Prostate cancer: diagnosis and management	General guidance
	Ulcerative colitis: management	General guidance
	Crohn's disease: management	General guidance
	Stroke and transient ischaemic attack in over 16s: diagnosis and initial management	General guidance
	Suspected neurological conditions: recognition and referral	General guidance
	Urinary incontinence and pelvic organ prolapse in women: management	General guidance
	Hypertension in pregnancy: diagnosis and management	General guidance
	Depression in children and young people: identification and management	General guidance
Interventional procedures	Endoscopic ablation for a pilonidal sinus	Standard arrangements
p. 2000.00	Endoscopic ablation for an anal fistula	Standard arrangements

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Programme	Topic	Recommendation
	Percutaneous mitral valve leaflet repair for mitral regurgitation	Standard arrangements
	Collagen paste for closing an anal fistula	Only in research
	Therapeutic hypothermia for acute ischaemic stroke	Do not use
	Bronchoscopic thermal vapour ablation for upper-lobe emphysema	Only in research
	Percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg	For acute iliofemoral DVT – special arrangements For distal DVT – only in research
	Percutaneous insertion of a cerebral protection device to prevent cerebral embolism during TAVI	Special arrangements
Medical technologies	Curos for preventing infections when using needleless connectors	Research recommendation
J	PICO negative pressure wound dressings for closed surgical incisions	Case for adoption supported
	Endocuff Vision for assisting visualisation during colonoscopy	Case for adoption supported
Diagnostics	Lead-I ECG devices for detecting symptomatic atrial fibrillation using single time point testing in primary care	Research recommendation
Public Health	No publications	
Managing Common Infections	No publications	
Social care	No publications	
Quality Standards	Physical activity: encouraging activity in the community	Sentinal markers of good practice
-	Dementia	Sentinal markers of good practice

Programme	Topic	Recommendation
Technology Appraisals	Brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma	Optimised
	Bosutinib for untreated chronic myeloid leukaemia	Terminated appraisal
	Tildrakizumab for treating moderate to severe plaque psoriasis	Optimised
	Certolizumab pegol for treating moderate to severe plaque psoriasis	Optimised
	Daratumumab with bortezomib and dexamethasone for previously treated multiple myeloma	Recommended for use within the CDF
	Cabozantinib for previously treated advanced hepatocellular carcinoma	Terminated appraisal
	Nivolumab with ipilimumab for untreated advanced renal cell carcinoma	Recommended for use within the CDF
	Enzalutamide for hormone-relapsed non-metastatic prostate cancer	Not recommended
	Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy	Recommended for use within the CDF
	Durvalumab for treating locally advanced unresectable non-small-cell lung cancer after platinum-based chemoradiation	Recommended for use within the CDF
	Ocrelizumab for treating primary progressive multiple sclerosis	Recommended
	Atezolizumab in combination for treating metastatic non-squamous non-small-cell lung cancer	Optimised
	Ertugliflozin with metformin and a dipeptidyl peptidase-4 inhibitor for treating type 2 diabetes	Optimised
	Lenalidomide plus dexamethasone for multiple myeloma after 1 treatment with bortezomib (part rev TA171)	Optimised
	Lenalidomide plus dexamethasone for previously untreated multiple myeloma	Optimised

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Programme	Topic	Recommendation
Highly Specialised Technologies (HST)	Inotersen for treating hereditary transthyretin amyloidosis	Recommended
Medtech Innovation Briefings (MIB)	LiverMultiScan for liver disease	Summary of best available evidence
3 ()	ADXBLADDER for detecting bladder cancer	Summary of best available evidence
	DuraGraft for preserving vascular grafts	Summary of best available evidence
	Peezy Midstream for urine collection	Summary of best available evidence
	SEM Scanner for pressure ulcer prevention	Summary of best available evidence
	Danis stent for acute oesophageal variceal bleeds	Summary of best available evidence
Guidance Surveillance Reviews	NG2 Bladder Cancer	No update
	NG79 Sinusitis (acute): antimicrobial prescribing (exception review)	No update

Programme	Topic	Recommendation
	NG84 Sore throat (acute): antimicrobial prescribing (exception review)	No update
	NG91 Otitis media (acute): antimicrobial prescribing (exception review)	No update
	NG109 Urinary tract infection (lower): antimicrobial prescribing (exception review)	No update
	NG110 Prostatitis (acute): antimicrobial prescribing (exception review)	No update
	NG111 Pyelonephritis (acute): antimicrobial prescribing (exception review)	No update
	NG112 Urinary tract infection (recurrent): antimicrobial prescribing (exception review)	No update
	NG113 Urinary tract infection (catheter-associated): antimicrobial prescribing (exception review)	No update
	NG114 Chronic obstructive pulmonary disease (acute exacerbation): antimicrobial prescribing (exception review)	No update
	NG117 Bronchiectasis (non-cystic fibrosis), acute exacerbation: antimicrobial prescribing (exception review)	No update
	NG125 Surgical site infections: prevention and treatment (exception review)	Partial update

Topic	Recommendation
CG161 Falls in older people: assessing risk and prevention	Full update
NG14 Melanoma: assessment and management	Partial update
CSG8 Improving outcomes for people with skin tumours including melanoma	Full update
NG19 Diabetic foot problems: prevention and management	No update
NG18 Diabetes (type 1 and 2) in children and young people: diagnosis and management	Partial update
NG17 Type 1 diabetes in adults: diagnosis and management	Partial update
NG28 Type 2 diabetes in adults: management	Partial update
	CG161 Falls in older people: assessing risk and prevention NG14 Melanoma: assessment and management CSG8 Improving outcomes for people with skin tumours including melanoma NG19 Diabetic foot problems: prevention and management NG18 Diabetes (type 1 and 2) in children and young people: diagnosis and management NG17 Type 1 diabetes in adults: diagnosis and management

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:

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

Appendix 5: Science, Advice and Research Programme progress report

NICE Scientific Advice

- 1. For the period of April, May and June 2019, NICE Scientific Advice has initiated 18 individual advisory projects. This includes 11 projects where companies have sought advice from NICE directly (including our first two projects offering a concurrent advice service alongside the EMA's advice process), 5 where NICE has given advice through the European Network for HTA's Early Dialogue procedure and 1 META Tool consultation. The team has also delivered 1 META Tool facilitator training day. A further 3 advisory projects have been confirmed with contracts in the process of being signed as well as a further 28 ongoing enquiries for projects starting later in the year.
- 2. During the same period, the International Knowledge Transfer Service has received 21 new enquiries, and delivered 13 international engagements including 3 training seminars, 6 speaking engagements and 4 short meetings. A further 20 enquiries are currently in progress and are yet to be confirmed including one larger consultancy project. The team continues to develop working relationships with a number of external stakeholders including Healthcare UK, The Department of International Trade (DIT), the Department of Health and Social Care, The Foreign Commonwealth Office (FCO), the NHS Consortium and the NHS Confederation. The team has agreed to act as an advisory partner to support the activities of the FCO Prosperity Fund Better Health Programme and is honoured to present at the launch event in June. The team are continuing to develop their broader international strategy and will set this out in a paper for the Senior Management Team in early Q2.
- 3. NSA has driven business growth through this period and has seen a significant increase in income compared to the previous quarter. The team continues to control spending and prioritise project work. Business development drives targeting biotechnology companies and academic/government funded research are being planned. Wider activities that NSA has supported during this period include CHTE 2020, the antimicrobial resistance project in partnership with NHS England, the Digital Consultation Evaluation project with NHS England, the HTx & EHDEN projects with the Science, Policy and Research programme, planning work for the Innovate UK Digital Health Technology Catalyst and also for the cobranded Executive MSc with the London School of Economics.

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Science Policy and Research

4. NICE is a partner in the Innovative Medicines Initiative (IMI) project NEURONET (Efficiently Networking European Neurodegeneration Research) which started in March 2019 and will run for 3 years. NEURONET is a coordination and support action (CSA) project which has the objective of boosting synergy and collaboration across a broad portfolio of IMI neurodegenerative disorders. The overarching concept of NEURONET is to collect and analyse information and outputs from the various neurodegenerative disorder's initiatives supported by IMI in order to accelerate the development and implementation of novel therapeutics in this area across Europe. Neurodegeneration diseases, including dementia, are a key priority for both the NHS and the UK government. Through partnership in this CSA, NICE will have a direct overview of and interaction with ongoing European research projects and benefit from connections with key opinion leaders and research projects in the disease area.

EUnetHTA

- 5. 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 as it develops the technical and scientific elements of a permanent model of HTA cooperation.
- 6. NICE published our third implementation report on the EUnetHTA website, including:
 - Analysis of over 150 examples of use of EUnetHTA assessments.
 - Preliminary data from Industry affiliates about their experiences of using EUnetHTA assessments in the national submissions for reimbursement.
 - A case study about how EUnetHTA colleagues use EUnetHTA tools and guidelines
 - An implementation strategy to support increased uptake of EUnetHTA assessments.

Appendix 6: Balanced Scorecard: April - June 2019

Delivering services and improvements

· · · · · · · · · · · · · · · · · · ·		Development and publication of guidance and evidence outputs (as specified in Business Plan) Outputs Planned Actual Cumulative PAC status									
Outputs	Measure	Target	Planned Year To Date	Actual Year To Date	Cumulative performance	RAG status					
Publish 3 public health guidelines	Publication within stated quarter	80%	0	0	100%	Green					
Publish 23 clinical guidelines	Publication within stated quarter	80%	9	12	133%	Green					
Publish 6 managing common infections guidelines	Publication within stated quarter	80%	0	0	100%	Green					
Publish 1 social care guidelines	Publication within stated quarter	80%	0	0	100%	Green					
Publish 78 technology appraisals or highly specialised technologies guidance	Publication within stated year	80%	15	16	107%	Green					
Publish 32 interventional procedures guidance	Publication within stated quarter	80%	11	11	100%	Green					
Publish 6 diagnostics guidance	Publication within stated quarter	80%	1	1	100%	Green					
Publish 7 medical technologies guidance	Publication within stated year	80%	3	3	100	Green					
Publish 38 medtech innovation briefings (MIBs)	Publication within stated year	80%	7	7	100%	Green					
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%	11 commercial and 4 MA briefings	11 commercial and 4 MA briefings	100%	Green					

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Development and publication of guidance and evidence outputs (as specified in Business Plan)								
Outputs	Measure	Target	Planned Year To Date	Actual Year To Date	Cumulative performance	RAG status		
Deliver up to 4 commissioning support programme topics to NHS England	Submission to NHS England Clinical Panel within stated quarter	80%	4	4	100%	Green		
Manage portfolio of up to 3 evaluative commissioning projects for NHS England	Submission to NHS England Clinical Panel within stated quarter	80%	1	0	0%	Red		

Notes:

Second Sight, the manufacturer of the Argus II implant, has advised that worldwide production has been suspended and the device's CE mark will lapse in August 2019. The CE mark is an important indication of a device's compliance with safety, quality and legal requirements relevant to its use.

Publish 52 guidance surveillance reviews	Publication within stated guarter	80%	18	21	117%	Green
Deliver up to 4 evidence summaries – antimicrobial prescribing	Publish within year	80%	0	0	100%	Green
Deliver up to 10 evidence reviews for NHSE specialised commissioning	Delivery to NHS England within year	80%	0	2	200%	Green
Deliver 8 quick guides for social care	Publication within year	100%	0	0	100%	Green
Deliver 16 quality standards	Publication within stated quarter	80%	3	2	67%	Amber

Notes:

One quality standard (school-based interventions) has been delayed. The Department for Education is considering their formal endorsement of the product, but capacity issues are holding up their decision.

Development and publication of guidance and evidence outputs (as specified in Business Plan)									
Outputs	Measure	Target	Planned Year To Date	Actual Year To Date	Cumulative performance	RAG status			
Deliver 1 indicator set	Publication within year	100%	1	1	100%	Green			
Deliver 30 endorsement statements	Publication within stated quarter	80%	7	4	57%	Amber			

Notes:

Delays have occurred in the publication of 3 statements due to applications taking more time than anticipated to complete where resource producers have needed to make changes, or the size of a resource has taken longer to assess due to the volume of recommendations they

encompass. This deliverable is expected to be back on track in quarter 2.

chicompace. The deliverable is	mpootod to be back on track in qu					
Deliver 50 shared learning	Publication within stated	80%	14	15	107%	Green
examples	quarter					
Publish 12 monthly updates of	Publication within stated	80%	3	3	100%	Green
the BNF and BNF C content	quarter					
Deliver a regular medicine	Publication to regular schedule	90%	13	13	100%	Green
awareness service (50 MAWs)						
Deliver update of 16 medicines	Publication within stated	80%	0	0	100%	Green
optimisation key therapeutics	quarter					
topics						
Deliver 24 medicines evidence	Publication within stated	80%	6	5	83%	Green
commentaries	quarter					
Deliver 7 IAPT (Improving	Publication within stated	80%	1	1	100%	Green
Access to Psychological	quarter					
Therapies) assessment						
briefings						

Adoption and impact

Provision of support products for the effective implementation of guidance							
Outputs	Measure	Target	Planned YTD	Actual YTD	Cumulative performance	RAG	
Publish resource impact products to support all NICE guidelines, positively recommended technology appraisals, medical technologies and diagnostics guidance at the point of guidance publication	Provide within year	90%	100%	100%	100%	Green	
Maintaining and developing reco	gnition of the role of NICE						
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

Delivering programmes and ac	Delivering programmes and activities on budget							
Outputs	Measure	Target	Planned YTD	Cumulative performance	RAG			
Effective management of financial resources	Revenue spend	To operate within budget	2018/19 Quarter 1 year-to date (YTD) budget was £12.5m.	Net YTD spend for 2018/19 Quarter 1 was £12.0m. This was a net under spend of £0.5m and is mainly due to vacant posts and income being ahead of plan.	Green			

Effective management of non-	Net income received	90%	The business plan	The year-to-date	Green
exchequer income	from non-exchequer income sources (including Scientific Advice, Office for Market Access, research grants, knowledge transfer) measured against business plan targets		income target was to receive £1.0m year-to-date (YTD) from non-exchequer sources.	income recognised is £1.2m so we are currently ahead of target.	

Maintaining and developing a ski	illed and motivated workforce			
Outputs	Measure	Target	Cumulative performance	RAG
Management of recruitment	Proportion of posts appointed to within 4 months of first advertisement	80%	95%	Green
Management of sickness absence	Quarterly sickness absence rate is lower than the average rate (3.33% as at January 2018) across the Specialist Health Authorities and other Statutory Bodies	3.33%	1.63%	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%	N/A	N/A
Notes: The staff survey report for 2019 is d	ue later in the year.			
Staff involvement	Hold monthly staff meetings	80%	100%	Green
Staff well-being	Implementation of NICE's quality standard for healthy workplaces: improving employee mental and physical health and wellbeing in respect of own staff	80% of quality statements	83%	Green
Sustainable development				
Recycled waste	% of total waste recycled	90%	100%	Green

Improving stakeholder satisfaction							
Improved satisfaction	Complaints fully responded to in 20 working days	80%	100%	Green			
Improved satisfaction	Enquiries fully responded to in 18 working days	90%	73%	Amber			

Notes:

Between October 2018 and March 2019 capacity within the enquiry handling team was significantly impacted by long term sickness and vacancies in key posts, including management capacity. During the same period the team saw significant campaigning activity on a number of high profile topics. The remaining team members were also required to contribute to development of a new CRM system to manage the team's workload. This combination resulted in a backlog of enquiries. The team had to prioritise enquiries where we have a statutory duty to respond and those from key stakeholder groups (performance for these enquiries has been maintained). The team put in place a number of measures to address the backlog which has reduced significantly from a peak of over 1000 to under 300. All but one vacancy is now filled. Performance has improved slightly from Q4 of 2018-19 to this quarter. We expect performance to continue to improve steadily from Q2

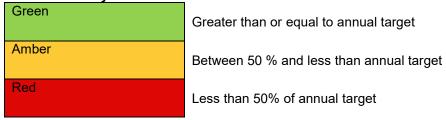
T erretmance has impreved eligina	y nom & 1 or 2010 to to this quarter: We expect performa	noo to oontinao to n	nprovo otodany ni	Jili QZ.
Improved satisfaction	Number of Freedom of Information requests	100%	100%	Green
	responded to within 20 working days			
Improved satisfaction	Parliamentary Questions contribution provided within	90%	100%	Green
	requested timeframe			
Ensuring stakeholders have	Percentage of planned availability, not including	98%	99.98%	Green
access to our websites as the	scheduled out of hours maintenance			
main communication channel				

Outputs	Measure	Target	Planned Q1 to Q2	Actual Q1 to Q2	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	4.6:1	230%	Green

Improving efficiency and speed of outputs							
Outputs	Measure	Annual target	Cumulative performance	RAG			
Speed of production	% STAs for all new drugs issuing an ACD or FAD within 6 months of the product being first licensed in the UK	90%	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 planned.							
Speed of production	% of Appeal Panel decisions received within 3 weeks	80%	N/A	N/A			
	of the hearing						
Notes:							
No appeal hearings have been held	d.						

RAG Status - Key



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July 2019

National Institute for Health and Care Excellence Annual report and accounts 2018/19

The Board is asked to formally receive the annual report and accounts.

Andrew Dillon

Chief Executive

July 2019

National Institute for Health and Care Excellence Finance and workforce report

This report gives details of the financial position as at 31 May 2019, the current forecast outturn for 2019/20 and an update on the workforce.

The Board is asked to review the report.

Ben Bennett

Director, Business Planning and Resources

July 2019

National Institute for Health and Care Excellence Finance and workforce report Date: 17 July 2019 Reference: 19/063

Financial Position as at 31 May 2019

Summary

1. Table 1 summarises the financial position as at 31 May 2019 and gives an estimated outturn for 31 March 2020. There is a full analysis in Appendix A.

Table 1 Financial Position at 31 May 2019

	Year to date (May 2019)				Estimated Outturn (March 2020)			
	Budget £m	Expenditure £m	Income £m	Variance £m	Budget £m	Expenditure £m	Income £m	Variance £m
Guidance & Advice Centres	8.0	8.1	(0.2)	(0.1)	49.3	49.9	(1.0)	(0.3)
Corporate Functions	2.2	2.3	(0.2)	(0.1)	13.8	15.1	(0.9)	0.3
Science Advice & Research	0.0	0.4	(0.4)	(0.0)	0.0	2.6	(2.6)	(0.0)
Income (non grant-in-aid)	(1.9)	0.0	(1.9)	(0.1)	(14.4)	0.0	(13.6)	0.8
Grand Total	8.4	10.8	(2.7)	(0.3)	48.6	67.5	(18.1)	0.8

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- 2. The table above shows a total underspend against budget of £0.3m (3%) at the end of May. This is equally split across underspends on pay and non-pay and an over recovery of income in the first 2 months of the financial year.
- 3. The full-year forecast position is that there will be an overspend of £0.8m (2% variance), wholly attributable to an under recovery of Technology Appraisal income in this first year of charging for these services. This is an estimate based on the number of appraisals that commenced during quarter 1 and the forecast position could change significantly as we progress through the year.

Financial Position as at 31 May 2019

4. Table 2 summarises the year to date financial position as at 31 May 2019 split between pay, non-pay and income.

Table 2 Year to date Financial Position

	Year to date (May 2019)					
	Budget £000	Expenditure £000	Variance £000			
Pay	6,354	6,284	(70)			
Non-pay	4,624	4,541	(84)			
Income	(2,611)	(2,710)	(99)			
Grand Total	8,368	8,115	(253)			

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- 5. Table 2 above shows total net expenditure to 31 May 2019 was £8.1m against a budget of £8.4m, giving an underspend of £0.25m (3%). The underspend comprised of:
- 6. £70,000 pay underspend partly due to a timing issue relating to increments. Small underspends will accumulate at the start of the year whilst each eligible member of staff awaits to receive their annual pay increment.
- 7. £84,000 non-pay underspend relating to depreciation and external contracts where the call off budget has not been utilised during the first 2 months of 2019/20.
- 8. £99,000 income target surplus due to TA and HST charging income being ahead of target and intellectual property and copyright license income generated within the Evidence Resources Directorate.
- 9. Appendix A shows in detail the financial position and forecast outturn per centre and directorate. Directors receive detailed monthly reports on the budget performance of their directorates and SMT receive a finance report detailing the summary position and issue on a bi-monthly basis.

Pay and resourcing

10. Pay expenditure to 31 May 2019 was £6.28m against an adjusted budget of £6.35m, resulting in an underspend of £70,000. The distribution across the centres is shown in table 3:

Table 3 Year to date Pay Figures by Centre

	Budget £000	Expenditure £000	Variance £000	Variance %
Centre for Guidelines	1,098	1,077	(21)	(2%)
Centre for Health Technology Evaluation	1,515	1,518	3	0%
Health & Social Care	1,415	1,404	(11)	(1%)
Evidence Resources	859	844	(16)	(2%)
Science Advice and Research	364	361	(3)	(1%)
Business Planning & Resources	503	503	1	0%
Communications	601	578	(24)	(4%)
Grand Total	6,354	6,284	(70)	(1%)

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- 11. The full year pay budget was originally £7.15m. This has been adjusted by transferring £0.8m of expected budget slippage associated with vacant posts into reserves (known as the part-year effect adjustment). This will be used to offset the unfunded pay award and pension increases notified during the final two months of 2018/19.
- 12. During May the total number of vacancies was 49 wte (a 7.2% vacancy rate). This has reduced from the 10% consistent vacancy rate in 2018/19 and the part year effect budgets have been removed for these posts as referred to above. The current vacancy rate of 7.2% is mainly due to a timing delay between old employees leaving and new starters coming into post. The reduction in the vacancy gap results from a range of initiatives that have been put in place by HR including the appointment of the dedicated recruitment advisor.
- 13. There are currently 8 agency staff employed across the organisation with a total spend in April and May 2019 of £73,000 (1% of total pay costs), this is similar to the position during the same period last year of £78,000.

Non-pay

- 14. Non-pay has contributed £84,000 to the current operational underspend for April to May 19, this is due to an underspend on depreciation and underspends on MedTech external assessment contracts.
- 15. The depreciation underspend is expected to grow in the short-term but will reduce in the latter part of the year as we commit expenditure on capital purchases such as IT hardware and improvements to the Manchester office.

Income

- 16. The year-to-date income target is currently showing an over recovery against budget of £99,000. Technology Appraisal and Highly Specialised Technology charging income, intellectual property and copyright license income and the Office for Market Access are all ahead of target and have generated more income than planned in the first 2 months of the year. This surplus is expected to reduce in subsequent months due to a slowdown of charging income against plan.
- 17. The Technology Appraisal and Highly Specialised Technology charging regime has been running for 2 complete months now. 6 STA topics started in April and 7 were started in May along with a Cancer Drugs Fund review, therefore a total of 14 current topics were underway by 31 May. Of the 14 invoices issued to companies, 13 have been paid. We expect payment for final outstanding topic soon. We will recognise income over the production time of each appraisal, typically 11 months. Most of the income received relating to appraisals starting in the first 2 months of 2019/20 will likely be recognised fully in 2019/20, but invoices raised from now on will see some income recognised in this year and some in 2020/21 over the time period of completing the appraisal.
- 18. To achieve the target of £4.8m income required to break even, we need to start approximately 6 new topics per month. In the first 2 months we started slightly more than this hence we are currently £60,000 ahead of target. However, only 3 topics commenced in June and it is likely that 5 will commence in July although changes to the schedule are common. This means that expected income will reduce from its current trajectory.
- 19. It is still too early to predict with any certainty what the final income figure for Technology Appraisal and Highly Specialised Technology charges will be in 2019/20. The Board is reminded that because of the delay in the final DHSC approval for the introduction of charging we expected a shortfall of up to £1.6m and the DHSC agreed to underwrite this if necessary.

- 20. A forecast income figure of £4m is the best estimate at this stage (which would result in a deficit of £0.8m), but there is the potential for a wide margin of error. We are keeping DHSC informed about the position.
- 21. We will continue to report to SMT and the Board progress against this plan. A dashboard with key information about income generated, work in progress and topic pipeline information is currently being developed.

Forecast Outturn

- 22. The current forecast is for the year-end outturn to be £0.8m overspent against budget (2% variance). This is due to the forecast deficit on Technology Appraisal income noted above. This forecast is inclusive of assumptions made about successful recruitment to vacant positions and income generating teams achieving their planned targets. It is expected that collectively all other programmes will break even.
- 23. The summary financial position analysed by directorate is shown in Appendix 1. It shows 2 significant forecast year end variances. The first is shown against Centre for Health Technology Evaluation (CHTE), where the total forecast underspend is £271,000. The main reason for this is that it is likely the flexible element of the MedTech External Assessment Centre contract will not be required in full in 2019/20.
- 24. The second significant variation shown relates to potential cost pressures (£0.4m) which we now expect are likely to materialise during the year. These cost pressures include:
 - Improvements to the Manchester office are planned for later in the year, including increasing the meeting room capacity, and updating the rear reception area. Although most of the expenditure will come from the £0.5m capital budget, there may be some revenue costs associated with the works that have not been budgeted for.
 - Investment is required to update the IT infrastructure and other technology, including implementing recommendations made by Civica in relation to data management and storage.
 - A need to make provisions in the accounts towards the end of the financial year for liabilities arising from the London office move (for example the financial impact of paying additional travel costs up-front as agreed at SMT recently) and potential transition costs relating to the NICE Connect project.
- 25. There are currently no reserves in place to fund the above cost pressures if they materialise. However, the current forecast assumes that a number of non-

National Institute for Health and Care Excellence Finance and workforce report Date: 17 July 2019 Reference: 19/063 recurrent underspends in teams (including the forecast underspend in CHTE noted above) will be sufficient to offset this potential cost. Therefore leading to an overall breakeven position, with the exception of the above noted TA cost recovery income.

Workforce

Resourcing

26. The project to bring recruitment in house is progressing and is on track. Following a procurement process, we have signed a contract with an applicant tracking and onboarding system supplier. This is a key milestone in the plan to bring recruitment in house, improve the candidate and manager experience and speed up the process. The system will be configured involving key stakeholders across NICE with the aim of going live in Autumn 2019.

Culture

- 27. Two Freedom to Speak Up Guardians have been appointed, one based in London, and one in Manchester. Their roles will complement the whistleblowing policy.
- 28. The 2019 NICE staff survey received a response rate of 85%. The staff survey report and organisational action plan will be presented to the Board at the September meeting.
- 29. The HR team has recently appointed an Organisational Development and Training Specialist who is going to develop our induction programme and management development offer, as well as supporting with organisational change during the NICE Connect transformation project.

Transformational Change

- 30. Our new HR System Lead has joined the team and is focussing on improving the data integrity and reporting on ESR for both HR and Finance teams. They are also improving the employee and manager experience of the self-service aspects of the system; more projects will follow.
- 31. In preparation for the London office move, HR have worked collaboratively with facilities and finance to develop and consult on a support package for staff relocating office base, which has been agreed by SMT.

Maximising Potential

32. HR have delivered mini masterclasses on 'improving performance' to managers across the organisation and have promoted the 'resolving issues at work'

National Institute for Health and Care Excellence Finance and workforce report Date: 17 July 2019 Reference: 19/063 classes which will take place over the summer and update managers skills related to informal grievances and disciplinary issues.

Appendix A: Summary of Financial Position

The table below is a summary of the financial position per centre and directorate as at 31 May 2019 and gives an estimated outturn to March 2020.

	Year to date (May 2019)				Estimated Outturn (March 2020)			
Centre / Directorate	Budget £000's	Actual £000's	Variance £000's	Variance %	Budget £000's	Outturn £000's	Variance £000's	Variance %
Income from other ALBS, Devolved Administrations and other miscellaneous income	(1,674)	(1,678)	(4)	0%	(9,627)	(9,633)	(6)	0%
Income from TA and HST cost recovery	(188)	(247)	(60)	32%	(4,800)	(4,000)	800	(17%)
Centre for Guidelines	2,764	2,771	7	0%	17,353	17,348	(5)	0%
Centre for Health Technology Evaluation	1,935	1,865	(71)	(4%)	11,855	11,584	(271)	(2%)
Health & Social Care	1,555	1,573	19	1%	9,287	9,239	(48)	(1%)
Evidence Resources	1,726	1,666	(60)	(3%)	10,757	10,737	(20)	0%
Science Advice and Research	17	12	(5)	(31%)	22	21	(1)	(3%)
Business Planning & Resources	1,401	1,369	(33)	(2%)	8,570	8,534	(36)	0%
Communications	680	667	(13)	(2%)	4,150	4,137	(13)	0%
NICE Connect	43	33	(10)	(23%)	432	428	(4)	(1%)
Potential cost pressures					0	400	400	n/a
Depreciation	108	85	(23)	(22%)	650	650	0	0%
Grand total	8,368	8,115	(253)	(3%)	48,648	49,445	797	2%

Download the data set for this table.

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July 2019

National Institute for Health and Care Excellence Finance and workforce report Date: 17 July 2019 Reference: 19/063

National Institute for Health and Care Excellence Annual Workforce Report 2018/19

The attached paper provides a summary of the workforce profile at 31 March 2019.

The Board is asked to receive the report.

Ben Bennett

Director, Business Planning and Resources

July 2019

National Institute for Health and Care Excellence Annual Workforce Report 2018/19 Date: 17 July 2019 Reference: 19/064

Summary

The annual workforce report includes a range of key human resource indicators that profile the NICE workforce. The workforce data is either a snapshot (as at 31 March 2019) or a cumulative for the financial year (1 April 2018 - 31 March 2019). This report is to give the Board and SMT greater detail about the makeup of the workforce: how it has changed during 2018/19 and the key events that have affected it. Below is a summary of the headline figures.

Workforce size

The average whole time equivalent (wte) workforce in 2018/2019 was 618 (compared with 613 in 2017/18).

Vacancy rates

Budgeted vacancy rates increased. There was an average of 64 budgeted vacancies in year, compared with 38 in the previous year. The increase was due to increasing capacity in CHTE, and vacancies being filled in the second half of the year. We expect this figure to stabilise back down over the coming year.

Turnover

Total turnover was 12.5%, which is similar to the previous year (12.2%), and lower than 2016/17 (13.2%). Voluntary turnover (staff resigning or retiring rather than being made redundant or being dismissed) increased to 10.5% compared with 8.4% in 2017/18. This increase requires further analysis and will be closely monitored over the coming year.

Flexible working

Uptake of flexible working arrangements remained high with 79% of employees with some form of flexible working arrangement.

Equalities profile

The overall profile of our workforce remained similar to the previous year.

- The proportion of females was 70% as at 31 March 2019 (68% in 2018).
- The proportion of staff aged under 40 remained almost the same as the previous year (56% in 2018/19).
- Overall there was little change in our Black and Minority Ethnic (BAME) profile, however there was an increase in the number of BAME staff at band 7 and above, from 14.9% to 16.6%.

Gender pay gap

Last year we published our gender pay reporting for the first time. Our overall mean gender pay gap this year is 5.3% and the median is 3.25%, an increase and decrease respectively on last year. Due to our size, the percentages can easily shift with relatively small staffing changes.

NICE's gender pay gap is significantly below the national average however we recognise we need to do more.

Sickness absence

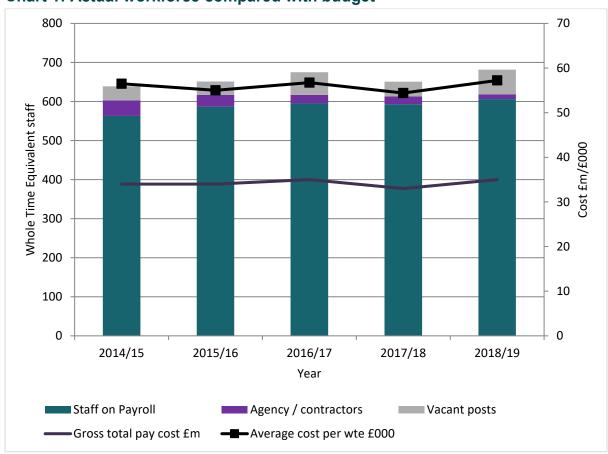
Sickness absence increased slightly to 2.6% compared with 2.3% the previous year. Whilst still less than the national average across Special Health Authorities and ALB's at 2.91%, this is something we will continue to monitor.

Introduction

- 1. The annual workforce report provides a detailed account of NICE's workforce.
- 2. The report is presented in 3 sections:
 - Workforce profile provides information about the size, grade and composition of the workforce
 - **Equality profile** summarises the equality information for the employed workforce, applicants and appointees.
 - **Key workforce developments** identifies the key internal and external factors that have affected the workforce in 2018/19
- 3. Where available, comparison will be drawn with information provided in the 2017/18 workforce report.

Workforce profile

Chart 1: Actual workforce compared with budget



You can download the data set for this chart

Cost and size of the workforce

- 4. Chart 1 shows two different types of data. The columns show the total budgeted workforce size over the past five years read against the left axis. The analysis of each column shows how this was made up of staff in post on the payroll, from agencies, contractors and the remaining unfilled vacancies. The staff numbers are the average for the financial year rather than a point in time. The lines on the chart show two types of financial information read against the right axis, the total expenditure on pay in each year in £m and the average cost per whole time equivalent (wte) in £000s. The staff costs are inclusive of employer on-cost for pensions and national insurance of about 23%.
- 5. The savings programme that has been in place since 2014/15 resulted in an overall reduction in total expenditure from £73m to £67m in 2018/19. However, our pay costs increased by £1.4m during this period whilst non-pay costs decreased by £7.8m. In that time pay costs as a proportion of total expenditure increased from 46% of the budget to 53%.
- 6. There was an average of 64 budgeted vacancies in year (9% vacancy rate), which is higher than 2017/18 (38 budgeted vacancies, 6% vacancy rate).
- 7. There were 152 unique job advertisements in 2018/19. The number of vacancies in 2018/19 was higher primarily due to increasing the capacity of the CHTE appraisal programme taking time to recruit and newly established teams such as the commercial liaison unit and data analytics team not filling posts until the second half of the year.
- 8. The unique job advertisements represent all planned and unplanned vacancies recruited to during the year. The budgeted vacancies were those we planned and budgeted for at the beginning of the financial year.
- 9. There was an average 12 wte agency workers or contractors in post in 2018/19, which was a reduction of 8 wte from 2017/18.
- 10. The total cost of the workforce in 2018/19 was £35.4m (inclusive of employer oncosts). This is an increase of £2m (6%) from £33.4m in 2017/18. Approximately half of this increase was due to the Agenda for Change pay deal, with the rest due to an increase in the average headcount across the year and pay grade drift. As at March 2019, there were 18wte (4.3%) more employees at bands 7-9, whereas the number of employees between bands 1-6 fell by 4wte (2.5%).

Turnover

Reference: 19/064

11. Employee turnover for 2018/19 was 12.5% which is similar to 2017/18 (12.2%). When leavers for reasons of redundancy and end of fixed-term contract are removed from the figures, the employee turnover is 10.49% in 2018/19

National Institute for Health and Care Excellence Annual Workforce Report 2018/19 Date: 17 July 2019 compared with 8.4% in 2017/18. There were 87 wte leavers during 2018/19, which is an increase from 83 wte in the previous year.

Turnover 2017/18

Turnover 2018/19

Turnover 2018/19

Turnover 2018/19

Turnover 2018/19

Turnover 2018/19

Turnover 2018/19

Chart 2a: Percentage overall turnover in each grade 2017/18 & 2018/19

You can download the data set for this chart

12. Chart 2a shows how these were distributed as a percentage across the grades. The trend line shows average turnover.

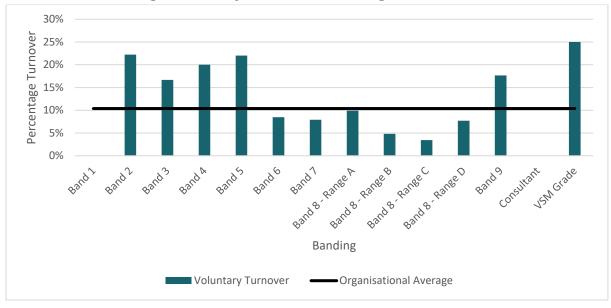


Chart 2b: Percentage voluntary turnover at each grade

You can download the data set for this chart

- 13. Chart 2b shows voluntary turnover which is where staff have resigned or retired.
- 14. There was high turnover in band 2 employees (a population of 9 wte), which is due to a combination of resignation and staff completing apprenticeships and not

National Institute for Health and Care Excellence Annual Workforce Report 2018/19 Date: 17 July 2019 Reference: 19/064 continuing their employment with NICE. At band 9 and VSM grades, the staff numbers are small so the average can easily be distorted. These leavers were due to resignations and planned retirements.

20% Percentage Turnover 15% 10% 5% 0% BP&R CFG CHTE ER H&SC Comms Directorate 2018/19 Turnover 2017/18 Turnover ■2018/19 Average Turnover — 2017/18 Average Turnover

Chart 3: Voluntary turnover by directorate 2017/18 & 2018/19

You can download the data set for this chart

15. Chart 3 shows the voluntary staff turnover in each directorate, with trend line showing the overall turnover rate.

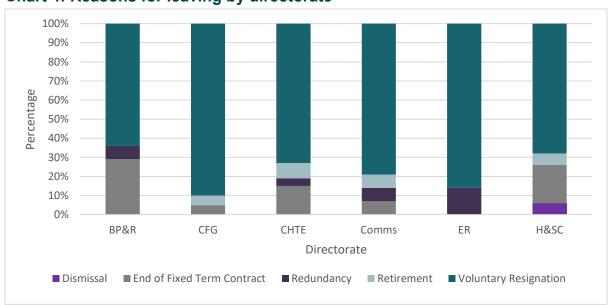
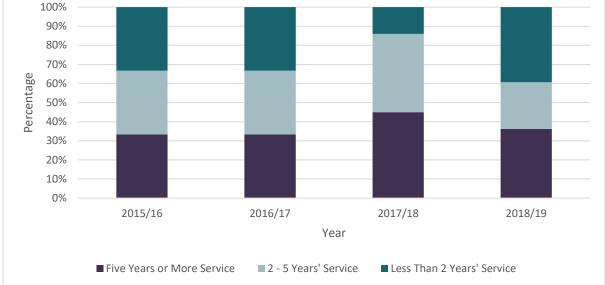


Chart 4: Reasons for leaving by directorate

You can download the data set for this chart

16. Chart 4 shows that voluntary resignation continues to be the most significant reason for leaving.

Chart 5 - leavers by length of service 100% 90% 80% 70%



You can download the data set for this chart

- 17. Chart 5 shows an increase in the proportion of leavers with less than 2 years' service when compared with previous years, which is quite different to last year's profile, but is similar to the leaver profile of 2015/16 and 2016/17.
- 18. The completion rate for exit interviews remained at 31% of leavers, despite the introduction of an online questionnaire to complement existing options of a faceto-face meeting with HR, the line manager or grandparent manager. We are continuing to encourage leavers to complete the survey, and working with line managers to encourage staff to complete an exit survey or interview.

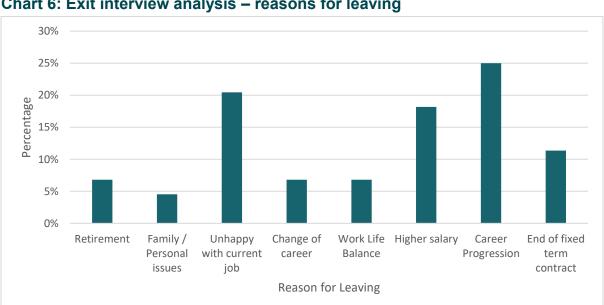


Chart 6: Exit interview analysis - reasons for leaving

You can download the data set for this chart

19. Chart 6 shows reasons for leaving as expressed in exit interviews. Respondents are able to select multiple reasons for leaving, as applicable.

Recruitment

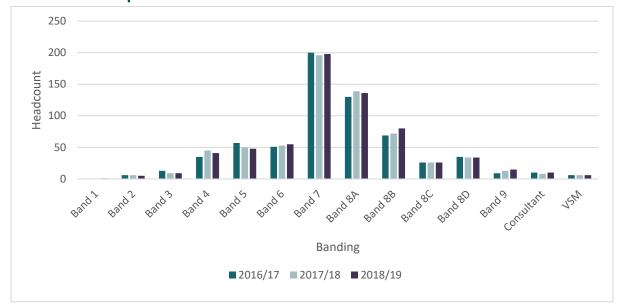
- 20. The number of unique job advertisements (excluding re-advertisements) in 2018/19 was 152, which is similar to 2017/18 (155), and the 2015/16 figure (141).
- 21. The total number of applicants, both internal and external, for all roles, was 6,643 in 2018/19 (compared with 5,336 in 2017/18). 13.3% of candidates were invited to interview (compared with 14.9% last year).
- 22. The average number of applicants per vacancy in 2018/19 was 43.4 (compared with 30 in 2017/8). We believe that the increase in the number of applications is largely due to our new marketing and attraction initiatives.

Temporary staffing

- 23. On 31 March 2019, a total of 12 staff were employed on the temporary staff bank. This is an increase compared with previous years (7 in 2018, and 6 in 2017). The level of appointments fluctuates throughout the year, and bank posts are typically used as short-term backfill for vacant posts. NICE is committed to treating bank workers fairly and only utilises the bank as intended for ad hoc assignments. Where it is considered more appropriate, roles are converted to formal fixed term contracts. Bank staff are employed on non-exclusive zero hours contracts.
- 24. In addition to bank staff we employed an average of 12 contractors and agency staff in 2018/19. The expenditure on contractors and agency workers decreased by 11% from £0.72m in 2017/18 to £0.65m in 2018/19. This was primarily as a result of a reduced usage of Digital Services contractors in the Evidence Resources directorate.

National Institute for Health and Care Excellence Annual Workforce Report 2018/19 Date: 17 July 2019 Reference: 19/064

Chart 7: Grade profile



You can download the data set for this chart

25. Chart 7 above shows the grade profile at 31st March in 2017, 2018 and 2019 by headcount. Seniority increases from left to right. The consultant category includes medically qualified senior managers, and other advisors and managers employed on medical terms and conditions. The profile remains similar to previous years. There was an overall small increase in the number of 6s, 8bs, 9s and consultants and decrease in the number of 2s, 4s, 5s and 8as.

Flexible working

26. A range of flexible working arrangements were in place, including part-time and compressed hours. The 2018 staff survey responses show that 79% of employees were working flexibly or had a formal flexible working arrangement in place.

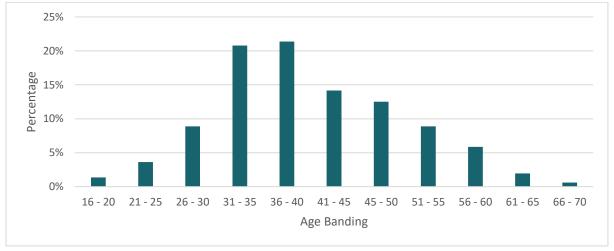
Equalities profile

- 27. This section provides a summary of the workforce profile by equality category, as at 31 March 2019. It includes some comparison to previous years to highlight notable changes. There is also a summary of the equalities profiles of job applicants throughout the year and of those who were successful in obtaining a role.
- 28. This information is held in the Electronic Staff Record (ESR) system. When candidates apply for a post through the NHS jobs online system, they are asked to complete an equalities questionnaire. This information is retained and, if the application is successful, transfers into the payroll data held by ESR. In the categories relating to disability, religious belief and sexuality a large proportion of

staff and applicants have chosen not to disclose this information; this is not untypical of many organisations in this type of data collection exercise.

Age

Chart 8: Age profile as a percentage of workforce in year

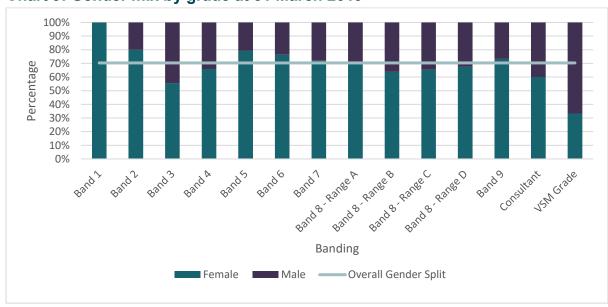


You can download the data set for this chart

29. Chart 8 shows the age profile at 31 March 2019. 56% of NICE's workforce were aged 40 or under. This is similar last year (55%).

Gender

Chart 9: Gender mix by grade at 31 March 2019



You can download the data set for this chart

30. Chart 9 shows the proportion of males and females in each grade at 31 March 2019. The overall gender split has not changed significantly over time. Band 8d showed the largest change. The proportion of females shown in the chart was

70.3% at 31 March 2019, comparable to 68.6% at 31 March 2018. The current system, ESR, will only allow you to record Male or Female so at present there is no option for employees who prefer to self-describe.

Gender pay analysis

- 31. NICE produced a gender pay gap report in line with legislation as at 31 March 2018. It was published on <u>our website</u>. The mean gender pay gap was 5.3%. These figures reflect the distribution of female and male staff across the pay grades. There were marginally more women than men in the lower half of our pay grades. These figures do not mean that male and female staff were paid differently for doing the same work at NICE.
- 32. NICE's gender pay gap is significantly below the national average however we recognise we need to do more.

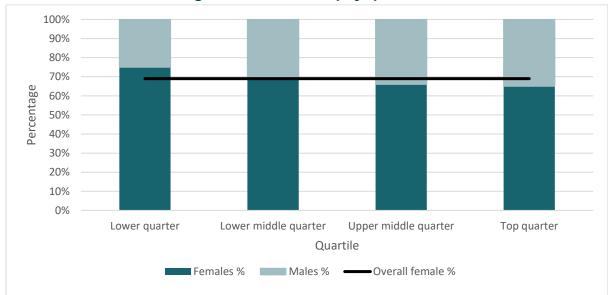


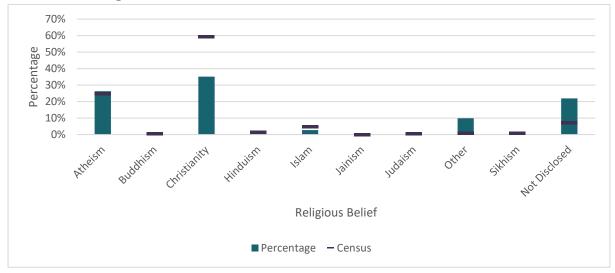
Chart 10: Distribution of gender across the pay quartiles

You can download the data set for this chart

Disability

- 33. Staff are encouraged to declare any disabilities, which may include learning disability or difficulty, long-standing illness, mental health conditions, physical impairment and sensory impairment. 26 staff declared a disability, which was 3.9% of the workforce. This is similar to the previous year (3.5%). Reasonable adjustments are made for staff and visitors with disabilities.
- 34. In December 2018, NICE achieved Disability Confident "Employer" status, to demonstrate and ensure that disabled people and those with long term health conditions can fulfil their potential and realise their aspirations in the workplace.

Chart 11 - religion and belief

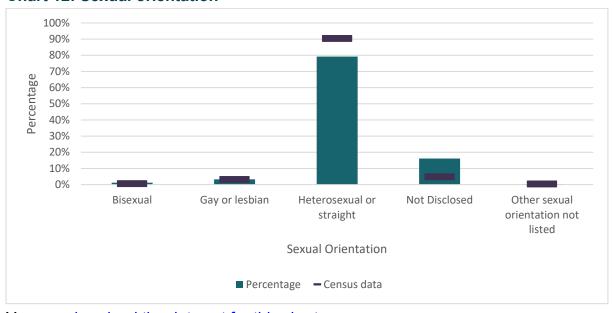


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35. Chart 11 shows the religious faith or beliefs that staff disclosed, compared with the 2011 census data. The profile is similar to the previous year. The largest group was Christian 35% (233) followed by atheism 26% (175). Employees who chose not to complete this question are identified as not disclosed.

Sexual orientation

Chart 12: Sexual orientation



You can download the data set for this chart

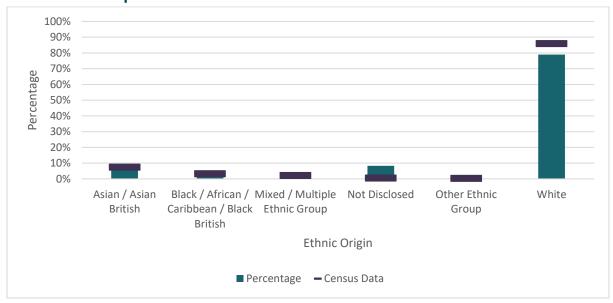
36. Chart 12 shows the sexual orientation data for the workforce compared with the 2017 annual population survey. The combined non-disclosure and non-specified rate was 16%. This profile is similar to 2017/18.

37. NICE continue to be Stonewall Diversity Champions, which is a framework designed to help employers to support lesbian, gay, bisexual and transgender employees to reach their full potential in the workplace.

Race

38. Chart 13 shows the race profiles of the overall workforce, compared with the 2011 census data.

Chart 13: Race profile



You can download the data set for this chart

- 39. There was little change in our profile from 2017/18 with, our proportion of white staff increasing slightly from 77% to 79%. Census data indicates that 86% of England and Wales is from a white background.
- 40. It appears that black, Asian and minority ethnic (BAME) staff continued to be under-represented in both office locations, given that 33% of the population of the City of Manchester and 40% of the population in London are non-white. However, the catchment area for both locations spreads beyond the city centres, and our staff numbers also included nationwide based homeworkers.

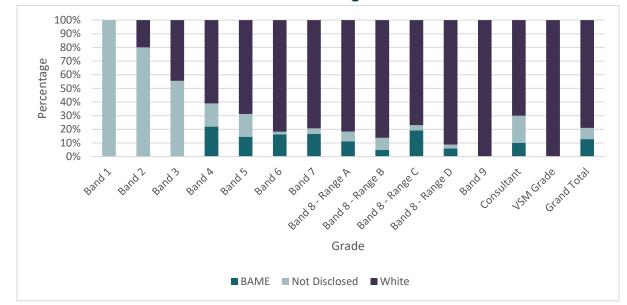


Chart 14: Distribution of BAME staff across grade

You can download the data set for this chart

- 41. Chart 14 shows the distribution of BAME staff across the pay bands at 31 March 2019. It continued to appear that BAME staff were under-represented in the more senior pay bands, although the analysis included staff who chose not to disclose their racial origin.
- 42. There was an increase in the number of BAME staff at band 7 and above, from 14.9% in 2017/18 to 16.6% in 2018/2019.
- 43. Job applications from a diverse range of candidates continue to be encouraged. We broadened our recruitment marketing efforts and utilised paid promotional ads on social media (Facebook, Twitter, Instagram) for our specialist and niche vacancies.
- 44. We are committed to continuing to promote opportunities to potential candidates and existing staff, by building networks with other public sector bodies and promoting development opportunities, some of which are of particular benefit or interest to staff from underrepresented groups, including BAME.
- 45. In 2019, NICE will be participating in the NHS Workforce Race Equality Standard (WRES), and will use this data to continue to develop action plans aimed at ensuring our BAME staff have equal access to career opportunities and receive fair treatment in the workplace.

Employment applicants and appointees

46. Data on employment applicants and appointees is gathered via the equality profile of individuals when they complete their application on the TRAC recruitment system. This data is now automatically transferred to the Electronic

- Staff Record (ESR) system. When ESR self-service was rolled out to all staff in April, we encouraged staff to update their diversity information. Staff now have access to update this information at any time.
- 47. There was a total of 6,643 applications for 152 posts which were advertised in 2018/19.
- 48. Charts 15-20 over the page show the relationship between the profiles of the total applicants, the NICE staff and successful applicants in year for a range of equalities areas including race, gender and religious belief.
 - Age we appointed 27 people over the age of 45 in 2018/19, which is an increase compared with 2017/2018 (12 people). We also saw a decrease in hires in 2018/19 of people aged between 25-34, from 83 in 2017/18 to 70 in 2018/19, and an increase of hires of people aged between 35-44, from 35 in 2017/18 to 46 in 2018/19.
 - Gender This year we appointed 36 men (26% of vacancies filled) and 113 women (74%), compared with 2017/2018 where we hired 39 men (29%) and 97 women (71%). The current Recruitment administrators, BSA, will only allow you to record Male or Female so at present there is no option for applicants who prefer to self-describe.
 - **Disability** In 2018/19, 386 (5.81% of total applicants) applicants disclosed having a disability, and of those, we appointed 8 (5.23% of those appointed).
 - Ethnicity In 2018/19:
 - 53% of all applicants and 77% of appointed candidates were white
 - 15% of applicants and 4% of appointed candidates were black or black British.
 - 22% of applications and 11% of appointed candidates were from an Asian or Asian British background
 - 3.54 % of applicants and 8.28% of appointed candidates did not disclose this information.
 - Sexual orientation 4% (292) of all applications (6643) disclosed they were gay or lesbian, of which we appointed 3% of 292. 5.9% of all applications chose not to disclose and 10% of those were appointed.
 5.93% of applicants did not disclose their sexual orientation, compared with 16.11% of staff.

National Institute for Health and Care Excellence Annual Workforce Report 2018/19 Date: 17 July 2019 Reference: 19/064

Charts 15 - 20 Applications, appointments, all NICE staff

You can download the data set for this chart



Key workforce developments

Organisational change

- 49. Organisational change affected 5 directorates in 2018/19, which primarily affected individuals rather than teams. Two affected employees had previously accepted fixed-term contracts as an alternative to redundancy in previous change programmes. One employee was successfully redeployed.
- 50. Two employees were made redundant as a result of reorganisation of team requirements, and one employee was placed at risk of redundancy.

Job evaluation

- 51. A total of 53 job evaluations were carried in 2018/19.
- 52. These comprised of 29 new posts, 1 review due to organisational changes, 18 updated job descriptions and 5 upgrades.

Employee relations activity

- 53. Table 1 provides data relating to the formal employee relations activities in 2018/19. The table does not include informal activity. The number of employee relations cases was 12, which is 2 less than in 2017/18. There have been no new Employment Tribunal hearings, however there has been some activity in this area.
 - the outcome for an Employment Tribunal hearing in March 2018 remains outstanding due to the Tribunal Chair being unavailable to confirm the outcome.
 - the outcome of a previous Employment Tribunal has been appealed by the complainant
 - a former employee withdrew their claim just ahead of a hearing.

Table 1: Employee relations case work figures

Case type	Number
Disciplinary	4
Grievance (including bullying & harassment)	3
Employment Tribunals	0
Performance management	2

Reference: 19/064

Health and wellbeing

54. The annual report and accounts give a figure of 2.6% for the sickness rate during the 2018 calendar year compared with a rate of 2.3% the previous year. The Department of Health and Social Care requires sickness absence rates to be calculated based on a 365-day year rather than actual days available for work. A 2.6% rate equates to an average of 5.9 days per wte. The data is obtained from the ESR system. Its accuracy relies on accurate reporting of sickness on ESR in line with the sickness absence policy, and the completion of return to work discussions between managers and staff.

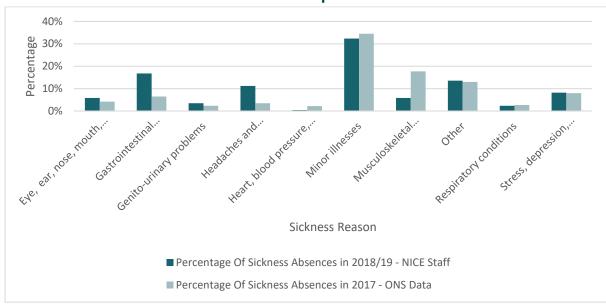


Chart 21 - Sickness reasons at NICE compared with ONS data

You can download the data set for this chart

- 55. Chart 21 compares NICE's sickness absence data against data from the Office for National Statistics (ONS). Minor illnesses counted for the highest number of absence occurrences followed by gastrointestinal problems. There has been an increase in the percentage of absences related to stress, depression, anxiety or psychiatric illness, however this is still in line with the Office for National Statistics (ONS). This is being monitored and a number of new interventions such as Welfare Action Plans, mental health first aiders and upskilling line managers have been put in place. There has been a reduction in the percentage of undisclosed reasons for absence. Long term sickness accounted for 64% of all days lost due to sick leave in 2018/19.
- 56. In 2018/19 a total of 54 referrals were made to occupational health service, (using a variety of methods as appropriate including telephone assessment, face to face assessment and consultant appointments). This is 9 higher than the previous year.

National Institute for Health and Care Excellence Annual Workforce Report 2018/19 Date: 17 July 2019 Reference: 19/064

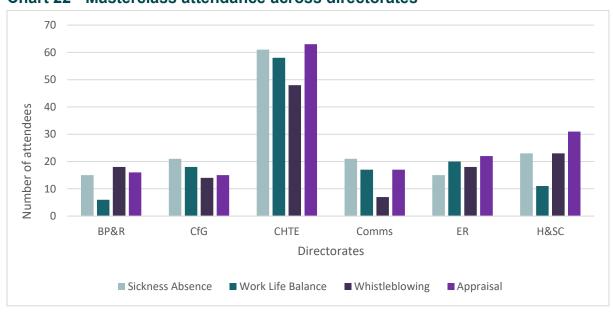
- 57. In 2018/19 we trained an additional 30 mental health first aiders as part of our ongoing commitment to support our staff with their mental wellbeing.
- 58. 269 people requested a flu voucher, compared with 187 in 2017/18.

Learning and development

- 59. During 2018/19 the total spent on training activities was £244,000. This figure excludes travel, subsistence and staff time.
- 60. We continued to invest in the development of our staff with 304 external training applications approved in 2018/19. This is a decrease of 64 applications in comparison to the previous year. This does not include internal training, conferences or L&D interventions supporting organisational initiatives.
- 61. In 2018/19 HR proactively engaged with teams in order to improve consistency and promote access to staff training identified through individual personal development plans. Consequently 94% of the available training budget was used throughout 2018/19.
- 62. Training throughout 2018/19 encompassed a wide range of topics with the majority focusing on technical analytical skills (analysis, health economics, statistics and critical evaluation and appraisal) which accounted for nearly half of all training. Other training included resilience, IT skills, data visualisation, digital programming, change management, project management and leadership training.
- 63. We have moved our e-learning activities onto ESR's online learning management system. As well as providing significant cost savings, a key benefit of ESR's OLM is that it provides us with real-time information about our staff's competencies and compliance with mandatory training. It also enables us to access a wealth of online learning opportunities provided by a range of NHS and related bodies, as well as the ability to design or purchase our own products.
- 64. HR continued to provide a range of internal training activities focused on core corporate skills. In 2018/19 the Learning and Development function concentrated on delivering targeted training. A total of 218 staff attended training in a range of areas including:
 - Equality & diversity
 - Equality impact assessments
 - Deaf awareness
 - Facilitation skills
 - Management and leadership

- Mental health first aid
- Mental wellbeing
- Personal resilience
- Presentation skills
- Project management
- Recruitment and selection
- Team development
- Investigation training
- 65. This list does not include statutory and mandatory training which has been completed via e-learning.
- 66. In 2018/19 the HR team delivered masterclass sessions to build the confidence and capability of line managers across the organisation when implementing key HR policies. Chart 22 below shows the breakdown of attendance by directorate. There was a total of 578 attendees for the following sessions:
 - Sickness absence
 - Work life balance
 - Whistleblowing
 - Appraisal

Chart 22 - Masterclass attendance across directorates



You can download the data set for this chart

- 67. NICE supported staff members with funding towards the achievement of necessary professional qualifications including HR, accountancy, facilities management and project management. Where possible, the apprenticeship levy was used for professional qualifications, to minimise the impact on the training budget.
- 68. In 2018/19 £45,000 was spent on conference attendance. This figure excludes travel and subsistence. The total staff time spent attending conferences was 202 days. Staff attended the Guidelines International Network (GIN) in Manchester, ISPOR in Barcelona and HTAI in Vancouver.

Apprentices

- 69. As part of the Government initiative to increase the number of apprenticeships, a 0.5% levy on employer's pay bills in excess of £3m was introduced in April 2017. The levy is managed through an online government portal and is collected through Pay As You Earn (PAYE). The levy funds can be drawn back down as funding to support the training and development of apprentices both newly recruited and existing staff. The actual levy costs to NICE in 2018/19 was £126,000.
- 70. The apprenticeship scheme is continuing to grow and develop. In 2018/19 a further 13 apprentices were offered learning contracts bringing the total number of apprentices to 25. This included 4 members of staff who progressed onto a higher programme having completed their previous apprenticeship with NICE.
- 71. There were 21 apprentices in Manchester and 4 in London. 19 had fixed term positions for the duration of the apprenticeship, and 6 had enrolled as permanent members of staff.

Future workforce developments

- 72. The HR Department have been developing initiatives, policies and procedures in line with NICE's Workforce Strategy which was formally approved by the Board in November 2018.
- 73. The team continues to support the development of NICE's workforce in alignment to the strategy, however, the key focus of the next 3 years will be changes that support strategic transformation programmes such as NICE Connect. A variety of elements from the Workforce Strategy will be pivotal to supporting this, such as culture, talent management and learning and development with a focus on future skills.
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July 2019

National Institute for Health and Care Excellence Revalidation annual report 2018/19

This report gives details of the policies, systems and processes needed to support the appraisal and revalidation of doctors, confirms that these are in place and that statutory requirements have been met. The report also highlights the position on revalidation for other registered health and care professionals, and the actions that NICE has put in place to address this.

The Board is asked to:

- Note NICE's statutory duties on medical appraisal and revalidation outlined in the report and the actions taken during 2018/19 to comply with these.
- Accept the report, which may be shared, along with the Annual Organisational Audit, with the Senior Responsible Officer (the Chief Medical Officer for England).
- Approve the 'statement of compliance' (Appendix A) which confirms that NICE, as a Designated Body, is in compliance with the Medical Profession (Responsible Officers) Regulations.

Professor Gillian Leng

Deputy Chief Executive and Director, Health & Social Care Directorate

July 2019

Executive Summary

- 1. The NICE Board is required to receive annual assurance that revalidation for registered medical practitioners is being properly implemented in line with policy and relevant guidance. This is the sixth annual report to be presented to the board and relates to the appraisal cycle for 01 April 2018 31 March 2019.
- 2. The Board is advised that NICE remains compliant with its own policy, national guidance and the quality assurance requirements for medical revalidation and can respond positively to all the statements detailed in the document, Statement of Compliance, attached as Appendix A.
- 3. The table below summarises activity for the 2018- 2019 medical appraisal cycle:

Table 1: Appraisal and revalidation activity 01 April 2018 - 31 March 2019

Registered medical practitioners with a prescribed connection with NICE	9
Medical appraisals completed	6
Medical appraisals not completed	1
Medical practitioners not scheduled to have a medical appraisal	2
Number of registered medical practitioners that were due to revalidate in 2018-19	
Revalidation recommendations made	3

- 4. One doctor did not complete their medical appraisal in the required timeframe, missing the deadline by 1 day. This was because the appraiser's new contract was delayed following a low number of submissions during the tender process which resulted in a waiver being required under procurement regulations. The doctor and the appraiser then had to arrange a mutually convenient time to meet within existing work commitments.
- 5. Two doctors were not scheduled to have an appraisal between 01 April 2018 and 31 March 2019. This was because:
 - One doctor was on maternity leave between May 2018 and March 2019.
 - The second doctor joined NICE in December 2018. This doctor did not hold a licence to practise between August 2017 and December 2018.
 - NHS England advise that after a return to practice there should be a delay
 of 6 to 12 months before the next appraisal. So, in line with this guidance,
 neither doctor was due to have an appraisal in 2018/19.

- 6. Nurse and midwife revalidation was introduced by the Nursing and Midwifery Council (NMC) on 01 April 2016 and 2 of the 5 registered nurses employed by NICE during 2018/19 revalidated in 2018/19.
- 7. The General Pharmaceutical Council (GPhC) started a phased introduction of revalidation for pharmacy professionals in October 2018. Twenty-three pharmacists employed by NICE revalidated during 2018/19. Sixteen of whom require registration for their role. Another 3 pharmacists have indicated that they will revalidate in the coming months, 1 of whom requires registration for their role. Three other pharmacists are not subject to GPhC revalidation requirements as they are registered with regulators other than the GPhC.
- 8. Key achievements in 2018/19 were:
 - Implementing relevant recommendations from the General Medical Council's (GMC) document Working with others to improve revalidation.
 NICE's medical appraisal and revalidation guidance for doctors and appraisers was updated to align to the guidance issued by the GMC.
 - Ensuring NICE's policies and procedures meet the updated requirements in the GMC's handbook "Effective Clinical Governance for the medical profession." This included the role of the following NICE policies and processes have in meeting the standards of the GMC's handbook:
 - Grievance policy
 - Whistleblowing policy, including "Freedom to Speak Up Guardians."
 - Revalidation of NICE's Deputy Responsible Officer, Dr Judith Richardson, and 2 Consultant Clinical Advisers.
 - Successfully supporting 23 employees who are registered pharmacists through their first revalidation.
 - Refreshing the job descriptions of 17 employees so there is a requirement to be a registered pharmacy professional in their role.

Purpose of the report

- 9. Revalidation has been introduced for medical, nursing and midwifery, and pharmacy professions. Medical revalidation is the only process which places a statutory duty on NICE.
- 10. The main purpose of this report is to provide the required assurance to the Board that NICE has policies, systems and processes in place that support the appraisal and revalidation of its registered medical practitioners and that these policies, systems and processes are subject to regular monitoring, evaluation and quality assurance.

- 11. The report responds to the requirements on medical revalidation in the Statement of Compliance (Appendix A) to be submitted to NHS England (NHSE).
- 12. This report also provides assurance to the Board that NICE has the necessary oversight to support other employees, who are registered health professionals to revalidate and meet the requirements of their registering body.

Revalidation of medical professionals

- 13. Medical revalidation was launched in December 2012 to strengthen the way that registered medical practitioners are regulated, with the aim of improving the quality of care provided to patients, improving patient safety and increasing public trust and confidence in the medical system.
- 14. All licensed doctors are required to show, every 5 years, that they are up to date and fit to practise. This is demonstrated through participation in annual medical appraisal, based on the GMC's core guidance for doctors, Good Medical Practice.
- 15. Revalidation recommendations, at the end of each 5-year cycle, are made to the GMC by NICE's Responsible Officer (RO) for those doctors with NICE as their designated body.
- 16. As a designated body NICE has a statutory duty to support its RO in discharging their duties under The Medical Profession (Responsible Officers) Regulations, 2010 as amended in 2013.

Governance arrangements

Leadership

- 17. The Deputy Chief Executive and Health & Social Care Director, Professor Gillian Leng, was appointed as the RO for NICE in 2012 and has attended the training required for this role.
- 18. The RO is supported by a Deputy RO, Dr Judith Richardson and by a Revalidation Adviser, Ben Dunbar.
- 19. Both the RO and deputy RO are appropriately trained and licensed medical practitioners.

External monitoring and reporting

20. The Annual Organisational Audit (AOA) which details the organisation's governance arrangements and revalidation activity is submitted to provide assurance to NHSE. The Annual Organisational Audit (AOA) has been completed for 2018-19 and submitted to NHSE on 29/05/2019.

- 21. NICE is also required to submit an annual Statement of Compliance to NHSE (Appendix A) after approval by the NICE Board.
 - Policy and guidance
- 22. NICE has a medical appraisal and revalidation policy which is aligned with national guidance. The policy is supported by guidance, developed by NICE, which sets out the medical appraisal and revalidation process and requirements, together with the role of the appraiser and the appraisee.
- 23. The medical appraisal and revalidation policy and supporting guidance have been reviewed and updated in accordance with the policy review schedule.

2018/19 medical appraisal and revalidation performance data

- 24. In April 2018, Dr Judith Richardson, Deputy Responsible Officer, was revalidated. Two more doctors, both Consultant Clinical Advisers, were revalidated in 2018/19. The GMC have confirmed that all these revalidations were made in line with their schedule.
- 25. In 2018/19 all doctors had a medical appraisal undertaken by an external appraiser.
- 26. One doctor did not complete their medical appraisal in the required timeframe, missing the deadline by 1 day. This was because the appraiser's new contract was delayed following a low number of submissions during the tender process which resulted in a waiver being required under procurement regulations. The doctor and the appraiser then had to arrange a mutually convenient time to meet within existing work commitments.
- 27. To reduce the risk of missing the appraisal deadline, the arrangements for appraisal scheduling will be made clearer. This means emailing doctors their appraisal due date and providing clarity of the window when they should hold their appraisal. Furthermore, contractual arrangements will be made well in advance.
- 28. Two doctors were not scheduled to have an appraisal between 01 April 2018 and 31 March 2019, this was because:
 - One doctor was on maternity leave between May 2018 and March 2019.
 - The second doctor joined NICE in December 2018. This doctor did not hold a licence to practise between August 2017 and December 2018.
 - NHS England advise that after a return to practice there should be a delay
 of 6 to 12 months before the next appraisal. So, in line with this guidance,
 neither doctor was due to have an appraisal in 2018/19.

29. Table 2, below, summarises activity for the 2018/19 appraisal cycle:

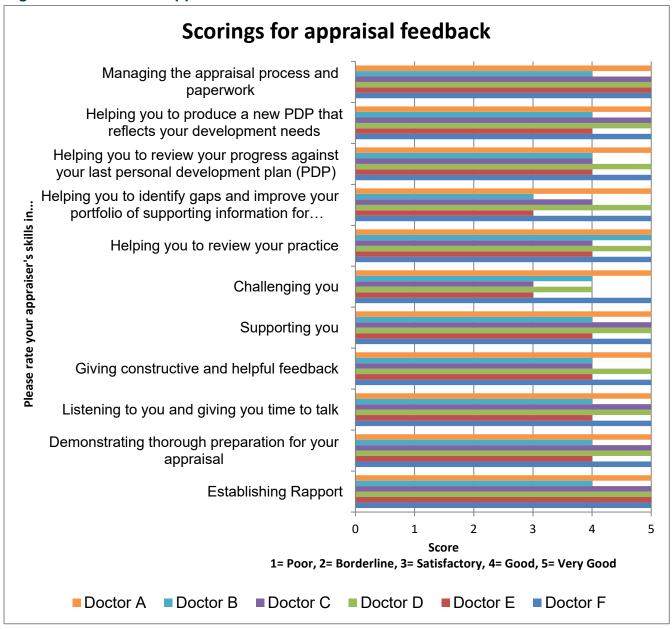
Table 2: Appraisal and revalidation activity 01 April 2018 - 31 March 2019

Registered medical practitioners with a prescribed connection with NICE	
Medical appraisals completed	6
Medical appraisals not completed	1
Medical practitioners not scheduled to have a medical appraisal	2
Number of registered medical practitioners that were due to revalidate in 2018-19	
Revalidation recommendations made	3

Quality Assurance

- 30. Attendance at RO Network events for the RO and Deputy RO is monitored with the required number of events, 3 per annum, attended in 2018/19. The 3 events attended included 2 Whitehall RO meetings run by the Department of Health & Social Care (DHSC).
- 31. In 2018/19, feedback was sought from all doctors on their appraisal conducted by the same external appraiser for NICE. Six doctors completed feedback forms;
 - All appraisees found the appraisal process satisfactory and would be happy to use the same appraiser again.
 - The appraiser was rated positively, scoring between 4 (good) and 5 (very good) for most questions.
 - All appraisees found the appraisal helpful in preparing for revalidation, useful for their professional and personal development and promoting quality improvements in their work.
 - The scores from those who have had more than one appraisal with the appraiser have improved.
 - The Deputy RO discussed the scores from early feedback on 'level of challenge with the external appraiser.

Figure to summarise appraisal feedback



Download the data set for this chart

Access, security and confidentiality

- 32. Completed appraisal forms make up part of a doctor's revalidation portfolio. Information relating to appraisals is classed as data of a personal or confidential nature and is held on a designated internal IT drive with access restricted to those with a specific role in medical appraisal and revalidation. This data is not accessible under the Freedom of Information Act (2000).
- 33. The Medical Appraisal Guide (MAG) form was used by all medical appraisees during the 2018/19 cycle. NICE did not identify any information breaches during this period.

Monitoring performance, responding to concerns and remediation

- 34. No areas of concern were raised about any doctor's conduct or medical practice between April 2018 and March 2019, and there are no doctors with a prescribed connection to NICE currently undergoing remediation or disciplinary procedures.
- 35. The statement outlining the process for NICE in responding to concerns highlighted in a previous Revalidation Board Report has been included in the following organisational policies:
 - Sickness Absence Policy.
 - Disciplinary Policy.
 - Improving Performance Policy and Processes.
 - Probation Policy and Procedure.

Support for Committee Members

- 36. NICE provides appraisal support for committee members, who are registered healthcare professionals, on an opt-in basis. This support includes:
 - Face to face feedback with Sir David Haslam, NICE Chair (committee Chairs only).
 - Provision of multi-source feedback (360° feedback) if requested, (committee Chairs only).
 - An annual summary confirming their contribution to NICE; including the type of input they provide and time commitment.

Revalidation of Nurses and Midwives

37. Nurse and midwife revalidation was introduced by the Nursing and Midwifery Council (NMC) on 01 April 2016. It aims to promote good practice across the

- whole population of nurses and midwives and ensure they are practising safely and effectively, strengthening public confidence in the professions.
- 38. In order to maintain their registration with the NMC, nurses and midwives in the UK will need to participate in the revalidation process every 3 years.
- 39. NICE does not specifically employ nurses and midwives in roles that require them to act as such. Completing the revalidation process is the responsibility of individual nurses and midwives.
- 40. Two of the 5 registered nurses employed by NICE during 2018/19 revalidated in 2018/19.

Revalidation of Pharmacy Professionals

- 41. The General Pharmaceutical Council (GPhC) introduced its processes for revalidation for pharmacists and pharmacy technicians (pharmacy professionals) in March 2018. It aims to show that trust in pharmacy professionals is well placed.
- 42. A phased introduction of revalidation started on 31 October 2018 and all pharmacy professionals are expected to complete part of the revalidation process in order to retain their registration. Pharmacy professionals will be required to undertake the full revalidation process from 31 October 2019.
- 43. NICE's Revalidation Committee appointed a registered pharmacist, Jonathan Underhill, as lead for the revalidation of pharmacy professionals in December 2016.
- 44. A position statement outlining the level of support NICE will offer for pharmacy professionals was approved by the Revalidation Committee in February 2018. This support includes:
 - A dedicated section for pharmacy professionals on the NICE Space revalidation page.
 - Updates on guidance.
 - Support to pharmacy professionals in developing networks for reflective discussion.
- 45. Members of the Revalidation Committee conducted a review of job descriptions for registered pharmacists to confirm the number of roles that required professional registration. This mirrored the previous approach used for medical professional's job roles.

- 46. Seventeen posts in the following categories were identified as requiring pharmacy professional registration at NICE:
 - Medicines Clinical Adviser (1 post).
 - Clinical Adviser (1 post).
 - Technical Adviser Medicines Education (1 post).
 - Associate Director Medicines Advice (1 post).
 - Medicines Implementation Consultant (4 posts).
 - Senior Medicines Adviser (2 posts).
 - Medicines Adviser (7 posts).
- 47. Refreshing the job descriptions for these 17 posts was approved at SMT in June 2018.
- 48. A further 9 individuals have indicated that they will maintain their registration although it is not an essential requirement for their role.

Regulation and revalidation of other professional groups

- 49. Nine employees at NICE are healthcare professionals registered with other regulators:
 - Six are registered with the Health and Care Professions Council (HCPC),
 1 of these is a registered social worker who requires current registration for their role.
 - Three other pharmacists are not subject to GPhC revalidation requirements as they are registered with regulators other than the GPhC.
- 50. The UK Public Health Register (UKPHR) announced their plans to introduce revalidation for their specialist registrants from April 2019. However, NICE does not employ anyone on the UKPHR.

Professional revalidation at NICE

- 51. NICE has a biannual Revalidation Committee and a Revalidation Management group which meets every two months.
- 52. The Revalidation Committee is responsible for advising and informing NICE on matters relating to professional revalidation and for reviewing and monitoring the effectiveness of medical appraisal and revalidation. The Committee includes members of the management group and NICE Non-Executive Board members.

- The Committee is currently finalising the process to invite a lay member to be part of the Committee.
- 53. The Revalidation Management group comprises the RO, Deputy RO, the revalidation lead for nurses and midwives, Rachel Ryle, the revalidation lead for pharmacy professionals, Jonathan Underhill, the HR Business partner with responsibility for medical staffing, Kelly Cuthbertson and the Revalidation Adviser. The group enacts the decisions of the Revalidation Committee.
- 54. During the year, the Associate Director of HR, Grace Marguerie held a position on the Revalidation Management group. To cover the secondment of the revalidation lead for nurses and midwives, Joanne McCormack held the interim role on the Revalidation Management group.
- 55. Professor Martin Cowie has been a Non-Executive Board member of the Revalidation Committee since March 2017. Dr Rosie Benneyworth was a member of the Revalidation Committee from July 2016 to February 2019 when she left her role with NICE.
- 56. Progress on doctor, nurse and midwife and pharmacy professional revalidation is reported to the Revalidation Committee and Management meetings.
- 57. In the event of concerns about a registered medical practitioner's practice being raised, the RO will investigate and ensure appropriate measures are taken to address and remediate the issue.
- 58. NICE's HR team is responsible for ensuring that all the necessary pre and postemployment checks for doctors and other registered healthcare professionals are completed. All the necessary checks were carried out during 2018/19.

Risks and Issues

- 59. Two key developments have been identified which may have an impact on the registration of health and care professionals:
 - The Children and Social Work Act (2017) introduced the potential transfer
 of the regulation of social workers in England from the HCPC to a new
 body, Social Work England by December 2019. This will affect one
 member of staff who is required to be registered for their role.
 Developments are monitored by the Revalidation Adviser and reported to
 the Revalidation Committee and Management group as appropriate.
 - In October 2017, the DHSC launched a consultation on proposed changes to the regulation of healthcare professionals across the four countries of the UK. The proposed changes reduce the number of regulators while aiming to maximise public protection, simplify the system

of regulation, foster greater consistency and reduce costs. This consultation was highlighted to all registered healthcare professionals employed by NICE. The outcome from the consultation was expected in 2018/19 but has been delayed. Once available it will be communicated to all NICE employees who are registered healthcare professionals.

- 60. Sixteen of the 17 pharmacy professionals at NICE who require registration for their role will need to revalidate at the same time. The GPhC has mitigation measures in place which include the phased introduction of revalidation and allowing peer review discussions to take place in group sessions. Also, the use of a reflective practice diary to support reflection being part of revalidation from October 2019. The expectation is that NICE does not need any mitigation measures besides those implemented by the GPhC.
- 61. The following national policy documents were reviewed during 2018/19. No additional actions were identified:
 - Implementing medical revalidation: findings from a national survey of Responsible Officers in England
 - NMC / Ipsos MORI Year 2 revalidation reports for Nurses and Midwives
 - UKPHR Revalidation
 - NMC Fitness to Practise Strategy
 - DHSC Consultation on Indemnity

Next Steps

- 62. Developments in revalidation and regulation of healthcare professionals continue to be monitored by the Revalidation Committee, these include:
 - Implementing the recommendations from the publication of the GMC's revised governance handbook in September 2018. These include:
 - Increasing the role of lay people in NICE's revalidation policies and processes. This includes inviting a lay representative to sit on the Revalidation Committee and asking them to participate in the peer review of NICE's revalidation policies and processes.
 - Implementing any changes to the feedback for medical appraisals, following updated guidance from NHS England.
 - Communicating updated GMC guidance on insurance and indemnity to relevant employees.
 - Assessing the impact of future consultations on NICE including:
 - The GMC's consultation on patient feedback.

- A pending DHSC consultation on reviewing the regulations for Responsible Officers.
- The outcome from the DHSC's consultation on proposed changes to the regulation of healthcare professionals.
- The RO becoming interim Chair of the Whitehall RO group. This is a supportive collaborative for all ROs who report to the Chief Medical Officer (DHSC) as their higher-level RO.
- Planning for a peer review of NICE's revalidation policies and processes and a reciprocal arrangement for 2020/2021.
- Assessing any impact on NICE from the NMC's evaluation of revalidation, expected to be published in July 2019.

Recommendations

63. The Board is asked to:

- Note NICE's statutory duties on medical appraisal and revalidation outlined in the report and the actions taken during 2018/19 to comply with these.
- Accept the report, which may be shared, along with the Annual Organisational Audit, with the Senior RO (the Chief Medical Officer for England).
- Approve the 'statement of compliance' (Appendix A) which confirms that NICE, as a Designated Body, is in compliance with the Medical Profession (Responsible Officers) Regulations.

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July 2019

Appendix A - Statement of Compliance

The Board of National Institute for Health and Care Excellence (NICE) has reviewed the content of this report and can confirm the organisation is compliant with The Medical Profession (Responsible Officers) Regulations 2010 (as amended in 2013).

Signed on behalf of the designate	ed body
Sir Andrew Dillon	
Official name of designated body: (NICE)	: National Institute for Health and Care Excellence
Name: Sir Andrew Dillon	Signed:
Role: Chief Executive, National Ir	nstitute for Health and Care Excellence (NICE)
Date:	

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National Institute for Health and Care Excellence NICE impact: adult social care

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

The Board is asked to review the NICE impact adult social care report 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

July 2019

National Institute for Health and Care Excellence NICE impact adult social care Date: 17 July 2019

Date: 17 July 2019 Reference: 19/066

Introduction

- The attached NICE impact report focuses on adult social care and reviews the uptake of NICE guidance in this area. It looks at people's experiences in adult social care, medicines management in care homes and the community and intermediate care including reablement. The report also includes a spotlight on using NICE quality standards to improve adult social care.
- 2. This report has been produced in pdf format and as a HTML webpage. To make sure that the impact reports meet accessibility requirements and the content can be more easily shared and promoted, future impact reports will be HTML webpages rather than a standalone pdf format. These will be developed by the corporate communications team.
- Printed copies of the web presentation will be produced for review at Board meetings by both board members and public attendees and of course other users of the report who may welcome the option to download and print the reports.

System support for implementation

4. The System Support for Implementation team is currently scoping options to provide support to proactive national partners in 2019/20, to address the implementation issues highlighted in this report. 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

- 5. The last NICE impact report, on <u>stroke</u>, was published on the NICE website on 24 May and was widely promoted.
- 6. What follows is a summary of the various activities and channels used to raise awareness amongst our stakeholders of the stroke impact report and the important issues it addresses:

Working with partners and key stakeholder organisations:

7. We worked closely with our stakeholders to encourage them to spread the word about the stroke impact report through their networks and communication channels. In total we have leveraged our relationships with professional bodies to ensure the report could be seen by more than 690,000 health care professionals, patients and the public. Below are some examples of the communication activities carried out:

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- The charity <u>Different Strokes</u> shared our report on its <u>website</u> which received 150 click-throughs. It also promoted the report via its social media accounts, Twitter (6.8K followers) and Facebook (59K followers). Different Strokes also included an announcement about our report in its stakeholder newsletter (4,000 recipients) and the 'Different Strokes coordinators update' bulletin (which goes out to around 40 local support groups).
- The Stroke Association cascaded our report to senior staff and included an announcement in its internal staff bulletin. It also tweeted our report to its 104K Twitter followers.
- The Care Quality Commission shared our report with its 130K Twitter followers. The report was also disseminated internally to senior colleagues.
- The Department for Health and Social Care tweeted our report to its 260K followers.
- The Health Quality Improvement Partnership included the impact report in its monthly email bulletin that goes out to approximately 16K subscribers.
- Public Health England included the report in its news bulletin, which goes out to just under 7,000 people.
- The Social Care Institute for Excellence shared our report in its SCIEline e-bulletin which goes out to 104K stakeholders.
- Diabetes UK shared the report through its healthcare professional Twitter account which has almost 500 followers.
- The British Society of Rehabilitation Medicine included a link to the report in its e-bulletin to 360 members.
- NHS Rightcare shared our report twice with its 4,000 Twitter followers.
 The report was also included in the NHS Rightcare news bulletin for 2 consecutive weeks.
- Healthwatch agreed to include our impact report within a stroke document it circulates to the entire Healthwatch network, which provides information on how local areas can get involved with the reconfiguration of stroke services.
- The Society and College of Radiographers shared our impact report with senior colleagues and via its managers network.
- The British Association of Stroke Physicians shared the report with its President, Professor Tom Robinson, and the Chair of its Clinical Standards Committee, Dr Fergus Doubal. Both will both disseminate to colleagues.

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- The British Heart Foundation is working with our adoption and impact team to promote the report.
- The Association of British Neurologists included the impact report in its monthly newsletter.
- The Atrial Fibrillation Association highlighted our report on its website.
- The National Health Executive (NHE), published a blog by Gill Leng: <u>How are we improving outcomes for those affected by stroke?</u> This forms part of a series of blogs that NHE is publishing on all of our impact reports.

Newsletters

8. We highlighted the stroke impact report, as well as the National Health Executive blog about it by Gill Leng, in the May editions of our <u>newsletters</u> to stakeholders: NICE News (25,213 subscribers) and Update for Primary Care (12,405 subscribers). Update for Primary Care subscribers demonstrated a particularly high interest in the report, downloading it 257 times (which equates to an impressive 14% of the traffic and is a very high spike in engagement by industry standards). The news item in NICE News also generated significant interest, with 220 downloads (which is 6% of the traffic and demonstrates a spike in engagement by industry standards).

Events

9. Our events team continues to promote our impact reports at all relevant events, exhibitions and speaking engagements, including this summer's Royal College of Nursing Congress and Health + Care conference. In addition, printed versions of our impact reports were available at our parliamentary reception in June.

Social media

10. On publication, we promoted the stroke impact report and accompanying National Health Executive blog via our NICE social media channels - Twitter, Facebook and LinkedIn - with each one receiving very good engagement rates.

Infographic - Twitter

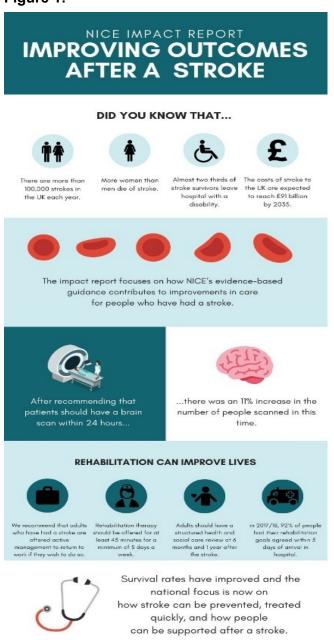
11. When the report was published in May, we immediately shared a link to it on Twitter with an accompanying infographic (figure 1). This initial tweet received 16,114 impressions (number of times the post had been viewed) and 52 clicks through to the report. As of the 11th June, we have promoted the report 3 more times after the initial tweet on publication

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Infographic - Facebook

- 12. As of the 11th June, our initial Facebook post had been viewed by 966 people and generated 94 reactions. There were only 3 link-clicks, however, so we repromoted the report with an infographic a week later which was viewed by 2,210 people, liked 27 times and shared 10 times.
- 13. In light of 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:



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July 2019



NICEimpact adult social care

Adult social care services help people with care and support needs to live better lives. Local authorities receive more than 5,000 requests for care and support each day. This report considers how NICE's evidence-based guidance contributes to improvements in adult social care.

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 service reconfiguration. It may also require additional resources such as training and new equipment.

We work with partners including Skills for Care, the Local Government Association, the Association of Directors of Adult Social Services, the Care Providers Alliance, the Think Local Act Personal partnership, the Social Care Institute for Excellence and NHS England to support changes. We also look for opportunities to make savings by reducing ineffective practice.



People's experience of adult social care and support p4

Most people who have help from adult social care services are satisfied overall but surveys suggest that more could be done to help people feel in control of their lives.

Managing medicines p9

Examples from our shared learning collection show how NICE's guidance on managing medicines for adults receiving social care has been used to improve care.



Intermediate care including reablement p11

Most people who use intermediate care services have a good outcome. Many more services are being commissioned in an integrated way as recommended by NICE, helping people to move between them depending on their needs.



Spotlight on using NICE quality standards to improve adult social care p16

Providers and commissioners have used NICE quality standards to assess performance and make improvements, as shown in these examples.

Commentary p18

Andy Tilden, interim CEO of Skills for Care, considers how NICE guidance can be used by people working in adult social care services.

Why focus on adult social care?

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.

Demand for adult social care is growing. People are living longer, and more people are living with complex care and support needs, including younger adults with a physical or learning disability. Local authorities in England spent nearly £18 billion on adult social care in 2017/18 and many people fund their own care and support, adding to the total spend. Nearly 1.5 million people are estimated to work in adult social care, across more than 21,000 organisations.

In 2013 NICE gained new responsibilities to develop guidance for people working in and using social care. Our <u>social care</u> <u>guidelines</u> make evidence-based recommendations on the effectiveness and cost-effectiveness of approaches and services. The social care guidelines included in this report were produced in collaboration with the <u>Social Care Institute</u> <u>for Excellence</u> (SCIE). All our social care guidance is coproduced with people who have lived experience of using social care.

In 2018 NICE published its first **quick guide**, providing key information for social care topics in a simple format. These are produced in collaboration with SCIE. We also develop health and public health advice and guidance, and many of these recommendations are also relevant to people who work in or use social care. All of our guidelines, quality standards and tools to help improve social care services are brought together on the NICE **social care community** page.

We routinely collect data which give us information about the use of our guidance. This report uses these data alongside real-life examples to look at how NICE's recommendations might be making a difference in priority areas of adult social care. We've also looked at areas where there's room for improvement.

Adults with social care needs are supported in 2 main ways: either formally through services they, their local authority or the NHS pay for, or informally by family, friends or neighbours. This report looks at the experience of people receiving formal care and support through adult social care services.

15
adult social care quick guides



Most people who have help from adult social care services are satisfied overall, but surveys suggest that more could be done to make sure people feel in control of their lives.

Our quick guide on what to expect during assessment and care planning helps people using adult social care services understand that services should help them live their life the way they want to. It's a quick, easy way to access key information from NICE.

People's experience of care and support

Adult social care and support helps people to achieve the outcomes that matter to them. People's experience of care and support, and how much they feel supported to live their life the way they want, is of key importance.

Around two-thirds of people said they were extremely or very satisfied with the care and support they received from adult social services in 2017/18. This is according to NHS Digital's **Personal Social Services Adult Social Care Survey** in England, which asked over 65,000 people what they thought about the local authority funded or managed care and support they received.

Adult social care is delivered by thousands of different provider organisations. This means that there is very little information about how well care processes recommended by NICE are being carried out nationally, and so we have used these survey results to look at outcomes for people using care and support services.

People's control over their daily life

Although most people said they were satisfied overall, only around a third of survey respondents said they can spend their time and have as much control over their daily life as they want.

NICE's <u>guideline</u> and <u>quality standard</u> on people's experience using adult social care services aim to help people understand what care they should expect, and improve their experience

'I was really disappointed with the care I got at first. I didn't like having someone in my home and they seemed to come and go. But things got better when the same carer came more often and she knew what I needed help with.' John, aged 81

by supporting them to make decisions about their care and support. We say that people's preferences and needs should be the basis on which to provide care and support to live an independent life.

Adult social care is provided in 3 main settings: residential care homes, nursing care homes and in the community. People using community services live at home; this includes homes such as supported living and sheltered housing.

In all settings more could be done to help people using care and support services feel in control of their lives, but particularly people using community services and nursing care When people were asked about having control over their lives and how they spend their time, the survey results varied depending on the setting where care and support was delivered. People using nursing care or community services were less likely to give a positive answer to these questions.

I have as much control over my daily life as I want



I'm able to spend my time as I want, doing things I value or enjoy



Good care and support

Less than half the survey respondents said they have as much social contact as they want with people they like. NICE says that people should be helped to maintain the personal relationships and friendships that matter to them. People using community services were least likely to agree with this statement. So, while everyone could be helped to have more social contact with people they like, more could be done for this group in particular.

More people said they feel clean and able to present themselves the way they like, with 58% of all respondents agreeing with this statement. Making sure that people's personal care needs are responded to in a dignified manner is a key part of NICE-recommended care. Although these results were better overall, less than half the respondents using nursing care said they feel clean and able to present themselves the way they like.

More could be done to make sure that everyone using care and support services has enough social contact and feels clean and able to present themselves the way they like

Do you have as much social contact as you want with people you like?



Do you feel clean and able to present yourself the way you like?



Supporting adults with learning disabilities

Seventy-eight percent of adults using learning disability support services said they're satisfied with the care and

'Being involved in my care is very important to me. I don't like people making decisions about me without involving me. I like to be kept up to date with what is happening after I've been assessed. I don't like not being told the reasons for decisions. I would like to discuss where I could live when I need extra support as I get older. I would like support to help me shower every day instead of once a week because I use incontinence pads.' Patricia Charlesworth, who is growing older with a learning disability

support they receive, but not everyone is able to spend their time as they like.

NICE has published a <u>suite</u> of guidance, standards and advice to help support people with learning disabilities to live well. Our guideline on the <u>care and support of people growing older with learning disabilities</u> aims to support people to access the services they need as they get older. It does not give a specific

age range in the recommendations because adults with learning disabilities often experience age-related difficulties at a younger age.

Most people using learning disability services are satisfied with their care and support but many don't have as much control over their daily life as they want Overall, adults using learning disability support services say they have satisfactory experiences of care. Most people (78%) said that the way they are helped and treated makes them think and feel better about themselves.

I am extremely or very satisfied with the care and support services I receive		78%	
I have as much control over my daily life as I want 43%			
I'm able to spend my time as I want, doing things I value or enjoy	65%		
I have as much social contact as I want with people I like	62%		

There is still more that can be done, particularly around making sure that people have as much control over their lives as they want. NICE says that practitioners should help people with learning disabilities to think about what they want from life as they age, and should ensure that care and support is tailored to their needs, strengths and preferences.

Using NICE social care guidance to improve the quality of care



Healthwatch Isle of Wight used NICE's guideline on older people with social care needs and multiple long-term conditions to help improve the quality of care in local residential care and nursing homes. When they looked at Care Quality Commission (CQC) inspection results, they found that the quality of care provided on the Isle of Wight compared badly with other areas in England.

Using feedback from the public, they identified themes and trends including poor personalised care, poor access to activities, and poor management of nutrition and fluids. They used NICE guidance to describe good care and highlighted this to service providers, council members and members of the public so that everyone knew what they should expect.

A team of Healthwatch authorised representatives visited 13 nursing and residential care homes and spoke to staff, residents and their families about their experiences. After sharing what they heard with the local authority, Clinical Commissioning Group and CQC, steps have been taken to improve care.

For example, residents now have a say in the types of activities they want to do, which has helped improve their quality of life. Thanks in part to Healthwatch Isle of Wight's efforts, most care and nursing homes have since received a good CQC rating and no homes are rated as inadequate. Healthwatch Isle of Wight have described their project, and what they learned during it, in a NICE shared learning example.

The oral health of people who live in care homes

The CQC recently carried out a <u>review of oral health care</u>, asking staff in 100 homes whether they were aware of NICE's guidance and were offering care in line with our recommendations. This is important because poor oral health can affect people's ability to eat, speak and socialise. NICE's <u>guideline</u> and <u>quality standard</u> aim to maintain and improve the oral health of people who live in care homes.

The CQC found that more than 60% of interviewees had heard of NICE's guidance, although only 28% said they'd read it. Some care homes were offering care in line with NICE guidance, even when they were not aware of this. Nearly three-quarters of interviewees said that residents had their oral health assessed on admission and 70% said each resident has an oral health section within their care plan.

However only a quarter of interviewees said their care home has a policy that sets out plans and actions to promote and protect residents' oral health. Nearly half said that their staff did not receive specific training in oral health care. We hope that the CQC review will draw attention to this important area of care and raise awareness of NICE's guidance.





Our quick guide on improving oral health for adults in care homes is aimed at care home managers and gives easy access to our recommendations.

Implementing NICE guidance in a local authority

To help provide excellent social care to people in Coventry, the city council have established a NICE implementation group. It aims to improve the quality of social care provision by making sure that services and the people working in them are aware of national policies and evidence-based practice. The group, which was set up by the principal social worker, carries out assessments to understand how services align with NICE recommendations and then monitors the implementation of actions.

By completing baseline assessments and relating outcomes to other data, such as data from complaints, the group has produced a robust assessment of the services they provide and raised the profile of social care within the council. They've also increased their understanding of different service areas by working together. More information about how the group works, and the key things they've learned, are available in a NICE shared learning example.

Discussing and planning medicines support and the rate are appearanced by the rate of the

NICE has produced quick guides for home care managers providing medicines support. These guides are an easy way to access the key recommendations from our guidance. They cover discussing and planning medicines support and effective record keeping and ordering of medicines.

More details about these and other shared learning examples are available on the tools and resources pages for our guidelines on managing medicines in care homes and the community.

You can also find links to helpful resources such as NICE baseline assessment tools, a webinar, and e-learning courses which have been endorsed by NICE. A care home manager who's used these said, 'the medicines management in care homes e-modules from PrescQIPP were a fantastic development resource.'

Managing medicines

Up to <u>1 in 10</u> hospital admissions in older people are medicines related, and as many as 50% of people don't take their medicines as intended. The risk of medicines-related problems can be reduced by supporting health and social care staff, people receiving social care and their families and carers to manage medicines effectively.

Many people receiving social care have multiple long-term conditions. It's important that people who are able to take and look after their own medicines are receiving all the help they need. It's also important to make sure health and social care staff can assess people's medicines support needs, and systems and processes are in place to make sure that people receive the medicines they need in a safe and effective way.

NICE has published guidelines and quality standards on managing medicines for adults receiving social care in <u>care</u> homes and <u>in the community</u>. These examples show how our guidance has been used to improve care and support.

Using NICE guidance to help manage medicines in the community

Castle Supported Living, a homecare provider, used NICE guidance to help them improve the support they give to adults with a learning disability. They carried out a baseline assessment of their service against the NICE guideline and put in place NICE recommendations such as identifying a medicines lead. They discovered that staff needed and wanted more training so all staff, including managers, have now received training and competency assessments.

After carrying out medicine support assessments, every person they support now has a detailed plan and easy-read information about their medicines. The organisation had support from other professionals during the process and this has led to increased partnership working with GPs, community pharmacists and the local medicines support team.

Managing medicines in care homes

In <u>Wigan</u>, a team of pharmacists and pharmacy technicians helped local care homes improve their management of medicines, which has been reflected in better Care Quality Commission (CQC) ratings in 13 homes. The project was supported by one of NICE's <u>medicines and prescribing</u> <u>associates</u>; a group of professionals who work with us to help support and promote high quality, safe, cost-effective prescribing and medicines optimisation.

The team worked with residential and nursing homes and local GPs to carry out structured medicine reviews for people living in care homes. In under 3 years the team completed

'The NICE medicines management guideline and associated tools and resources have supported development of our knowledge, skills, competencies and medicines processes. We've improved our compliance against both internal and external audit from 76% to 99%, which has been sustained over the last 12 months. I would definitely recommend this guideline and resources, including free access to the BNF online. It has improved our practice significantly.' Rachel Shortt, Registered Manager of The Garth Nursing and Residential Home

medicine reviews for 749 people. They made an average of 4 recommendations per person, such as stopping medicines or changing the dose.

Feedback from GPs, the local authority and CQC inspection reports suggested that staff in some care homes needed more support with the safe use and handling of medicines, so the team carried out baseline assessments of care homes against the NICE guideline. They

then supported 29 care homes to put NICE guidance into practice, helping with areas such as documentation, medicines storage and the management of controlled drugs.

Supporting people who work in social care to put our medicines management guidance into practice

The NICE medicines team produced resources and training for NICE associates on our guidelines on managing medicines for adults receiving social care in care homes and in the community. They discussed local implementation plans at regional meetings and shared examples of good practice at national training days.

Associates have worked on a range of local and national projects in social care, from patient-led

medication reviews, the development of local policies and assessment tools, to nationally available e-learning packages for care workers developed for Skills for Care.

Our medicines implementation consultants, working with the NICE field team, have delivered training on how NICE supports quality and safety in social care to staff working in care homes and social care across England.

Intermediate care including reablement



Intermediate care is a multidisciplinary service. Home-based intermediate care and reablement take place in people's own homes or care homes. Bed-based intermediate care takes place in hospitals, care homes, nursing homes and standalone intermediate care facilities.

NICE has produced quick guides for people using intermediate care services and staff delivering them. These are a quick, easy way to access key information from our guidance.

Admission to hospital and delayed discharge can affect people's physical and mental wellbeing and make them increasingly dependent on support services.

Multidisciplinary intermediate care services have a crucial role to play in supporting

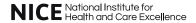
people to recover and regain independence.

More people are living longer, often with complex or multiple medical conditions, putting increasing pressure on the NHS and social care services. NHS Digital's <u>Health Survey for England</u> found that people aged 80 or over were more than twice as likely to need help with daily activities as people aged 65 to 69. Intermediate care and reablement services can help people, particularly older people, remain independent by:

- providing support and rehabilitation to people at risk of admission to, or who have been in, hospital
- helping make their transfer out of hospital as smooth as possible
- ensuring they don't have to move into residential care until they really need to
- offering short-term support to people living at home who find daily activities difficult.

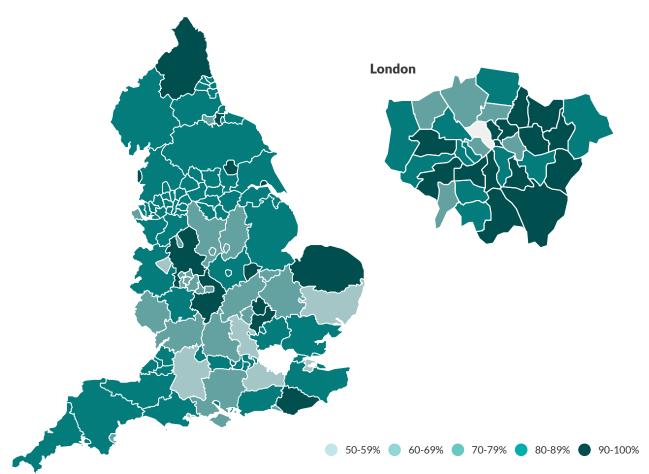
'The occupational therapist came around the day after I came out of hospital and put rails up for me and a toilet seat. I felt much safer. Later in the day a really nice carer with a big smile on his face came in and said he would be coming three times a day for two weeks to help me spruce up, get meals, help me with my medicines and keep the place tidy. I felt more confident immediately and thought – yes – I can manage at home.' Beatrice, aged 82

Intermediate care works. The NHS Benchmarking Network's National Audit of Intermediate Care found that 93% of people receiving these services in England in 2018 improved or maintained their independence.



There's wide variation across England in the proportion of people who were able to stay at home after receiving reablement or rehabilitation services

NHS Digital's <u>Adult Social Care Outcomes Framework</u> found that 83% of people aged 65 and older who received reablement or rehabilitation services after being discharged from hospital were still at home 91 days later, but there's a lot of variation across the country.



To improve outcomes, NICE's <u>guideline</u> and <u>quality standard</u> set out how people should be referred and assessed for intermediate care including reablement, and how these services should be delivered.

Starting and ending intermediate care

The National Audit of Intermediate Care found that 17% of people who were referred for bed-based intermediate care waited more than 2 days for the service to start in 2018.

NICE recommends 2 days as the maximum waiting time for this service because it's likely to be less successful if there's a delay. Only 44% of commissioners reported that they have a local waiting time target in their service specification for bed-based intermediate care.

96% of people receiving reablement

of people receiving reablement services were aware of what they were aiming to achieve

95%

of people were involved in setting those aims

Almost all people receiving intermediate care or reablement services said they were aware of what they were aiming to achieve and were involved in setting those aims. NICE recommends that people starting intermediate care discuss and agree personalised goals, which is important if they're to regain their confidence and independence.

It's also important that there's a clear plan for what happens when the service ends. NICE says this should be agreed with the person and their family or carers. Most people (93%) receiving home-based intermediate care or reablement said they were given enough notice about when their care from the community team was going to stop. Nearly 9 in 10 people receiving bed-based intermediate care said they were involved in decisions about when they would go home.

Reablement services

The focus of reablement is on helping people relearn how to perform their daily activities, like cooking meals, washing and getting about, after a deterioration in their health or when they have increased support needs. It's a community-based service, usually delivered to people in their own home.

Reablement has the highest proportion of social care staff of all intermediate care services. More than half the people working in it are social care support workers or social workers. Most reablement services provide support for up to 6 weeks

and the average duration of service was 31 days in 2018.

'Reablement is often someone's first contact with social services. It's a very important service and everyone should have the opportunity to engage. It's always a pleasure when someone regains independence, often with the use of aids and techniques promoted by the reablement assistants.' Claire G, Social Care Support Officer, Reablement, Lancashire County Council

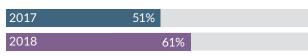
The National Audit of Intermediate Care shows how successful reablement is. Eightysix percent of people completed their package of care and around two-thirds of those had no ongoing homecare needs after receiving the service.

Commissioning integrated services

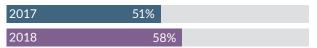
The National Audit of Intermediate Care found that more integrated services are being commissioned. In 2017, NICE recommended that different intermediate care services, such as home-based and bed-based intermediate care, should be delivered in an integrated way. This can make it easier for people to move between services, depending on their changing needs.

A higher proportion of commissioners are commissioning integrated services since NICE's guideline was published in 2017

Integrated home-based intermediate care and reablement services



Integrated home-based and bed-based intermediate care services



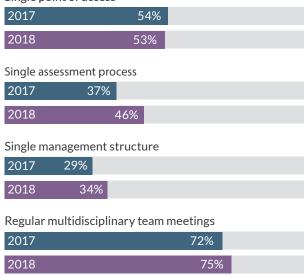
Although there have been improvements in commissioning, many services are not yet delivering care in a fully integrated way. NICE lists some ways of delivering integrated care that services should be working towards, including a single point of access and assessment process. This can help make sure that people get the right care and support when they need it.

Most integrated services have multidisciplinary team meetings, but a single point of access is less common. Only 37% of commissioners report that there's a single point of access for their whole intermediate care system, so there's more to do in this area.

Most integrated services have improved their delivery of these NICE-recommended components of integrated care

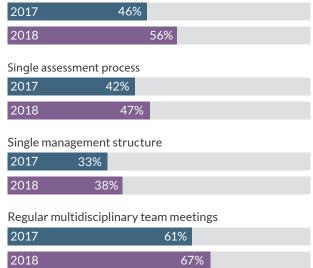
Integrated home-based intermediate care and reablement services

Single point of access



Integrated home-based and bed-based intermediate care services

Single point of access



Commissioning an integrated Home First service in Bristol

The city council, clinical commissioning group and community health provider in Bristol helped more people return home from hospital by working together and commissioning an integrated rehabilitation and reablement service. They used NICE guidance on intermediate care and transition between inpatient hospital settings and community or care home settings for adults with social care needs to help them address local issues.

The health and care partners in Bristol knew they had a higher rate of delayed transfers out of hospital than other areas. They also found that many people who hadn't previously been

'Being able to reference that we used NICE guidance in our design processes and in creating our Standard Operating Procedures gave us the ability to give challenging messages with the backing of NICE credentials. This was particularly helpful when communicating changes with the acute providers.' Richard Hills, Health and Care Interface – Partnership Manager, Bristol City Council

known to social care were being transferred from hospital straight into long-term care.

Their new Home First service aims to bring people out of hospital then assess and support them in their own home. Early results are encouraging. The integrated service supported 38 people to go home from hospital in the week before Christmas

2018, one of the busiest times of the year. The separate rehabilitation and reablement services had only been able to support between 20 and 25 people a week.

They've described how they set up the service, and what they learned along the way, in a NICE shared learning example.

Improving access to community crisis response services

Crisis response is a community-based service, provided to people in their own home or a care home, which aims to avoid hospital admissions. It usually involves an assessment and may provide short-term interventions. NICE says that services should ensure that the crisis response can be started within 2 hours from receipt of a referral when necessary.

In line with this recommendation, NHS England's Ageing Well Programme seeks to implement a new 2 hour waiting standard for crisis response services by 2023/24. The NHS Long Term Plan highlights that achieving this, through extra investment and productivity reforms in community health services, could free up over a million hospital bed days.

Spotlight on using NICE quality standards to improve adult social care

NICE has produced a quality improvement resource to help commissioners use our quality statements and recommendations in local work such as contract specifications, quality dashboards or self-assessment tools. The resource brings together NICE quality standards and our guidelines on managing medicines in an easy to use format, mapped against Care Quality Commission key lines of enquiry.

NICE <u>quality standards</u> set out priority areas for quality improvement. Each standard includes a set of statements to help improve quality, and information on how to measure progress.

Our quality standards help people understand the quality of services and care they should expect. Providers and commissioners use them to assess performance and make improvements. These examples show how people have used NICE quality standards to improve the quality of the care they're providing or commissioning.

Using NICE quality standards in social care commissioning



London ADASS (the London branch of the Association of Directors of Adult Social Services) have worked with a group of social care commissioners and the NICE field team to develop a commissioning quality schedule based on NICE quality standards. Standards for care homes have been agreed and rolled out across all 33 London local authorities, meaning all commissioners and all providers in the region are now using NICE quality standards. Standards for home care services are being developed and piloted with input from NICE and will be rolled out next year.

Improving quality in care homes



The Orders of St John Care Trust, a charity care provider, used 5 of our quality standards to create audit tools for their 70 care homes. These audits helped them identify areas for improvement, such as **supporting people to live well with dementia**. The audits also helped them confirm they were already following best practice in other areas and raised awareness of NICE standards and recommendations across the organisation.



Their audit template has now been revised to encourage homes to develop practice even further, in excess of the NICE quality standards. They've described how they developed their audits, what they've learned from the process and how they're continuing to improve quality, in a NICE shared learning example.

A quality improvement project using NICE quality standards led to a reduction in unexpected hospital admissions from care homes in East Berkshire. The project used our quality standard on urinary tract infections (UTI) in adults, alongside recommendations from NICE guidelines. It was supported by one of NICE's medicines and prescribing associates.

The project promoted hydration and correct diagnosis in 4 care homes which had a higher than average number of admissions for UTIs. It focused on training as well as introducing food and fluids charts and structured drinks rounds. Since it started, the incidence of UTIs has reduced.

The project's already been rolled out to another 9 care homes in the local area and there's been lots of interest from other areas. More details, including how the project was implemented and what project leads did to make it so successful, are available in a NICE shared learning example.

Quality matters: working better together



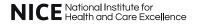
The quality of adult social care matters, because people who use services should be able to expect person-centred care that is safe,

effective, caring and responsive. The **Quality Matters** initiative is a shared commitment to high quality adult social care, co-led by partners from across the sector including NICE. It recognises that no single person or organisation can improve the quality of adult social care on their own.

To help local health and adult social care systems work better together to improve quality, NICE and

our national partner organisations have produced the unlocking capacity: smarter together resource. It's aimed at system leaders with the power to work differently. It shows how collaborative working between health and adult social care can improve outcomes for people and make better use of limited resources.

It includes case studies from local areas, and lists high level steps to support collaborative working. It also includes details of the offers and resources produced by national organisations, including NICE, to support local systems with collaborative work.



Commentary

Andy Tilden, May 2019

What this report reinforces is Skills for Care's view that a skilled and knowledgeable workforce will be pivotal in making sure that people who need care and support in our communities can access services that will support them to live full lives in the way they want.

That might be enabling an older person to maintain their dignity or supporting a young adult with learning disabilities to be an active member of their local community. It is true that adult social care is, in the general public's eye, an often invisible support system that can empower people to live life as independently as they can.

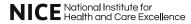
It is also true that improving outcomes for people supported by the social care workforce is nuanced. What constitutes a good care outcome is dependent on many factors, so what the person with care and support needs knows is a good outcome for them will not always be the same as a family member(s) perspective, or those supporting that individual.

Making sure workers in adult social care get the best out of NICE guidelines and quality standards is about framing guidance in a way that gives people the knowledge they need so they then have the confidence to act. The NICE social care quick guides provide evidence led information that will assist care workers in their decision making.

Looking at the work described in this report, both commissioners and providers have demonstrated how NICE quality standards can be used alongside CQC Key Lines of Enquiry to assess and improve standards of care and support. Sometimes it's about confirming that existing practice is of good quality, and at other times it's about challenging commissioners and providers to think and behave differently.

Skills for Care is an active NICE partner, locally and nationally, with a range of support and resources for social care employers and commissioners on **our website** that, when used alongside NICE guidance, can assist employers and commissioners with decision making around the issues raised in this report.





We would like to thank Andy Tilden and Jim Thomas at Skills for Care for their input, and we are grateful to the CQC and NHS Benchmarking for their contributions to this report. We would also like to thank all the people who spoke to us about their experience of care and support, or about using NICE guidance in practice, and allowed us to quote them in this report.

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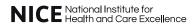
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Review of methods for health technology evaluation programmes

This paper details the scope of the methods review for 4 health technology evaluation programmes in the Centre for Health Technology Evaluation: technology appraisals programme (TA), highly specialised technologies programme (HST), medical technologies evaluation programme (MTEP), and the diagnostics assessment programme (DAP).

Stakeholders have been engaged in the development of the scope through the working party and steering group for the review.

The Board is asked to consider and approve the scope of the methods review for health technology evaluation programmes.

Meindert Boysen

Director, Centre for Health Technology Evaluation

July 2019

Introduction

- 1. NICE updates its published methods from time to time, in order to ensure they are robust and up to date. There is a high level of interest from stakeholders in the methods across the NHS, patient groups, industry, government and the academic community. Iterative feedback from these stakeholders since the previous major update of our methods has been taken into account to arrive at the list of proposed topics in this paper.
- 2. The purpose of the review is to optimise NICE evaluation methods to support the ambition of the NHS to provide high quality care that offers good value to patients and to the NHS. The review is not starting with a blank sheet of paper. This is an incremental development of NICE's existing world class approach to evaluating new health technologies. The aim of this work is to review and amend the methods if changes are clearly needed and well justified.
- 3. The Department of Health and Social Care has indicated that during the course of the review, NICE should consider what more it can do to better support the uptake of new innovative products in a timely and efficient manner; take into consider international best practice to improve the access environment in the NHS. In addition, the Department notes the evolution of integrated care systems in the NHS and would like any relevant methodological changes to take this into account.
- 4. For medicines, the review is linked to the commitments made in the 2019 <u>Voluntary scheme for branded medicines pricing and access</u> (2019 Voluntary Scheme). In particular, to engage Industry and other relevant stakeholders as active participants in the review, including inputting on scope, participating in working discussions, and providing views on recommendations. Arrangements for this are in place through the working party and the steering group.
- 5. A number of specific commitments of the 2019 Voluntary Scheme have an impact of the scope of the review:
 - The standard cost effectiveness threshold used by NICE will be retained at the current range (£20,000 to £30,000 per QALY gained) and not changed for the duration of the scheme [paragraph 3.20].
 - The Department expects that any future changes to NICE methods and processes would respond to the new types of innovation coming to the market, be consistent with improving the health gain achieved by spending on new innovative medicines, and support faster adoption of the most clinically and cost effective medicines. These would be subject to public consultation in the usual way [paragraph 3.22].

 NICE will clarify its approach to managing uncertainty in the appraisal of a new technology, brief its committees on the types of uncertainty and ensure that committee discussions focus on those areas of uncertainty that have the most significant impact on estimates of cost effectiveness [paragraph 3.41].

Alignment of methods across programmes

- 6. There is significant overlap, replication and cross-refencing between the existing methods for guidance produced for the centre's 4 health technology evaluation programmes: technology appraisals (TA), highly specialised technologies (HST), medical technologies evaluation programme (MTEP), and the diagnostics assessment programme (DAP). We aim to consolidate well-accepted existing methods in a single manual, whilst retaining differences that are clearly needed and well justified.
- 7. It is anticipated that there will be a consolidated methodology for general principles for evidence identified, synthesis and interpretations, clearer reference case(s) (the framework used to address the main questions in the evaluation), clearer decision-making criteria and types of recommendations that can be made. We also aim to standardise terminology across the guidance types to make it easier for all stakeholders to understand.
- 8. We are working towards a single manual to cover both the methods and processes for all the Centre's health technology evaluation programmes, and the plan is to consult on this combined manual in time for final publication by the end of 2020.
- 9. Future updates to the methods will be done in a modular format rather than a full manual update, to ensure that we can efficiently respond to methodological and policy changes.

Governance and approach

- 10. A methods steering group has been set up with responsibility for connecting key strategic developments within NICE, and allows for appropriate input from NHS England, the Department of Health and Social Care and an independent academic adviser. The steering group will use its collective knowledge of the health and care landscape to consider the changing national policy landscape and its impact. They'll have oversight of the entire review and update.
- 11.A methods working group consisting of senior NICE staff, academics, patients, life sciences industry, NHS England and Department of Health and Social Care has been established. The methods working group will use their

- expertise to make operational decisions about the project. They'll also oversee the delivery of work, as instructed by the steering group.
- 12. A patient working group will get feedback from patient organisations; look at international examples of patient involvement; identify themes that are important to patients. The group will feed back their proposals for improved patient involvement.
- 13. Focussed task and finish groups will oversee and carry out specific review work, including setting detailed scopes, commissioning methodological work from academic centres and enabling discussion of proposals with stakeholders.

Proposed scope of the methods review

- 14. The table below contains a short and simplified description of the topics that it is proposed should be included in the scope of the methods review. The topics considered within the current update are:
 - Modifiers considered in decision making
 - Exploring uncertainty
 - Types of evidence (sources and synthesis)
 - Health-related quality of life
 - Technology-specific issues
 - Discounting
 - Cost-minimisation methods
 - Equality considerations in guidance development
 - Costs used in Health Technology Assessment (HTA)
 - Position of technologies in the care pathway
 - General approach to decision making
- 15. The topics fall broadly into 3 categories, and the intention is to address the first category as the highest priority:
 - Factors that will address the expectations outlined in the 2019 Voluntary Scheme.
 - Scientific and methodological innovations affecting the types of products NICE will evaluate in the future, and the types of evidence that will be available to NICE.

- Other general improvements to methods, including systematisation of committee's value judgements to support consistent decision making.
- 16. The topics being considered in the methods review are presented in summary form in Table 1. Each topic is described in more detail in the Annex. The impact in terms of health gain and spending from any significant changes to methods will be considered.

Table 1 - Summary of main topics in scope for methods review 2019-20

Topic	Main issues to be addressed	Reason for inclusion and other comments
Modifiers considered in decision making	Currently, clinical and cost effectiveness are key decision-making criteria used by NICE committees when making recommendations. However, they are not the only basis for decision making. Committees can also consider the extent of uncertainty, unmet need, burden of illness and disease severity, the innovative nature of the technology and equalities considerations. This aim of this topic is to review how a committee might apply a specific maximum weight or threshold modifier in making its recommendations. Some of these factors, instead of being numerical, may be considered qualitatively by the committee. The review will explore if the current additional factors that could be used by a committee as part of the structured decision-making framework are still relevant for patients and the NHS, whether there is case to change them, and if any additional factors should be taken into account, quantitatively or qualitatively. Additional factors such as NHS policy priorities, well-being, experience of care, organisational efficiency, and curative potential may be explored.	2019 Voluntary Scheme. This topic is a high priority. A draft specification has been developed and discussed by the Methods Working Group.
Exploring uncertainty	The aim of this topic is to review whether there is a case to change how uncertainty is explored or quantified in our methods, and the approaches that can be taken to try and reduce the uncertainty during guidance production. This includes reviewing extrapolation methods in the absence of long-term evidence and use of data analytics and real-world evidence.	2019 Voluntary Scheme.

Types of evidence (sources and synthesis)	The aim of this topic is to review the types of evidence considered across the different Centre for Health Technology Evaluation (CHTE) programmes. The assessment of evidence will also be considered (such as quality of the evidence). This includes how randomised, non-randomised and real-world evidence is currently considered. A randomised controlled trial is a comparative study in which people are randomly allocated to intervention and control groups and followed up to examine differences in outcomes between the groups, whereas in non-randomised studies people will be allocated to the groups using methods that are not random. Real-world studies may include those where the investigator observes the natural course of events with or without control groups (for example, audits, registries). The use of qualitative evidence, patient evidence and expert elicitation will also be explored.	Scientific and methodological innovations.
Health-related quality of life	This topic will consider how quality of life is incorporated into economic analyses and considered by committees. This includes reviewing the use of EQ-5D and associated valuation sets, patient reported outcomes, quality of life for children and young people, carers and for people with rare diseases.	Scientific and methodological innovations.
Technology-specific issues	This topic will include issues that are specific to types of technologies not included in other topics. Examples are, reviewing the new regulations for medical devices and in vitro diagnostics (IVDs), and information governance and usability of medical technologies. It will also address the methodological challenges of evaluating products that have been developed on the molecular basis of tumour responses rather than the site of the tumour (also known as tumour agnostic or histology-independent indications).	Scientific and methodological innovations.
Discounting	Costs and benefits incurred today are usually valued more highly than costs and benefits occurring in the future. Discounting health benefits	Scientific and methodological innovations.

	reflects a preference for benefits to be experienced in the present rather than the future. Discounting costs reflects a preference for costs to be experienced in the future rather than the present. In evaluating technologies, NICE discounts future costs and benefits. The Department of Health and Social Care does not consider that a change to the discount rate should be made at this time.	
Cost-minimisation methods	The aim of this topic is to review the methodology for cost minimisation analysis and ensure consistency across the different programmes that use this approach. The review will ensure that methods to assess clinical non-inferiority or similarity are informed by best available health economic methodological research.	Other general improvements to methods. This topic will help us prepare for the planned NHS England medtech funding mandate.
Equality considerations in guidance development	In this topic we will collate responses and legal advice to equality issues that have arisen during guidance development and appeals. NICE will update and align how we respond to potential equality issues and complete equality impact assessments. Potential equality issues arising from new types of technologies are in scope.	Other general improvements to methods.
Costs used in Health Technology Assessment (HTA)	This topic will consider which costs are the most appropriate to use in economic analyses that our guidance is based on. This can include intervention or comparator costs, carer costs and future unrelated costs. It will also consider circumstances where even at zero cost some technologies are not cost-effective.	Other general improvements to methods. The work is likely to be relevant to the new funding mandate for cost saving technologies.
Position of technologies in the care pathway	This topic will consider the methods for assessing the clinical and cost- effectiveness of the position of technologies within a care pathway. The work will align with the work being done for NICE Connect.	Other general improvements to methods.
General approach to decision making	This topic will consider how evidence is assessed and presented to appraisal committees and how committees should consider evidence and make recommendations.	Other general improvements to methods.

This includes reviewing how information is presented to committees, the assessment of evidence, the use of incremental analysis and net benefit approaches.	
The wording of recommendations, the use of 'only in research' and research recommendations will be reviewed.	

17. The following topics will be completed after 2020 but are included in this paper for information and context as they reflect work that will be needed in order to ensure the Centre's methods are future proofed, particularly for new types of technologies and data that are becoming available:

Table 2 - Summary of methods topics after 2020

Topic	Main issues to be addressed	Reason for inclusion
Genomics	This topic will address existing guidance on genomic technologies and testing strategies, and the methods that should be used in the future. It will consider pragmatic approaches to delivering NICE guidance on genomic technologies that meet the needs of the NHS, patients and key system partners.	Scientific and methodological innovations.
Antimicrobial resistance technologies	This topic will review the existing guidance on medical device and diagnostics that address antimicrobial resistance (AMR) and identify methodological areas that may need updating, focusing on technologies that identify the cause of infection, reduce the need for antibiotics, control infection, and optimise the use of current antibiotics. This topic will also consider if committees should apply any weighting to medical technologies that address AMR. It will determine pragmatic approaches for evaluating AMR technology and intends to engage with key system partners, such as the UK AMR Diagnostics Collaborative.	Scientific and methodological innovations.

Date: 17 July 2019 Reference: 19/067

	NICE is currently working with the Department of Health and Social Care (DHSC) and NHS England on the issue of antimicrobial resistance. The Policy Research Unit in Economic Evaluation of Health and Care Interventions (EEPRU) for new antimicrobials will continue as a separate project, but will inform the methods for assessing antimicrobial resistance technologies.	
Digital technologies	This topic will review the methods used to assess digital technologies in existing guidance and consider the future needs for methods in this area. A choice of methodological approaches will likely be needed to evaluate digital technologies because of the wide variety of value propositions they offer. The work will align with the current NICE pilots of digital health	Scientific and methodological innovations.
	technologies and with the ongoing work of the data and analytics team.	

Timelines

- 18. Work will be commissioned on specific methodological areas from July 2019 to January 2020.
- 19. We plan to review the findings and prepare a draft programme manual for consultation in Summer 2020.
- 20. We anticipate that the final programme manual will be published in December 2020.
- 21. An implementation plan will be put into practice in 2021.

Conclusion

- 22. The methods update will allow us to respond to the 2019 Voluntary Scheme as well as making changes to address new methods and types of health technologies. It will also enable us to consider well justified improvements suggested by stakeholders.
- 23. Subject to Board approval of the proposed topics, they will appear on the website, alongside other information about the methods update, which is already available.
- 24. The Board is asked to:
 - consider and approve the scope of the methods review for health technology evaluation programmes.
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July 2019

Detailed description of methods review topics

Modifiers considered in decision making

- 25. At the moment, clinical and cost effectiveness are key decision-making criteria when committees make recommendations. However, it is recognised that these are not the sole basis for decision making, and that many other factors are considered. Some of these additional factors are associated with a specific additional maximum weight, captured by an explicit modifier of the thresholds (such as for highly specialised technologies, when significant QALY gains are identified in highly specialised technologies, and life extending treatments at the end of life within technology appraisals). Others are qualitatively considered by the committee. There are several other factors that are currently deliberatively considered by committees, these include, the extent of uncertainty, unmet need, burden of illness and severity, the innovative nature of the technology and equalities considerations. This review will explore if the current other/additional factors are still relevant for patients and the NHS and in line with NICE's remit. It will address whether there is need for modification or adaptation of currently considered other/additional factors, for example, through the application of specific weights. It will also explore if any additional factors currently not considered in the decision making should be taken into account, quantitatively or qualitatively, including the scenario of technologies which do not fully meet the highly specialised technologies topic selection criteria but which go beyond what is normally considered in the technology appraisals programme. The topic will investigate whether there is a need to amend any of the modifiers, and if required, which and how other factors can be adequately captured. Additional factors such as NHS policy priorities, wellbeing, experience of care, organisational efficiency, curative potential may be explored.
- 26. This work relates to NICE's consultation on Value Based Assessment in 2013. The 2013 consultation proposed an approach to incorporate wider societal impacts and burden of illness. Following that consultation, the NICE Board indicated that there was no consensus for the proposed changes. In particular, the approach for incorporating wider societal benefits was not supported by stakeholders. We do not believe that has been any substantial advancement in methodological research in this area and will document this. Therefore, it is unlikely that wider societal impacts will be incorporated using the approach outlined in the 2013 NICE consultation.

Exploring uncertainty

- 27. Exploring and understanding uncertainty is an important part of the health technology assessment process. The reasons for uncertainty are extensive, but these include uncertainty with the evidence, the synthesis of evidence and assumptions made within economic modelling. The extent of evidence uncertainty is often because the evidence does not fully match the needs of an appraisal (such as a marketing authorisation including a population that was not included within the clinical trials), or the available evidence may not yet be mature or complete (such as a marketing authorisation being granted at a point when not all the evidence is available). Therefore, the aim of this work is review how uncertainty is explored or quantified, and the approaches that can be taken to try and reduce the uncertainty within the timeframe of guidance production. This includes reviewing the use of data analytics and real-world evidence to resolve uncertainty with the evidence.
- 28. Extrapolation methods for treatment benefits and harms in the absence of evidence will be explored, including complex newer techniques.
- 29. This work will absorb the work and findings from the 2017 NICE discussion paper on 'Methods for handling uncertainty and risk to support patient access to promising health technologies'.

Types of evidence (sources and synthesis)

- 30. The types of evidence that are considered within a health technology assessment vary within each company submission and according to the value proposition of the technology. We will review the types of evidence considered across the different NICE programmes. This includes the source and how randomised, non-randomised and real-world evidence is currently considered. The use of qualitative evidence, patient evidence and expert elicitation will also be explored.
- 31. The assessment, interpretation and synthesis of evidence will be reviewed. This includes assessment of quality and interpretation of statistical evidence, clinical information and the methods for evidence synthesis and adjustment techniques. This also includes indirect analysis, matching adjusted indirect analyses and methods adjusting for treatment switching.
- 32. Where appropriate, methodological good practice outlined in NICE Decision Support Unit's Technical Support Documents may be absorbed, or expanded as appropriate.
- 33. The use of real-world evidence will be reviewed. There are ongoing projects exploring real world evidence, and data analytics as part of the 'widening the

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- evidence base: the use of broader data and applied analytics in guidance development'. We aim to collaborate and align where appropriate on this topic.
- 34. It is anticipated that some differences between the types of evidence considered for different technologies will need to be retained due to the wide variation in value propositions, particularly between diagnostic and treatment technologies.

Health-related quality of life

- 35. This topic will address how quality of life is incorporated into economic analyses and considered by committees, addressing factors including the following:
 - Patient reported outcome measures
 - EQ-5D 3L/5L and valuation sets
 - Core outcome sets and outcomes for mental health
 - Age adjustment
 - Quality of life for carers, children and young people, and for people with rare diseases
- 36. The NICE Science Policy and Research programme are carrying out work to address these factors, and this will be aligned appropriately with, and incorporated into, the methods update.

Technology-specific issues

- 37. This review will consider issues that are specific to types of technologies and are not included in other parts of the review. An example is reviewing the new regulations for medical devices and in vitro diagnostics (IVDs) and consider how these changes may affect the current methods used at NICE. Consideration will also be given to current methodological approaches for considering version control, information governance and usability of medical technologies.
- 38. It is anticipated that regulators may approve technologies across anatomical sites and histologies in future. That is, approval of technologies that are not limited to a specific site or histology. This creates challenges in terms of the uncertainty because of the type of evidence available (such as basket trials) for each population or site. NICE's Science Policy and Research programme have a number of methodological research projects exploring these issues. In addition, NICE has several on-going technology appraisals for histology independent indications. Lessons and findings from the research and

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appraisals will be taken into account, and so the anticipated completion of this work is 2020.

Discounting

- 39. NICE discounts costs and benefits in the future because costs and benefits incurred today have a higher value than costs and benefits occurring in the future. The current approach to discounting is described NICE's "Guide to the methods of technology appraisal 2013" and "Interim Process and Methods of the Highly Specialised Technologies Programme". The approach for diagnostic tests, medical devices and within guidelines is broadly similar.
- 40. Committees in TA and HST can apply non-reference discounting rates of 1.5% for both costs and benefits in exceptional circumstances where treatment restores people who would otherwise die or have a very severely impaired life to full or near full health, and when this is sustained over a very long period.
- 41. The basic discount rate originated from the Treasury: The <u>Green Book 2003</u> stated that costs and benefits should be discounted at a rate of 3.5% for the first 30 years (declining after that). The advice was clarified in <u>2018</u>, and now explicitly states that present value of life years and quality-adjusted life years (QALYs) should be discounted at a rate of 1.5%. In addition, the discount rate has been the focus of companies and patient groups who believe that different discount rates could be used.
- 42. A recent review of the cost effectiveness methodology for immunisation programmes and procurement (CEMIPP) has considered the case for change of the discounting rate, taking into account the clarification provided in the Green Book. The Government has decided not to accept the three key recommendations of the report (on reducing the cost-effectiveness threshold to £15,000 per Quality-Adjusted Life Year (QALY), changing the health discount rate to 1.5%, and changing the time horizon of the analyses).

Cost-minimisation methods

- 43.MTEP currently uses 'cost-minimisation' (referred to as 'cost-consequence' analysis) for both medical devices and diagnostic technologies that claim to offer resource savings. The NHS Long Term Plan highlighted these technologies as of particular interest and a funding mandate for cost saving medical technologies is expected in April 2020.
- 44. TA also uses a 'cost-minimisation' approach (referred to as 'cost comparison') within its fast track appraisal process. This approach is used for technologies which provide similar or greater health benefits at similar or lower cost than

- technologies already recommended in technology appraisal guidance for the same indication.
- 45. The aim is to review and critique the current approaches to cost minimisation used, ensure that 'cost minimisation' methods are informed by the latest and best available health economic methodological research, review the methods to assess clinical non-inferiority, identify any inconsistencies in methodology across the different programmes and align them where appropriate. This work will also determine the appropriate scenarios in which cost minimisation should be applied, such as for biosimilars and alternative technologies, and unless the outcome of this project indicates otherwise, determine a single standard 'cost-minimisation' method for use in health technology assessment.

Equality considerations in guidance development

46. Potential equality issues are frequently raised during guidance development within NICE and the Centre for Health Technology Evaluation (CHTE) Equality Expert groups provide advice on more complex issues. This review will collate responses and legal advice to equality issues that have arisen during guidance development and appeals. An updated and aligned approach to responding to potential quality issues and completing equality impact assessments will be developed for use by CHTE. This review will also consider potential equality issues that could arise due to new types of technologies such as site-agnostic technologies, genomics and digital health. This work will have relevance to handling potential equality issues across NICE so we aim to collaborate with the NICE Equality and Diversity Group (NEDG) and the editorial team, to ensure shared learning and alignment across NICE.

Costs used in Health Technology Assessment (HTA)

47. This review will consider several issues that have been identified around which costs are the most appropriate to use in economic analyses. This can include intervention or comparator costs, carer costs and future unrelated costs. This is particularly true for medical devices and diagnostics, where most products are not commissioned nationally so there are often uncertainties in how an intervention should be costed. For example, some companies may provide a list price whilst others may provide an average selling price. In addition, some technologies, particularly in-vitro diagnostics, may have variable pricing structures which are dependent on throughput or include volume-based discounts. These prices are routinely offered to the NHS but are not publicly available, meaning that the prices used in guidance may not truly reflect the price paid by the NHS.

- 48. All programmes are also seeing technologies which may have a large budget impact, for which innovative pricing structures may be required, particularly for technologies which have a high acquisition cost but which can be used for multiple purposes that are outside the scope of an assessment.
- 49. Furthermore, consideration will be given to circumstances where even at zero acquisition cost, some technologies cannot be considered cost-effective.
- 50. The work is likely to be relevant to the proposed new NHS England funding mandate for cost saving medical technologies.

Position of technologies in the care pathway

51. This review will consider the methods needed to assess the clinical and cost effectiveness of the position of technologies in the care pathway. The clinical and cost-effectiveness of a technology within the care pathway may be affected by the sequence that treatments are used. The work will align with the work being done for NICE Connect, which aims to provide pathways that reflect the organisation and delivery of prevention, treatment and care.

General approach to decision making

52. The general approach to decision making is an important part of the health technology assessment process. It is important that a committee is given the right information in an accessible way for them to make recommendations. The review includes how information is presented to committee and whether more visual tools can be used. It will examine the approach for considering cost-effectiveness evidence including the use of pair-wise analysis, fully incremental analysis or net benefit analysis. It will explore systematisation of committee's value judgements to support consistent decision making. It will examine whether existing frameworks, such as 'Grading of Recommendations Assessment, Development and Evaluation (GRADE)' are appropriate to use for health technology assessment. The types of recommendations that a committee can make will be considered including the wording of recommendations, reviewing the use of 'only in research' or research recommendations.

Genomics

53. This review will consider existing guidance on genomic technologies and testing strategies, and the methods used. Historically, genomic technologies have tended to focus on a specific indication but with the introduction of whole genome sequencing, a substantial increase in diagnostic information will be gained from one test. The identification of new genomic risk factors is also

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- likely to be an area of future development so existing methods for assessing predictive and prognostic genomic tests will also be reviewed.
- 54. The review will include considering any new developments in the methods for assessing genomic technologies, review current approaches to appraising companion diagnostics, how the new In Vitro Diagnostic Regulation (IVDR) may inform NICE methods for genomics (particularly the in-house exemption), and consider pragmatic approaches to delivering NICE guidance on genomic technologies that meet the needs of the NHS, patients and key system partners.

Antimicrobial resistance technologies

- 55. The UK 5 year action plan and 20 year vision for antimicrobial resistance highlights the important role medical technologies, particularly diagnostics, can play in tackling antimicrobial resistance. This work will review the existing guidance on medical device and diagnostics that address antimicrobial resistant (AMR) and identify methodological areas that may need updating. It is anticipated that key areas for the methods review in AMR will be for medical technologies that identify the cause of infection, reduce the need for antibiotics, infection control, and optimising the use of current antibiotics. This work will also consider if committees should apply any weighting to medical technologies that address AMR or whether AMR is already considered under the other factor, innovation, within existing methods. This work will determine pragmatic approaches for evaluating AMR technologies and intends to engage with key system partners, such as the UK AMR Diagnostics Collaborative.
- 56. NICE is currently working with the Department of Health and Social Care (DHSC) and NHS England on the issue of antimicrobial resistance. This review will align with ongoing work in evaluating new antimicrobials to ensure shared learning and alignment where appropriate. It is expected that the work of the Policy Research Unit in Economic Evaluation of Health and Care Interventions (EEPRU) for new antimicrobials will continue as a separate project, although it may inform methods for assessing antimicrobial resistance technologies.

Digital technologies

57. NICE will review the methods used to assess digital technologies in existing guidance and consider the future needs for methods in this area. It is anticipated that a choice of methodological approaches will be needed to evaluate digital technologies because of the wide variety of value propositions they offer, particularly the differences between digital technologies that offer a treatment and those that offer a diagnostic or monitoring purpose. This is not dissimilar to the approach already taken for medical devices and diagnostic

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technologies. Consideration will be also be given to technologies that include a digital element rather than being solely digital. The work will review and align with the current NICE pilots of digital health technologies and with the ongoing work of the data and analytics team.

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Policy on declaring and managing interests for advisory committees

This report gives details of proposed amendments to the policy on declaring and managing interests for advisory committees following its first year of operation. The amendments seek to reinforce the risk based approach to handling interests and take account of feedback from guidance teams, the conflicts of interest reference panel, and the discussion at the June Board Strategy meeting.

The Board is asked to approve the policy for immediate implementation across the advisory committees.

Professor Gillian Leng

Deputy Chief Executive and Director, Health and Social Care Directorate

July 2019

Introduction

- 1. In January 2018 the Board agreed a new policy on declaring and managing interests for advisory committees to come into effect from 1 April 2018. Given the extent of the changes it was agreed to review the policy after one year. This review has taken place, drawing on feedback from guidance teams and the conflicts of interest reference panel that comprises executive and non-executive directors. The amendments also seek to address the recommendations in a research study published in the British Medical Journal (BMJ) about funding from the life sciences industry to patient groups participating in NICE's technology appraisal programme.
- 2. The Board reviewed the proposed updated policy at the June Board Strategy meeting and supported the policy for formal approval.

Amendments to the policy

Ensuring a proportionate approach

3. In response to feedback from the reference panel, amendments have been made throughout the policy to address concerns about the impact of the policy on committee recruitment. For example, new text has been added in paragraphs 3 and 26 to highlight the need for a proportionate approach, and that the management of interests needs to be taken in the context of ensuring the committees have access to the expertise they need. Following the discussion at the June Board Strategy meeting, the senior management team considered further the text box after paragraph 34 and agreed to maintain the statement that individual members and co-optees should not be appointed if they have specific interests that mean they are likely to be excluded from more than 50% of the committee's discussions.

Financial interests

- 4. The section on direct financial interests has been amended to clarify what should be declared (including speaking engagements and sitting on advisory boards).
- 5. New footnotes have been added to clarify that employment in the public sector for example in the NHS does not require declaration; and to reference the bar on committee membership for Department for Health and Social Care staff, and people working in NHS England/NHS Improvement's national functions.
- 6. The existing footnote in this section has been amended to clarify that reasonable travel, accommodation and attendance costs would generally be those a public sector body would offer. Only costs above this level require declaration.

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- 7. The approach for handling private practice has been revised in response to feedback from the Centre for Guidelines and the reference panel's annual review. The policy agreed in 2018 states that a committee member may be able to participate if their clinical experience is considered vital to the discussion. The proposed amended policy states that such committee member can participate if their complete exclusion from the meeting would diminish the committee's access to clinical expertise on the matter under discussion. The table also now includes the text that was previously in the appendix about which types of private practice may present a greater risk of conflict of interest. The amendments seek to address a concern that the previous approach was detrimentally affecting committee recruitment.
- 8. New text in paragraph 27 clarifies that open declaration would usually be sufficient if an individual received sponsorship to attend a past event and has no ongoing relationship with the sponsoring organisation. This is because the scope to benefit has ended, and reflects the approach for other historic financial interests (e.g. ceased private practice and former shareholdings).

Non-financial interests

- 9. The table in paragraph 37 has been amended to reflect the outcome of the reference panel's annual review. The amended policy states that open declaration will usually be sufficient when someone has expressed a past view on the matter under consideration, especially where these views are balanced across the committee. The reference panel and the Centre for Guidelines were concerned that the wording in the current policy could unintentionally encourage a default exclusion from the discussion of those who had published research in the area under consideration, and this could detrimentally affect the committee's access to topic specific expertise.
- 10. In response to a recent case referred to the reference panel, text has also been added to this table to highlight the need for a nuanced/risk assessed approach when considering how to respond when an individual holds office in a relevant organisation.
- 11. When reviewing the 2018 policy the Centre for Guidelines raised the issue of the time frame for declaring interests and suggested extending the period for declaring non-financial interests beyond 12 months. This was previously considered by the Board following the public consultation in 2017 following which it was agreed that older interests should instead be considered as part of the recruitment process. The reference panel supported this approach and agreed text should be added to reference this. This has been added in a new paragraph (29).

12. New text has also been added (paragraph 30) to recognise that it may be necessary to appoint candidates who have previously expressed strong views on a topic, and in such circumstances care should be taken to ensure the committee contains a balance of views.

Interests of stakeholder organisations

- 13. In November 2018 the BMJ <u>published research</u> on the disclosure of financial interests by patient organisations contributing to NICE's technology appraisals. <u>NICE's rapid response</u> clarified NICE's disclosure requirements when an individual attends a committee to give evidence, and committed to look at what more could be done to reduce the risk of bias in this area.
- 14. In response to the research, the policy includes a new requirement (paragraph 39) for any stakeholder invited to make a written submission to an advisory committee to declare their organisation's interest in the matter under review. This includes any financial interest in the technology or comparator product, funding received from the manufacturer of the technology or comparator product, or any published position on the matter under review. This declaration would cover the preceding 12 months and will be available to advisory committee alongside the stakeholder's submission.
- 15. In addition, the policy now states that where a witness has been nominated by a stakeholder organisation, the individual should declare both their own interests and also those of the nominating organisation this includes any financial interest the organisation has in the technology or comparator product, funding received from the manufacturer of the technology or comparator product, or any published position on the matter under review. Where the witness has not been nominated by an organisation, the declaration is limited to their own interests. In both circumstances, the declaration would cover the preceding 12 months and be available to the advisory committee.
- 16. Text has also been added (paragraph 19) to state that indirect interests arise when a committee member is appointed to a committee to represent an organisation, an individual attends a meeting to speak on an organisation's behalf, or an organisation makes a written submission to the committee.

Links to other transparency initiatives

17. A new provision has been added (paragraph 53) to state that NICE may from time to time periodically review publicly available sources of information, such as the ABPI register, to provide assurance that interests are being appropriately declared. This follows a recent international conference on best practice in managing interests.

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Other changes

- 18. Cross reference has been added to NICE's statement on engagement with tobacco industry organisations, which restricts the involvement of those involved with 'tobacco organisations' with the advisory committees.
- 19. The paragraphs on the publication of interests have been updated to reflect the approach taken across the guidance programmes to implement the policy and the way guidance is published on the website. Appendix A has been updated accordingly.
- 20. A statement has been added that a deliberate failure to disclose an interest could in the most serious cases be treated as misconduct and result in referral to a relevant professional body (paragraph 59).
- 21. In response to feedback, the declarations of interest form will be revised to provide more prompts on the types of interest that need to be declared (drawing on the extended form developed by the Centre for Guidelines for guideline committee chairs). As this will be longer, and potentially in MS forms, it has been removed from the policy.
- 22. The terms of reference for the reference panel (appendix B) have been amended to state there will be 3 NEDs in line with the current membership.
- 23. In response to feedback, a glossary has been added (appendix E).

Next steps

- 24. Once approved, the revised policy will be implemented with immediate effect, without the lead in period that was required in 2018. This is because the amendments are less material than when the 2018 policy was introduced, and the changes should further aid the committees' access to the expertise they require.
- 25. The accompanying frequently asked questions will be updated to reflect the amendments to the policy and to clarify issues raised in feedback from guidance teams. Training will also be provided to the guidance teams to help ensure consistent implementation.
- 26. The policy will be reviewed every 3 years unless an earlier review is needed.

Conclusion

27. The Board is asked to approve the revised policy for immediate implementation across the advisory committees.

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July 2019



Policy on declaring and managing interests for NICE advisory committees

Also includes witnesses, expert commentators and other contributors

Responsible Officer: Deputy Chief Executive

Author: Corporate Office

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Next review date: July 2022

Version control sheet

Version	Date	Author	Replaces	Comments
1	January 2018	Corporate office	N/A	New policy specifically for advisory committees, based on the NHS England's managing conflicts of interest in the NHS.
1.1	July 2019	Corporate office	Version 1	Updated after the first year of operation.



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Introduction

- NICE aims to achieve and maintain high standards of probity in the way
 we conduct our business. These standards include impartiality,
 objectivity, integrity, and the effective stewardship of public funds.
 Managing potential conflicts of interest is an important part of this
 process.
- 2. Effectively managing interests and identifying potential conflicts is essential if health and care professionals, and the public, are to maintain confidence in our work. It is central to how we develop guidance, and appoint members to our advisory committees¹.
- 3. This policy supports a culture in which we are transparent about the interests of those who are members of, or work with, our advisory committees, so that the effect of interests is known, understood and managed. It aims to ensure that the advisory committees have access to the appropriate expertise on the areas under consideration, while minimising the risks to their perceived ability to objectively consider the evidence.
- 4. The policy provides guidance on:
 - what interests need to be declared and when
 - how declared interests should be recorded
 - when a declared interest could represent a conflict of interest and the action that should be taken to manage this.

Scope

- 5. This policy applies to everyone involved in our advisory committee discussions, including the following groups:
 - advisory committee chairs
 - advisory committee members, including co-opted and topic-specific members or experts
 - those invited to give evidence or advice to advisory committee meetings, including expert witnesses
 - technology appraisal and highly specialised technologies appeal panel chairs and members

¹ See also the NICE appointments to advisory bodies policy and procedure.

- organisations that are formally represented on, or making written submissions to, advisory committees.
- 6. The principles in this policy also apply to other NICE contributors to products that do not use a formal committee process, for example, peer reviewers who provide a medicines evidence commentary.
- 7. A separate policy applies to:
 - Board members and employees of NICE
 - agency workers and contractors on temporary contracts
 - secondees (people seconded to NICE from other organisations)
 - employees of the external guidance centres and the 'evidence contractors' working directly or indirectly to supply evidence that is used by the advisory committees.

Defining and categorising interests

- 8. Committee members and advisers bring a range of experiences and perspectives to NICE's work. It is likely they will have a variety of interests, arising from different contexts and activities done in a professional or personal capacity. This can include employment and other sources of income, speaking engagements, shareholdings, publications and research, and membership of professional or voluntary organisations.
- 9. Having advisory committee members with varied interests is a positive attribute, but it is vital that interests are openly declared so they can be appropriately managed. Declaring an interest does not mean there is a conflict of interest.

All interests should be declared if, in the view of a reasonable person, they are relevant, or could be perceived to be relevant, to the work of the NICE committee in question.

- 10. Interests that are not, or could not be perceived to be, relevant to the NICE committee's work need not be declared. This could include, for example, membership of sports and recreation societies, positions in local community groups, and shareholdings in companies unrelated to NICE's work.
- 11. For the avoidance of doubt, a person living with a disease or condition relevant to the matter under discussion, or who has a family member in

- that position, is not seen as an interest and this does not need to be declared.
- 12. It is important to exercise judgement, and if there is any doubt as to whether an interest is relevant to the committee's work, it should be declared. This includes indirect interests, such as those relating to family and friends, when they are known. In the case of particular uncertainty, further advice is available from the NICE team or external developer. When there are no interests to declare, a 'nil return' should be made.
- 13. The following categories describe the types of interests relevant to the work of NICE. In each case, a benefit may be a gain or avoidance of a loss.

Direct interests

- 14. A direct interest is when there is, or could be perceived to be, an opportunity for a person involved with NICE's work to benefit. This benefit could be financial (a financial interest) or non-financial (a non-financial personal or professional interest). These are explained further below.
- 15. **Financial interests:** When a person gets direct financial benefit. This means anything of monetary value, including: payments for services; equity interests, including stocks, stock options or other ownership interests; and intellectual property rights, including patents and copyrights and royalties arising from such interests.

 Examples of financial interests are:
 - Work in the commercial sector², including a directorship, employment, consultancy, that attracts regular or occasional payments or benefits in kind such as hospitality. This includes payments for speaking engagements and sitting on advisory boards, and clinicians undertaking private practice.³

As outlined in NICE's <u>statement on engagement with tobacco industry organisations</u>, individuals working for, or holding office in, tobacco organisations cannot be appointed to NICE's advisory bodies. (Tobacco organisations include the tobacco industry, and organisations speaking on behalf of, or funded by the tobacco industry.)

² The term 'commercial sector' refers to businesses and trade associations. Those particularly relevant to NICE include private health and social care providers, companies involved in products that might affect the public's health such as food, alcohol and tobacco industries, and companies with an interest in products, technologies and services that apply to the health and care sector.

³ Employment in the public sector – for example in the NHS – does not require declaration. However, NICE's policy on appointments to advisory committees excludes employees of the Department for Health and Social Care from membership of the advisory committees, together with NHS Improvement and NHS England employees who are employed in any of these organisations' national (as opposed to regional or local) functions.

- Ownership or part ownership of a healthcare provider, including a GP who is a partner in a practice or a community pharmacist who owns their business.
- Direct payment from the commercial sector to attend a meeting, conference or event, over and above funding to support reasonable travel, accommodation and attendance costs.⁴
- Shareholdings or other investments in the commercial sector (unless these are held in a managed fund where the person does not have the ability to instruct the fund manager as to the composition of the fund).
- Personal payment from the commercial sector to undertake research.
- 16. **Non-financial professional and personal interests:** When a person has a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation. This can include situations where the person:
 - Is an advocate for a particular group or is a member of a lobbying or pressure group with an interest in health or social care.
 - Holds office or a position of authority in a professional organisation such as a royal college, a university, charity, or advocacy group.
 - Is actively involved in an ongoing or scheduled trial or research project aimed at determining the effectiveness of a matter under review.
 - Has published a clear opinion about the matter under consideration.
 - Has authored or co-authored a document submitted as an evidence publication to the relevant NICE advisory committee.

Indirect interests

- 17. An indirect interest is when there is, or could be perceived to be, an opportunity for a third party closely associated with the person in question to benefit. This could be through a close association with another person or organisation that has a financial or non-financial interest (as defined above), and could benefit from a decision the person is involved in making through their work on an advisory committee.
- 18. Indirect interests can arise from people (such as close relatives, close friends and associates and business partners), and also employers (for example with research grants or other funding to the unit in which they work).

⁴ As a general guide, this would be expenses above a level a public sector body such as NICE would usually offer.

19. They can also arise when a committee member is appointed to a committee to represent an organisation, an individual attends a meeting to speak on an organisation's behalf, or an organisation makes a written submission to the committee. These organisational indirect interests would not usually preclude participation in the committee, but should be declared to ensure transparency about the organisation's interest in the matter under review.

Declaring interests

- 20. Committee chairs and members make their first declaration when applying for a specific advisory committee role. Witnesses and other contributors make their first declaration when invited to contribute to a committee meeting. The **initial declaration** covers the preceding 12-month period. Consideration should also be given to any new interests that are not currently held but are known will arise during involvement with the committee (for example a new research project).
- 21. People will be prompted to **update** their declaration:
 - before each meeting, by email
 - at the start of each meeting, orally
 - · each year (standing committees), by email.
- 22. Any new information provided before or during meetings, or at the annual update, is added to the original declaration, to give a full picture of the 12 months before beginning work with NICE.
- 23. It is the person's responsibility to identify and declare interests at the earliest opportunity, and to ensure this declaration remains up-to-date.
- 24. A summary of the process for declaring interests is set out in appendix
 A.

Identifying and responding to potential conflicts of interest

- 25. The response to declared interests depends on a person's role within the advisory committee (for example, chair, member, adviser, witness) and what is being considered by the committee.
- 26. Each case is different and the circumstances must be clarified with the people involved to assess the perceived risk of a conflict of interest.

 When the interest is specific to the topic under discussion, there is

greater likelihood of a conflict of interest (see below). Good judgement is needed to ensure proportionate management of risk. Decisions on managing interests must balance the need for advisory committees to have access to the appropriate expertise on the areas under consideration, while minimising the risks to their perceived ability to objectively consider the evidence.

There is a **conflict of interest** when a reasonable person would consider that an individual's ability to apply judgement or act in the work of NICE is, or could be perceived to be, impaired or influenced by one of their interests.

Responses to declared interests

- 27. There are 3 potential responses following a declaration of interest:
 - No action other than the process of open declaration the person can engage in all aspects of the committee's work. This is usually because nothing is considered to represent a perceived conflict of interest, but may in some circumstances be because an open declaration is considered sufficient to mitigate any risk of conflict. Open declaration will usually be sufficient if a financial interest occurred in the last 12 months and is no longer held. For example, if a person has ceased to hold shares or undertake relevant private practice, or received sponsorship to attend a past event and has no ongoing relationship with the sponsoring organisation. This is because the potential to benefit has ceased.
 - Partial exclusion the person can engage in committee discussion or provide advice to the meeting (for example, because of their expert knowledge), but is excluded from developing recommendations and decision-making on the matter relating to the interest. Involvement may be limited to answering direct questions from the committee.
 - Complete exclusion the person can have no input to a specific topic, either from the start (non-appointment) or for part of the committee's work relating to that topic. For example, where the person has a financial interest and could financially benefit from the outcome of the committee's discussions. When an interest leads to exclusion for a specific topic, it may be appropriate to withhold any confidential meeting papers for that item especially when the person could benefit from the information.

Interests at appointment

- 28. Assessment of an applicant's declared interests and curriculum vitae is done by a senior member of the NICE guidance programme (or external contractor), who agrees a final declaration with each applicant. The appointment panel considers whether any interests mean that they cannot be appointed. In the case of doubt, the relevant director considers the declared interests and, in very unusual circumstances, the decision is referred to the 'conflict of interest reference panel' (see appendix B for terms of reference).
- 29. As part of the appointment process the panel will need to consider whether there are any issues from before the 12 month declaration period that could question the individual's ability to evaluate evidence objectively. For example, where the individual has expressed views on the matters under consideration by the committee, the panel will want to ensure the proposed appointee is open to alternative views and is committed to work impartially.
- 30. NICE recognises that some topics are particularly contentious. If the appointment of people with strong views (and who therefore have a non-financial professional and personal interest) is necessary to ensure the committee has access to the required expertise, then care should be taken to ensure that the committee contains a balance of views.
- 31. Examples of how interests are handled during the appointment process are given in appendix C.

Chairs

- 32. The chairs of advisory committees are in a special position in relation to the work of their committee and have greater scope to influence the outcome of discussions. The chair helps the committee to work collaboratively, ensures a balanced contribution from all committee members and takes decisions about the potential conflicts of interest of their committee members. Chairs are appointed for their expertise and skill in chairing groups, and although they may have some knowledge of the topic, this is not their primary role in the group. Specialist knowledge is provided by other committee members.
- 33. The interests of potential chairs need to be considered in relation to the type of committee. Topic-specific guideline committees cover a defined area, therefore it is possible (and necessary) to identify and exclude possible conflicts of interest before appointment. This means chairs of topic-specific committees cannot have any direct interests. Standing committees cover a broad range of topics, therefore potential conflicts

can generally be handled on a meeting-by-meeting basis (see box below).

Appointing chairs

Topic-specific guideline committees:

Chairs cannot have any direct interests (financial, non-financial professional or personal) that relate to the services, interventions, products, or delivery of care to be considered within the scope of the guideline.⁵

It may also be inappropriate for chairs to have relevant indirect interests, including when a close family member could potentially gain financially from the person's work with NICE.

Standing committees:

Chairs cannot have any direct financial interests that relate to the development, manufacture or marketing of products that may be considered by the committee.

Other financial interests, such as private practice, direct non-financial or indirect interests, can usually be dealt with on a case-by-case basis at the relevant meeting. If these interests cover a significant portfolio of the committee's work, non-appointment may be necessary because the chair may need to be repeatedly excluded from the committee's discussions.

Members and co-optee members (standing and topic-specific guideline committees)

34. Members and co-optees are selected to bring a range of interests and expertise to the committee's discussion. Often these interests need no more than open declaration, but they can result in partial or complete exclusion from the committee discussion when there is a conflict of interest.

Appointing members to all committees

Individual members and co-optees should not be appointed if they have specific interests that mean they are likely to be excluded from more than 50% of the committee's discussions.

⁵ This does not include GPs (partner, salaried or locum) with a general interest in the topic through the provision of primary care services

Handling interests at committee meetings following appointment (standing committees and topic-specific guideline committees)

Specific interests are those that relate to matters under consideration at a particular meeting, and these interests are where conflicts are most likely to arise. Specific interests include anything that relates to, or informs, a potential recommendation, including all:

- products and competitor products
- interventions, including public health interventions and diagnostic tests
- topic areas, such as diagnosis or investigation of clinical issues
- underpinning research papers or economic analyses.

Specific interests do not include having a general interest in the topic under discussion, such as providing social care, or pharmacy or laboratory services, or through being a salaried employee in a commercial organisation that provides these services.

Income received from consultancy or other advisory services will be treated as a specific interest when it relates to the product under consideration, or the comparator to that product. Advisory services on matters unrelated to these products is not a specific interest. This is explained further in the examples in appendix E.

Before the meeting

- 35. In advance of each committee meeting, the NICE guidance team (or external contractor) identifies the issues being considered at the meeting. The NICE guidance team (or external contractor) reviews the list of declared interests from the chair, members and co-optees to determine whether there are any potential conflicts of interest relating to these specific areas.
- 36. The NICE guidance team (or external contractor), in consultation with the chair, considers the actions needed and notifies the affected person. In the event of an unresolvable disagreement or uncertainty between the chair and a member of the advisory body, the view of the relevant NICE programme director or authorised deputy must be sought. When uncertainty or disagreement remains, the programme director may decide to escalate the issue to the director. Following discussion with the programme director, the director will either resolve the matter or refer

this to the 'conflicts of interest reference panel' for consideration (see appendix B for terms of reference).

37. The general approach to handling specific interests at meetings is listed in the table below. Whenever the interest leads to excluding the chair, the vice chair will cover that item. Specific examples are given in appendix D.

Specific interests at committee meetings	Approach to handling at meetings
Direct financial interests	Any member or standing committee chair with a specific financial interest leaves the meeting for the duration of the relevant item, unless the financial interest has ended and there is no scope to benefit from the committee's discussion.
	In exceptional circumstances, when a member has particular expertise that would otherwise not be available to the committee, they may attend to answer specific questions, but would not usually take part in the decision-making.
	When the interest relates to private practice and income in the commercial sector, a member can participate if their complete exclusion from the meeting would diminish the committee's access to clinical expertise on the matter under discussion. ⁶ The level of involvement (full involvement or partial
	exclusion) will depend on the scope for potential benefit (and risk of conflict of interest). For example, full participation may be appropriate if the individual works predominantly in the NHS and the private practice is provided on a sessional basis and mirrors NHS activity. Whereas there is greater scope for a perceived conflict of interest when non-NHS income is directly contingent on the volume of a specific procedure.

⁶ Consideration should be given to whether the relevant clinical experience could be accessed in other ways, for example through written submission.

Direct, non-financial interests (personal and professional)	A member or standing committee chair with a specific non-financial interest may need to leave the meeting for the relevant item, if it is felt that the interest (such as publications authored or public statements made) could reasonably be interpreted as prejudicial to an objective interpretation of the evidence. A decision on participation should balance this risk with the benefit of the committee's access to their expertise. Open declaration or partial exclusion will often be sufficient, especially where these views are balanced across the committee.
	When the interest relates to holding office in an organisation, it will be important to consider the extent that the organisation has expressed a view on the matters under consideration and if this could reasonably be perceived as affecting the office holder's ability to objectively consider the evidence under review.
	Involvement in guidelines developed in accordance with international criteria does not usually lead to exclusion from the meeting.
Indirect interests	Any member or chair with specific indirect interests usually needs to do no more than declare this interest. However exclusion may be needed when a close family member could potentially gain from the committee's work.

Witnesses and other contributors (non-committee members)

- 38. Others contributing to the committee are likely to be either providing expert advice or giving a particular perspective, but will not be contributing to the final decision-making.
- 39. Any stakeholder invited to make a written submission to an advisory committee should declare their organisation's interest in the matter under review. This includes any financial interest in the technology or comparator product; funding received from the manufacturer of the technology or comparator product; or any published position on the matter under review. This declaration would cover the preceding 12 months and will be available to advisory committee alongside the stakeholder's submission.
- 40. In the case of oral evidence, every effort will be made to select experts who do not have a conflict of interest that would require a member of the

committee to withdraw from the discussion. However, there is discretion to invite an expert with such a conflict when the work of the committee would be seriously compromised without their testimony. For example, in an area where the number of experts is very small and there has been close collaboration between a clinical specialty and the life sciences industry in developing new technologies.

41. Where a witness has been nominated by a stakeholder organisation, the individual should declare their own interests and also those of the nominating organisation – this includes any financial interest the organisation has in the technology or comparator product; funding received from the manufacturer of the technology or comparator product; or any published position on the matter under review. Where the witness has not been nominated by an organisation, the declaration is limited to their own interests. In both circumstances, the declaration would cover the preceding 12 months and will be available to the advisory committee.

At the meeting

- 42. At each meeting, a copy of all declared interests, including those of the chair, any co-optees, additional invited experts and organisations making written submissions, is made available to the committee.
- 43. The chair asks whether there are any new interests to be added or any potential conflicts of interest specific to the issues being considered at the meeting. This is to confirm, and to potentially add to, the interests that have already been identified before the meeting.
- 44. If a person is aware that a product or service under consideration is, or may become, a competitor of a product or service developed, manufactured, sold or supplied by a company in which they have a current financial (either direct or indirect) interest, this should be declared.⁷
- 45. The chair informs the meeting attendees of the actions agreed in relation to any specific interests.

Records and publication

46. All declared interests that are relevant, or potentially relevant, to the work of the NICE committee are logged on a register of interests for that

⁷ In the technology appraisal programme, competitors are comparator products outlined in the appraisal scope. Potential competitors are products which have been referred by Minsters to NICE for appraisal.

- committee. This is available on the NICE website and at the start of each committee meeting, and updated as needed.
- 47. For members and the committee chair, the register will include the interests from the date of appointment plus the preceding 12 months. If there is a reappointment to a standing committee, the register will include the interests from the date of reappointment plus the preceding 12 months.
- 48. For standing committees and topic-specific guideline committees, the interests of those who attended the committee to give evidence or advice will also be published.
- 49. A written audit trail is maintained of the information considered and any actions taken. The committee minutes record the interests declared and action taken in response. Interests are also published alongside guidance publications.

Exceptions

50. If people have substantial grounds for believing that publishing their interests should not take place, then they should contact the Associate Director, Corporate Office to explain why. In exceptional circumstances, for instance when publishing information might put a person at risk of harm, information may be withheld or redacted. However, this would be the exception and information will not be withheld or redacted merely because of a personal preference.

Wider transparency initiatives

- 51. In keeping with the purpose of this policy, NICE fully supports wider transparency initiatives in healthcare. For example, we strongly encourage people to give their consent for payments they receive from the pharmaceutical industry to be disclosed as part of the Association of British Pharmaceutical Industry (ABPI) Disclosure UK initiative. These 'transfers of value' include payments relating to:
 - speaking at and chairing meetings
 - training services
 - advisory board meetings
 - fees and expenses paid to healthcare professionals
 - sponsorship of attendance at meetings, which includes registration fees and the costs of accommodation and travel, both inside and outside the UK
 - donations, grants and benefits in kind provided to healthcare organisations.

- 52. Further information about the scheme can be found on the <u>ABPI</u> website.
- 53. NICE may from time to time periodically review publicly available sources of information, such as the ABPI register, to provide assurance that interests are being appropriately declared.

Dealing with breaches

54. There will be situations when interests will not be identified, declared or managed appropriately and effectively. This may happen innocently, accidentally or because of deliberate actions. For the purposes of this policy, these situations are referred to as 'breaches'.

Identifying and reporting breaches

- 55. To ensure that interests are effectively managed, staff, those participating in our committees and stakeholders are encouraged to speak up about actual or suspected breaches.
- 56. Anyone who is aware of actual breaches of this policy, or who is concerned that there has been, or may be, a breach, should report these concerns to the chair of the committee and a senior member of the NICE (or guideline developer) team.
- 57. NICE investigates each reported breach according to its specific facts and merits, and gives relevant parties the opportunity to explain and clarify the circumstances.
- 58. Following investigation NICE:
 - decides if there has been, or is potential for, an actual breach and if so, the materiality of the breach
 - assesses whether further action is required
 - considers who should be made aware of the breach
 - takes action and clarifies the policy, if necessary.
- 59. A deliberate failure to disclose an interest could in the most serious cases be treated as misconduct and result in referral to a relevant professional body.

Learning and transparency

60. Reports on breaches, the effect of these, and action taken is considered by the senior management team and audit and risk committee at least annually.

61. To ensure that lessons are learnt and managing interests continually improves, anonymised information on breaches, the effect of these and action taken is published on the NICE website.

Review

62. This policy will be reviewed every 3 years unless an earlier review is needed.

Relevant legislation, guidance and NICE policies

- The Bribery Act 2010, which includes the offences of offering or receiving a bribe
- Freedom of Information Act 2000
- ABPI: The Code of Practice for the Pharmaceutical Industry (2016)
- ABHI Code of Business Practice
- MedTech Europe Code of Ethical Business Practice (2015)
- NHS Code of Conduct and Accountability (July 2004)
- NICE Standards of Business Code of Conduct
- Appointments to advisory bodies policy and procedure
- NICE gifts and hospitality policy
- NICE non-staff re-imbursement policy



Appendix A: process for declaring interests

Committee chairs and members

Declaration of interests submitted with application

Reviewed by senior member of NICE guidance programme or developer to identify whether application can proceed or the candidate is excluded on the grounds of a conflict of interest.



Further declaration of interests submitted when candidate appointed

Interests reviewed by senior member of NICE guidance programme or developer and those relevant, or potentially relevant, to the work of the committee added to the committee's register of interests and published on the NICE website.



Committee members asked to declare any additional interests before a meeting taking account of the items to be discussed

Discussion between chair and guidance team on any declared interests and the position of the committee member at the meeting.



Declared interests available to committee members at the committee meeting

At the start of the meeting, attendees asked to declare any changes to the declared interests and any potential conflicts of interest in relation to the items to be discussed.

Interests recorded in the minutes and added to the register.



Publication of interests alongside final guidance and in committee register of interests



NICE will prompt appointees for annual declaration.

Witnesses and other contributors to committees (that is, non-committee members)

Declaration of interests submitted with application

Reviewed by senior member of NICE guidance programme or developer to identify whether application can proceed or the candidate is excluded on the grounds of a conflict of interest



Further declaration of interests submitted when candidate appointed

Senior member of NICE guidance programme or developer reviews interest.

Interests relevant or potentially relevant to the work of the committee published on the NICE website



Committee members asked to declare any additional interests in advance of a meeting taking account of the items to be discussed

Chair and guidance team discuss any declared interests and the position of the committee member at the meeting



Declared interests available to committee members at the committee meeting

At the start of the meeting, attendees asked to declare any changes to the declared interests and any potential conflicts of interest in relation to the items to be discussed.

Interests recorded in the minutes and published.



Appendix B: conflict of interest reference panel terms of reference

Objectives

- To provide advice to directors, with a short turnaround time, on novel and contentious matters relating to conflicts of interest.
- To help promote consistency in the handling of challenging cases.
- To review decisions made by the reference panel in the previous year on an annual basis, to consider whether any amendments to the policy on declaring and managing interests for advisory committees are needed.

Membership

 Three non-executive directors (including the audit and risk committee chair who will chair the panel) and 2 senior management team members from non-guidance producing directorates.

Ways of working

- Email with the option to meet by teleconference should this be needed. In the case of a teleconference, a quorum will be 1 non-executive director and 1 senior management team member.
- NICE's Corporate Office will retain a record of referrals to the panel, and the advice given, to inform future cases.

Appendix C: examples of handling interests at appointment

Topic-specific guideline committees: examples of non-appointable chairs

Guideline topic	Chair not appointable	Rationale
Acute heart failure	Cardiologist with specific expertise in managing heart failure, exemplified by a portfolio of research interests and publications in this area.	This represents a direct non-financial professional interest (published clear opinion on matters within the scope of the guideline).
Epilepsy in adults	Neurologist with private practice that provides specialised epilepsy procedures.	This represents a direct financial interest as the areas of work done in private practice are within the scope of the guideline.
Obesity	Academic with significant grants for research into diet and obesity from industry bodies.	This represents a direct financial interest (grants from the commercial sector) and a non-financial professional interest (published clear opinion).
Physical activity	Spouse runs a business providing lifestyle coaching and physical activity sessions.	This represents an indirect interest that could be perceived as affecting the judgement of the chair.
Home care	Board member of a charity providing home care services.	This represents a direct non-financial interest (holds office in a position of authority).
Alcohol interventions in schools	Professor of public health at an academic institution, who has research interests in school-based alcohol interventions and has expressed a clear opinion supporting a particular behavioural intervention that is being considered in the guidance.	This represents a non- financial professional interest (has published a clear opinion about the matter under consideration).

Topic-specific guideline committees: examples of appointable chairs

Guideline topic	Chair appointable	Rationale
Eating disorders in young people	Adult psychiatrist with a practice focused on anxiety and depression.	There are no direct interests in the topic under discussion.
Medicines management in care homes	Manager of a large care home, which is privately owned and mostly funded by the private sector.	There are no direct interests in the interventions covered in the guideline. The manager is salaried so there is no scope for direct personal gain from the committee's work.
Smoking cessation	Director of public health in a local authority, with no research interests or published opinions on research opinion.	There are no direct interests in the interventions under consideration (an expressed opinion that smoking is harmful is to be expected). There is no scope for direct gain from the committee's work.
Asthma: diagnosis and management	A GP (partner or salaried) who has an interest in asthma, but no recent publications in this area or scope to personally financially gain from the recommendations in the guideline.	The GP has a general interest in asthma and primary care services, but there is no scope for direct gain from the committee's work.

Standing committees: examples of non-appointable chairs

Committee	Chair not appointable	Rationale
Technology appraisal and highly specialised technologies	Hepatologist with a significant research portfolio, most of which is funded by the pharmaceutical industry, some as personal payments.	The personal payments represent direct financial interests (grants from the commercial sector) that would be perceived as a conflict, and the broad portfolio would probably mean exclusion from more than 50% of the committee's discussions.
Indicator committee	GP who has income from the Quality and Outcomes Framework.	This represents a direct financial interest because the GP's income could be affected by the decisions of the committee.

All committees: examples of non-appointable members

Committee	Member not appointable	Rationale
Technology appraisal and highly specialised technologies	Member with a broad portfolio of shares in the pharmaceutical industry (unless these are held in managed funds where the person does not have the ability to instruct the fund manager as to the composition of the fund).	This represents a direct financial interest and the broad portfolio covering a number of companies would probably mean exclusion from more than 50% of the committee's discussions.
Guideline on high blood pressure	Cardiologist with a broad portfolio of research funded primarily by the pharmaceutical industry.	This represents a direct financial interest and the extent of research portfolio funded by a number of companies would probably mean exclusion from more than 50% of the meetings.

Appendix D: examples of handling specific interests at meetings

Example of interests	Action and rationale
Consultancy fee received by a committee member from the company producing the product under consideration, or	The action depends on the nature of the consultancy undertaken.
	Complete exclusion – if this relates to the product under consideration, or the comparator, as the interest is a specific direct financial interest.
the comparator.	Declare and remain – if the consultancy is unrelated to the product under consideration or the comparator, as the interest is not specific.
	If the consultancy income from the manufacturer of the product under review, or the comparator, accounts for a majority of the person's income then it may be appropriate to exclude the person from the discussion (in the way an employee of the manufacturer would be – see below example).
Technology appraisal committee member employed by a company that manufactures a competitor to the product under review.	Complete exclusion –this represents a direct financial interest. It may be appropriate to withhold from the member confidential information in the meeting papers for the topic if these contain commercially sensitive information.
Private practice income	Chairs - complete exclusion.
from the procedure, intervention or delivery of care under consideration.	Members – can participate if their complete exclusion from the meeting would diminish the committee's access to clinical expertise on the matter under discussion. The level of involvement (full involvement or partial exclusion) will depend on the scope for potential gain (and risk of conflict of interest). For example, full participation may be appropriate if the individual works predominantly in the NHS and the private practice is provided on a sessional basis and mirrors NHS activity. Whereas there is greater scope for a perceived conflict of interest when non-NHS income is directly contingent on the volume of a specific procedure.

 $^{^{\}rm 8}$ Consideration should be given to whether the relevant clinical experience could be accessed in other ways, for example through written submission

Publications in which a member expresses a clear opinion about the intervention being considered.	Potential exclusion – this is non-financial professional interest and the response will depend on the nature of the view expressed and the risk to perceived objectivity. In determining the level of involvement the chair should consider the balance between this risk and the benefit of the member's input to the committee. Open declaration or partial exclusion (i.e. the member to remain in the room to answer questions but not take part in decision-making) will often be sufficient.
Grant income received by the member's employer from the company that manufactures the product.	Declare and remain – this is an indirect interest, because the income goes to the employer.
Spouse doing research in the area under discussion.	Declare and remain – this is an indirect interest with no direct financial gain.
Employee of a charity or professional body with an interest in the condition.	Declare and remain – this is a direct interest, but with no clear financial benefit to the person. However, a person may need to be excluded if they hold a senior position of authority in an organisation that has expressed a clear opinion on the issue, if this could reasonably be interpreted as affecting their objective interpretation of the evidence.
Research publications covering epidemiology of the condition.	Declare and remain –this is not an intervention that might be recommended in the guidance.
Previous member of a guideline on the same topic produced by a professional body.	Declare and remain – the guideline was produced collaboratively by consensus and was not the person's own work. The benefit of their expertise in this topic outweighs a risk of perceived bias.
Indicator Advisory Committee member who is a GP.	Declare and remain – while the GP's income could ultimately be affected, the benefit of their expertise in this topic outweighs a risk of bias.

Appendix E: glossary

Interests – examples include employment and other sources of income, speaking engagements, shareholdings, publications and research, and membership of professional or voluntary organisations.

All interests from the last 12 months need to be declared, if in the view of a reasonable person, they could be perceived to be relevant to the work of the NICE committee in question.

A **direct interest** is when there is, or could be perceived to be, an opportunity for a person involved with NICE's work to benefit. Direct interests can be

- Financial where the person gets direct financial benefit
- Non-financial where the person gets a non-financial benefit such as increasing or enhancing their professional reputation

An **indirect interest** is when there is, or could be perceived to be, an opportunity for a third party closely associated with the person in question to benefit.

Conflict of interest - when a reasonable person would consider that an individual's ability to apply judgement or act in the work of NICE is, or could be perceived to be, impaired or influenced by one of their interests.

A conflict of interest is most likely to arise when the interest is **specific** – this means it relates to matters under consideration at a particular meeting and/or informs a potential recommendation.

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National Institute for Health and Care Excellence

Public Involvement Programme: annual review 2018/19

This review details public involvement activities across NICE in 2018/19. This includes our regular reporting of public involvement activities; the implementation of further actions developed from the 2017 review of public involvement at NICE; and new work to involve people with learning disabilities, and children and young people in developing our guidance and quality standards.

Our thanks go, as always, to the large number of people who have shared their knowledge and experiences of care with us to ensure that our guidance fully reflects the needs of needs of patients, people using services, their families, carers and the public.

The Board is asked to receive the report.

Professor Gillian Leng

Deputy Chief Executive and Director, Health and Social Care Directorate

July 2019

National Institute for Health and Care Excellence Public Involvement Programme annual review 2018/19 Date: 17 July 2019

Reference: 19/069



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Introduction

- 1. This report describes the work of the Public Involvement Programme (PIP), and broader public involvement activities across NICE, in 2018/19.
- We have structured our report this year by drawing on the <u>National Standards for Public Involvement in Research</u> as developed by the National Institute for Health Research (NIHR). The themes identified in the standards align with NICE's approach to public involvement and PIP contributed to their development via our membership of INVOLVE.
- 3. The past year has been an increasingly busy one for PIP as NICE has continued to expand and develop its offer to the health and social care systems. We have focussed activities this year particularly on engaging and supporting people who are often seldom heard or whose needs may not be adequately met by standard involvement practices.
- 4. We have continued to support and promote public involvement at a national and international level through our work with the Health Technology Assessment International (HTAi) Patient and Citizen's Involvement Group (PCIG) and through the Guidelines International Network (G-I-N) Public Working Group, as well as attending and presenting at a range of national and international conferences.
- 5. In 2017 we published the outcomes of our strategic review of public involvement and took forward 7 commitments which have now been embedded into our work. Improving how we reach and recruit people, expanding our use of social media and providing feedback to people who have submitted evidence to us are three examples of this continuing work. We have also been contributing to work across NICE to improve our taxonomy and harmonise the terms we use to describe different aspects of our work.
- 6. Finally, our work supporting the shared decision making agenda has continued and expanded over the year with the 5th meeting of NICE's Shared Decision Making Collaborative; publication of processes for developing decision aids; and an increase in the profile of shared decision making activities across NICE.

Facts and figures

Recruiting and identifying people to take part in our work

7. PIP supports the recruitment of people who use services, carers and members of the public across all NICE work programmes. In most cases we describe the people we recruit as lay members but some variation in that terminology occurs across NICE. In 2018/19 we received 434 applications for 68 vacancies and in the end recruited 71 people to NICE committees.

- 8. The disparity between the number of vacancies and the number of people recruited was due to more people being recruited for 9 committees than was initially planned. This was due to a combination of:
 - receiving high quality applications which led committee teams to opt to recruit more people
 - additional populations being identified during scoping and recruitment
 - recruiting from an existing pool of previous applicants rather than running a new recruitment activity.
- 9. These additional lay members offset five topics where we were either unable to recruit a lay member or not able to recruit to all vacancies on a committee. This was due to either the topic being very specialised or it being a topic area where there is little voluntary and community sector organisation presence. In these cases, we are exploring other ways of capturing patient views and experiences.

500 434 450 400 350 300 250 200 150 100 51 49 50 12 8 0 Guideline committee ΤΟΤΑΙ Topic expert members Core members members ■ No. of vacancies ■ No.of successful applicants ■ No. of applications

Figure 1 – recruited lay members and applicants

Download the data set for this chart

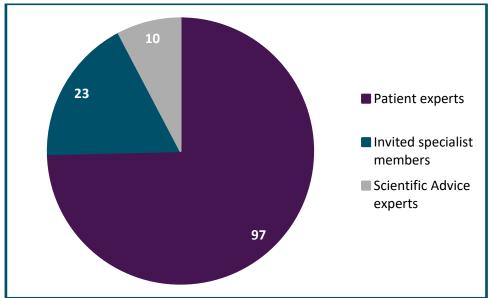
At any one time we are supporting around lay members

10. We have helped to support interviews for lay member positions by developing a suite of interview questions, a scoring matrix, and an accompanying guide to assist NICE teams and developer centres when holding interviews for lay members. This is in addition to the shortlisting criteria developed the previous year.

130
invited members and patient experts supported this year

11. As well as recruiting lay members we have supported 23 people to join our quality standards advisory committees as invited specialist committee members, 10 people to contribute to NICE scientific advice meetings, and 97 people to share their knowledge and experience with committees as a patient expert.

Figure 2 – patient experts and invited specialist members



Download the data set for this chart

Inclusive opportunities

Involving people with learning disabilities in the development of NICE quality standards.

12. For two quality standards addressing the needs of people with learning disabilities in development this year we adjusted our standard support to enable people with learning disabilities to participate fully in the work.

- 13. For this work four experts by experience (the equivalent of lay members) were appointed to the NICE quality standards advisory committee. All four people use NHS and/or social care services, and have extensive experience of contributing the experiences, views and preferences of people with learning disabilities to inform policy development and service improvement strategies.
- 14. We explored the needs of the experts by experience and in partnership with the committee and the experts by experience themselves we decided to:
 - commission a specialist facilitator to support the experts by experience and provide advice to NICE staff and committee chairs
 - increase the length of the committee meetings from a half day to a full day
 - provide the facilitator and experts by experience with the facilities and resources to meet to prepare for the committee meeting in advance
 - develop EasyRead versions of papers and slides at every stage.
- 15. For the topic engagement exercise for the two quality standards we produced EasyRead versions of the documents for stakeholders. However, a follow up survey into their usefulness yielded a poor response and stakeholders who did respond said that they didn't need to use the EasyRead documents as they were responding as an organisation rather than eliciting responses from people who use services. We therefore decided not to go ahead with producing an EasyRead version of the draft quality standard for consultation.
- 16. The audience insight team are assessing the experiences of the experts by experience, their supporters, and other committee members including the chair and NICE staff to report on the impact of the adjustments on the development of the quality standards. We would like to thank the quality standards, publishing and audience insight teams for their help with this work.

Engaging with children and young people

- 17. NICE is starting work on a number of topics that relate to the health and wellbeing of children and young people. These include (but are not limited to):
 - Looked after children and young people
 - Children and young people with disabilities and severe complex needs
 - Babies, children and young people's experience of healthcare
 - Social and emotional wellbeing in primary and secondary education
- 18. In addition, the myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) guideline will focus in part on the needs and experiences of children and young people affected by the condition.

- 19. To produce meaningful guidance, the views and experiences of children and young people must be included in the products that seek to address their needs. However, the way we work poses some challenges in involving this subpopulation:
 - NICE committees cannot recruit members who are under the age of 16
 - committee meetings take place during weekdays, which would pose a challenge for young people in full time/ mainstream education
 - the NICE process is not typically young person friendly and would need to be adapted in order to engage with children and young people satisfactorily.
- 20. PIP have worked with senior colleagues in NICE to explore a cohesive strategy to involve young people in a way that genuinely brings their voices into the guidance we produce. Initial ideas include:
 - commissioning a specialist organisation to set up an external reference group that conducts this work in a focused way, alongside the relevant NICE committees
 - using the same group(s) across multiple guidelines to optimise the use of resources
 - ensuring we incorporate lessons from similar work done on the child abuse and neglect guideline
 - providing enough lead-in time when procuring external support in case a tender process is needed, based on estimate of cost.
- 21. As of March 2019, the scope for the guideline on children and young people with disabilities and severe complex needs is changing to reflect feedback from Department of Education and the Department for Health and Social Care. The guideline will now focus on service delivery. Given that specific remit a focus group of children and young people is being considered for this guideline.

Improving how we reach and recruit new lay committee members

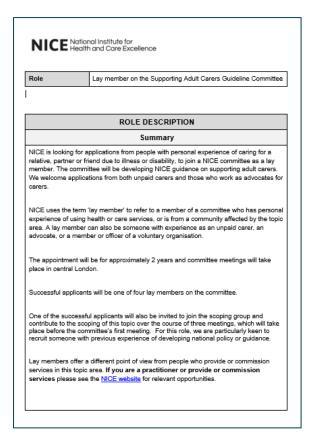
- 22. This year we continued the work we began in 2017/18 to help achieve the first objective in NICE's Equality Scheme: to increase the proportion of advisory body position applications that are from individuals who describe themselves as from black, Asian and minority ethnic (BAME) groups.
- 23. Following successful focus groups in Manchester and London with BAME groups, one significant barrier to involvement the groups identified was the lay member recruitment documents. They were seen to be too long, technical, corporate and not user-friendly.

- 24. As a response to this feedback, PIP re-designed all the lay member recruitment documents. The key changes included:
 - changing the layout to allow key information to be more prominent
 - using images and colour
 - removal or explanation of formal language to increase accessibility
 - addition of a 1-page poster to use on social media and for organisations to promote to their members.

Overall, **106** individuals attended the focus groups to help improve lay member recruitment at NICE

25. We held a third focus group in Sandwell and Dudley to user-test the draft recruitment paperwork, resulting in the documents being finalised and piloted in lay member recruitment across NICE programmes. It was felt that the issues identified during the focus groups were not specific to BAME applicants and might be barriers for others. Therefore, we piloted the documents with a view to using them for all lay recruitments, after receiving positive feedback from NICE corporate office.

Image 1: recruitment paperwork development Before



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After



- 26. We first used the new formats for recruiting to the babies, children and young people's experience of health care guideline which yielded 31 applications with 6 lay members being recruited. This topic was selected due to the main target audience for the recruitment being young people aged between 16-19. We engaged with national and local youth organisations via Twitter to inform them of the guideline and inform their members of the recruitment, with one tweet alone generating over 14,000 impressions.
- 27. Following further successful piloting with recruitment for clinical guidelines for management of common infections and in the diagnostics assessment programme we will use the documents for all future lay member recruitments.
- 28. To ensure the NICE website complies with standards for accessibility, the pictures in the new recruitment documents had to be removed as they were not compatible with screen readers. To address this issue, in 2019/20 PIP will be working with the communications directorate to explore options to develop online recruitment. This would allow the pictures to be included and ensure that all our content is accessible for all those using the NICE website.

Exit surveys

29. In 2018/19 we sent all lay committee members whose work came to an end that year an exit survey to hear about their experience of working with NICE. We

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- received 37 responses to the survey out of 78 sent, yielding an overall response rate of 47%. This is consistent with the response rate from the previous year.
- 30. This year we developed and implemented a simplified survey, reducing the number of questions from 9 to 6 to make it easier for people to complete and focus on the key issues they wanted to tell us about. Ninety-five percent of people rated their experience of working with us as 'good' or 'excellent'.

■ Excellent
■ Good
■ Adequate

Figure 3 – overall experience of working on a NICE committee

Download the data set for this chart

'I am very grateful to NICE and the other committee members for making me welcome and valuing my contribution' – NICE lay member

31. Participants reflected on both the positive and negative aspects of their work with NICE and no single issue dominated their comments as a cause for concern. We have shared the data from the exit survey with teams across NICE to both reflect on what has gone well and to address any issues or challenges that lay members have identified.

'For the first few meetings, certain confident academia-orientated colleagues had more of the 'floor'. However, after being in touch with the Chair, the ensuing meetings were more equally managed' – NICE lay member

Working together

Expanding the public involvement programme's international reach

32. In 2018/19 PIP has taken part in international conferences and initiatives, sharing best-practice developed through NICE's extensive experience in

National Institute for Health and Care Excellence Public Involvement Programme annual review 2018/19 Date: 17 July 2019 Reference: 19/069 involving people who use services, their families and carers in guidance development.

European Society of Cardiology

33. In June 2018 the PIP collaborated with the European Society of Cardiology on a patient engagement workshop in Brussels to prepare patients and healthcare professionals for working together to develop clinical guidelines. We ran a training session with patients from across Europe.

Guidelines International Network (G-I-N)

- 34. In September 2018 the PIP gave an oral presentation discussing our <u>innovative</u> <u>approach to involving young people in guideline development</u> at the G-I-N annual conference hosted in Manchester by NICE and SIGN (Scottish Intercollegiate Guidelines Network). We also presented 4 posters covering:
 - the contribution of voluntary and community sector organisations to the development and use of NICE guidance (2 posters)
 - our use of social media
 - our work on shared decision making.
- 35. PIP is a core member and vice-chair of <u>G-I-N Public</u> working group which promotes good practice on involving patients and the public in developing and implementing guidelines. In February 2019 we surveyed all G-I-N members for their feedback on the <u>G-I-N Public Toolkit</u> to inform its update and development. The toolkit assembles international experience and best practice examples of successful patient involvement to support guideline developers who are considering involving patients.

Health Technology Assessment International (HTAi)

- 36. Members of the PIP team belong to the <u>Health Technology Assessment</u> <u>International's Patient and Citizens' Involvement Group</u> (HTAi PCIG). The group brings together international organisations and individuals across sectors with a keen interest in patient and citizen involvement in health technology assessment.
- 37. Over the year we have worked on a number of projects with our colleagues in PCIG. These include:
 - contributing to an upcoming publication in the International Journal of Technology Assessment in Health Care titled 'Two case study comparisons of sightings of patient input in HTA appraisal final recommendations and committee discussion summaries for the HTA agencies CADTH, NICE and SMC'
 - speaking at the PCIG workshop and giving two oral presentations at the 2018 HTAi conference in Vancouver

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- sharing and developing best practice in HTA, and contributing to projects and conference plans at the annual HTAi PCIG face-to-face meeting in Stockholm
- successfully submitting abstracts for the 2019 HTAi conference in Cologne. We will be taking part in the HTAi PCIG workshop, two panel sessions and one oral presentation and two vignettes (short oral sessions) showcasing patient involvement at NICE.

PARADIGM

- 38. We have also worked with PCIG on a European project called PARADIGM
 (Patients Active in Research And Dialogues for an Improved Generation of Medicines) focusing on the area of patient involvement in early dialogues with HTA bodies and life sciences companies, in a similar way to NICE scientific advice.
- 39. Via a scoping meeting and workshop, we have identified the following areas where additional tools, resources and guidance are needed:
 - patient recruitment processes
 - patient interview guidance
 - minimum standards framework for patient involvement
 - rationale for patient involvement in Early Dialogues.
- 40. This work was presented at the ISPOR meeting in Barcelona by members of the HTAi PCIG group, including NICE.

Supporting shared decision making

NICE Shared Decision Making Collaborative

- 41. In June 2018 PIP facilitated the 5th meeting of the NICE Shared Decision Making Collaborative. A total of 81 people took part in the meeting, with a wide range of organisations and people with an interest in shared decision making taking part. Delivered through a combination of plenary and parallel sessions, lunchtime networking and demonstrations the agenda covered:
 - NICE's role in the shared decision making landscape
 - an overview of shared decision making in the system
 - technology to support shared decision making
 - values-based practice in support of shared decision making
 - parallel sessions covering:
 - describing the evidence

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- developing initiatives
- decision making in challenging fields
- future developments.

Collaborative member Sam Finnikin summarised the day in his blog for the BMJ.

A process guide for producing patient decision aids

- 42. In collaboration with the NICE medicines and technology programme and the publishing team, PIP published a <u>process guide for developing NICE patient decision aids</u> in April 2018. The guide drew on international best practice in the field such as the International Patient Decision Aids Standards (IPDAS) and the Development Methods for Ottawa Patient Decision aids.
- 43. The process guide details in what circumstances a patient decision aid might be a helpful addition to a guideline or other NICE guidance and provides a referral route for suitable topics. The guide then gives an overview of the decision aid development process and who should be involved in reviewing and refining the decision aid.

Support and learning

Supporting people to take part in our work



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- 44. As part of the support offered to lay members, we reviewed and updated the toolkit we send to people when they start working with us.
- 45. The toolkit equips lay members with the knowledge and understanding of what to expect during guidance development, how to prepare for meetings and how they can have the greatest impact on their committee.
- 46. We co-produced the toolkit with current and previous lay members who were able to highlight key areas where they felt support and information was needed and share some hints and tips of what worked best for them.
- 47. Feedback, to inform future development of the toolkit is generated through regular conversations with lay members and through the exit survey.

Training days

- 48. As part of our support for new lay members joining guideline committees, we ran 5 face-to-face training days to equip them with the knowledge and skills to get the most out of their time on the committee. Our agenda included:
 - developing guidelines what evidence we use and how we find it
 - preparing for meetings and what to expect
 - making an impact sharing knowledge, experience and ideas.

Training day rating
4.7/5.0

Very good!

- 49. We invited speakers from both within NICE and our developer centres, and former lay members who shared their experiences of working with NICE and provided top tips for working effectively as a lay member. In total 46 people received training this year.
- 50. We asked lay members to evaluate each training day to let us know what went well and what could be improved. 100% of lay members who responded rated the day as a whole as 'very good' or 'good' giving a mean score of 4.7 out of 5.
- 51. Attendees found the day inclusive and really valued the opportunity to speak and share experiences and concerns with other lay members. They also appreciated the mix of presentations and exercises throughout the day. There was some difference of opinion as to whether the training day worked better depending or not on whether a lay member had already been to their first committee meeting.

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Date: 17 July 2019 Reference: 19/069 Our upcoming <u>online training modules</u> may help to mitigate some of the issues around the timing of training days. Finally, some lay members expressed an interest in further training particularly around health economics.

'The mix of attendees was excellent. The experienced lay members were generous and thoughtful in the points they offered. The interaction between the PIP team and the attendees was superb – knowledgeable, approachable team' – NICE lay member

NICE lay member event

52. On 27 March 2019 the PIP hosted a successful event with 17 lay members of standing committees to celebrate their contribution to NICE guidance. The event also explored the challenges they faced as lay members, allowed them to share their experiences, and learn about new developments at NICE.

4.4/5.0
Good!

- 53. We developed the programme for the day by consulting with lay members to ensure the day was shaped around their needs. Consequently, the programme included a mix of learning and sharing experiences, with presentations, exercises, and discussion.
- 54. Participants gave very positive feedback about the event, with an average score of 4.4/5.0. All sessions received high average scores, and comments indicated that it had been a useful and valuable day.

'Feel part of [the] NICE 'family'. Inspired to improve' - NICE lay member

- 55. Lay members appreciated the opportunity to network, share experiences and ideas, and learn about new developments at NICE. Discussions around patient evidence in guidance development and how guidance is implemented, and a Q&A with NICE senior staff were also highly valued.
- 56. In celebrating 20 years of the patient/public voice in NICE's work and the role of lay members, participants enjoyed hearing about the impact they have had, and how the guidance they've supported to produce was being used and making an

National Institute for Health and Care Excellence Public Involvement Programme annual review 2018/19 Date: 17 July 2019 Reference: 19/069 impact. Lay members also suggested actions for NICE to improve our public involvement and how they can have a greater impact on committees as lay members. This included offering annual performance reviews for lay members and establishing a buddying scheme.

'Once again it was a privilege to meet lay members of NICE committees at the annual event on 27th March. Their commitment and enthusiasm for the complex tasks they undertake is truly impressive and NICE would be a lesser organisation without them'— Angela Coulter, NICE non-executive director

Online training modules

- 57. We have begun developing a series of online training modules as part of a plan to widen our training offer to all lay members of NICE committees and make the most effective use of resources. This approach offers training content in short and easy to assimilate modules that can be accessed at any time. This independent learning will be supplemented with telephone sessions run by a public involvement adviser or using webinar technology.
- 58. The modules for the online learning are a combination of those identified in a survey of lay members, the current content of induction material and face-to-face training, and the collective experience of the staff team. Some are generic modules applicable to all lay members, with a smaller number tailored to a specific type of topic or NICE guidance. The planned module content ranges from how we use evidence and develop guidance, to tips on effective committee working and supporting the use of NICE guidance.
- 59. We have produced content for the first two modules which focus on the role and value of the lay member and tips for being effective on a NICE committee. Lay members are providing us with feedback on the content and will be taking part in user testing of the online products which will be hosted on an e-learning platform.

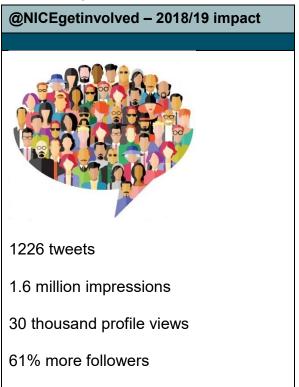
Communications

Social media

60. We have continued to increase our presence on social media using the PIP team's MICEgetinvolved account. This has helped us to reach more members of the public and different communities, and work and communicate more effectively with our stakeholders.

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Table 1 - A snapshot of social media activities



Using Twitter to tackle issues people have with NICE



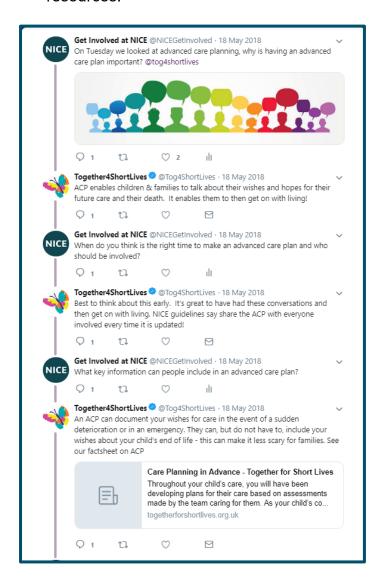
61. We use Twitter to have conversations with people who we wouldn't normally be in touch with. This includes being able to address any concerns people have about NICE. There are many misconceptions about NICE, so by using social media we're able to inform people and promote how they can help develop our guidance.

Celebrating public involvement at NICE



- 62. We continue to use Twitter to work more closely with our lay members, both past and present. We also run campaigns and participate in national conversations, such as volunteer's week.
- 63. This helps us to publicly thank our lay members, promote how valued lay members are at NICE and celebrate achievements. We're also able to promote how we encourage public involvement at NICE and promote opportunities for people to help shape our guidance.

- Working in partnership with key stakeholders
- 64. Voluntary and community sector organisations play a huge role in helping NICE recruit lay members and patient experts; develop our guidance; and implement it.
- 65. Through targeted campaigns, we've worked with organisations to promote NICE guidance. This conversation with Together for Shorter Lives helped to raise awareness of advanced care planning and signpost people to additional resources.



Public involvement on the NICE website

66. Throughout 2018/19 PIP has worked in partnership with the NICE web team to redevelop all the public involvement webpages on the NICE website. We have revamped the whole structure of the public involvement section of the site to help people find the information they need more quickly, starting with a new landing page which offer routes to advice about using NICE guidance and information about getting involved in NICE's work.

National Institute for Health and Care Excellence Public Involvement Programme annual review 2018/19 Date: 17 July 2019 Reference: 19/069 67. The new pages include testimony from people who have worked with NICE about their experience, examples of how patient input and evidence can inform NICE recommendations, and information about the public involvement programme and the support we offer. We are grateful to our colleagues in the web team for all their hard work creating the pages with us.

Speaking engagements and meetings with voluntary and community sector organisations

- 68. In 2018/19 PIP presented at 18 national and international events. Our talks covered patient and public involvement in guidelines, technology appraisals and highly specialised technology evaluation. We also presented NICE's work on shared decision making and contributed to discussions around how evidence-based guidance can support individual decisions.
- 69. In 2018/19 we also held 15 meetings with voluntary and community sector organisations or umbrella groups. These meetings either discussed NICE work in a specific topic area and the opportunities for organisations to get involved in the work, or they covered our public involvement activities at a more strategic level.

Identifying and sharing examples of impact

Collating and sharing the impact of patient involvement for interventional procedures and highly specialised technologies

- 70. Best practice in public involvement¹ tells us that feedback on evidence submitted to us by voluntary and community sector organisations is both desirable and beneficial. Feedback helps organisations to understand what the impact and usefulness of the evidence they submitted to us was and helps them to develop their future submissions. The act of providing feedback also helps HTA agencies to reflect on how they consider and use patient evidence.
- 71. Following pilot work started in response to the public involvement review, we have now implemented a feedback process in the interventional procedures and highly specialised technologies programmes. There are two elements to this work:
 - capturing the committee's views on the impact of submissions of evidence from voluntary and community sector organisations, via forms designed and piloted by the committees and NICE staff

¹ <u>https://www.htai.org/interest-groups/patient-and-citizen-involvement/pcig-home/values-and-standards</u>

- summarising and feeding back to the organisations who submitted evidence via a letter to help them to see where their input has been useful and help improve further submissions.
- 72. Information from the impact forms, highly specialised technology evaluations and the feedback letters will form the basis for an oral session at the 2019 HTAi conference in Cologne.

Voluntary and community sector use of NICE guidance

- 73. There are many ways voluntary and community sector organisations use NICE guidance. From using NICE recommendations to evaluate services to providing information to the public, there is no standard practice within the sector.
- 74. As part of the development of the new <u>public involvement webpages</u> we produced information to encourage and enable organisations to use our guidance, including sharing examples of how organisations have used NICE guidance to support their work. These included:
 - developing questions informed by NICE guidance to ask service providers and commissioners to evaluate local services
 - assessing public concerns to understand if services didn't meet expected standards.
 - using NICE guidance to support service improvement recommendations
 - checking if strategic plans and commissioning decisions align with NICE guidance
 - enhancing the information voluntary and community sector organisations provide to the public to include NICE guidance.
- 75. To support this information, we worked with six local and national organisations to provide real life examples of where organisations had used NICE guidance to enhance their work. One example was Healthwatch Manchester, who spoke to patients to understand their experience of a patient transport service following relocation of dialysis from one hospital to another. Using our renal replacement therapy quality standard, they were able to measure their findings and develop recommendations to improve patient experience and access.

Evaluating a new approach to including young people's voices in NICE guidance

76. At the Guidelines International Network conference in 2018, PIP presented an evaluation of a new approach to involving young people in developing a NICE guideline on child abuse and neglect. For this guideline, an external reference group was convened to help the committee identify the perspectives and

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- priorities of young people affected by abuse and neglect. This method of involvement was chosen as a way of providing input at key stages of guideline development, considering the sensitivity of the topic and the benefits to young people of a peer group environment.
- 77. Facilitated by a voluntary organisation with expertise in involving children and young people who have experienced abuse the reference group met separately on 4 occasions during guideline development. Young people were asked to:
 - provide insight on specific questions and issues
 - comment on the recommendations
 - contribute ideas to a version of the final guideline for young people.
- 78. Each reference group meeting took place in a workshop style, with a support worker present. Young people reported feeling included, able to contribute and that their experiences were heard and validated. Reference group facilitators presented the group's feedback to the guideline committee after each meeting, feeding back the committee's use of their contributions to the young people at each subsequent meeting. Young people also met some committee members.
- 79. The way that young people's views were heard, validated and incorporated into the guideline was valued enormously by the reference group. Their experiences were often difficult to hear and raised serious concerns about current practice. The reference group felt that the guideline committee and staff responded empathetically and sensitively, which allowed them to continue to take part in what could have been a re-traumatising experience but was instead felt to be an empowering and healing journey.
- 80. The reference group approach was evaluated, including feedback from the young people taken from the facilitator's report, plus findings from a survey of the committee and the guideline's technical lead. All committee members who responded to the survey felt that the reference group worked well to bring young people's experiences and views to guideline development but had mixed views on how helpful these contributions were to their work. The guideline's technical lead felt the reference group made a substantial contribution to the recommendations, specifically:
 - giving more detail about how young people wanted professionals to work with them
 - helping to provide more detail in the recommendations about reasons why young people don't disclose abuse and neglect
 - giving strong importance to the issue of choice of therapeutic interventions.

National Institute for Health and Care Excellence Public Involvement Programme annual review 2018/19 Date: 17 July 2019 Reference: 19/069 81. The reference group concluded their work by co-producing a version of the guideline for other young people.

Commentary from patients for interventional procedures guidance

- 82. We use the term patient commentary to describe questionnaire-based evidence from people who have experience of the procedures considered by our interventional procedures (IP) programme. We summarise and present information provided by patients with direct experience of a procedure to the committee alongside other forms of evidence.
- 83. Last year we started to ask committee members about the impact of patient commentary in developing interventional procedures guidance. This year we analysed and considered the results of the information committee members gave to us. Our analysis again told us that commentary from patients routinely had an impact on the committee's decision making. Key findings identified that patient commentary is equally useful for guidance updates as for new guidance. The interpretation and assessment of 'impact' varied across committee members, but the majority agreed the patient commentary reinforced the other evidence.
- 84. Measuring the impact of commentary from patients appears to have raised its profile with committee members as our analysis of published guidance shows that it includes more reference to patient issues since we have started asking the committee about the impact of the commentary than in preceding years. To date no discernible patterns of impact have been identified, and we are working on criteria for when patient commentary should not be sought. These patterns may emerge as the quantity of data increases.

Table 2 - Interventional procedures case study

Transurethral water vapour ablation for benign prostatic hyperplasia

We received 15 questionnaires from people who had had transurethral water vapour ablation for benign prostatic hyperplasia. The committee noted the published evidence demonstrated the procedure to be safe and to work well. Patients were supportive of the procedure with most people reporting improvement in symptoms. The committee added a comment that patients may need a urinary catheter for several days after the procedure.

Conclusion and future plans

85. 2018/19 was a year filled with new initiatives and development of our more established areas of work. We expect that 2019/20 will deliver much of the same and we look forward to embracing new opportunities for public involvement in NICE Connect and in response to changes in the Centre for Health Technology National Institute for Health and Care Excellence

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Evaluation. We'll also reaffirm our commitment to shared decision making at our 6th Collaborative meeting in June 2019. Finally, we look forward to continuing to work with the people and voluntary and community sector organisations who contribute so much to NICE's work through their lived experience, knowledge and commitment to improving health and social care services and outcomes for all.

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July 2019



AUDIT & RISK COMMITTEE

Unconfirmed minutes of the meeting held on 19 June 2019 at the NICE London Office

Present

Dr Rima Makarem Non-Executive Director (chair)

Elaine Inglesby-Burke Non-Executive Director (via telephone)

Tom Wright Non-Executive Director

In attendance

Andrew Dillon Chief Executive

Ben Bennett Business Planning and Resources Director
David Coombs Associate Director - Corporate Office
Catherine Wilkinson Deputy Director - Business Planning and

Resources

Jane Lynn Head of Financial Accounts

Elaine Repton Corporate Governance & Risk Manager (minutes)

Andrew Jackson National Audit Office (NAO)
Andrew Ferguson National Audit Office (NAO)

Hassan Rohimun Ernst & Young (EY)

Apologies for absence

 Apologies for absence were received from Sheena Asthana, Jane Newton and Niki Parker.

Declaration of interest

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

Minutes of the last meeting

The minutes of the meeting held on 24 April 2019 were agreed as a correct record.

Action Log

4. The committee reviewed the action log noting that the actions were either closed or due in September 2019.

EXTERNAL AUDIT

Audit completion report 2018/19

5. The committee reviewed the NAO's report of their findings from the audit of the 2018/19 financial statements. Hassan Rohimun, on behalf of the NAO, confirmed that there were no significant issues or misstatements identified during the audit and he therefore anticipated a recommendation to the



Comptroller and Auditor General that the 2018/19 financial statements be certified with an unqualified audit opinion.

- It was reported that one misstatement had been identified (£1.1m invoicing for technical appraisal charges), which when corrected had reduced both receivables and payables but had no impact on the net position or stated income for NICE.
- 7. The committee noted that two recommendations made in the previous year's report regarding the segregation of duties in posting manual transactions, and income and expenditure classifications, had both been addressed and been closed.
- 8. The Committee congratulated the officers on a positive audit report and noted the content of the draft Letter of Representation to be signed by Andrew Dillon as Accounting Officer, and the draft Audit Certificate from the Comptroller and Auditor General, subject to the approval of the report and accounts by the Board.

ANNUAL REPORT AND ACCOUNTS 2018/19

Briefing note to the annual report and accounts

- Jane Lynn presented a briefing note on the financial statements explaining how NICE had performed against its key financial duties and describing the main features of the accounts.
- 10. The committee discussed two potential judicial reviews relating to NICE's technology appraisal and highly specialised technologies programmes, and noted the potential legal costs arising from these. Given the obligating events the decisions by NICE that are subject to challenge took place in 2018/19 the committee supported a proposal from management to adjust the 2018/19 annual accounts in compliance with IAS 37 provisions, contingent liabilities and contingent assets. It was agreed that the accounting treatment, and the likely level of expenditure involved, be finalised in consultation with the NAO following a management discussion with NICE's legal advisers on the level of financial risk from the two potential challenges. It was also agreed that a paper on this matter should be prepared for the Board meeting later that day which is due to approve the annual report and accounts.

ACTION: CW/AJ

11. The report was noted.

Summary of the audit reports ISAE 3402 – for finance and accounting and employment shared services

12. The committee reviewed two third-party assurance reports from PricewaterhouseCoopers LLP for users of the NHS Shared Business Services (SBS) for the finance & accounting and employment shared services. Both audit reports were unqualified with the exception of one (of 16) control

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Unconfirmed minutes of the Audit and Risk Committee held on 19 June 2019
Poto: 17 July 2019

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objectives relating to payroll data where auditors had been unable to obtain sufficient evidence that validation checks, segregation of duties and reports being sent to clients, were operating effectively.

- 13. Catherine Wilkinson provided context advising that this audit report related to all the organisations using the NHS Shared Business Service, and that NICE had its own small experienced payroll team who carry out additional checks to provide assurance that NICE payroll data is processed accurately. The committee was satisfied with the additional checks and controls provided by the in-house team and noted management's assurance that the current model represents best value for NICE.
- 14. The third-party assurance reports were noted.

Draft annual report and accounts 2018/19

- 15. The committee reviewed the draft annual report and accounts for 2018/19 commenting it was a really positive document and a great illustration of the significant and wide ranging nature of NICE's work. Catherine Wilkinson added a special thanks to Jane Lynn and her team for all their efforts.
- 16. The annual report and accounts were recommended for approval to the Board, subject to the resolution of the matters noted under paragraph 10 above.

CORPORATE OFFICE

Counter fraud functional standard GovS:13 – NICE strategy, policy and response plan

- 17. The committee was asked to approve a draft counter fraud strategy, policy and response plan, which has been developed to ensure NICE is able to comply with its new obligations under the Cabinet Office's counter fraud functional standard GovS:13.
- 18. David Coombs advised that further work was planned over the summer to complete an annual return, a fraud risk assessment and an annual action plan, all of which were required to be submitted to the Cabinet Office by 2 September 2019. These documents will be circulated to the committee by email in advance of the submission date, for comment and review, and also included in the papers for the committee's meeting on 4 September.

ACTION: DC/ER

- 19. The committee briefly discussed the key areas of risk to NICE including bank mandate fraud, travel expenses and recruitment. The committee sought assurances that external fraud risks would be considered as well as internal risks. David Coombs advised that NICE was supported by the DHSC Anti Fraud Unit who provide alerts on fraud risks and can provide specialist investigators, if required.
- 20. The draft strategy, policy and response plan was approved.



FUTURE MEETING DATES

- 21. The Committee confirmed its meetings in 2019 would take place at 2.00pm on:
 - 4 September 2019
 - 28 November 2019 (Thursday)
 - 22 January 2020
 - 22 April 2020

The meeting closed at 10.20am.

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.

Dr Paul Chrisp, Centre for Guidelines (Item 13)

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

Jane Gizbert, Director, Communications (Item 15)

Alexia Tonnel, Director, Evidence Resources Directorate (Item 16)

Professor Gillian Leng, Director, Health and Social Care Directorate (Item 17)

July 2019

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Date: 17 July 2019 Reference: 19/071 – 19/075

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 April, May and June 2019. It also highlights areas of work and specific guidelines that are felt to be of particular note for the Board.

Performance

- 2. Twelve clinical guidelines were published during April, May and June 2019. The urinary incontinence and pelvic organ prolapse in women guideline was due to publish in June 2019 but publication was brought forward to April, in response to a request by the Department of Health and Social Care. The suspected neurological conditions guideline was due to publish in April 2019 but was postponed until May due to cross-refences in the stroke guideline which published in May. The prostate cancer update was due to publish in April but was postponed until May to ensure that the NHS England commissioning policy and the guideline recommendations were aligned. The update to the guideline on depression in children was due to publish in April, but a postponement was agreed until June to allow for a discussion with key stakeholders of the depression in adults guideline. All other deliverables are on track.
- 3. Twenty-one surveillance reviews were published during this reporting period of which 13 were exceptional reviews. All other deliverables are on track.
- 4. One of the surveillance reviews was a combined review of the guidelines on managing type 1 diabetes in adults, type 2 diabetes in adults, and types 1 and 2 diabetes in children. These guidelines all require partial updates. We are exploring using the surveillance review to inform the drug sequencing work in diabetes and utilising the committee established to inform the NICE Connect project to take forward the recommended areas to update.
- 5. The surveillance team continues to collaborate with ONS on a project about using linked data in guideline development and most recently held a joint workshop to discuss next steps. The development stage of the work began in June 2019.
- Quarterly review meetings were held with both internal and external guidance developers and suppliers. All contractors are within budget and delivering their key objectives.

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- 7. A new contractor, Linney, is now in place for the provision of storage and distribution of paper copies of the BNF and BNFC. They are working closely with the producers of the BNF and their printers to coordinate the forthcoming campaign delivery of BNF78 and BNFC 2019. A recent survey of the use of paper copies of BNF and BNFC in universities has informed the decision on print quantities for the forthcoming campaign.
- 8. The GP Reference Panel continues to provide helpful feedback on guideline scopes and draft guideline recommendations related to primary care.
- 9. In May, we hosted the 12th meeting of the UK GRADE Network steering group (comprising members from NICE, SIGN, UCL, Cochrane and the BMJ Knowledge Centre). Members agreed to extend membership to include representatives from the Campbell Collaboration and the UK-based centres of the Joanna Briggs Collaboration.
- 10. 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.

Notable issues and developments

- 11. A constructive meeting was held on 24 May with representatives from a group of stakeholders that has expressed concerns over aspects of the update to the guideline on the management of depression in adults.
- 12. An agreement in principle has been reached to collaborate with the British Thoracic Society (BTS) and the Scottish Intercollegiate Guidelines Network (SIGN) on the development of a single consistent guideline for diagnosis and management of asthma.
- 13. Recommendations relating to the use of synthetic polypropylene or biological mesh insertion for women with recurrent anterior vaginal wall prolapse have been withdrawn from the guideline on urinary incontinence and pelvic organ prolapse in women. The guideline provides a link and refers instead to the NICE interventional procedures guidance 599 on transvaginal mesh repair of anterior or posterior vaginal wall prolapse. The change was made to provide clarity regarding the relationship between the guideline and interventional procedures guidance, and to take account of a material change since publication in the availability of products CE-marked for the indication which was referred to in the guideline recommendations.

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July 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 April, May and June 2019. It also highlights key developments in the centre during that period.

Notable developments

- 2. There have been several notable developments in the three months of the 2019/20 business year that have an impact on CHTE's activities. We briefly list them here, with details provided in the rest of the report.
 - Launch of HealthTech Connect
 - Start of the charging regime for technology appraisals and highly specialised technologies
 - Move of Accelerated Access Collaborative, with an expanded remit, to NHS England and NHS Improvement
 - Inquiry into the NICE methods review by the All-Party Parliamentary Group on Access to Medicine and Medical Devices
 - Launch of the methods review for health technology evaluation programmes
 - Announcement that NICE will host the 2021 HTAi Annual Meeting in Manchester, together with Healthcare Improvement Scotland (HIS) and the All Wales Therapeutics & Toxicology Centre (AWTTC)

Performance

Centre Coordination Team

3. During April, May and June, CCT have coordinated recruitments for 15 positions within CHTE & SAR. These vacancies have been created by staff leaving, maternity cover and the creation of new roles. While most of these recruitment campaigns are at the offer stage, some vacancies are at an earlier stage of the process.

National Institute for Health and Care Excellence Centre for Health Technology Evaluation progress report Date: 17 July 2019 Reference: 19/072 4. In April, May and June 5 recruitments are in progress for 20 committee members and 1 chair, across 7 committees. We have appointed 1 new professional member.

Commercial and Managed Access Programme

- 5. The Commercial and Managed Access Programme (CMAP), established during 2018/19, includes the Managed Access team (previously the Cancer Drugs Fund team), the Commercial Liaison Team (CLT), the NICE Office for Market Access (OMA) and the Accelerated Access Collaborative Secretariat (AACS). These programmes focus on facilitating and supporting guidance production and market access during formal guidance processes.
- 6. The CLT is working directly with colleagues at NHS England and NHS Improvement (referred to as NHSE in the rest of this report) to inform the development of the commercial framework and assess its potential impact. A detailed programme of work has been agreed to develop and implement the working processes needed to deliver a seamless interface for all relevant commercially related conversations between companies, NHSE and NICE. Recruitment to the team continues, with new staff joining in June 2019, and all roles expected to be filled by early September 2019. During this time, the PASLU component of the CLT is continuing to issue PAS advice to NHS England. Completion of 38 commercial access agreements (PASs) is anticipated in 2019/20 with 11 PAS advice reports issued to NHS England in the first quarter.
- 7. The Managed Access Team (MAT) (previously the Cancer Drugs Fund (CDF) team) has formed with a broader focus on all types of managed access now possible under the 2019 Voluntary Scheme for Branded Medicines Pricing and Access. We anticipate up to 17 Managed Access Agreements (MAA) will be developed in 2019/20. In the first quarter, four MAAs have been finalised and associated guidance published. Briefing notes have been prepared for a further four topics which are likely to be finalised in the second quarter.
- 8. The MAT is coordinating data collection arrangements for 29 live Cancer Drugs Fund (CDF), 3 HST and two further technology appraisal topics. An additional topic is being considered for managed access, which is neither CDF nor HST demonstrating the potential new flexibilities of the 2019 Voluntary Scheme. Data collection for five CDF topics will end before 31 March 2020, which will see these topics re-appraised, so they can exit from the fund.
- 9. In April 2019 the Office for Market Access (OMA) moved from Science Advice and Research back into the Centre for Health Technology Evaluation. In the first few months of this financial year, OMA have delivered an Early Access to Medicine Scheme (EAMS) engagement, a knowledge transfer session and a

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- multi-stakeholder engagement. These three different types of engagement illustrate the varied opportunities that OMA provides for the life sciences industry and system partners to engage. OMA has a healthy pipeline of prospects and is currently on track to achieve cost recovery at the end of the financial year.
- 10. In April 2019 the Accelerated Access Collaborative Secretariat (AACS) moved from Science Advice and Research back into the Centre for Health Technology Evaluation. In April 2019 it was announced that NHSE would take on responsibility for a new AAC, with an expanded remit. The AACS team have worked closely with NHSE and OLS during this transition phase to provide support where needed. The AACS team continues to provide governance support, both for the existing and new structures in the new AAC. The team have continued their work on developing the AAC's approach to identification and selection of early stage products, with proposals put to the AAC board in June. The team continues to support NHSE in their development metrics for the 12 rapid uptake products.

Commissioning Support Programme

- 11. The Commissioning Support Programme closed on 31 May. Completed documents were passed to NHS England apart from resource impact documents for the last two topics on the programme's work schedule, for which a deadline of mid-June was agreed.
- 12. Discussions are ongoing between NHS England and NICE to identify any licensed medicines that would otherwise have been passed to the Commissioning Support Programme. Options for taking these products forward within the appropriate appraisal or policy framework are being explored.

Diagnostics Assessment Programme

- 13. The programme had a target to publish 6 pieces of diagnostics guidance in 2019/20. It will instead publish 5 pieces of guidance. The launch of the assessment of the topic, The ARCHITECT Urine NGAL assay, NephroCheck Test and NGAL Test to help assess the risk of acute kidney injury for people who are being considered for admission to critical care assessment was delayed. This was due to capacity in the team as a result of a vacant position and members of the team working on a technology appraisal. The final guidance for this topic is now expected to be published in April 2020.
- 14. In April 2019, the programme started an assessment of Testing strategies for Lynch syndrome in people with endometrial cancer which is due to publish in July 2020. Guidance is currently in development for 6 groups of diagnostic technologies, and a further two new topics have been selected for guidance development later in the year. In May 2019, the programme published guidance

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- on digital <u>Lead-I ECG devices for detecting symptomatic atrial fibrillation using</u> <u>single time point testing in primary care</u> which recommends further research on how using the devices affects the number of people with atrial fibrillation detected and the effect on primary and secondary care services.
- 15. The programme has been providing technical, project management and administrative support to the Technology Appraisal programme for 3 technology appraisals. The programme is also progressing work for the Accelerated Access Collaborative to facilitate the implementation of diagnostics guidance on 'high sensitivity troponin tests for early rule out of AMI' (DG15), and 'faecal immunochemical tests to guide referral for colorectal cancer' (DG30). Discussions with NHS England and other system partners on the evaluation of genomic technologies are also ongoing and it remains a key focus area for the programme.

Interventional Procedures Programme

- 16. The Interventional Procedures Programme were scheduled to publish 10 guidance publications from April to June 2019. It is confirmed that this target will be met.
- 17. IPAC has considered the most recent evidence base on "Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues". This was an update of IPG196. Their draft recommendations are due to go out for consultation in June 2019.

Medical Technologies Evaluation Programme

- 18. The programme published 3 pieces of guidance between April and June in line with target. Guidance is currently being developed on a further 5 technologies.
- 19. The programme published 7 MedTech innovation briefings between April and June with briefings in development on 12 more technologies. There are a further 20 technologies awaiting a decision on progress to a MIB and we expect to meet our target of 34±4 for 2019/20.
- 20. The programme began work on an NHS England-commissioned project to adapt the medical technologies guidance development process and methods for digital health technologies. The aim is to develop medical technologies guidance on a small number of pilot digital health technology topics. The team will also be working on phase II of the evidence standards framework for digital technologies as part of this project.

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HealthTech Connect

21. HealthTech Connect fully launched in April 2019. It supports the development and adoption of devices, diagnostics and digital health technologies, and over 300 companies have registered to use the system. The NICE MTEP team have used HealthTech Connect to identify 18 topics that are progressing through NICE topic selection process.

Observational Data Unit

- 22. The Commissioning through Evaluation (CtE) report on SABR for oligometastatic disease has been submitted to NHS England. This will form part of the evidence base for NHS England's forthcoming review of the Specialised Services commissioning policy. Reports are currently being developed for 2 additional SABR indications. The team is also managing the data collection on 1 further CtE topic (rituximab for idiopathic membranous nephropathy).
- 23. The EUnetHTA Register Evaluation and Quality Standards Tool (REQueST) and vision paper have been submitted for public consultation.

Technology Appraisals and Highly Specialised Technologies

- 24. In May 2019 the HST programme published its ninth piece of guidance Inotersen for treating hereditary transthyretin amyloidosis'. The topic was recommended for routine commissioning.
- 25. All four technology appraisal committees have now considered a topic under the new STA process which was published in April 2018. At the time of writing 55% of new STA committee discussions have resulted in a 'straight to final guidance' decision.
- 26. Collectively, the programmes published 16 pieces of guidance between April and June. They remain on target to publish 78 pieces of final guidance in the 2019/20 business year. The programmes are working on 79 (69 TA and 10 HST) 'live' topics that are currently between the formal invitation to participate and final guidance publication stages. Another 23 topics are scheduled to start between the July and September NICE Board meetings.
- 27. Between April and June 17 topics have been subject to the budget impact test process at the committee submission stage. Three of these have been completed; 1 topic has met the budget impact test and 2 did not. The outcome of the remaining 14 topics is still to be confirmed.
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July 2019

National Institute for Health and Care Excellence Communications Directorate progress report

- 1. This report sets out the performance of the Communications Directorate against the directorate's business plan objectives during April, May and June 2019. The business plan objectives are listed at the end of the report.
- 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. During May, three different patient groups organised protests outside our London and Manchester offices, and outside the entrance to our annual conference at the Deansgate Hilton in Manchester, to campaign against: our recommendations of mesh implants for pelvic organ prolapse and stress urinary incontinence; our appraisal of nusinersen for spinal muscular atrophy; and our recommendations on the use of electroconvulsive therapy to treat severe depression. On becoming aware of the groups' intentions to protest at our property and event, the communications team took a number of steps to ensure a clear approach for responding to the protesters respectfully and professionally. These included:
 - statements to deliver to the protestors onsite;
 - a media handling plan in case of journalists in attendance;
 - line up senior spokespeople to meet and greet the protestors in person;
 - briefings for the office facilities teams (and the security staff at the Hilton).
- 5. We are continuing to develop digital content to increase our engagement and reach with key audiences. In response to a requirement from the public involvement programme for a suite of induction materials for lay committee members, we created a new online learning resource to take committee

- members through the process in an engaging and informative way. Initial feedback has been very positive.
- 6. We are providing advice and practical support to teams across NICE to meet accessibility standards for online content. As part of this work we are moving content from pdf documents to accessible web pages, for example the register of interests for the <u>Board</u> and <u>SMT</u>. We have also explored options and made recommendations for developing accessible versions of the NICE Impact reports.
- 7. As part of our day-to-day internal communications support, we developed an animation to promote the new workforce strategy and are currently working on a communications strategy for the London office move.
- 8. We are delivering ongoing internal and external communications support to the NICE Connect project. We are in the early stages of a project to develop a suite of material, including a video, to promote the transformation vision to employees and external stakeholders.

Audience insights

- 9. The reputation research work has been completed and the findings of this work will be presented in the August 2019 board meeting. The field work comprised of three stages, an online survey of stakeholders, MPs and members of the public (n1594), in-depth interviews with senior members of key organisations (n32) and two focus groups with stakeholder who have varying levels of engagement with NICE (n14). The research has also provided support for the NICE Connect project and 20th anniversary celebrations.
- 10. Transcripts from the in-depth interviews and focus groups of the reputation research has been analysed in further detail to pick out key elements for the NICE Connect project, in particularly in relation to the strength of recommendations workstream. A summary report has been written and shared internally. The findings will be presented and discussed at the next working group for this workstream.
- 11. The team attended a joint meeting with the CQC. It involved members from the NICE audience insight and resource and impact team with members of the CQC communications and analytical teams in London. A presentation was given about how we conduct our work and engage with our stakeholders for insight work and work conducted on the impact reports. This was greatly appreciated by the CQC team. We have agreed to share our work across organisations in the future to enable us to share findings and learn from each other's approaches.

- 12. SNAP enterprise license has been rolled out across the organisation. All relevant team members are receiving training across July and will then be responsible for their own surveys. The field team is the latest team to be set up with an account. The audience insight team has supported the teams by transferring all surveys over from Survey Monkey, which has considerable impact on the capacity of the team, as a lot of new survey requests have also been received from across the organisation. Moving to SNAP meets all relevant GDPR regulations and ensure that all surveys sent from NICE in the future are consistent in terms of branding, governance statements etc. This process has also provided an opportunity for the Audience Insights team to review all current surveys and ensure they are following best practice when it comes to user research.
- 13. A consultation collection form was set up to assist the data and analytics team to collect comments from a public consultation on their statement of Intent. This is a document to enable external organisations to understand the types of data that we already use in our process and methods.
- 14. The findings from the evaluation of involving people with learning disabilities in meeting on quality standards was presented back to the relevant committees. The findings were generally positive and provided elements to consider moving forward not only for the involvement for people with learning disabilities but also for future meetings in general.
- 15. Support has been provided to assess the best way to collect feedback on the patient decision aids. Several surveys have been set up but have had limited responses. Continued discussions and support will be provided to determine the best way to collect feedback from relevant audiences for these products.

Editorial and publishing

16. In April, May and June we prepared 378 documents for digital publication.

17. We prepared and published:

- 6 new and 6 updated guidelines
- 32 new and 2 updated guidance documents (diagnostics, medical technologies, technology appraisals, interventional procedures and highly specialised technologies)
- 2 new and 2 updated quality standards
- 8 new advice products
- 41 new pieces of information for the public

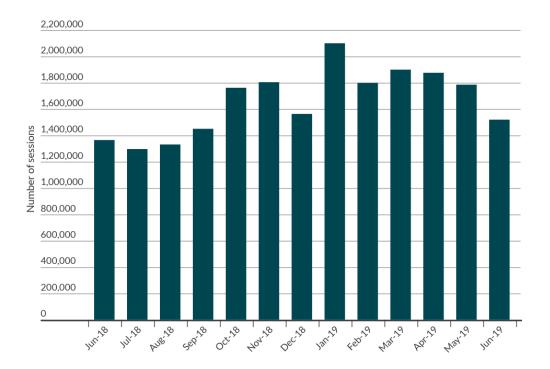
- 192 evidence documents (28 HTML/converted documents and 164 downloadable documents)
- 87 tools and resources (17 HTML/converted documents and 70 downloadable documents).
- 18. In terms of NICE Pathways, in April, May and June we:
 - Published 4 new pathways
 - Fully updated 8 pathways
 - Updated 43 pathways to take account of new guidance or advice (for example, adding new health technology guidance)
 - Updated a further 44 pathways to add related pathway links or as maintenance updates.
- 19. There are now 270 live pathways, which consist of 2,188 pieces of guidance and advice and Clinical Knowledge summaries
- 20. As part of the ongoing training we offer for all staff, in this reporting period we ran several writing for NICE workshops. As usual, these were well received.
- 21. Work continues to improve the accessibility of published content and ensure we meet new accessibility legislation. We are auditing all of the content in NICE Publications and InDev in preparation for rolling out the necessary changes. The team has been working with digital services colleagues to update our templates to improve accessibility, and publishing and communications colleagues are developing presentations on accessibility that will be run across the guidance and adoption and impact teams.
- 22. Significant new decision aids were produced and published, including 3 patient decision aids on surgery for stress urinary incontinence, uterine prolapse and vaginal fault prolapse (published in April); and 2 patient decision aids on decompressive hemicraniotomy surgery, which were published with the stroke and transient ischaemic attack update in May.
- 23. Three algorithms were published on lung cancer: systemic treatment options for advanced squamous NSCLC, systemic treatment options for advanced non-squamous NSCLC, and intrathoracic staging before radical treatment.
- 24. The Annual Report and Accounts for 2018/19 has been produced and is about to be laid before parliament and published. This includes an expanded 'highlights' section to promote and celebrate NICE activity across the previous financial year.

25. Based on user feedback we added links across our entire suite of quality standard to the 'How to use quality standards' document. We have also updated all technology appraisal overviews to provide the year of next review for our entire suite of technology appraisals.

Website performance

- 26. The news stories on our website were viewed almost 170,000 times between 1 April and 30 June, a 20% increase on the same period last year. The most popular stories were on a new treatment for an <u>enlarged prostate</u>, viewed 8,364 times; encouraging use of <u>greener inhalers</u>, viewed 6,969 times, and on the retirement of the NICE app viewed 6,887 times.
- 27. There were a total number of 5.2 million sessions on the NICE website which represents a 11% increase on the same period in 2018.

Chart 1: Number of sessions on nice.org - April - June 2019



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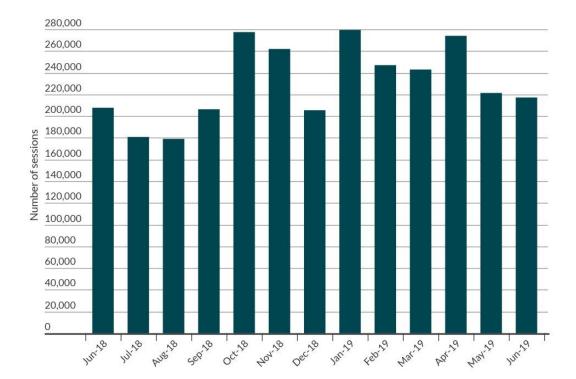


Chart 2: Number of sessions on Pathways April - June 2019

Download the data set for this chart

Enquiries

- 28. During April, May and June we responded to 3,312 enquiries which included 67 MP letters, 28 Freedom of Information (FOI) requests, and 23 parliamentary questions.
- 29. A third of the MP letters and a number of PQs related to the appraisal of nusinersen for the treatment of SMA. We also received a high number of public enquiries on this topic.
- 30. The development of guidance on cannabis-derived products for medicinal use has prompted a number of enquiries from people wanting to get involved. We also continue to receive enquiries from stakeholders regarding the ongoing development of the depression guideline, with the majority expressing concern about the extended timeline.
- 31. Requests for information under the FOI Act have been wide ranging from financial information to superseded versions of technology appraisal guidance and archived meeting minutes relating to interventional procedure guidance.

32. The team has continued to work hard to reduce the backlog of enquiries. There are now under 300 enquirers awaiting a response so we are now close to our normal range of open enquiries.

Events

- 33. The 2019 NICE Annual Conference took place on Thursday 9 May at the Hilton Deansgate in Manchester. It was attended by 530 delegates, with 15 organisations sponsoring and exhibiting at the event. The programme saw 47 experts speak in 16 sessions during the one-day event.
- 34. Close to 200 delegates completed the post-event evaluation form, of which 88% rated their overall event satisfaction as positive and 83% would recommend the conference to a colleague. 91% of delegates thought the conference definitely or mostly met their objectives for attending. Overall, delegate feedback was very positive, including:

"A very good snapshot of everything that is happening in life sciences and NICE's role in supporting that."

"Extraordinarily informative with a lively and engaged audience."

"A focused and enjoyable update and highlight of the future trajectory of NICE drawing on past experience."

- 35. NICE 2020 is due to take place on 3 June 2020.
- 36. A special reception for stakeholders to celebrate NICE's 20th anniversary took place on 12 June at the Palace of Westminster, with 110 guests in attendance. Baroness Nicola Blackwood, Parliamentary Undersecretary of State for Innovation, sponsored the event and delivered an opening address. We also heard speeches from NHS England's chief executive, Simon Stevens, ABPI chief executive, Mike Thompson and Guardian columnist, Polly Toynbee. Following the speeches, 20 awards were presented to people who have made distinguished contribution to NICE over the last 20 years. The event was very well received by guests, with messages of thanks and congratulations received both on the evening and in the days following the reception.
- 37. In May and June, NICE exhibited at four events: the RCN Congress in Liverpool which attracted over 4,000 nurses; the National Care Forum conference in London which attracted over 120 key decision makers in the social care sector;

the Health + Care exhibition at London's Excel centre which was visited by over 10,000 frontline staff from across the NHS and social care; and Health Technology Assessment International's (HTAi) annual meeting in Cologne, which bought together over 1,200 representatives from HTA bodies across the globe. At this latter event in Cologne, the HTAi secretariat formally announced that NICE, Health Improvement Scotland and the All Wales Therapeutics and Toxicology Centre would be jointly hosting HTAi's 2021 annual meeting in Manchester.

38. NICE staff and committee members delivered 8 speaking engagements during April, May and June, including: Jane Silvester, Associate Director, Social Care and Leadership, spoke at the Social Care Conference in Salford about supporting the sector to improve quality and care; Meindert Boysen, Director, CHTE, spoke at the Future of Pharmaceutical Pricing and Access to Medicines event in London; Professor Cameron Swift, specialist committee member of the Hip fracture in adults quality standard spoke at the Hip Fracture Summit; and Deputy Chief Executive Gill Leng, spoke at the Innovating Patient Summit about optimising patient care and improving patient satisfaction.

Media

- 39. Sentiment percentages for media coverage in April, May and June were as follows:
 - Positive 80%
 - Neutral 4%
 - Negative 16%
- 40. Positive coverage was driven by our activity on the launch of our prostate cancer guideline in the <u>Telegraph</u>, <u>Daily Mail</u> and the <u>Times</u>, and the widespread coverage we received for our physical activity quality standard, with broadcast coverage on BBC Breakfast and Sky News, as well as print and online editions of <u>The Sun</u>, the <u>Daily Mail</u>, and <u>Daily Telegraph</u>.
- 41. Coverage in the <u>Daily Mail</u>, <u>Guardian</u>, and <u>Independent</u> of our guidance on pelvic organ prolapse and stress urinary incontinence which included recommendations on mesh implants drove a higher percentage of negative coverage than we normally receive. As did technology appraisals of the medicines orkambi, nusinsersen, aimovig and cerliponase alpha.
- 42. Other high-profile national coverage for NICE in the last 3 months included our guidance on activities for dementia patients, which was widely reported and well-received in the Mail, Telegraph and some trade outlets including the Nursing Times. We were given a supporting statement by the Health Secretary.

- 43. There was balanced coverage following publication of our draft <u>guidance</u> on indoor air pollution. Only a handful of outlets criticised the guidance for being 'obvious', 'common-sense' and 'nanny-state'. The <u>Daily Mail</u>, <u>Telegraph</u>, <u>Sun</u> and <u>Metro</u> picked this up.
- 44. Our recommendations on workplace exercise received a similar treatment in the media with coverage from the <u>Independent</u>, <u>Daily Mail</u> and <u>Telegraph</u>. Again, there was some criticism over the recommendations being from the 'nanny-state', but most of the coverage was very positive.

Social media and podcasts

- 45. On Instagram we now have over 1,950 followers, a 14% increase since the board report in May 2019. From April to June, we have seen impressive engagement on our Instagram and LinkedIn posts, overall receiving 1,039 likes, shares or comments on Instagram and 5,650 likes, shares or comments on LinkedIn. Our posts on Twitter are continuing to get wide coverage overall receiving 2,047,961 impressions (number of times posts are seen) over this 3-month period.
- 46. Between April and June 2019 we released 3 new NICE Talks podcast episodes looking at managing asthma, encouraging active travel to reduce air pollution and reducing the risk of melanoma. Together these 3 episodes have received 2,999 plays.

Notable issues and developments

47. Reduced capacity across a number of teams in the directorate continues 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 and quality of support to the business.

Communication directorate objectives 2019-2020:

- 48. Ensure guidance and related products from NICE are of the highest quality and that the publishing and editorial function continues to deliver outputs of the highest standard during the NICE transformation programme.
- 49. Design and deliver a rolling programme of audience research that supports and informs the corporate business objectives.
- 50. Deliver a programme of strategic communication activities which promote NICE's work and support the uptake of NICE's offer.

- 51. Contribute communication expertise to the Connect (pathways) project and lead the communications and audience insights work to deliver the proof of concept phase.
- 52. Ensure communications is centralised and coordinated in the directorate by taking an integrated approach to planning and delivering communications.
- 53. Shape and manage our resources in order to support NICE and its strategic objectives effectively and efficiently.
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July 2019

National Institute for Health and Care Excellence Evidence Resources progress report

- 1. This report sets out the performance of the Evidence Resources Directorate against our business plan objectives during April, May and June 2019. It also highlights the usage performance of the NICE Evidence suite of on-line services at the end of June 2019.
- 2. The Evidence Resources Directorate is responsible for the following key functions and services:
 - We provide a high-quality information service to NICE centres and directorates;
 - We manage third party access and re-use of NICE content, including internationally;
 - We support the Centre for Health Technology Evaluations (CHTE) with their digital health evaluation programme;
 - We support NICE's digital transformation activities and maintain all NICE's live digital services;
 - We manage the provision of NICE Evidence Services.

Performance

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

Information Services

- 4. A key objective of the directorate is to deliver efficient and high-quality information services to the NICE centres and directorates. In the last 3 months, alongside undertaking searches to support guidance development, work has focused on strategic developments, including:
 - Supporting the CHTE 2020 programme by providing information services input into the topic selection (workstream 2) and guidance process workstreams (workstream 5b);
 - Refining our processes to identify data sources at the scoping stage of guideline development, helping to inform NICE's position on the use of broader sources of data;

 Continuing a range of research projects to improve the efficiency of the searching and sifting processes, including exploring the use of machine learning technologies.

Content re-use

5. A key objective of the team is to articulate and promote NICE's value propositions associated with the re-use of NICE content outside of the UK. In the last three months, the team has responded to 52 requests to re-use NICE content. 27 quotes to re-use NICE content were issued and 16 content and 2 syndication licences were signed. The total income invoiced is £42,656.00

Digital Health

- 6. Our directorate is supporting CHTE to explore with NHS England the options for a digital health technology evaluation workstream, building on the Evidence Standards for Digital Health Technologies published in 2018/19. Over the last three months, we have focused on supporting the following activities:
 - development of NHS England's business case, contributing to Senior Management Team (SMT) and Board papers and project plans outlining the pilot work programme, as part of the internal project team;
 - setting up and Chairing the external Steering Group for the pilot;
 - promoting the use of NICE's Evidence Standards for Digital Health
 Technologies at a wide range of events and conferences and liaising with
 a broad range of external partners and influencers.

Digital Services

Strategic planning

- 7. The first objective of the Digital Services (DS) team for 2019/20 is to identify digital investment priorities, and their sequencing, to align with the NICE Connect project transformation work, reviewing the roadmap quarterly. Over the last three months activity has focused on:
 - Working with NICE SMT and Digital Services governance groups to prioritise the areas of work that are currently planned in 2019/20 as part of our ongoing roadmap;
 - Establishing regular quarterly mechanisms of communication with SMT members and their senior teams to provide regular formal opportunities to review the DS roadmap and revisit prioritisation to ensure activity remains targeted to the highest value work for NICE;

 Ongoing work to support the shaping and next steps of NICE Connect and the preparation of plans and papers to present to the NICE Board and input into business planning for 2020/21.

Delivery of strategic digital services projects

- 8. Our second objective is to deploy our digital expertise to deliver business-led strategic projects in line with an agreed roadmap. Over the last three months activity has focused on:
 - The Evidence Management platform (delivering web tools for searching evidence, systematic review needs and building an evidence surveillance capability): Two feature releases have been completed in the last three months. The release made additional functionality available to a wider user group at NICE.
 - The Comment Collection project (work to bring efficiencies to the external consultation process): Spend control approval to continue development to support complex consultations was received from the DHSC and Government Digital Services (GDS). This work will commence later in 2019/20 in line with the prioritisation discussed with SMT.
 - Work to support configuration of a new identity management solution to replace our current in-house 'NICE Accounts' solution: work paused for a few weeks. Development is currently focused on the central management portal.
 - Contacts and planning: A 'discovery phase' to replace the Contact
 Database and Planning Tools previously managed by NICE IT and to look
 at the longer-term solution to support operational productivity at NICE
 completed in June. Next steps are to consolidate this with the emerging
 vision and priorities for the NICE Connect programme. This will ensure the
 tools are not considered separately but in the wider context of our
 transformation across process, organisation structure and how we
 manage our data.

Live services maintenance and improvements

- 9. Our third objective is to manage and maintain the live digital services of NICE utilising user insight and strategic service goals to prioritise use of resource:
 - NICE Digital Services operated within the service levels (99.7%) agreed with DHSC for availability (uptime) with 99.98% average performance in the last three months.
 - In the last 3 months, 112 defects were closed. In the same period, 17 Change Control Requests were completed.

Cross-cutting updates

- 10. Recruitment: A campaign to recruit to four vacancies (Associate Digital Performance Analyst, Technical Tester, User Experience Designer and Web Ops Engineer) was launched in June.
- 11. The remaining contractor working for NICE DS finished work at the end of June meaning that the team is now resourced fully by permanent staff members.
- 12. Talent management update: NICE have signed a training agreement with GDS who provide best practice training for agile software development within the public sector. These courses are being promoted to the team. There has also been incremental uptake of the Udemy learning platform since April. Ensuring the capability growth of the digital team is essential to the aspirations of the NICE Connect programme.
- 13. External collaborations: We have held a series of conversations about terminology and interoperability standards including:
 - Setting up a Care Vocabularies Consortium in collaboration with NHS
 Digital to bringing together taxonomists from different Arm Length Bodies;
 - Discussions with developers of decision support tools to understand their needs of NICE content;
 - Discussions with the Professional Record Standard Body (PRSB)
 regarding making links between decision support needs, health record
 system standards, the Care Vocabulary Consortium and NHS X to ensure
 visibility and alignment of this work;
 - Discussions with the PRSB, NHS Digital and Kings College London regarding jointly establishing a forum and driving research into computable knowledge as part of the concept of a learning health system for the UK.

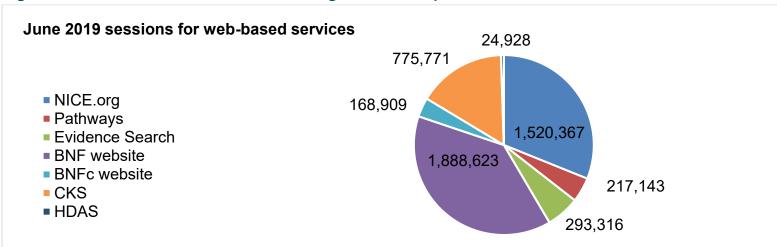
NICE Evidence Services

- 14. A core objective of the directorate is to maintain and monitor the performance of NICE Evidence Services which include CKS, HDAS, the BNF microsites, Evidence Search, and the Medicines Awareness Service. Over the last three months, new activity has included starting the negotiation on the England-wide licence to access the Cochrane library. The current licence ends in April 2020.
- 15. To provide these services, a key objective of the team is to enable access to the new National Core Content collection and to procure any additional content in line with Health Education England's (HEE) commissioning decisions. In April 2019, the new content was made seamlessly available to users.

Performance statistics for NICE Evidence Services

16. Figure 1 and table 1 below summarise the position of all NICE's digital services at the end of June 2019, contrasting the relative size of the externally facing services of NICE, measured in number of 'sessions'. This financial year so far NICE digital services have received over 5 million sessions a month; this represents an average of almost a million more sessions a month than the same period last year.

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



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

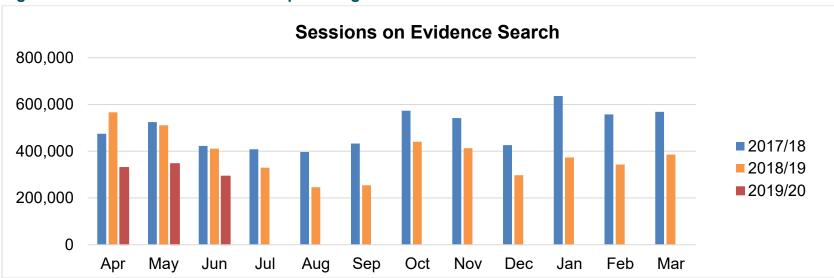
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Total sessions* in June 2019 across NICE web-based services	4,889,057
% year-on-year variance	20%
% month-on-month variance	-12%
Total sessions for the full year ending in May 2019 across NICE web-based services	59,159,973
% year-on-year variance	32%

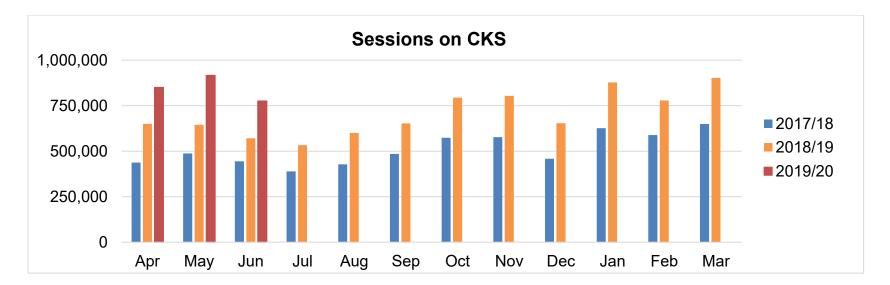
National Institute for Health and Care Excellence Evidence Resources Directorate progress report

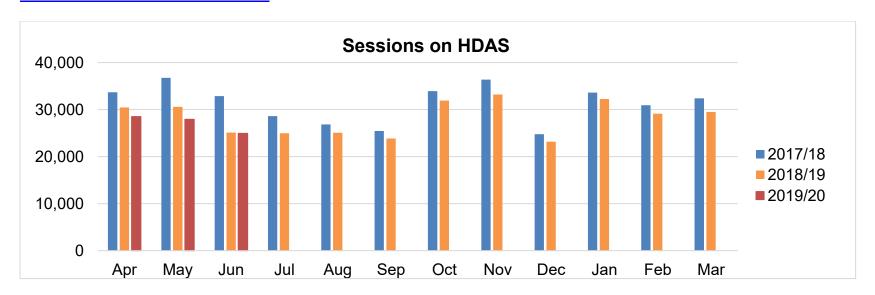
Date: 17 July 2019 Reference: 19/074

- 17. 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.
 - Between April and June CKS received 36% greater sessions than last year; this growth is similar to other months'.
 - Evidence Search has seen over a third of sessions less in comparison with the previous year.
 - HDAS has also remained behind last year's traffic with 6% fewer sessions.



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





18. Figures 5-6 illustrate the performance of our BNF microsites. BNF and BNFc microsites started the new financial year with a strong performance; they received respectively an average of 47% and 89% greater sessions than April-June 2018.

Sessions on BNF site 2,500,000 2,000,000 1,500,000 2017/18 2018/19 1,000,000 **2019/20** 500,000 0

Oct

Nov

Dec

Jan

Feb

Mar

Sep

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

Aug

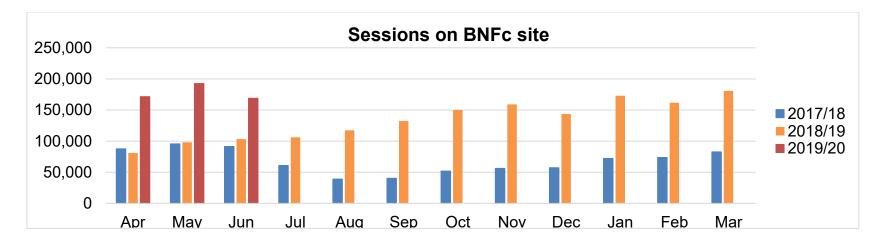
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Apr

May

Jun

Jul



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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 April, May and June 2019. A summary is also provided for areas of work that have seen significant progress and are of note for the Board.
- 2. The Chief Executive's Report details the delivery of quality standards.

Performance

- 3. The directorate has achieved its planned deliverables for this reporting period, with the exception of the following, where delivery has been partly dependent on external parties. These are expected to meet planned performance during the year:
 - Four of 7 endorsement statements.
 - One of 4 implementation support initiatives.
 - Four of 5 budget impact assessments completed for submitted technology appraisals.
- 4. Key publications are detailed in Appendix 1. Progress includes the following areas of work, as set out in the business plan.

Deliver and support the adoption of accessible, up to date and adaptable advice, fully aligned to the needs of our users

Adoption support products for topics identified by the Centre for Health Technology Evaluation

5. For the first time, NICE has produced bespoke support for a technology appraisal with a managed access agreement. An information sheet, co-badged with NHS England (NHSE), Lupus UK, British Isles Lupus Assessment Group Biologics Register and Glaxo Smith Kline was sent to relevant stakeholders to help improve the lower than anticipated uptake of belimumab for treating active autoantibody-positive systemic lupus erythematosus.

NICE Connect

Reference: 19/075

6. The NICE Connect external engagement group met in April and considered NICE's future product portfolio and joint working on pathways. Exploration of options for presentation of NICE's future content continues through the pathway committee's work on medicines sequencing.

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- 7. The vision and ambition for NICE Connect and the initial findings from associated audience insight and user testing work were presented at an engagement event involving representatives from national social care organisations. The cultural and organisational differences in social care that NICE Connect will need to take into account were highlighted, and feedback will be developed into a report. Further engagement with the sector will take place as work progresses.
- 8. Staff engagement on the vision and ambition for NICE Connect, and planning for future priorities, has taken place throughout June and July including meetings with senior staff and lunch and learn sessions for all staff. The lunch and learn sessions attracted around 150 staff, which generated questions and suggestions to help shape the work.
- A report will be presented to the Board in September summarising the work on NICE Connect, and making the case for change and recommending initial priorities.

Patient & public committee member recruitment

- 10. The ratio of applications to vacancies during the reporting period was 4.6:1, with the target being 2:1 or greater. 74 applications were received for 16 vacancies.
- 11. Of note, there were no suitable applicants for the fever in under 5's guideline committee on the first round of recruitment, and the second round generated one application. The management of common infections committee looking at impetigo received one application that did not meet the required criteria. A decision was made not to undertake further recruitment, therefore discussions are taking place with the guideline development teams to explore ways of attracting appropriate lay representatives for committees.
- 12. Eight patient experts have been identified to give testimony at committee meetings and at NICE's Scientific Advice meetings, and 6 people have been coopted as specialist committee members onto Quality Standards Advisory Committees.

Shared Decision Making (SDM)

- 13. The shared decision aid on inhalers for asthma, which published in April, was part of a proof of principle project to include environmental information in a decision aid. Publication was covered in 150 news articles, including in the Telegraph and the Independent.
- 14. NICE held the 6th meeting of its Shared Decision Making Collaborative on 6th June. The event was attended by 48 people from national public sector, voluntary and community, academic and commercial organisations.

 Presentations included how different countries are implementing SDM, and a new

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consultation model to promote SDM in conversations with people with multimorbidities. Key issues discussed included:

- The need to develop a central place for people to access patient decision aids.
- Moving SDM from being an aspiration to being a core component of care.
- Embedding SDM into the training of all people who work in health and social care.
- 15. These themes, and others identified during the day, will form the basis of an updated Collaborative action plan.

Play an active, influential role in the national stewardship of the health and care system

- 16. Progress against the strategic engagement plan metrics for this reporting period is set out in Appendix 2.
- 17. National level engagement during this period has included:
 - NICE and the Care Quality Commission (CQC) continuing to progress the
 agreed actions on increasing the profile and use of NICE guidance in
 CQC inspections set out in the December 2018 Board report on
 Engagement with the CQC. Following recent changes in senior leaders
 across the CQC, including at Chief Executive level, work is taking place to
 ensure that effective working relationships continue with both CQC's
 policy and operational teams.
 - Establishing an advisory group, including representatives from key
 national social work organisations, to support the development of NICE's
 social work campaign and additional resources for social workers.
 - Continuing to work with NHS RightCare to use NICE guidance in developing toolkits for clinical commissioning groups and STPs. The <u>NHS</u> <u>RightCare Frailty Toolkit published</u> in June and was informed by NICE guidance and associated products.
 - Providing a webinar for members of the NHS RightCare programme which gave an overview of NICE's remit, products and how to use them. This webinar was to support capability building in the RightCare programme.
 - Delivering a presentation at the Getting It Right First Time clinical leads event on our guidance, associated products and support for implementation which generated several requests for collaborative working with some speciality areas.

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- 18. The Field team focus for local and regional engagement during this period included:
 - Supporting Public Health England (PHE) regional activity. For example, collecting practical tools, resources and guidance for cardiovascular disease that can have the most impact on health outcomes in the East of England and building relationships with the new Directors of Public Health.
 - Working with the 7 What Works Network centres to understand challenges faced by Grimsby and Wakefield as part of a pioneering project on disadvantaged places. As a result, NICE has been invited to help these local partnerships use NICE products more effectively to deliver their priorities.
 - Supporting the Sustainability and Transformation Partnerships (STPs) and Integrated Care Systems (ICSs) North Respiratory Improvement Event led by NHS RightCare. NICE has been invited to join a wider transformation group to support delivery of the NHS Long Term Plan priorities.
 - Providing advice and support to provider organisations' NICE manager networks, including the network in Wales, to help them implement NICE guidance and quality standards.

Take advantage of new data sources and digital technologies in developing and delivering our advice

- 19. The data analytics external reference group met in April and considered the Life science's industrial strategy and evaluation of digital health technologies.
- 20. The consultation on the Statement of Intent that sets out NICE's ambition to use a broader range of data analytics in its work runs from June to September, and includes a series of targeted engagement events.

Generate and manage effectively the resources needed to maintain our offer to the health and care system

21. A seventh Improving Access to Psychological Therapies (IAPT) assessment briefing was published on Be Mindful, an online mindfulness-based cognitive therapy course, designed to treat depression, stress and anxiety. The IAPT expert panel concluded that Be Mindful did not match the eligibility criterion for a therapist-guided model of care and did not recommend its progression to the NHSE evaluation in practice phase of the programme.

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Support the UK's ambition to enhance its position as a global life sciences destination

Accelerated Access Collaborative (AAC)

22. The Health and Social Care directorate has been invited to support 5 of the 7 AAC working groups. Each group has a designated NHSE relationship manager and a lead Academic Health Science Network (AHSN) and meets on a monthly basis. Topics being specifically supported by the HSC directorate are high sensitivity troponin (rapid algorithms), PSK9i, PIGF, UroLift and HeartFlow.

Innovation scorecard

23. The innovation scorecard published in April. Ownership of the scorecard has been transferred from the Office of Life Sciences to the AAC as part of its expanded remit, and early discussions are now taking place on its future strategic direction. NICE is working with NHSE to identify the 5 highest health gain categories as part of the commitments made in the 2019 voluntary scheme for branded medicines pricing and access.

Notable issues and developments

24. This section includes significant developments or issues that occurred in the reporting period.

NHS Long-Term Plan (LTP) Implementation Framework

25. NICE will be part of forthcoming discussions on developing a joint offer of cross-system support from Arms-Length Bodies following the publication of the NHS LTP Implementation Framework on 27 June. The framework provides guidance, a process and metrics to support regional and local systems in developing strategic plans that describe how they will deliver the majority of commitments set out in the LTP by 2023/24. These plans will inform the development of an overarching implementation plan which is expected to be in place by 31 December 2019.

Regional Medicines Optimisation Committees (RMOCs) Evidence Summaries

26. NHSE recently proposed a new RMOC operating model that removes the role of the committees in appraising new medicines. The change is due to the introduction of the new 2019 voluntary scheme for medicines that will result in NICE appraising more medicines through its technology appraisal programme. It is proposed that RMOCs instead focus on the regional leadership of medicines optimisation initiatives and NHSE has confirmed that RMOC evidence reviews will no longer be commissioned from NICE in 2019/20.

National Institute for Health and Care Excellence Heath and Social Care Directorate progress report Date: 17 July 2019 Reference: 19/075 27. The NICE and Health and Social Care business plans set out an objective to produce up to 12 RMOC evidence summaries in 2019/20 (subject to topic referral). The risk associated with a variable volume of topic referrals was captured in the Health and Social Care business plan. As such, NICE's financial plans did not include this workstream as a potential source of income and no additional recruitment took place to support activity. The NICE and Health and Social Care directorate business plans will be updated to reflect that this programme of work will not proceed as initially planned. The pilot evidence summary (doxylamine/pyridoxine for nausea and vomiting of pregnancy) developed as part of this programme published in June 2019.

Quality in Public Health: A shared responsibility

28. NICE is a member of the Quality Framework for Public Health Action Planning Group which is responsible for taking the implementation of the framework forward. The group reports to the Public Health Systems Group and held its first meeting on 13 June. NICE is supporting the work and expects a stronger focus on the profile and use of NICE guidance as work progresses.

Quality Improvement round table event

- 29. In June, a Quality Improvement roundtable workshop was held, following a similar successful event last year. It was hosted by NICE and co-chaired by Gill Leng, Deputy Chief Executive (NICE) and Hugh McCaughey, National Director for Improvement and Steve Powis, Medical Director (NHSE and NHS Improvement). This is an important area for NICE as quality improvement initiatives are essential for putting NICE guidance into practice.
- 30. Thirty-eight representatives attended from a range of organisations including the Health Foundation, CQC, PHE, NHS Digital, Healthcare Quality Improvement Partnership, The Healthcare Improvement Studies (THIS) Institute, Academy of Royal Colleges, Health Education England (HEE), The Kings Fund, AHSN network, Royal College of General Practitioners, Scottish Government, and 3 provider trusts.
- 31. As a result of the meeting, NICE will begin to develop some proposals around how best to include our products in the proposed new quality framework. The framework is intended to build on the Shared Commitment to Quality for Health and the Developing People Improving Care framework.

Shared Learning Awards

32. The Shared Learning Award was presented at the NICE Conference in May. The award went to Pancreatic Cancer UK and University Hospitals Birmingham for their model of fast-track surgery for pancreatic cancer for the management of operable patients.

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33. The two runners up were:

- The Scarred Liver Project: a new diagnostic pathway to detect chronic liver disease submitted by the University of Nottingham and Nottingham University Hospitals NHS Trust
- Perinatal Mental Health Matrix: improving NHS Perinatal Mental Health Services submitted by the Thames Valley Strategic Clinical Network.
- 34. The directorate supported the NICE Into Action category of the Chief Allied Health Professional Officer Awards. Three examples were identified for the event in July. A further 7 examples will be developed into shared learning case studies.

Appendix 1: Publications - April, May and June 2019

The table below provides a list of guidance and advice produced in the reporting period.

Product title	Product type
Agreed NICE and NHS England process for using Belimumab for treating active autoantibody-positive systemic lupus erythematosus	Adoption support
'Difficulties sitting still or concentrating: Support in the NHS i- THRIVE Grid' and 'Difficulties sitting still or concentrating: Support outside of the NHS (parents) i-THRIVE Grid'	Endorsement statement
UK Sepsis Trust: screening and action tools	Endorsement statement
Contraceptive choices at a glance chart	Endorsement statement
brainstrust patient guide	Endorsement statement
Doxylamine/pyridoxine (Xonvea) for treating nausea and vomiting of pregnancy	Evidence summary
Plerixafor for stem cell mobilisation in patients of any age with haematological tumours other than multiple myeloma and lymphoma	Evidence Review Specialised Commissioning
Plerixafor for stem cell mobilisation in patients aged >24 years with non-haematologic solid tumours	Evidence Review Specialised Commissioning:
Be Mindful for adults with depression	IAPT assessment briefing
Antibiotic stewardship: duration of antibiotic treatment for common infections frequently exceeds guideline recommendations	Medicines Evidence Commentary (MEC)
New MHRA drug safety advice: March 2019 to May 2019	Medicines Evidence Commentary (MEC)
Antipsychotic treatment: risk of unexpected death in children and young people	Medicines Evidence Commentary (MEC)
Bone and joint infections: are oral antibiotics safe and effective compared with intravenous antibiotics?	Medicines Evidence Commentary (MEC)
Respiratory tract infections: UK study finds prescribing feedback and decision support tools reduced antibiotic prescribing in primary care	Medicines Evidence Commentary (MEC)
Stroke:decompressive hemicraniectomy surgery in people under 60	SDM product
Inhalers for asthma for use by people aged 17 years and over	SDM product
Surgery for uterine prolapse	SDM product

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Product title	Product type
Surgery for vaginal vault prolapse	SDM product
Surgery for stress urinary incontinence	SDM product
A Community of Practice for Non-medical Prescribing Leads	Shared learning example
Atrial Fibrillation (AF) Holistic Care Pathway	Shared learning example
Being creative in times of crisis: how the development of a Group Supervision model has supported carers to be able to care	Shared learning example
Childhood Asthma Management in Primary Care - Implementation of Exhaled Nitric Oxide and Spirometry Testing (CHAMPIONS study)	Shared learning example
Developing Inpatient Therapy Groups to Deliver Peer support as well as Health and Wellbeing Education	Shared learning example
Dignity and Self Harm: User Experiences of Emergency Care - Healthwatch Bucks	Shared learning example
Ensuring compliance with NICE guidance significantly improves outcomes in Multiple Pregnancy	Shared learning example
Fit for Falls - Falls prevention across the system	Shared learning example
How we used a World Café as a springboard to support heart failure teams in Kent, Surrey and Sussex to implement the new NICE guidelines for chronic heart failure.	Shared learning example
Implementing NICE Guidance for Stable Chest Pain Patients (CG95 & MTG32) to Appropriately Diagnose Patients with Suspected Coronary Artery Disease	Shared learning example
Improving the care of head and neck cancer patients with collaborative dietetics and speech and language therapy intervention	Shared learning example
Introducing new technology to improve peripherally inserted central catheters (PICC) placement	Shared learning example
Running Cognitive Stimulation Therapy (CST) groups as part of core Community Mental Health Team (CMHT) work	Shared learning example
The creation of a therapy scanning wall on the stroke unit for visual inattention: understanding its assessment and therapeutic use.	Shared learning example
University Hospitals Bristol Implementation of PICO Incision Management Negative Pressure Wound therapy in the high-risk Cardiac Surgery Patient Group.	Shared learning example
NICE stroke impact report	Topic based impact report

Appendix 2: Strategic Engagement Plan Metrics

Table 1 below provides details of progress for all national strategic engagement metrics and Table 2 provides details of progress for regional / local metrics, for the period April to June 2019.

Table 1 Strategic Engagement Plan – National Metrics	Comments
References to NICE guidance and standards included in 80% of relevant Long Term Plan (LTP) publications to support quality improvement	Measures to be determined once LTP implementation plans are available.
100% alignment of 2019/20 GIRFT reports with NICE guidance, standards and indicators	No GIRFT reports produced in quarter 1.
10% of 'outstanding' primary care inspection reports published in 2019/20 reference NICE within the inspection evidence table	4 relevant reports published during April-June all referenced NICE.
Integration of evidence standards framework for digital health technologies into NHS Digital's Digital Applications Assessment Questionnaire (DAQ) as part of the application process for DHTs to be placed on NHS.UK by end of Q2	A draft version of the DAQ standards incorporating the NICE evidence standards will be available for comment in July, with a planned publication date of September.
Office of Life Sciences (OLS) accept the business case for funding the expansion of the medtech work, including digital evaluations	NICE is continuing to seek clarity from NHS England, Office of Life Science and the DHSC as to the mechanism for NICE receiving this additional funding.
NICE support an expanded and aligned horizon scanning functionality between health care partners involved in the AAC	The leadership for the Accelerated Access Collaborative has moved to the Specialised Commissioning Directorate in NHS England. Opportunities to align the activities of NICE and NHS England on horizon scanning will continue.
NICE guidance and quality standards are included in implementation plans agreed for the Quality Framework for the Public Health System, Quality in Public Health: A Shared Responsibility	Measures to be determined following publication of the implementation plan.

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Table 1 Strategic Engagement Plan – National Metrics	Comments
NICE guidance and quality standards embedded in 6 out of 10 'What Good Looks Like' (WGLL) themed publications	NICE referenced in 2 WGLL publications in this period as planned.
NICE guidance and quality standards are included in NHS Long Term Plan action plans relating to key areas on prevention (alcohol, obesity and smoking)	Measures to be determined once LTP implementation plans are available.
Two meetings take place with key contacts in the DfE early years and schools directorate	Key contacts in the DfE currently being identified.
Promotion of collaborative working (Unlocking capacity: smarter together) between health and adult social care at 4 events	Two events have taken place in this period; with a total of 4 by the end of March 2020.
Inclusion of 3 quality standards measures within the Quality Matters (QM) data framework	Initial plans to be presented at QM board meeting - meeting rescheduled from May to July.
20% of 'outstanding' social care inspection reports published in 2019/20 to reference NICE	Fourteen of 91 'outstanding' reports (15%) published in quarter 1 reference NICE.
Reference to NICE in the guidance supporting new professional standards for social work, developed by Social Work England	A meeting is being sought with Sarah Backmore (Executive Director of Standards) to progress this.

Table 2 Strategic Engagement Plan – Regional and Local Metrics	Comments
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	Engagement with 5 (17%) of STPs/ICS as planned.
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)	Engagement with 7 networks during quarter 1 (3 planned).
12 mental health strategic clinical networks are supported to understand and use NICE guidance and standards to deliver NHS Long Term Plan / 5YFV mental health priorities	The online mental health resource for local partnerships due at the end April was delayed (campaign will use a PowerPoint version to enable work to progress).
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	One example of supporting local delivery of the Long Term Plan as planned and 4 examples of supporting ongoing CVD prevention work, exceeding planned delivery in quarter 1.
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)	Three examples of working with regional branch networks of ADASS, with a total of 5 planned by the end of March 2020.
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	No activity planned for quarter 1.

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