NICE National Institute for
Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

PUBLIC BOARD MEETING

There will be a Public Board Meeting on the 15 March 2017 at 1.45pm in Durham Town Hall, Market Place, Durham, DH1 3NJ.

AGENDA

17/018	**Apologies for Absence** To receive apologies for absence	(Oral)
17/019	**Declarations of interests** To record any conflicts of interest	(Oral)
17/020	**Minutes of the Board meeting** To approve the minutes of the meeting held on 18 January 2017	(Item 1)
17/021	**Matters arising** To consider matters arising from the minutes of the last meeting	(Oral)
17/022	**Chief Executive's report** To receive the Chief Executive's report *Andrew Dillon, Chief Executive*	(Item 2)
17/023	**Finance and workforce report** To receive a report on NICE's financial position to the end of January 2017 and an update on the workforce strategy *Ben Bennett, Director, Business Planning and Resources*	(Item 3)
17/024	**Business plan 2017-18** To approve the business plan for 2017-18 *Andrew Dillon, Chief Executive*	(Item 4)
17/025	**Revisions to the NICE Standing Orders, Standing Financial Instructions and Reservation of Powers to the Board and Scheme of Delegation** To agree the amendments to the governance documents *Ben Bennett, Director, Business Planning and Resources*	(Item 5)
17/026	**Uptake and impact report** To review the report *Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate*	(Item 6)

17/027	**Appropriate disinvestment and investment offer from NICE: update**	(Item 7)
	To receive an update	
	Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate	

17/028	**A replacement for the Health Service Circular 2003/011 (The interventional procedures programme: working with the National Institute for Clinical Excellence to promote safe clinical innovation)**	(Item 8)
	To approve the proposed replacement	
	Professor Carole Longson, Director, Centre for Health Technology Evaluation	

17/029	**Consultation on changes to the technology appraisal and highly specialised technologies programmes**	(Item 9)
	To consider the responses to the consultation and agree the changes to the programmes	
	Professor Carole Longson, Director, Centre for Health Technology Evaluation	

Director's report for consideration

| 17/030 | Centre for Health Technology Evaluation | (Item 10) |
| | *Professor Carole Longson, Director, Centre for Health Technology Evaluation* | |

Directors' reports for information

| 17/031 | Centre for Guidelines | (Item 11) |

| 17/032 | Communications Directorate | (Item 12) |

| 17/033 | Evidence Resources Directorate | (Item 13) |

| 17/034 | Health and Social Care Directorate | (Item 14) |

| 17/035 | **Committee minutes** | (Item 15) |
| | To receive the unconfirmed minutes of the Audit and Risk Committee held on 25 January 2017 | |

| 17/036 | **Any Other Business** | (Oral) |
| | To consider any other business of an urgent nature | |

Date of the next meeting
To note the next Public Board meeting will be held on
17 May 2017 in Chester Town Hall, 33 Northgate Street, Chester, CH1 2HQ.

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Public Board Meeting held on 18 January 2017 in the Education Centre, University Hospital Lewisham, London, SE13 6LH

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

Professor David Haslam	Chair
Professor Sheena Asthana	Non-Executive Director
Dr Rosie Benneyworth	Non-Executive Director
Professor Angela Coulter	Non-Executive Director
Professor Martin Cowie	Non-Executive Director
Elaine Inglesby-Burke	Non-Executive Director
Dr Rima Makarem	Non-Executive Director
Andy McKeon	Non-Executive Director
Tom Wright	Non-Executive Director

Executive Directors

Sir Andrew Dillon	Chief Executive
Professor Gillian Leng	Health and Social Care Director and Deputy Chief Executive
Ben Bennett	Business Planning and Resources Director

Directors in attendance

Professor Mark Baker	Centre for Guidelines Director
Jane Gizbert	Communications Director
Alexia Tonnel	Evidence Resources Director

In attendance

David Coombs	Associate Director – Corporate Office (minutes)
Mirella Marlow	Programme Director – Device and Diagnostic Systems and Deputy Centre for Health Technology Evaluation Director

17/001 APOLOGIES FOR ABSENCE

1.   Apologies were received from Tim Irish and Professor Carole Longson.

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17/002 CONFLICTS OF INTEREST

2.   None.

17/003 MINUTES OF THE LAST MEETING

3.   The minutes of the public Board meeting held on 16 November 2016 were agreed as a correct record.

17/004 MATTERS ARISING

4.   The Board reviewed the actions arising from the Board meeting held on 16 November 2016. It was noted that:

- Centres and directorates are addressing the issues arising from the staff survey through locally developed action plans.

- A report on the regional engagement events is included on the agenda for this meeting.

- The NICE Charter has been updated to reflect the discussion at the last Board meeting and published on the website.

- An update on NICE's support for appropriate investment and disinvestment is scheduled for the March Board meeting.

- Sheena Asthana has been appointed as the fourth member of the Audit and Risk Committee. As discussed at the last meeting, four members are felt to be sufficient for the current time.

- Following the submission of expressions of interest and a subsequent ballot amongst Board members, Tim Irish will take up the role of Senior Independent Director when Andy McKeon retires from the Board in May.

- The Senior Management Team have agreed an updated risk appetite statement which will be presented to the Board in February, following consideration by the Audit and Risk Committee next week.

17/005 CHIEF EXECUTIVE'S REPORT

5.   Andrew Dillon presented his report, describing the main programme activities to the end of December 2016 and the financial position to the end of November. He highlighted that the proposals for NICE to recover the costs of the technology appraisal (TA) and highly specialised technologies (HST) programmes from the participating companies are on hold until the Government completes its life sciences strategy. The financial plan for 2017-18 has been updated accordingly. If NICE does not receive permission to proceed with the cost recovery proposals then actions for addressing the resulting financial shortfall in 2018-19 and beyond will be brought to the Board.

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6. Following questions from the Board, Andrew Dillon confirmed that NICE continues to implement its revised role with the Cancer Drugs Fund (CDF) in line with the agreed timescale. Also it was noted that the actions to address the recommendations from the triennial review are largely complete. Work remains ongoing to confirm NICE's future international activities, and the Board will be updated on this area in May. There is also an outstanding action to investigate the possibility to benchmark NICE with international comparators.

7. The Board received the report.

8. A member of the public referred to the work undertaken to map the respective roles of NICE and Public Health England (PHE), and asked whether there is a diagram available to explain these roles to the public. Gill Leng stated that she would discuss further with colleagues in PHE how the respective roles of the two bodies could be explained to the public.

ACTION: Gill Leng

9. In response to a question from a member of the public about the mental wellbeing and independence for older people quality standard, Andrew Dillon outlined the nature and role of a quality standard. It was noted that the quality standard in question, and all others published by NICE, are available on the NICE website.

17/006 FINANCE AND WORKFORCE REPORT

10. Ben Bennett presented the report which outlined the financial position as at 30 November 2016 and provided an update on the workforce strategy. The full year forecast out-turn is a £3.1m underspend against the revenue resource limit. Ben highlighted the update on the 2020 programme in the report, and the activities planned in the upcoming 'healthy work week'. In addition, he noted that the learning management system is now live.

11. Rima Makarem, chair of the Audit and Risk Committee, asked about the income received from the NICE Scientific Advice service, and whether there are restrictions on its use. Ben Bennett advised that income generated from non-exchequer funded activities can be retained at the year-end. The internal policy has been that such income is usually reinvested in the same area.

12. The Board received the report.

17/007 REGIONAL STAKEHOLDER EVENTS

13. Jane Gizbert presented the report that summarised the report from the four regional stakeholder events held in the autumn of 2016. She asked the Board to consider how to respond to the feedback and to reflect on the value of these type of events as a means of NICE engaging with its stakeholders in the context

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of NICE's broader stakeholder engagement activities. Jane thanked colleagues involved in organising the events.

14.   The Board discussed the report and the feedback from the events. Whilst mindful of the need for caution in interpreting the feedback given the level of attendance, a number of themes were noted. NICE was seen as a credible and trusted brand, but awareness of NICE's full remit was low, particularly in the areas of social care and public health. Attendees requested more help with implementing NICE guidance, and feedback indicated the scope to clarify NICE's role in relation to other national organisations, particularly Public Health England. In the Board's discussion it was suggested that NICE should consider the format for NICE guidance, including whether the various types of NICE guidance could be simplified in both content and type. Also, any future events should be arranged around integrated care, in line with the national and local drive to integrate care. Closer alignment of NICE standards with Care Quality Commission inspection criteria was also suggested.

15.   The Board discussed whether the events should be repeated, taking account of the level of attendance, the costs of organising the events, and the request at the Bristol event to hold a follow-up session. It was noted that the recurring themes and conclusions from the events tended to reinforce previous feedback rather than identify new issues. The Board agreed to consider whether to repeat the events as part of a wider discussion of NICE's engagement with stakeholders through conferences and events. A paper setting out proposals will be brought to the February Board Strategy meeting.

16.   The Board agreed the report for publication on the website. The report should also be circulated to the attendees, with an explanation that NICE will consider whether to repeat the events in the context of NICE's wider engagement activities.

ACTION: Jane Gizbert

17.   A member of the public asked if NICE holds meetings in venues specifically used by black and minority ethnic groups, and whether Board papers are routinely published in a range of languages. Andrew Dillon confirmed that where guidance particularly affects part of the population, NICE will consider the scope for targeted engagement activities. As copies in other languages are not routinely requested, translation of the Board papers is not felt to be an appropriate use of public funds.

17/008 NICE AND THE LIFE SCIENCES INDUSTRY

18.   Andrew Dillon presented the position paper that set out the ways NICE works with the life sciences industry in the development of guidance, and by participating in national and international policy. The paper presents a public statement of NICE's role and commitment to supporting the growth of a thriving life sciences sector and concludes with NICE's proposed contribution to the

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Government's life sciences industrial policy. Andrew thanked Carole Longson for her contribution to the paper.

19. The Board discussed and endorsed the paper. It was agreed that the paper should be amended to reference the diversity of the life sciences sector and also note NICE's role in relation to medicines optimisation. Noting this paper is focused on the Government's life sciences industrial strategy, Andrew Dillon agreed to consider the scope for an accompanying paper that sets out NICE's broader relationship with the diverse life sciences industry, which could for example, include further detail on medicines optimisation and medical devices and technologies.

ACTION: Andrew Dillon

20. Martin Cowie referred to the proposal to design and manage novel evidence generation processes and new data driven funding models for fast track approval and reimbursement of cost effective technologies. He noted the importance of balancing this innovation with NICE's reputation for rigorous evaluation of evidence. Andrew Dillon noted these approaches are an important way of taking account of uncertainty and providing advice on new technologies. Mirella Marlow noted that 'real world' data can be an option where evidence from randomised controlled trials is not available.

17/009 A SHARED COMMITMENT TO QUALITY: REPORT FROM THE NATIONAL QUALITY BOARD

21. Gill Leng presented the recently published report from the National Quality Board (NQB) and highlighted the impact for NICE. She confirmed that NICE will continue to work with partners in the NQB to embed the framework across the health system.

22. Andy McKeon asked whether there is further scope to promote NICE guidance through incorporation in the Care Quality Commission standards. Also, whether NHS providers' could measure the implementation of NICE guidance through clinical audits, and report the results in their quality accounts. Gill Leng confirmed that the Health and Social Care directorate will be looking at how to increase the uptake and implementation of NICE guidance as part of its work programme.

23. The Board noted the report.

17/010 PATIENT SAFETY AND THE REDUCTION OF RISK OF TRANSMISSION OF CREUTZFELDT-JAKOB DISEASE

24. Mirella Marlow presented the proposal to update NICE's guidance on the reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) in light of the change in evidence base and circumstances since the guidance was

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published in 2006. She outlined the proposed methodology for this update, utilising a sub-committee of the Interventional Procedures Advisory Committee.

25. The Board approved the proposal to update the guidance through the approach outlined in the report.

17/011 REMUNERATION COMMITTEE MEMBERSHIP

26. David Haslam presented the paper on the membership of the Remuneration Committee. In addition to the NICE Chair, the committee has in practice comprised the Audit and Risk Committee Chair and the Vice Chair (and Senior Independent Director) in recognition of the synergies between these positions and the committee's governance role. The proposal is to formalise this in the committee's terms of reference and standing orders. If the Senior Independent Director is also the Vice Chair or Audit and Risk Committee Chair, then a fourth non-executive director will be appointed to the committee.

27. The Board approved the amendments to the Remuneration Committee's Terms of Reference and Standing Orders, and delegated to the NICE Chair the authority to appoint a fourth member of the committee, should this be required.

28. Following a query from Gill Leng, it was agreed that the committee's role in relation to the clinical excellence awards would be clarified. Any resulting amendments to the Remuneration Committee's terms of reference will be brought back to the Board for approval.

ACTION: Andrew Dillon / David Haslam

17/012 DIRECTOR'S REPORT FOR CONSIDERATION

29. Mark Baker presented the update from the Centre for Guidelines. He drew the Board's attention to key items of note in the report, and outlined changes in the Centre over the last 18 months, and the further changes planned in the next 18 months. These include a reduction in the number of guideline committees and a shift in focus from developing new guidelines to maintaining existing guidelines.

30. Mark Baker responded to a number of questions from the Board on the report, and confirmed that the Centre is likely to complete the planned number of surveillance reviews by the end of the year. He commented on the decision not to renew the contract with the Social Care Institute for Excellence (SCIE) to produce NICE's social care guidelines. Given SCIE developed guidelines in accordance with NICE's processes and methods, transfer of responsibility for producing the guidelines should not have a significant impact. Mark confirmed that the emergency and acute medical care service delivery and organisation guideline is in development and due to publish by the end of the year.

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31. The Board discussed the accessibility of NICE guidelines, the role of shared decision making, and the extent to which lay members are able to effectively contribute at committees. Mark Baker highlighted that the NICE pathways visually present NICE's recommendations; but the narrative in the guidelines is important in explaining the rationale for recommendations. The upcoming guidance on managing common infections will utilise a shorter and more visual format. If this is successful, the scope for wider adoption in NICE guidance can be explored. The Board noted the current consultation on proposals for improving how patients and the public can help develop NICE guidance. Also, NICE's role in promoting shared decision making was noted and welcomed. Board members highlighted that shared decision making should be a mindset to inform ongoing discussions between clinicians and service users, rather than limited to specific decision points in the care pathway.

32. The Board received the report and thanked Mark Baker for the work of the Centre.

17/013 – 17/016 DIRECTORS' REPORTS FOR INFORMATION

33. The Board received the Directors' Reports.

34. In response to a query from the Board, Mirella Marlow confirmed that a range of options are being considered to address the risk regarding capacity within the technology appraisals programme, and the Senior Management Team will review these shortly.

35. A member of the public asked whether the reports to the Board could provide more information on how NICE takes equalities considerations into account, when for example, recruiting staff and committees, and developing guidance. Andrew Dillon confirmed NICE's commitment in these areas, highlighting that NICE's methods and processes outline the approach for taking account of equalities considerations when developing guidance. He noted that although equality issues did not explicitly feature in reports to this meeting, further information on this is included in the annual equality report to the Board.

17/017 ANY OTHER BUSINESS

36. None.

NEXT MEETING

37. The next public meeting of the Board will be held at 1.45pm on 15 March 2017 in the Town Hall, Market Place, Durham, DH1 3NJ.

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Chief Executive's report

This report provides information on the outputs from our main programmes to the end of February 2017 and for the financial position to the end of January, together with comment on other matters of interest to the Board.

The Board is asked to note the report.

Andrew Dillon

Chief Executive

March 2017

Introduction

1. This report sets out the performance of the Institute against its business plan objectives and other priorities, for the 11 months ending 28 February 2017 (10 months to the end of January for the financial position). It also reports on guidance published since the last public Board meeting in January and refers to business issues not covered elsewhere on the Board agenda.

Performance

2. The current position against a consolidated list of objectives in our 2016-17 business plan, together with a list of priorities identified by the Department of Health, is set out in Appendix 1.

3. 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 2016 and February 2017 is set out in Charts 1 and 2, below.

**Chart 1: Main programme outputs: April 2016 to February 2017**
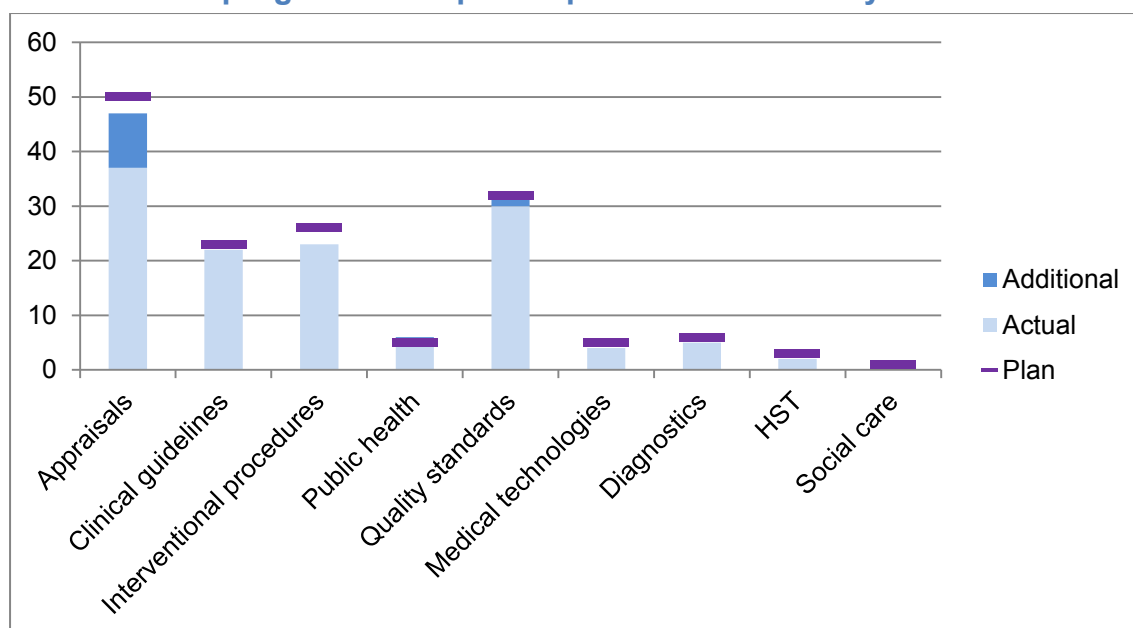
Notes to Chart 1:

a) IP refers to Interventional procedures (minimally invasive surgery)

b) HST refers to the highly specialised technologies programme (drugs for very rare conditions)

c) Medicines summaries consist of both summaries (information on indications, harms and costs) of newly licensed medicines, and advice on the use of licensed medicines in diseases and conditions for which they are not licensed

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

4. 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 January is set out Appendix 4.

5. The performance of other Institute programmes is set out in Chart 2, below.

Chart 2: Advice programmes main outputs: April 2016 to February 2017
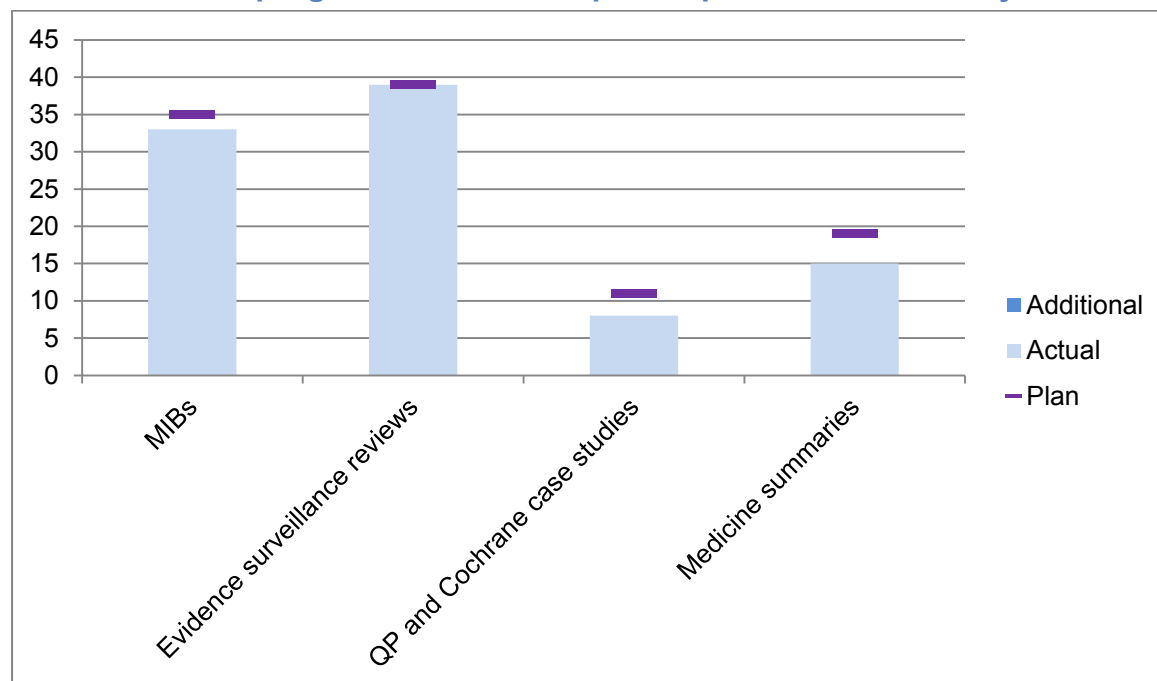

Notes to Chart 2:

a) MIBs (medtech innovation briefings) are reviews of new medical devices
b) QP (Quality and Productivity) and Cochrane reviews report on opportunities for making better use of resources
c) Medicines summaries provide information on new medicines and on the unlicensed or off label use of medicine

Financial position (Month 10)

6. The financial position for the 10 months from April 2016 to the end of January 2017 is an under spend of £2.7m (5.6%) against a net budget (taking into account projected income) of £47.8m, compared to £1.7m (4.4%) against a budget of £38.7m at the end of month 8. Non pay is under spent by £1.2m (3.5%) against budget. Pay is £1.5m (5.2%) under spent against budget. The currently estimated year end position is an under spend of £3.4m (5.9%). The

position of the main budgets is set out in Chart 3. Further information is available in the Business Planning and Resources Director's report.

Chart 3: Main programme spend: April 2016 to January 2017 (£m)
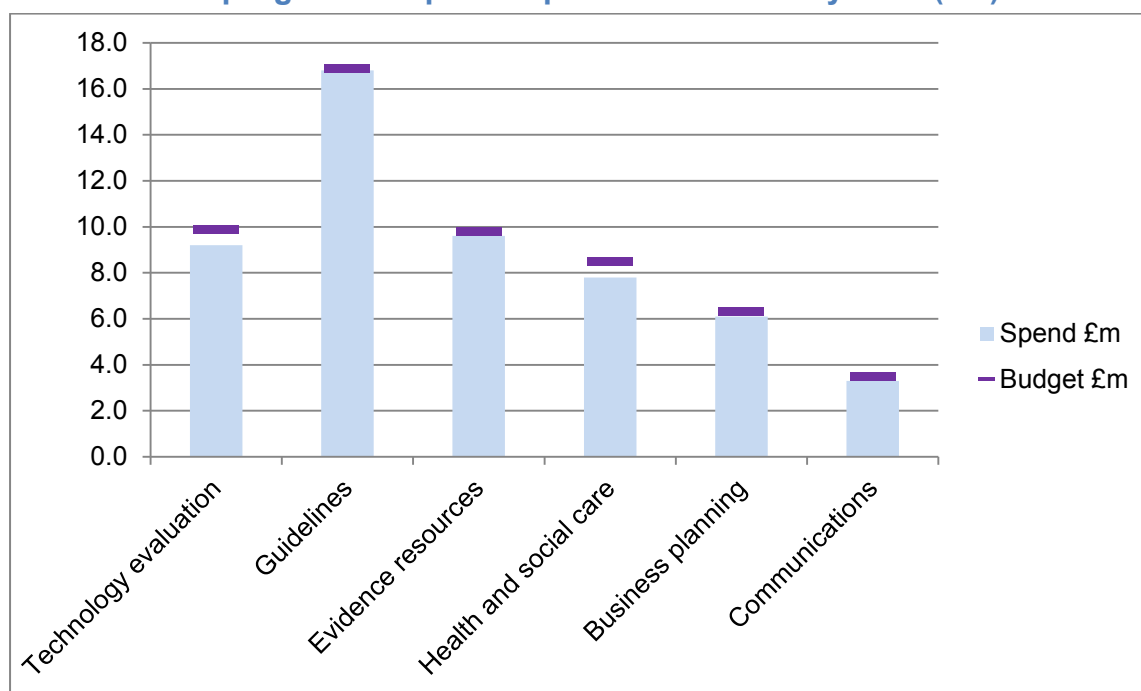
Life sciences strategy

7. I have been invited to join the Senior Officials Leadership Group, which is part of the governing structure for the process from which the Government's Life Sciences Strategy will emerge. This helpful development will increase our influence as the strategy takes shape and will add to the engagement we have so far had with the Office for Life Sciences and the Department of Health. Other members of the Leadership Group come from NHS England, the Department of Health, the Office for Life Sciences, Innovate UK, the MHRA and the Department for Business, Energy and Industrial Strategy. The next meeting of the Group takes place on 15 March.

Appendix 1: Business objectives for 2016-17

In managing its business, NICE needs to take account of the objectives set out in its business plan, the organisational and policy priorities for NICE set out by the Department of Health. In addition, NICE shares responsibility, with other national agencies, for the governance of NHS England's Five Year Forward View. The table below consolidates and tracks progress with the main elements of these influences on our work in 2016-17.

Objective	Actions	Update
Content		
Publish guidance, standards and indicators, and provide evidence services against the targets set out in the Business Plan and in accordance with the metrics in the balanced scorecard.	Guidance, standards and evidence services published and provided in accordance with the schedule set out in Appendix 2 and the balanced scorecard Delivery within the range allowed for in the balanced scorecard	Performance against our business plan objectives is set out elsewhere in the Chief Executive's report. The next balanced scorecard will be published with Board papers in May.
Develop plans to ensure that NICE's guidance products meet the needs of social care providers and commissioners. This includes adapting NICE's methods and processes to ensure that they are appropriate in a social care context and, for public health, ensuring alignment with PHE priorities and ensuring NICE guidance supports local public health services.	Continue to engage with the social care and public health sectors to understand their needs and expectations of NICE guidance Redesign processes and methods to better deliver against these expectations and produce definitive plans by September 2016	This work is being taken forward as part of an updated, Institute-wide implementation strategy. The leadership role for engaging with the social care communities rests with the Health and Social Care Director. New processes are now in place to improve strategic engagement across social care and public health, and new strategic engagement metrics have been agreed for reporting to the Board in 2017-18.
Develop and then implement the first year of a three year strategy to reshape the offer from	Strategy agreed with the Board and principal stakeholders by July 2016	The Board agreed the strategic basis for NICE's offer to the health and care system

Objective	Actions	Update
NICE, to take account of the reduction in Department of Health Grant-in Aid funding.	Actions monitored through regular reports to the Senior Management Team and the Board. A balanced budget has been set for 2017-18.	at its meeting in October 2015 and through discussion at subsequent meetings. In June 2016 it received a report on the detail of the structural changes and in October it received a report on progress to date. The Board will receive the 2017-18 Business Plan for approval at the March meeting.
Develop the methods, processes and capacity to implement the new Cancer Drugs Fund, in conjunction with NHS England.	CDF transition arrangements completed, in accordance with the schedule for 2016-17 agreed with NHS England New methods and processes operational from April 2016 Additional capacity in place by end July 2016	All operational arrangements for the new CDF are now in place.
Manage the change from the existing to the new commissioning arrangements for social care guidance efficiently and sympathetically.	Agree the terms of the transition process with the current contractor by July Put in place the 2016-17 actions in the transition process	Arrangements have been agreed with the Social Care Institute for Excellence (SCIE) on the non-renewal of the contract for developing NICE social care guidelines by the end of 2017-18. A schedule for the completion of current guideline development work has been agreed. Arrangements are now in place for future social care topics to be commissioned from the Guidelines Development Centres.
Implement the relevant recommendations in the final report of the Accelerated Access Review	Assess and report to the Board on the financial, operational and reputational	The Accelerated Access Review report has been published and its findings are being considered in the context of the government life sciences industrial strategy. We are

Objective	Actions	Update
	implications of the final report for NICE guidance programmes Develop an implementation plan and report to the Board on progress with its implementation	engaging actively with the Office for Life Sciences to provide input to the strategy, exploring areas where NICE can contribute and identifying additional resource requirements where necessary.
Review options for the long term development of NICE International's health systems development work in low and middle income economies	Identify and evaluate the options for the long term future of NICE International Board consideration of the preferred option in June Complete the actions for the preferred option by December	The Board received a report on the options for the future of NICE International's work in low and middle income economies at its June meeting. The NICE International team transferred to Imperial College in September 2016, to develop the Gates and DFID-funded work on the International Decision Support Initiative.
Engagement		
Share the stewardship of the Five Year Forward View with the other Arm's Length Body signatories.	Regular participation in the governance arrangements (the main Board and its programme groups) of the Five Year Forward View Strategies and policies, developed by the Five Year Forward View Board are informed, where appropriate, by NICE and its outputs	The Chief Executive and Deputy Chief Executive attend the Five Year Forward View Board (now called the ALB Board) meetings and NICE is represented on the associated programme boards. We have engaged with the development of the local Sustainability and Transformation planning process, at a national level, and locally, through the Implementation Consultants. There is a monthly internal meeting of staff directly engaged with 5YFV activities to track engagement opportunities.

Objective	Actions	Update
		NICE is a co-signatory to two new strategic frameworks produced in conjunction with the other Arm's Length Bodies: the Quality strategy; and the Developing People – Improving Care leadership strategy. We will also be a co-signatory to the new London Devolution Agreement.
Ensure that all new guidance topics that are commissioned align with a health and care system priority, strategy or policy and that each guidance publication clearly articulates the case for adoption for its key audiences.	Each topic associated with a system priority, strategy or policy System owner identified for each topic The case for adoption published for each topic	A senior clinical lead in NHS England is engaged with each clinical guideline. All guidance topics have been confirmed as priority topics with the Department of Health and/or NHS England. Each public health guideline, including the management of common infections, has a designated Public Health England Topic Adviser who attends meetings of the Committee and is involved in all aspects of guideline development.
Identify and operate systems and processes, with NHS England and Public Health England, which ensure that business critical functions are delivered, duplication avoided and opportunities to contribute to and participate in complementary activity are identified and acted on.	Identify the key business relationships between the two organisations by April 2016 Develop and track metrics to assess and monitor the successful operation of these relationships in line with updated partnership agreements	All relationships between NICE and NHS England and Public Health England (PHE) have been mapped, and an updated Partnership Agreement has been signed with PHE. We are tracking progress in the relationships through regular quarterly meetings. The first guideline to be jointly badged with PHE was published in

Objective	Actions	Update
		December 2016, on encouraging the uptake of HIV testing.
Work with the MHRA, the Office for Life Sciences and NIHR to ensure timely technology appraisal guidance on EAMS products is delivered on the timeline agreed with the Department of Health	Ensure the timeline for all EAMS designated products in the technology appraisal programme is consistent with the Scheme's expectations	Our process for engaging with companies and the MHRA on EAMS (Early Access to Medicines Scheme) products is in place and continues to be applied successfully to EAMS products.
Ensure that NICE is compliant with its duties under the Equalities Act 2010	Publish annual equality report in September 2016 Develop an action plan to deliver equality objectives	The annual equality report was presented at the September Board meeting. The cross Institute equality and diversity group is overseeing actions to deliver the equality objectives at its quarterly meetings.
Adoption and Impact		
Develop a consolidated set of metrics and data to assess the uptake and impact of the guidance and evidence services provided by NICE.	Measure and report against a set of indicators that enable the Senior Management Team and the Board to exercise a judgement about the uptake and use of a defined range of guidance and evidence services.	The first biannual uptake and impact report was considered and accepted by the Board at its September meeting. The next report is presented elsewhere on the agenda for the March Board meeting.
Continue to work with CQC to ensure that NICE quality standards and guidelines complement and reinforce essential standards, building on existing work to map NICE Quality Standards into the CQC inspection work.	Agree with CQC on the extent of use of relevant guidance and quality standards in their inspection regime. Put in place a process for sampling the use made of the guidance and standards	Regular meetings are held between NICE and CQC to review how we are working together, and to embed the use of guidance and standards in the CQC inspection process. We have been working closely with CQC to inform 'Quality Matters', a new quality framework for adult social care.

Objective	Actions	Update
Redesign and promote, in conjunction with NHS Improvement, NHS England and the Local Government Association, a comprehensive resource for commissioners and providers on the use of NICE guidance to help make savings, improve productivity and promote optimal use of interventions.	Redesigned resource available from April 2016 Usage monitored and reported to the senior Management Team and the Board	There is an ongoing project to improve the online NICE disinvestment resource so it provides a more useful experience for users. The Board received a progress report at its meeting in November 2016, and a further update is presented elsewhere on the agenda for the March Board meeting.
Subject to the release of budget for this programme of work, Contribute to the National Information Board Framework for Action through the development of an endorsement scheme for health apps, working closely with Public Health England and HSCIC.	Secure the resources necessary for NICE to be able to make a meaningful contribution to the work Subject to adequate resourcing, agree a programme of work with the key partners Deliver against the 2016-17 elements of the agreed work plan	The Centre for Health Technology Evaluation commenced the piloting of 4 Health App Briefings during Q3 following approval of a draft process and methods statement by the Senior Management Team. These will be completed in Q1 2017-18.
Take into account the views and concerns expressed by key stakeholders through the government-wide RepTrak reputation research project	Report RepTrak metrics to the Senior Management Team and the Board	The Reputation Institute has provided additional pro bono consultancy work and the questionnaire has been finalised subject to sign off by the Senior Management Team. The Reputation Institute has given permission for us to use their RepTrak questions in the survey and will carry out the analysis using their trademarked methodology. The survey will go live at the end of March.

Objective	Actions	Update
Productivity		
Operate within resource and cash limits in 2016-17. Actively manage the appropriate application of any non-recurrent funding as early as practicable in the financial year.	Performance against plan for all budgets monitored and reported to the Senior Management Team and the Board	The Institute is on track to operate within its resource and cash limits. Further information is available in the Business Planning and Resources Director's report.
Complete the implementation of the Cabinet Office's Triennial Review recommendations published in July 2015	Review progress and complete a 'one year on' report in July 2016 Complete all actions by December 2016	A full progress report, 'one year on' was provided to the July 2016 Board meeting. The recommendations have been addressed or incorporated into the business objectives in 2017-18.
Promote a culture of continuous improvement within the organisation and uphold the ambition to remain a world-renowned organisation, benchmarking where possible its systems, processes and outcomes against best players internationally	Identify the programmes which might be suitable for benchmarking and assess what, if any, international benchmarking is possible by September Identify 10 publications in peer reviewed international journals which assess and provide an opinion on one or more aspects of NICE's work and submit to the Board for consideration in March	As above, this has been transferred to the business objectives for 2017-18.
Implement the first year of a three year strategy to manage the reduction in the Department of Health's Grant-In-Aid funding and plan for a balanced budget in 2017-18.	Centres and directorates identify savings in order enable the Institute to manage within the reduced Grant in aid funding it received from DH by April Management of change exercises completed in accordance with a schedule agreed and monitored by the SMT	The savings required for the first year (2016-17) have been achieved and we are currently on track to achieve the structural changes and savings required for 2017-18. The SMT reviews progress each month and the Board receives a written or oral update at each meeting. The first management of

Objective	Actions	Update
		change exercise, related to implementing the savings targets in the Evidence Resources Directorate, was approved in August 2016 and implementation completed in October. Management of change exercises are now nearing completion in the Centre for Guidelines, and Health and Social Care and Communications directorates. Consultation recently closed on a management of change exercise in the Business Planning & Resources Directorate.
Put in place arrangements to charge the cost of the technology appraisal programme to industry users, from April 2017	Key stakeholder agreement to charging obtained by September Board regularly appraised of the financial, operational and reputational risks Financial and operational arrangements designed and tested by April 2017 Charging arrangements are able to go live from September 2017 at the latest	Following discussion with the Department of Health, it has been decided that NICE's cost recovery proposals will be considered in the context of the emerging life sciences strategy, in the Spring.
Develop a strategic plan to grow the commercial activity over the next 10 years. This should explore, for example, offering advice, digital protocols, assessments or a subscription service to other countries.	Identify and evaluate the options for increasing income from non-Grant-in-Aid sources, inside and beyond the UK Evaluate the options for the most effective vehicle for delivering this activity, by June 2016	Arrangements are in place to review NICE's international offer following the transfer of the international Decision Support Initiative work, together with the associated staff, to Imperial College in September. A series of proposals describing a range of international services are being brought to

Objective	Actions	Update
	Prepare business cases for each element of the programme by December 2016	the Senior Management Team, including content re-use and knowledge sharing value propositions. An outline of the international strategy of NICE will be brought to the Board in Q2 2017-18.
Enthuse and enable staff to deliver on the Institute's objectives, ensuring that every member of staff has a clear set of personal objectives, a personal development plan and an annual appraisal.	All staff have clear objectives supported by personal development plans Staff are fully briefed on the strategy to manage the changes needed to reshape NICE as a consequence of the reduction of Department of Health Grant-in-Aid funding Current global job satisfaction index in the annual staff survey is maintained or improved	Arrangements are in place for all staff to have objectives and an annual appraisal. Briefings at Institute and team level have taken place on the changes associated with the Institute's business plan and the savings programme. The latest global satisfaction index (percentage of staff who think that NICE is a good, very good or excellent place to work, which was 77% in 2015), was published in September 2016.
Develop an approach to succession planning and attracting and retaining talent and recruiting appropriately skilled staff to key posts, including achieving the specified 2.3% of apprenticeships	As an addition to the workforce strategy, develop a proposal for the Board which defines succession planning as it should apply to NICE, together with a set of actions to deliver on its objectives Secure compliance with the target for apprentices by July 2016	We are fully engaged with the Department of Health and Arm's Length Body-wide arrangements for talent management. Enhanced arrangements are now in place to secure leadership continuity in the Institute's centres and directorates. We currently have 11 apprentices in post against a year-end target of 14; 3 more positions are being advertised with plans for a further 7 over the coming months.

Appendix 2: Extracts from the Directors' reports

Director	Featured section	Section/ reference
Health and social care	NICE has secured resources to test the feasibility of a process to assess the potential environmental impact of guidance recommendations (sustainability impact assessment). This is a unique opportunity for NICE and The Sustainable Development Unit, funded by NHS England and Public Health England, to work collaboratively to provide guidelines for addressing the environmental impact of health care. This work feeds into the national cross system group for sustainable development of the health and care system and NICE has been used as an exemplar in the Sustainable Development Unit's 'Health Check 2017', which focussed on the contribution of arm's length bodies to environmental sustainability. The NICE sustainability steering group will use the results of this feasibility study to influence future work and consider whether NICE appraisals should be sensitised to take account of environmental impact as well as cost impact.	Section/para; para 17
Guidelines	Following the establishment of the Centre for Guidelines in July 2016, a major redesign of the Centre's functions has been proposed in line with NICE's approach to reducing its cost base whilst maintaining the breadth of its offer. Plans will be fully implemented from March following appointments to the new structures over the next two months. The Management of Change exercise has affected every team with changes in both personnel and ways of working. However, any delays in the production have been kept to a minimum. The future programme remains secure and strengthened as a result of the changes.	Section/para: para 6 and 7
Technology evaluation	In October 2016 the Board approved a business case for consultants to undertake the initial work on the CHTE 2020 transformation project. It has not been possible to proceed as planned, mainly because it has not been possible to secure an external consultancy. Instead we have developed an in-house option which is within the budget	Section/para 6

	set for the consultancy project. This option involves existing senior staff taking on additional responsibilities to develop and implement the change project, and backfilling some of their current duties with fixed term or bank staff. Senior staff with time formally allocated to the project include two programme directors (Mirella Marlow and Meindert Boysen) and an associate director (Jenniffer Prescott). We also have a small contingency provision to engage with external consultants if required.	
Evidence resources	A new risk to the digital programme delivery was identified in January 2017. This is related to a change in the IR35 legislation which is coming into force in April 2017. The new legislation will require that a public sector body receiving services from an off payroll intermediary establish whether an employment relationship exists with the intermediary. Some of NICE's digital projects may need to be paused to accommodate a loss of contractors currently providing development services to NICE. A similar challenge is currently being faced by most public sector organisations.	Section/para: 8
Communications	During January and February we responded to 1997 enquiries. We responded to 34 MP letters, with the majority focussing on breast cancer topics. We also contributed to 43 Parliamentary Questions with further interest in the proposed changes to technology appraisals and highly specialised technologies, alongside questions about the availability of continuous glucose monitoring systems and new treatments for pancreatic cancer. We responded to 15 requests made under the Freedom of Information Act. Requested information varied widely and covered our expenditure on alcoholic drinks, salary ranges at all levels of the organisation, further enquiries as part of a campaign on our guideline on chronic fatigue syndrome/myalgic encephalomyelitis and information on anti-depressant prescribing practice.	Section/para 4 and 5
Finance and workforce	Since the previous board report, the savings achieved to date has increased by £1.4m. These are savings that have been taken from the budget following the restructures within Centre for Guidelines, Health and Social Care and Communications. The number and cost of redundancies within these teams cannot be confirmed at the time of writing (2 March 2017) as staff currently at risk of redundancy are still in the redeployment	Section/para: 31-33

period of the management of change process. An update will be provided in the next finance and workforce board report.

The remaining £0.1m of planned 2017-18 savings relates to changes to posts within the Business Planning and Resources directorate. The management of change exercise commenced in February 2017 and is expected to conclude early in 2017/18.

Savings have been front-loaded where possible in order to account for potential slippage in the timeline and uncertainties in some of the savings plans. Therefore there is planned contingency in 2017-18 of £0.5m, assuming the savings mentioned above materialise. This will be used for any short-term cost pressures in 2017-18, transition costs that may arise from future savings programmes or used to set up any new activity such as new outputs produced in response to the accelerated access review.

Appendix 3: Guidance development: variation against plan April 2016 to February 2017

Programme	Delayed Topic	Reason for variation
Clinical Guidelines	2 topics delayed	Familial hypercholesterolaemia (standing committee update): Additional review questions added after this update was commissioned. Publication now planned for Q1 2017/18.
		Mental health of people in prison: 4 week delay to publication following additional quality assurance. Publication date to be confirmed.
	1 topic planned for this financial year but published early	Spondyloarthritis: Published early due the rescheduling of topics. Published in February 2017 (Q4 2016-17).
Interventional procedures	3 topics delayed	Perirectal hydrogel injections to localise prostate cancer irradiation: A resolution request has been accepted and is being considered at Committee on 9 March 2017. The publication date will be scheduled after the meeting.
		Surgical repair of vaginal wall prolapse using mesh: Rescheduled as the programme were awaiting relevant clinical trial information. Anticipated guidance publication date September 2017 (Q3 2017-18).
		Irreversible electroporation for treating pancreatic cancer: Not quorate during December Committee Meeting and therefore discussion did not take place and guidance publication delayed. Anticipated guidance publication will be April 2017 (Q1 2017-18).
Medical technologies	1 topic delayed	Enduralife: Delayed as Committee meeting not quorate. Publication now planned in March 2017 (Q4 2016-17).

Programme	Delayed Topic	Reason for variation
Public Health	No variation against plan 2016-17	
	1 additional topic published in 2016-17, that was not planned for this financial year	Antimicrobial stewardship (AMS): When the business plan was drafted, this topic was not included in the business plan.
Quality Standards	2 topics delayed	Community engagement: effective strategies for behaviour change: Additional consideration required following discussion with Guidance Executive. New publication date is March 2017 (Q4 2016-17).
		Healthy workplaces: improving employee mental and physical health and wellbeing and lowering sickness absence: Clarification required following discussion with Guidance Executive. New publication date March 2017 (Q4 2016-17).
	2 additional topics published in 2016-17, that were not planned for this financial year	Falls (update): Developed as additional capacity became available. Published in January 2017 (Q4 2016-17).
		Menopause: Developed as additional capacity became available. Published in February 2017 (Q4 2016-17).
Diagnostics	1 topic delayed	Virtual chromoendoscopy for real-time assessment of colorectal polyps during colonoscopy: The External Assessment Group (EAG) was asked to carry out further work on the Diagnostics Assessment Report (DAR) prior to consideration by the committee. Committee meetings rescheduled for November 2016/February 2017. Publication now due in May 2017 (Q1 2017-18).
Technology Appraisals	13 topics delayed	Lung cancer (non-small-cell, non-squamous, metastatic) - nivolumab (after chemotherapy): Following the committee meeting on Wednesday 15 June

Programme	Delayed Topic	Reason for variation
		2016, the company that markets nivolumab (Bristol-Myers Squibb), requested to make a further submission including a Patient Access Scheme. NICE agreed that the appraisal could be referred back to the committee. Anticipated guidance publication date is June 2017 (Q1 2017-18).
		Idiopathic pulmonary fibrosis – pirfenidone: An appeal hearing was held on 2 December 2016. The final guidance publication date is now anticipated to be July 2017 (Q2 2017-18).
		Neuroblastoma (high risk, children) - dinutuximab (maintenance): An appeal hearing was held on 30 September 2016. Following the Appeal Panel NICE has taken the decision to suspend the appraisal until there is certainty about the availability of dinutuximab in England, as a consequence of manufacturing and production issues. The final guidance publication date remains to be confirmed.
		Gout - lesinurad (2nd line): The company which has the rights to lesinurad has switched during the course of this appraisal from AstraZeneca to Grünenthal. As a result, NICE has agreed to reschedule the second committee meeting for this topic to enable the company to be adequately prepared. The rescheduled committee date is to be confirmed. The final guidance publication date remains to be confirmed.
		Lymphoma (mantle cell, relapsed, refractory) – ibrutinib: The final guidance publication date remains to be confirmed.
		Pancreatic cancer (metastatic) - nanoliposomal irinotecan (post gemcitabine): We were not in a position to release the ACD following the first Appraisal Committee meeting because the marketing authorisation for the technology had not been granted (and the topic was referred prior to April 2016 and therefore not subject to the new scheduling options for cancer topics as part of

Programme	Delayed Topic	Reason for variation
		the arrangements for the CDF). The ACD has now been released and the second Appraisal Committee Meeting will be held on 31st January 2017. Final guidance publication is anticipated in April 2017.
		Hepatocellular carcinoma (advanced and metastatic) - sorafenib (first line) (TA189): CDF reconsideration. A second ACD has been released. Final guidance publication is to be confirmed.
		Breast cancer (refractory, HER2 positive) - trastuzumab-emtansine (TA371): CDF reconsideration. The final guidance publication date is to be confirmed.
		Lymphoma (non-Hodgkin's, indolent, rituximab-refractory) - obinutuzumab (with bendamustine): The publication date remains to be confirmed.
		Waldenstrom's macroglobulinaemia – ibrutinib: The publication date remains to be confirmed.
		Psoriatic arthritis - secukinumab and certolizumab pegol: Following the release of a second ACD the publication date is anticipated to be May 2017 (Q1 2017-18).
		Colorectal cancer (metastatic, unresectable) - MABp1 (after oxaliplatin and irinotecan): The company have not made a submission to NICE. We are discussing the next steps with the company. The publication date is to be confirmed.
		Hodgkins lymphoma (CD30 positive) - brentuximab vedotin (after ASCT): Following the release of a second ACD the publication date is anticipated to be May 2017 (Q1 2017-18).
	10 additional topics published in 2016-17,	Lumacaftor–ivacaftor for treating cystic fibrosis homozygous for the F508del mutation: At the time of planning the 2016-17 work programme, we had intelligence that this appraisal may not follow routine timescales and would be

Programme	Delayed Topic	Reason for variation
	that were not planned for this financial year	delayed. At this point, the scale of the delay was not known, therefore was not listed as a planned output for this year. Published in July 2016 (Q2 2016-17).
		Prostate cancer (advanced, hormone dependent) - degarelix depot: An appeal was received against the original FAD in 2014, which resulted in the requirement for the appraisal committee to reconsider the topic. At the time of planning the 2016-17 work programme the scale of the delay was not known, therefore this topic was not listed as a planned output for this year. Published in August 2016 (Q2 2016-17).
		Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases: It was not clear at the point of submitting topics planned for 2016-17 that this appraisal would actually publish in this business year. Therefore, it was not included in the planned projects. We are pleased to say that we have now been in a position to publish this additional piece of guidance. Published in September 2016 (Q2 2016-17).
		Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor: It was not clear at the point of submitting topics planned for 2016-17 that this appraisal would actually publish in this business year. Therefore, it was not included in the planned projects. We are pleased to say that we have now been in a position to publish this additional piece of guidance. Published in October 2016 (Q3 2016-17).
		Apremilast for treating moderate to severe plaque psoriasis: Additional to plan for this financial year as the appraisal is a rapid review of TA368. Therefore, it was not included in the planned projects. We are pleased to say that we have now been in a position to publish this additional piece of guidance. Published in November 2016 (Q3 2016-17).

Programme	Delayed Topic	Reason for variation
		Diabetes (type 2) - dapagliflozin (partial review of TA288): This guidance published following a straight to FAD. It was not clear at the point of submitting topics planned for 2016-17 that this appraisal would actually publish in this business year. Therefore, it was not included in the planned projects. We are pleased to say that we have now been in a position to publish this additional piece of guidance. Published in November 2016 (Q3 2016-17).
		Breast cancer (HER2 positive) - pertuzumab (neoadjuvant): Additional to plan for this financial year. It was not clear at the point of submitting topics planned for 2016-17 that this appraisal would actually publish in this business year. Therefore, it was not included in the planned projects. We are pleased to say that we have now been in a position to publish this additional piece of guidance. Published in December 2016 (Q3 2016-17).
		Pomalidomide for multiple myeloma previously treated with lenalidomide and bortezomib: This guidance published in January 2017. Publication brought forward following straight to FAD.
		Sofosbuvir–velpatasvir for treating chronic hepatitis C: This guidance was published in January 2017. It was not clear at the point of submitting topics planned for 2016-17 that this appraisal would actually publish in this business year. Therefore, it was not included in the planned projects. We are pleased to say that we have now been in a position to publish this additional piece of guidance.
		Apremilast for treating active psoriatic arthritis: This guidance published in February 2017 (Optimised). Additional to plan for financial year as the appraisal is a rapid review of TA372. Therefore, it was not included in the planned projects.

Programme	Delayed Topic	Reason for variation
Highly Specialised Technologies (HST)	2 topics delayed	Hypophosphatasia - asfotase alfa (1st line) [ID758]: An appeal has been received. Guidance publication date to be confirmed.
		Lysosomal acid lipase deficiency - sebelipase alfa [ID737]: An appeal has been received. Guidance publication date to be confirmed.
	1 topic planned for this financial year, but published early	Fabry disease - migalastat [ID868]: Originally planned to publish in March 2017, but published in February 2017 (Q4 2016-17).
Social Care	No variation against plan 2016-17	

Appendix 4: Guidance published since the last Board meeting in January

Programme	Topic	Recommendation
Clinical Guidelines	Spondyloarthritis in over 16s: diagnosis and management	General guidance
	Cerebral palsy in under 25s: assessment and management	General guidance
Interventional procedures	Lateral interbody fusion in the lumbar spine for low back pain	Standard arrangements
	Trabecular stent bypass microsurgery for open-angle glaucoma	Standard arrangements
Medical technologies	HumiGard for preventing inadvertent perioperative hypothermia	Recommended for further research
	HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography	Recommended
Diagnostics	Molecular testing strategies for Lynch syndrome in people with colorectal cancer	Recommended
	Integrated multiplex PCR tests for identifying gastrointestinal pathogens in people with suspected gastroenteritis (xTAG Gastrointestinal Pathogen Panel, FilmArray GI Panel and Faecal Pathogens B assay)	Not recommended
Public Health	Drug misuse prevention: targeted interventions	Develop and support population level initiatives
	Antimicrobial stewardship: changing risk-related behaviours in the general population	Develop and support population level initiatives
Quality Standards	Menopause	Sentinal markers of good practice

Programme	Topic	Recommendation
	Tuberculosis	Sentinal markers of good practice
	Learning disabilities: identifying and managing mental health problems	Sentinal markers of good practice
	Intrapartum care	Sentinal markers of good practice
	Falls in older people	Sentinal markers of good practice
	Stable angina	Sentinal markers of good practice
Technology Appraisals	Everolimus for advanced renal cell carcinoma after previous treatment	Recommended
	Apremilast for treating active psoriatic arthritis	Recommended
	Pomalidomide for multiple myeloma previously treated with lenalidomide and bortezomib	Recommended
	Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after chemotherapy	Recommended
	Ibrutinib for previously treated chronic lymphocytic leukaemia and untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation	Recommended
	Sofosbuvir–velpatasvir for treating chronic hepatitis C	Recommended
	Mepolizumab for treating severe refractory eosinophilic asthma	Optimised

Programme	Topic	Recommendation
Highly Specialised Technologies (HST)	Migalastat for treating Fabry disease	Recommended
Evidence summaries – new medicines	Severe sialorrhoea (drooling) in children and young people with chronic neurological disorders: oral glycopyrronium bromide	Summary of best available evidence
	Parkinson's disease with motor fluctuations: safinamide	Summary of best available evidence
Evidence summaries – unlicensed/off label medicines	Refractory extrapulmonary sarcoidosis: infliximab	Summary of best available evidence
Medtech Innovation Briefings (MIB)	Eazyplex SuperBug kits for detecting carbapenemase-producing organisms	Summary of best available evidence
	U-Drain for people needing night drainage of urine or dialysis fluid	Summary of best available evidence
	Smart One for measuring lung function	Summary of best available evidence
	Smartinhaler for asthma	Summary of best available evidence
	Boston Keratoprosthesis Type I for corneal blindness	Summary of best available evidence

Programme	Topic	Recommendation
	CentriMag for heart failure	Summary of best available evidence
	Ekso exoskeleton for rehabilitation in people with neurological weakness or paralysis	Summary of best available evidence
Evidence Surveillance Reviews	Postnatal care up to 8 weeks after birth	Surveillance review decision
	Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care	Surveillance review decision
	Hypertension in pregnancy: diagnosis and management	Surveillance review decision
	Ectopic pregnancy and miscarriage: diagnosis and initial management	Surveillance review decision
	Surgical site infections: prevention and treatment	Surveillance review decision
	Neonatal infection early onset; antibiotics for prevention and treatment	Surveillance review decision
	Caesarean section	Surveillance review decision
	Inducing labour	Surveillance review decision
	Multiple pregnancy: antenatal care for twin and triplet pregnancies	Surveillance review decision
	Healthcare-associated infections: prevention and control in primary and community care	Surveillance review decision
	Peripheral arterial disease: diagnosis and management	Surveillance review decision
Quality and Productivity case studies	Reducing preventable waste in hospital theatres	Examples of quality and productivity improvements

Programme	Topic	Recommendation
Cochrane case studies	No publications	

National Institute for Health and Care Excellence

March 2017

National Institute for Health and Care Excellence

Finance and Workforce Report

This report gives details of the financial position as at 31 January 2017, the forecast outturn for 2016-17 and information about the workforce.

The Board is asked to review the report.

Ben Bennett

Business Planning and Resources Director

March 2017

National Institute for Health and Care Excellence
Finance and workforce report
Date: 15 March 2017
Reference: 17/023

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Summary

1. Table 1 summarises the financial position as at 31 January 2017. There is a full analysis in Appendix A.

Table 1: Financial position at 31 January 2017

	Year to date				Estimated Outturn			
	Budget £m	Expenditure £m	Income £m	Variance £m	Expenditure Budget / Income Target £m	Expenditure £m	Income £m	Variance £m
Guidance & Advice	45.0	44.8	(1.3)	(1.5)	53.9	53.7	(1.5)	(1.7)
Corporate	10.6	10.9	(0.7)	(0.5)	12.8	13.0	(0.8)	(0.6)
Income	(8.4)	0.0	(8.4)	0.0	(10.1)	0.0	(10.1)	0.0
Reserves	0.6	(0.2)	0.0	(0.8)	1.9	0.8	0.0	(1.0)
Net Operational Total	**47.8**	**55.5**	**(10.4)**	**(2.7)**	**58.5**	**67.6**	**(12.5)**	**(3.4)**
NICE International	0.0	2.2	(2.1)	0.1	0.0	2.2	(2.1)	0.1
Scientific Advice	(0.2)	0.9	(1.1)	(0.1)	(0.2)	1.1	(1.5)	(0.2)
NICE Total	**47.6**	**58.6**	**(13.7)**	**(2.7)**	**58.3**	**70.9**	**(16.1)**	**(3.4)**

N.B. The figures in the table are rounded from Appendix A

2. The current position shows a total under spend of £2.7m (5.6%) for the first ten months of 2016-17. This is attributable to vacant posts, under spends on the non-pay budget and additional unbudgeted income generation.

3. The full year forecast outturn is a £3.4m (5.9%) under spend against the revenue resource limit. The reasons for material variances are detailed in this report.

4. The forecast position is after assuming that we will incur further expenditure of £1.0m in relation to potential liabilities resulting from organisational change. As some organisational changes take effect during the final quarter of 2016-17 the under spend may grow as a result of successful redeployment of at-risk staff, holding posts and attrition.

5. Work is progressing to manage the 30% reduction in our Department of Health grant funding by 2019-20. Plans are in place for this to be achieved and a balanced budget is expected for 2017-18.

6. Progress on the implementation of the workforce strategy is detailed in Appendix B. It includes information and updates relating to transformational change, resourcing, maximising potential, pay and reward and the culture of the organisation.

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Financial Position as at 31 January 2017

7. Total net operational expenditure for the first ten months of 2016-17 was £45.1m (see Appendix A for a breakdown). This was a £2.7m (5.6%) under spend against budget.

8. NHS England fund a number of work programmes at NICE resulting in funding in excess of £5.0m for 2016-17. This currently consists of funding for Medical Innovation Briefings (£0.45m), the Observational Data Unit (£0.6m), Mental Health Access and Waiting Times Standards (£1.5m) and costs associated with operating the Cancer Drugs Fund (£2.9m) and the new Commissioning Support Programme (£0.3m). Income and expenditure are in line with expectations for MIBs, ODU and Access and Waiting Times showing break-even positions for these work programmes.

9. The year to date total under spend of £2.7m consists of £1.3m against pay, £0.8m against non-pay and additional income of £0.4m.

Pay

10. Net operational pay expenditure for the first ten months of 2016-17 was £28.0m, which was £1.5m (5.2%) under spent against budget. Of this, £0.4m is currently allocated to pay reserves.

11. As at 31 January 2017 there were 629 whole time equivalent (wte) substantive employees, which included 22.1 wte agency and contractor staff.

12. There are currently 46.3 wte vacant posts in a budgeted establishment of 675 wte, which equates to 6.9% of the total budgeted workforce. Throughout the management of change recruitment, unless by exception, was advertised internally in order to maximise employment opportunities for employees affected by Management of Change exercises. This worked well and as a result we are expecting to make less than 20 redundancies as opposed to the original estimate of in excess of 50. As the first wave of management of changes are coming to an end these restrictions are being temporarily relaxed.

13. The annual target for apprentices employed at NICE by the end of 2016-17 is 14 wte posts (2.3% of the workforce). We currently have 11 apprentices in post, with a further 3 currently being advertised and plans to recruit a further 7 apprentices over the coming months. We are therefore confident that we will reach or exceed this target in year. We need to maintain this target each year, we plan to do so in part by moving some of our apprentices further on in their qualifications. Thus far the budgetary impact has been minimal as teams have used various creative approaches to funding them including using part time vacant balances and pay slippage.

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Agency staff

14. Spending on agency staff continues to fall. Chart 1 below shows agency spend by quarter for the last financial year and the first three quarters of 2016-17. The most recent quarter shows a fall of 19.1% compared to the same period last year (December 2015).

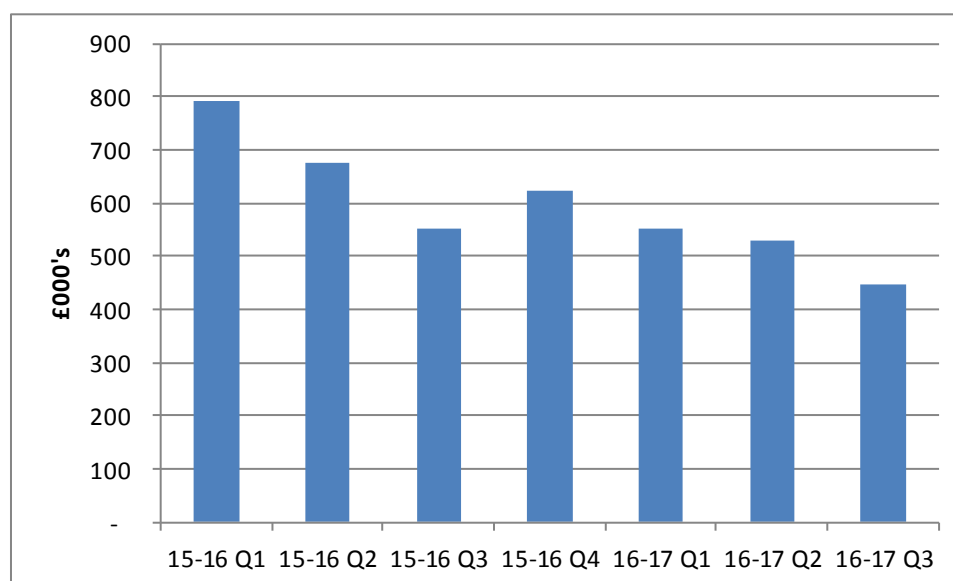Chart 1: Agency spend per quarter since April 2015

Chart 1: Agency spend per quarter since April 2015

Sickness Absence

15. Table 2 shows the average reported sickness rate by directorate for the first ten months of this year compared to the 2015-16 annual rate. The public sector average for the UK in 2013 was 2.9% (ONS data).

Table 2: Percentage absence per WTE by Directorate

Centre / Directorate	Percentage (%) absence per WTE			
	2015-16	2016-17		
	Annual (%)	Quarter 1 (%)	Quarter 2 (%)	Quarter 3 (%)
Centre for Health Technology Evaluation	1.29	1.71	1.67	1.49
Communications	2.35	1.49	1.64	2.47
Evidence Resources	1.79	1.12	0.90	2.68
Health and Social Care	2.18	0.74	1.51	3.38
Centre for Guidelines	2.74	2.31	3.00	2.43
Business Planning and Resources	0.82	4.19	4.69	1.99
% Total	**1.86**	**1.93**	**2.23**	**2.41**

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16. The average notified sickness absence rate for the period 1 April 2016 to 31 January 2017 was 2.2%, equivalent to an annualised average of 4.95 days per wte. This compares to the total average reported for 2015-16 of 4.7 days per wte. However sickness rates do tend to rise over the winter months and during periods of organisational change and uncertainty so they need to be treated with a degree of caution until a full year's data is obtained.

Non-Pay expenditure

17. Net operational non pay expenditure in the first ten months of 2016-17 was £33.9m, which was an under spend of £1.2m (3.5%) against budget.

18. Most sub-categories of non-pay are close to break-even, with the exceptions being under spends arising from the knock-on effect of vacancies and committee costs. Notable examples are lower than budgeted travel, subsistence and programme support costs (£0.8m under spent against a budget of £4.0m).

19. We have also received two refunds relating to unspent monies in 2015-16 with the National Collaborating Centres (Royal College of Psychiatrists and Royal College of Physicians), which has been allocated to non-pay reserves (£0.2m).

20. We have incurred additional non-pay expenditure (£0.2m) in the Centre for Guidelines on the British National Formulary (BNF) printing costs. The BNF is currently printed in Europe so fluctuations in the exchange rate has led to increased expenditure for the BNF72 and BNFC 2016-17.

21. Additional non-pay expenditure (£0.1m) has been incurred in Digital Services due to the dual running of hosting contracts during the transition to our new provider at the start of the year and additional one-off computer hardware purchases (£0.1m) in IT to upgrade the existing infrastructure. Further additional expenditure (£0.2m) relating to in year redundancies has also been incurred as teams re-profile their workforce in light of the ongoing 2020 saving requirements.

Other operating income

22. Other operating income is showing as £0.4m greater than expected for the first ten months of the year. This is due to income generated by the Office for Market Access and receipts for copyrighted documents and content being above expectations. The Medicines and Prescribing Programme is receiving income through delivering training to pharmacists on the GP pharmacist training pathway in partnership with the Centre for Pharmacy Postgraduate Education (CPPE). Finally, as mentioned above due to the BNF printing expenditure being higher than budgeted this also has a knock on effect for recharges to the Devolved Administrations resulting in more income being received (£0.1m).

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Forecast outturn

23. The net operational forecast under spend for 2016-17 is £3.4m (5.8%). Of this, £1.7m relates to pay and the vacancies across the Institute noted above. At the start of the year any anticipated pay slippage is moved centrally to reserves and a part year effect pay budget is allocated to teams.

24. Non-pay is expected to under spend by £1.2m by the end of the year. Of this:

    - The Centre for Health Technology Evaluation is expected to under spend by £0.1m on non-pay, against a budget of £4.6m. The main reason for this is an under spend against the Research Support Unit contract (£0.1m), although this under spend is being used for additional temporary staffing in 2016-17.

    - The Centre for Guidelines is forecast to break-even on non-pay due to increased expenditure on BNF printing costs mentioned above, although this is offset by under spends on committee costs in the Updates and Public Health Internal Guidelines teams.

    - The Health and Social Care directorate is expected to under spend by £0.1m due to under spends on committee running costs within the Quality and Leadership teams.

    - The Business Planning and Resources directorate is forecasting an under spend of £0.3m, mainly due to office running costs, legal fees and Non-Executive Director recruitment fees within the Corporate Office.

    - All under spending budgets are being reviewed as part of the business planning process in order to enable reductions where possible.

    - The remaining under spend on non-pay is due to unutilised reserves of £0.6m.

25. Other operating income is expected to amount to £0.4m more than expected. This is due to the additional income generated by the Office for Market Access Team, Medicines and Prescribing Programme and copyright / content explained above as well as ad-hoc additional income for grants and travel / speaker fee reimbursements.

26. The forecast assumes that £1.0m of reserves will be utilised in order to meet liabilities arising from restructures in the Centre for Guidelines, Health and Social Care, Business Planning and Resources and Communications directorates and other non-recurrent costs associated with organisational change consultations.

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27. Scientific Advice is currently forecast to generate a surplus of £165,000 in 2016-17 as well as carrying an accumulated reserve of £232,000 from previous financial years.

28. The Board is reminded that under the particular financial framework that NICE operates within it is not permissible to exceed the revenue resource limit in any year under any circumstances. This is therefore a risk that has to be very cautiously managed and this is done by maintaining some contingency in the projected year end position.

NICE 2020

29. The Board received a detailed report on progress on the 2020 project at its strategy meeting in January 2017. A summary of the progress to date is given here. Overall the project is risk rated "green".

30. Table 3 details the baseline deficit projection of the savings required to achieve the 30% budget reductions, the savings achieved to date and the phasing of further planned savings.

Table 3: Savings achieved and planned

	2016-17	2017-18	2018-19	2019-20
	£m	£m	£m	£m
Baseline Deficit Projection	-0.2	-4.4	-8.8	-14.0
Cumulative Savings achieved to date	1.2	4.8	3.6	3.8
Planned savings		0.1	5.5	10.2
Expected budget variance Surplus / (Deficit)	**1.0**	**0.5**	**0.3**	**0.0**

31. Since the previous board report, the savings achieved to date has increased by £1.4m. These are savings that have been taken from the budget following the restructures within Centre for Guidelines, Health and Social Care and Communications. The number and cost of redundancies within these teams cannot be confirmed at the time of writing (2 March 2017) as staff currently at risk of redundancy are still in the redeployment period of the management of change process. An update will be provided in the next finance and workforce board report.

32. The remaining £0.1m of planned 2017-18 savings relates to changes to posts within the Business Planning and Resources directorate. The management of change exercise commenced in February 2017 and is expected to conclude early in 2017-18.

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33. Savings have been front-loaded where possible in order to account for potential slippage in the timeline and uncertainties in some of the savings plans. Therefore there is planned contingency in 2017-18 of £0.5m, assuming the savings mentioned above materialise. This will be used for any short-term cost pressures in 2017-18, transition costs that may arise from future savings programmes or used to set up any new activity such as new outputs produced in response to the accelerated access review.

Better Payment Practice Code

34. As a public sector organisation NICE is required to pay all non-NHS trade creditors in accordance with the Better Payment Practice Code. The target is to pay 95% of all valid invoices by the due date or within 30 days of receipt of the goods, whichever is the later. NICE's performance against this code is shown in table 4 below.

Table 4: BPPC April 2016 – January 2017

	Number	£000's
Total non-NHS bills paid 2016-17	2,554	30,464
Total non-NHS bills paid within target	2,416	29,415
Percentage of non-NHS bills paid within target	**94.6%**	**96.6%**
Total NHS bills paid 2016-17	176	1,202
Total NHS bills paid within target	165	1,174
Percentage of NHS bills paid within target	**93.8%**	**97.6%**

35. Annually NICE pays 96% of its invoices to Non NHS Suppliers and 4% to NHS Bodies. Payments to Non NHS Suppliers are twice weekly by BACs and to NHS Bodies twice monthly.

36. A daily report of 'Invoices at Risk of Failure' is now utilised to reduce the risk of late payments and increased efforts are being made across the team to speed up the approval process, this includes communicating with budget holders about the impact of delaying invoice approvals.

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Appendix A – Summary of financial position as at 31 January 2017

Comparison of budget with expenditure and year end projection - 31st January 2017		Year to Date				Estimated Outturn			
Centre / Directorate		Budget £000s	Expenditure £000s	Variance £000s	Variance %	Budget £000s	Expenditure £000s	Variance £000s	Variance %
Centre for Guidelines	Pay	5,756	5,748	(8)	(0%)	6,929	6,924	(5)	(0%)
	Non pay	11,725	11,756	31	0%	13,980	13,986	6	0%
	Income	(579)	(720)	(141)	(24%)	(654)	(795)	(141)	(22%)
	Total	16,901	16,784	(117)	(1%)	20,255	20,115	(140)	(1%)
Centre for Health Technology Evaluation	Pay	6,481	5,999	(483)	(7%)	7,793	7,308	(484)	(6%)
	Non pay	3,804	3,750	(54)	(1%)	4,569	4,494	(75)	(2%)
	Income	(369)	(505)	(135)	(37%)	(470)	(622)	(152)	(32%)
	Total	9,916	9,244	(672)	(7%)	11,892	11,180	(712)	(6%)
Health and Social Care	Pay	6,393	5,980	(413)	(6%)	7,667	7,158	(509)	(7%)
	Non pay	1,990	1,909	(81)	(4%)	2,388	2,295	(93)	(4%)
	Income	0	(31)	(31)	--	0	(30)	(30)	--
	Total	8,383	7,858	(525)	(6%)	10,055	9,423	(633)	(6%)
Evidence Resources	Pay	5,171	5,037	(134)	(3%)	6,213	6,029	(184)	(3%)
	Non pay	4,636	4,648	12	0%	5,563	5,544	(19)	(0%)
	Income	(25)	(66)	(41)	(163%)	(45)	(91)	(46)	(101%)
	Total	9,782	9,619	(162)	(2%)	11,731	11,482	(249)	(2%)
Subtotal Guidance and Advice		44,982	43,505	(1,476)	(3%)	53,933	52,200	(1,733)	(3%)
Communications	Pay	3,131	3,030	(101)	(3%)	3,769	3,630	(139)	(4%)
	Non pay	329	261	(68)	21%	390	309	(81)	(21%)
	Total	3,460	3,291	(169)	(5%)	4,159	3,940	(220)	(5%)
Business Planning and Resources	Pay	2,191	2,227	36	2%	2,633	2,672	39	1%
	Non pay	4,808	4,580	(227)	(5%)	5,828	5,522	(305)	(5%)
	Income	(654)	(676)	(22)	(3%)	(785)	(817)	(32)	(4%)
	Total	6,345	6,131	(213)	(3%)	7,676	7,378	(298)	(4%)

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Appendix A (*Continued*)

Centre / Directorate		Year to Date				Estimated Outturn			
		Budget £000s	Expenditure £000s	Variance £000s	Variance %	Budget £000s	Expenditure £000s	Variance £000s	Variance %
Income	Income	(8,418)	(8,422)	(4)	0%	(10,127)	(10,130)	(3)	0%
	Total	**(8,418)**	**(8,422)**	**(4)**	**0%**	**(10,127)**	**(10,130)**	**(3)**	**0%**
Depreciation / Capital Adjustments	Non pay	833	761	(73)	(9%)	1,000	913	(87)	(9%)
	Total	**833**	**761**	**(73)**	**(9%)**	**1,000**	**913**	**(87)**	**(9%)**
Reserves	Pay	458	16	(442)	(97%)	485	30	(455)	(94%)
	Non pay	132	(177)	(309)	(234%)	1,393	809	(584)	(42%)
	Total	**590**	**(161)**	**(751)**	**(127%)**	**1,877**	**839**	**(1,038)**	**(55%)**
NICE Operational Total	**Pay**	**29,581**	**28,037**	**(1,544)**	**(5%)**	**35,489**	**33,752**	**(1,737)**	**(5%)**
	Non pay	**28,256**	**27,488**	**(768)**	**(3%)**	**35,111**	**33,872**	**(1,239)**	**(4%)**
	Income	**(10,046)**	**(10,420)**	**(374)**	**(4%)**	**(12,080)**	**(12,485)**	**(405)**	**(3%)**
	Total	**47,791**	**45,105**	**(2,687)**	**(6%)**	**58,520**	**55,139**	**(3,380)**	**(6%)**
NICE International	Pay	718	323	(395)	(55%)	862	323	(539)	(63%)
	Non pay	2,308	1,867	(441)	(19%)	2,769	1,867	(902)	(33%)
	Income	(3,026)	(2,084)	942	31%	(3,631)	(2,084)	1,548	43%
	Total	**0**	**106**	**106**	**n/a**	**0**	**106**	**106**	**n/a**
Scientific Advice	Pay	731	726	(5)	(1%)	880	874	(6)	(1%)
	Non pay	242	145	(96)	(40%)	290	252	(38)	(13%)
	Income	(1,175)	(1,148)	26	2%	(1,410)	(1,530)	(120)	(9%)
	Total	**(202)**	**(277)**	**(75)**	**n/a**	**(240)**	**(404)**	**(165)**	**n/a**
NICE Grand Total		**47,589**	**44,934**	**(2,656)**	**(6%)**	**58,280**	**54,841**	**(3,439)**	**(6%)**

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Appendix B – Workforce Strategy Update at 28 February 2017

The workforce strategy was approved at the July 2015 Board meeting. Work is continuing to progress activities in all five areas of demand that were identified, which will develop further over the coming year. The table below outlines activity that is currently underway.

Transformational change	
• Enabling change • Business and workforce planning	HR has supported the change management process affecting three directorates. This involved the development of an implementation plan aligned to the change process which maximised redeployment opportunities across all directorates affected. This approach has significantly reduced the number of anticipated redundancies. Staff who remain at risk of redundancy are now being supported by HR. This support includes the offer of outplacement support which has been procured from Right Management.
Resourcing	
• Recruitment • Retention • Innovation	HR is continuing to provide support and training to managers in using the TRAC recruitment system which was rolled out in July 2016. The Business Services Authority (BSA – our outsourced recruitment provider) ran training for managers in February, and updated materials will be added to NICE Space in the coming weeks. BSA continues to perform well against KPIs, and we are seeing the benefits that the streamlined TRAC system is bringing. In January, the average time from advertising to offer stage was 27 days, against NICE's operational target of 45 days.
Maximising potential	
• Leadership and management • Managing performance • Succession planning and talent management	In January, HR has launched a new learning management system, NICE Learning Zone. The system is being used to manage all internal training bookings, including health and safety inductions, lunch and learn sessions and Writing for NICE workshops. It also has a range of e-learning modules on a range of topics including induction, health and wellbeing, leadership and management and handling change.
Pay and Reward	
• Total reward • Pay review	The £95k exit payment cap for public sector workers will be introduced when the regulations are confirmed. HR will continue to communicate with staff as soon as an enactment date is confirmed. NICE is responding to the IR35 legislation with a collaborative effort between the Finance, Procurement and HR teams in order to fully understand the organisational impact and risks. The SMT has agreed that NICE will run a local Clinical Excellence Award scheme for 2017, which recognises exceptional performance in consultants. The HR team will

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shortly be writing to all eligible consultants to advise them of the application process.

Culture	
- Engaged workforce - Inclusive workforce - Wellbeing at work	NICE's annual Healthy Work Week ran in January and was well received by staff. A range of activities were arranged across the Manchester and London sites, and a range of resources were added to NICE Space and NICE Learning Zone for all staff, including homeworkers, to access. On-site activities included lunchtime walks and runs, Pilates and mindfulness, as well as mental health awareness sessions. The SMT has agreed the timelines for the 2017 Staff Survey, which will be launched in May 2017. This year, the Health and Wellbeing questions will be extracted from the main survey, and run as a separate survey which focusses exclusively on wellbeing and will be used to shape the activities of the Health and Wellbeing Strategy Group. NICE has ended its contract with OH Assist, its former Occupational Health provider, following a period of poor achievement of KPIs and inconsistent customer service. Health Assured has now been appointed as NICE's new occupational health supplier.

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Business plan 2017-18

The business plan sets out our business objectives and performance measures for 2017-18. It has been updated since the version reviewed by the Board in February to reflect feedback from the Board and the Department of Health.

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

Andrew Dillon

Chief Executive

March 2017

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Business Plan: objectives and performance measures

2017 - 2018

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Introduction

1.   This plan sets out our business objectives and performance measures for 2017-18.

2.   Our purpose is to help improve the quality, sustainability and productivity of health and social care. We do this by producing guidance and information on effective practice and public health interventions, which enable people working in health and social care to make better decisions with and for those for whom they are providing services. We take account of value for money in developing our guidance, by recognising that new forms of practice need to demonstrate the benefits they bring against what they displace, and by recommending better targeting of interventions of limited value and opportunities for disinvesting from ineffective interventions. Our objectives also support the delivery of NHS England's Five Year Forward View and the Department of Health's Shared Delivery Plan.

3.   We promote our guidance and information using our own as well as a range of third party channels, including digital media and we help people to use it by providing practical support tools. NICE has a unique role in the health and care system transformation given its remit across health care, public health and social care and is therefore well placed to adopt this system-wide perspective.

4.   Established in April 1999 to reduce variation in the availability and quality of NHS treatments and care, our role was extended in 2005 to include advice on effective and cost effective public health practice. In 2009, we were asked to produce quality standards, derived largely from our clinical guidelines and to take responsibility for developing and maintaining clinical and public health indicators in the Quality and Outcomes Framework (QOF). At the same time, our technology evaluation programme was extended and we added more capacity to evaluate medical devices and diagnostics. Since 2013, our remit has included guidance and quality standards for adults' and children's social care, and highly specialised technologies for very rare conditions.

5.   Our objectives are framed around our three strategic objectives which bring together our priorities:

*   Delivering guidance, standards, indicators and evidence, helping to achieve high quality, sustainable services, supporting the health and care system to use its resources efficiently, and contributing to a thriving life sciences industry;

*   Supporting adoption and impact by working with others to provide practical tools and support to help people make the most of our work and to measure its use;

*   Operating efficiently, by using our resources productively and sustainably, and by supporting our staff to deliver on their full potential.

The context in which we work

The health and care system

6.   Demographics, constrained resources, public expectation and a wave of new technologies are combining to present the health and care system with both challenges and opportunities. Much of what is needed can be done by the NHS, but much too will require collaboration with local government, voluntary organisations and employers. This argues for a renewed effort to do what we know will help to promote good health and prevent ill-health, support patients to gain control of their care through using shared budgets, and promote better integration of care between hospitals and general practitioners and between the NHS and social care. The Department of Health is supporting the move to better integrate services, supporting local councils to help them work more effectively with health and social care organisations.

The 2015-20 Spending Review

7.   The Government Spending Review, published in November 2015, sets a challenging agenda for the public sector. Although the NHS settlement provides for small real terms growth and some front loaded investment in service transformation, the outlook is still difficult and the position for local government is even more so, with funding constraints likely to impact significantly on those aspects of social care for which we are producing guidance. NICE, too, is affected by the Review. The Department of Health has confirmed that our strategic savings challenge will be a real terms reduction of 30% in our Grant-in-Aid administration funding and a 10% reduction in our programme funding, from our 2015-16 baseline to be achieved by 1 April 2019. This amounts to a reduction of around £14m off our projected 2016-17 baseline. Although achieving savings of this magnitude will require significant changes to the nature and extent of what we can offer, we believe that we can nevertheless keep the essential shape of our offer, combining a range of guidance, standards and indicators, with an array of evidence services, adoption support and added value, fee for service programmes. We have developed a strategic savings programme which is currently underway.

Working with our system partners

8.   We are committed to supporting the NHS, public health and social care, and organisations in the wider public and voluntary sector to deliver these changes, making the best use of their resources by setting out the case for investment and disinvestment through our guidance programmes and our other advice. From identifying specific recommendations that can save money, to advice on reconfiguration to support disinvestment from ineffective services, NICE has a range of products and services to help realise savings that can be reinvested. We will work collaboratively with the Department of Health, NHS England and Public Health England, and our other national partners and professional bodies, on their plans for a clear and compelling long-term vision for the future of health

and care services, and ensure that our advice and guidance forms an integral part of their plans for change and supports a sustainable future.

9.   We need to ensure that our guidance is designed to work with a system that:

- Is operating with limited real-term funding growth in health, and real terms reductions for social care and local government;
- Is seeking significantly improved quality of care and value for money through a variety of means, including more integrated working in the sustainability and transformation plan (STP) footprints, and sharing of services and resources at local level;
- Designs and delivers services in conjunction with patients and users, and external partners;
- Is devolving resources and decision-making to local communities;
- Is increasingly dependent on shared knowledge of the needs of those it serves;
- Will require a sophisticated commissioning structure, in both the NHS and local government, handling multiple influences and ownership;
- Is experimenting with a range of service delivery models;
- Offers choice to those using it, with that choice being defined in different ways in different settings.

Supporting decommissioning

10. In the next 5 years, as the health and care system faces significant financial challenges, NICE will continue to help drive the optimal use of resources. To do this, we will build on the existing portfolio of disinvestment work, including developing our offer to support appropriate care. We will continue to support the optimal use of medicines and 'deprescribing' through the work of the Medicines and Technologies Programme, including focussed work on specific medicines. We also provide a 'forward view' that will show anticipated costs, by quarter, for future technology appraisal guidance. This will support the commissioning process, particularly for specialised products.

11. We will continue to actively engage with partner organisations to identify and improve uptake of disinvestment opportunities. In particular, we are working with NHS England's RightCare, NHS Improvement and the CQC to coordinate and align medicines optimisation activities. Mapping our medicines optimisation work and other disinvestment opportunities into the RightCare approach of maximising value by reducing variation will help provide greater traction across the system. NICE is also supported by the Healthcare Financial Management Association (HFMA) policy and research committee, which has a reputation for demonstrating how disinvestment in services can result in better clinical outcomes and patient experiences.

12. Another strand of NICE work to optimise NHS expenditure relates to 'Shared Decision Making', in which patients and clinicians work together to determine a test or treatment package that reflects patients' preferences. This approach has the benefit of improving patient satisfaction and, in many cases, of also

reducing the use of more expensive, invasive technologies. NICE is working with NHS England to support this agenda, through a number of strands of work. This includes making the evidence base for NICE guidance more accessible, considering a guideline on shared decision making, and providing a repository for a range of online tools.

Digital health and care services

13. Expectations regarding the potential of digital interventions and services to transform the delivery of care, improve access and save costs remain high across the health and social care system. In practice however, whilst the evidence base for digital technologies is improving, it remains limited and the confidence of decision makers to recommend or fund these technologies continues to be low. NICE is committed to supporting the evaluation of digital technologies going forward with a number of initiatives. In early 2017, NICE piloted the development of Health App Briefings (unfunded) to provide a summary of the evidence available on apps with a relatively mature evidence base. These briefings would be available to health professionals, commissioners and the public to help understand the strengths and weaknesses of the digital product they cover. In a separate initiative, NICE is preparing to support NHS England deliver the digital IAPT pilot programme. NICE will continue to engage with NHS England to identify and support other high priority digital programmes.

Public expectations of NICE

14. As NICE guidance and quality standards extend their reach beyond clinical and public health practice and into social care, the expectations of people for whom NICE is working will continue to rise. We already know that investing in disease prevention and health promotion is good value for money. We will use our public health guidance and quality standards to support the arrangements for public health in England to promote that message.

15. The Government is committed to enabling the public to influence the development and delivery of health and social services. NICE has, from its inception, actively encouraged and supported the involvement of patients, service users, carers and the public (organisations and individuals) in the development and implementation of its guidance and advice, and in providing versions of this guidance and advice in accessible formats. In 2017 we will work closely with NHS England to improve support for shared decision making between patients and professionals. Over the years, NICE has broadened opportunities for public scrutiny of our decisions by providing access for the public to the meetings of our advisory bodies. In 2016, we reviewed our arrangements for engaging patients, service users and the public. The actions arising from this review will be implemented during 2017-18, following a public consultation on our proposals.

16. What we offer is enhanced by NICE Evidence Services. This programme has extended our functions beyond guidance production to providing a comprehensive evidence and information service for healthcare, public health

and social care. This includes an on-line portal for easy access to evidence, accredited guidance and other products, an evidence service targeted at primary care and specialist information services for accessing bibliographic content purchased by the NHS.

17. Work to develop the digital presentation of all NICE products, including standards, will continue to improve and widen access to our content. This includes a pathway presentation on the NICE website and the ability to personalise access to our advice.

Public health

18. Since the transfer of most of the local responsibility for public health from the NHS to local government in 2013, NICE has worked closely with local authorities to ensure that guidance and related products are clear, relevant and accessible. We have also continued to build on our existing relationships with NHS audiences, and with Public Health England, which continues to deliver many public health interventions and programmes.

19. Working through the STP footprints, we will support local authorities to achieve coherent and co-ordinated commissioning strategies across the boundaries of healthcare, social care and public health, and for prevention and health improvement services and programmes. Health and Wellbeing Boards also have responsibility for producing Health and Wellbeing Strategies which are informed by joint strategic needs assessments (JSNAs) but which should be evidence-based in terms of setting out priorities. NICE guidance, advice and standards, on clinical practice, public health and social care, provide an important resource for the local government and NHS leaders responsible for these arrangements. NICE Evidence Services, with its remit to support health, public health and social care, will provide rapid access to evidence and best practice advice.

20. The partnership agreement between NICE and Public Health England (PHE), refreshed and updated in early 2016, sets out how the two organisations will work together to share and develop knowledge and intelligence on healthcare and on public health interventions and services at a national and local level. We are working with PHE to jointly badge guidelines, and to actively support implementation of recommendations for public health at a local level. We will continue to work with PHE to ensure that there is no duplication in our roles in compiling evidence on effective public health interventions.

21. NICE is leading and contributing to a number of work areas to support the fight against antimicrobial resistance. These include the development of a series of short clinical guidelines on the management of common infections and a new product, Antimicrobial Prescribing Advice, to support the stewardship of new antimicrobials coming to market. Work areas also include considering the potential role for Technology Appraisal guidance for some antimicrobials and exploring how links to up-to-date information on resistance rates can be included in the BNF.

Social care

22. NICE guidance and quality standards for social care are commissioned by the Secretary of State for Health and, in the case of children's social care, the Secretary of State for Education. The first of these quality standards for social care was published in 2013. They are intended for use in conjunction with the frameworks and regulation already in place, providing practical support to help drive up the quality of adult and children's care. They also support the work of local Health and Wellbeing Boards and help local people hold commissioners and providers to account.

23. We recognise that resource allocation decisions are a matter for local councils and believe that using an evidence-based approach to cost-effectiveness can assist local commissioners in making these decisions. This highlights the importance of ensuring that quality standards describe cost effective practice.

24. Ministers want the standards to be flexible enough to support the 'social care context'. Our social care quality standards therefore take account of personalisation, so that the evidence and the standards are accessible enough to inform the choices of the personal budget-holder as commissioner. To ensure they are designed and presented in a way that meets the needs of the individuals who deliver social care and the organisations they work for, we produced two 'short guides' in 2016. These were well received by the social care sector, and we will roll these out further during 2017.

25. The social care community has long been an important audience for any NICE guidance and advice that impacts on broader health issues, particularly from our public health programme. NICE has experience in developing guidance across the health and social care interface in areas such as dementia. As arrangements for integration continue to develop within STP footprints, and within the devolution arrangements in Manchester, we will support this important emphasis on integration with our guidance and standards.

Life sciences industry

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

27. Our relationship with the industry is complicated. Our primary responsibility is to help those who use the health and care services and those who care for them get the best outcomes and to use the resources available effectively. However, because of the impact we have on the companies whose products we review, we also have a responsibility to consider the impact of our work on them. This requires a delicate balance but we can help the industry make it more likely that

the products they bring to the NHS will address the needs of patients in an affordable way and, as a result, enhance their prospects in the market.

28. 2017 will be a challenging year for the NHS, as it enters one of the most difficult periods in its history. With marginal real terms funding increases, resources will need to go further and every opportunity for more efficient ways of working will need to be deployed. Spending on drugs, devices and diagnostics will inevitably come under ever greater scrutiny. At the same time, the Government is developing a life sciences industrial strategy, in recognition of the importance of the sector to the UK economy, as the country prepares to leave the European Union. And Government and industry will discuss future medicines price regulation arrangements after the 2014 Pharmaceutical Price Regulation Scheme comes to an end in December 2018.

29. We want to reduce the risk for companies introducing products to the UK market by helping them focus their value proposition on the most compelling data. We want to work with companies and the NHS to design and manage novel evidence generation processes and new data-driven funding models for fast-track approval and reimbursement which provide benefits to patients and make the best use of NHS resources. Building on the international value of a positive NICE appraisal, we want to extend our support for companies by increasing the visibility and accessibility of the Office for Market Access and Scientific Advice Programme outside the UK. And we want to support the UK in developing a world-leading approach to using data to track outcomes and manage early access to worthwhile new technologies.

30. Our vision for a thriving relationship between the industry regulators and the NHS is an environment which enables and promotes adaptive, integrated regulatory approval, followed by the fast, data-driven evaluation, reimbursement and adoption of compelling, affordable value propositions. In 2017, subject to the outcome of consultation, we will be implementing changes to better manage access to new drugs and medical technologies (devices and diagnostics) by simplifying and speeding up the appraisal process. These changes will benefit patients by providing access to the most effective and cost effective new treatments more quickly and will help the life sciences industry by increasing the opportunities for companies to help manage the introduction of their new technologies into the NHS.

NICE's unique offer

31. In a changing environment, it will be important for NICE to display some important characteristics, which will remain relevant regardless of the nature of the changes taking place. This allows us to produce guidance and standards that promote better integration between health, public health and social care services. Our work will therefore be:

- *Distinct:* delivering 'only from NICE' recommendations and services;
- *Aligned:* informing and enabling the ambitions and capacities of the health and care system;

- *Robust:* working with transparency, rigour, inclusiveness and contestability;
- *Efficient*: using our resources carefully, delivering our work when it is needed and responding to changes in the needs of the people and organisations we serve.

32. Wales, Scotland and Northern Ireland have each developed their own approach to the organisation and management of their health and care services. They use different combinations of the guidance and advice we produce in ways which reflect their priorities, the needs of their staff and the local resources they have available to inform evidence-based practice. We tailor our relationship to the needs of each country and have effective working and contractual arrangements with the agencies which undertake complementary functions.
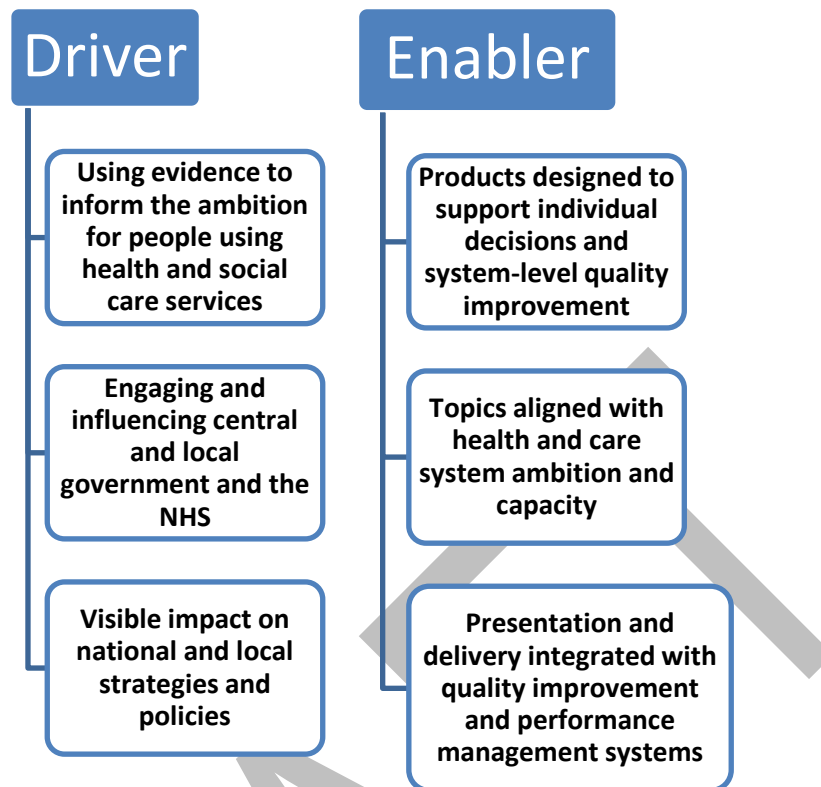
Programmes and objectives

Strategic Objectives

33. Our strategic objectives for 2017-20 are to:

- Deliver guidance, standards, indicators and evidence, helping to achieve high quality, sustainable services, supporting the health and care system to use its resources efficiently, and contributing to a thriving life sciences industry;

- Support its adoption and impact by working with others to provide practical tools and support to help people make the most of our work and to measure its use;

- Operate efficiently, by using our resources productively and sustainably, and by supporting our staff to deliver on their full potential.

34. NICE has the potential to both drive and enable the design and the effective delivery of services provided by the health and care system. Our knowledge of the evidence for good quality care and outcomes and our ability to convert it into guidance and other forms of information which those working in both systems can use to improve their decisions, puts us in a unique position to influence the nature and shape of services into the future.

35. The graphic below summarises our ambition for NICE.

Driver	Enabler
Using evidence to inform the ambition for people using health and social care services	**Products designed to support individual decisions and system-level quality improvement**
Engaging and influencing central and local government and the NHS	**Topics aligned with health and care system ambition and capacity**
Visible impact on national and local strategies and policies	**Presentation and delivery integrated with quality improvement and performance management systems**

36. The business objectives together with the accompanying actions for 2017-18 are on page 29. The 'balanced scorecard', which sets specific targets based on these objectives, is presented in Appendix 1. Details of the publication outputs for each programme are provided in Appendix 2.

Programmes, products and services

Content

37. *Quality standards:* NICE quality standards provide clear, concise statements of high-priority areas for quality improvement. In 2013, following publication of the Health and Social Care Act, the scope of our quality standards grew to encompass public health and social care. They help organisations improve quality by providing measures of best practice to support ongoing performance improvement, and can provide information both for commissioners and providers. The programme supports the integration of services by covering topics in health, public health and social care. Over 30 standard topics are in development at any one time, through a process that actively involves those with expertise and understanding of current services. Quality standards include content related to all three dimensions of quality – safety, effectiveness and patient experience – and take into account overall cost impact.

38. Although quality standards are not mandatory, they are an important driver for change within the arrangements for commissioning and service delivery in health and social care. Both the Secretary of State and NHS England must have regard to NICE quality standards. Quality standards are also identified as

a key tool for bringing clarity to and measuring quality, as part of the National Quality Board's Shared commitment to quality. In public health, NICE is working with Public Health England to support their use in local government, including actively encouraging an ongoing process of data collection. To facilitate use of quality standards by commissioners, in response to feedback, we are reformatting quality standards to enable them to more easily be aligned to local priorities.

39. Quality standards cover a broad range of topics (healthcare, social care and public health) and are relevant to a variety of different audiences, which will vary across the topics. Audiences include: commissioners of health, public health and social care; staff working in primary care and local authorities; social care provider organisations; public health staff; people working in hospitals; people working in the community and the users of services and their carers. The presentation of quality statements allows users to define and select the statements relevant to their particular area of interest, for example in terms of setting, audience, condition, or population.

40. ***Guidance on health technologies:*** technology appraisals develop recommendations for the NHS and patients on drugs and treatments based on their clinical and cost effectiveness. We appraise all new drugs for cancer, and significant license extensions for cancer drugs. We consider a subset of all other new technologies offered to the NHS. Regulations provide for the mandatory funding of drugs and treatments which are recommended in a technology appraisal and that funding must normally be available within 3 months of a positive appraisal. Patient entitlement to these drugs is set out in the NHS Constitution.

41. NICE also has responsibility for evaluating and providing advice to NHS England, on selected highly specialised technologies which have been developed for treating conditions which affect very small number of patients (in England). Regulations provide for the mandatory funding of drugs and treatments which are recommended in a highly specialised technologies evaluation and that funding must normally be available within 3 months of a positive evaluation. Patient entitlement to these drugs is set out in the NHS Constitution.

42. NICE will continue to lead on the topic selection programme for the technology appraisal and highly specialised technologies evaluation programmes for the Department of Health. We will build a strong working relationship with the new contract holder for the NIHR Horizon Scanning functionality; National Institute for Health Research Innovation Observatory (NIHRIO) based in Newcastle.

43. Medical technologies (devices and diagnostics) are notified directly to NICE, usually by commercial sponsors and sometimes by clinical leads, and the Medical Technologies Advisory Committee (MTAC) decides which technologies should be evaluated, and by which guidance programmes. Our ***medical technologies guidance*** aims to identify cost saving interventions and recommends them to the NHS when the sponsor's case for adoption is supported by the evidence. The guidance is based on advantages to patients

and to the NHS, compared with current practice, and it includes detailed consideration of costs, care settings and of the whole patient pathway.

44. Our *diagnostics guidance* advises the NHS and patients on the clinical and cost effectiveness of diagnostic technologies. The Diagnostic Advisory Committee produces guidance on a range of related technologies that have the potential to transform clinical diagnosis pathways to achieve better outcomes. The potential of technologies to provide a diagnosis at the "point of care" and to avoid attendances in secondary care is often an important consideration.

45. In 2014, NICE began to produce *Medtech Innovation Briefings (MIBs)* to provide the NHS and social care with objective information on promising medical technologies as an aid to local decision making by clinicians, commissioners and procurement professionals, and to inform patients about new technologies. We will work collaboratively, particularly with NHS England, to develop MIBs as a rapid responsive resource where the need for information has been identified directly from the NHS. We will also exploit the potential of MIBs to address technologies across the whole spectrum of NHS and social care settings.

46. Since July 2016, a team at NICE is working with colleagues in NHS England to support the arrangements laid out for the 'Appraisal and Funding of Cancer Drugs (including the new *Cancer Drugs Fund*); a new deal for patients, taxpayers and industry'. We will continue this work in 2017-18, and in particular will be appraising a number of cancer drugs currently on the fund that we have not looked at before. We will also support the consideration of data collection agreements for drugs that have the potential to be included in the new fund, and work with Public Health England and NHS England to monitor data collection during the CDF period.

47. From 2017 onwards, NICE will be developing outputs and activities to support NHS England's commissioning of specialised services through the new *Commissioning Support Programme (CSP)*. NICE will develop a statement outlining its involvement in NHS England's clinical policy consideration process at the start of the 2017-18 business year.

48. NICE will continue to provide advice to the Department of Health on the feasibility of operating patient access scheme proposals put forward by companies through the *Patient Access Schemes Liaison Unit (PASLU)*. We will explore with colleagues in NHS England how PASLU can support the consideration of commercial access agreements proposed as part of the Cancer Drugs Fund.

49. *Interventional procedures guidance* advises on the safety and efficacy of treatments and approaches to diagnosis. It includes procedures used in hospital, in the community and in patients' homes. An interventional procedure is one used for diagnosis or treatment that involves making a cut or hole in the body, entry into a body cavity or using electromagnetic radiation (including X-rays or lasers). Topics for this programme are referred by any source including: manufacturers, patients, other programmes at NICE and the health

professionals who wish to use them. The outputs are applied with consistency in the NHS and in the private health sector.

50. *NICE guidelines:* make evidence-based recommendations on a wide range of topics, from preventing and managing specific conditions, improving health, and managing medicines in different settings, to providing social care and support to adults and children, and planning broader services and interventions to improve the health of communities. Guidelines covering clinical and social care topics aim to promote individualised care and integrated care, for example, by covering transitions between children's and adult services and between health and social care. There is also an emerging programme of service delivery guidance, complementing an earlier and highly influential programme of cancer services guidance which was completed in 2006.

- *Clinical guidelines* consist of sets of recommendations on the appropriate treatment and care for patients with specific diseases and conditions. Though not covered by a funding requirement or the NHS Constitution, they are an important reference for patients, health and social care professionals and commissioners in the NHS. Like other NICE guidance, the recommendations in our clinical guidelines are assessed for both their clinical and cost effectiveness and they integrate other guidance outputs, such as technology appraisals, and interventional procedures, when these are relevant to the topic. Importantly, our clinical guidelines are also the primary source for our quality standards and form the main source for the development of NICE Pathways.

- The current portfolio of clinical guidelines is approximately 200; the largest collection of clinical guidelines in the world. A further 10-15 topics have been referred to the programme by NHS England and these will be commissioned over the next two years. At any given time, between 55 and 65 clinical guidelines (including updates) are in development.

- Maintaining the currency of the guidelines portfolio is a vital element of its relevance to the NHS and its suitability as the principal source for Quality Standards. As the portfolio has grown, reviewing and updating guidelines has become a major activity in the programme. The nature and extent of the library, in the longer term, will need to be agreed with the Department of Health and NHS England.

- *Social care guidelines:* The 2012 Health and Social Care Act established a new responsibility for NICE to develop guidance and quality standards for social care in England. This provides an opportunity to apply an evidence-based system to decision-making in the social care sector, similar to that provided for the NHS. It will also allow us to produce guidance that promotes better integration between health, public health and social care services, and will be developed in close partnership with, rather than imposed upon, service users and carers, practitioners and organisations working in social care. The programme currently has between 7 and 10 guidelines for social care in development at one time. Following significant engagement with stakeholders, to understand their

priority areas and the specific needs of our social care audiences, an extended list of topics will enter the scoping and development phase during 2017.

- *Public health guidelines:* NICE guidance in public health covers a range of topics largely addressing health improvement and wider determinants, such as tobacco cessation services and prevention of obesity. It is a significant programme of work that has between 20 and 24 topics under development at any one time. In 2014, we were referred a library of over 60 public health topics to inform future quality standards and final agreement on the guidelines portfolio will be reached in 2017, covering a broad range of topics that have been prioritised with partners, including Public Health England. Included in this work is a programme of new guidance on the management of common infections which will be additional to the portfolio of quality standards and will assist the national strategy to reduce antimicrobial resistance.

51. *Medicines and prescribing:* We provide a comprehensive suite of guidance, advice and support for optimal use of medicines. These include a horizon scanning function for new drugs (*UK Pharmascan*), evidence summaries, key therapeutic topics, medicines awareness services and the associates programme. Prescribing advice is commissioned through the British National Formulary (BNF), and information about licensed drugs is available through NICE's digital evidence resource. We are working with the BNF on data structure and standardisation, and on the section on antimicrobial use to support the drive to reduce antimicrobial resistance.

52. Evidence summaries provide information for the use of unlicensed/off-label drugs in conditions where there is no licensed alternative. We also produce evidence summaries for new medicines which are not the subject of a timely Technology Appraisal. These products do not constitute formal recommendations, but summarise the available evidence to facilitate commissioning policies and local decision-making.

53. *NICE menu of indicators* provide a range of evidence-based indicators to support national and local measurement of quality improvement. NICE has a robust process in place for developing indicators, which was recognised in 2015 through two independent reviews carried out by the King's Fund and the Health Foundation.

54. Indicators developed by NICE are used in the QOF to reward general practice for the provision and to standardise improvements. NICE will work closely with NHS England to support planned changes to general practice indicators in England.

55. NICE also produces indicators for public health, and to help Clinical Commissioning Groups identify areas for improvement, to enable them to compare their care processes and outcomes with other groups, locally and nationally. NICE will work closely with NHS England to ensure indicator development reflects their priority areas.

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

57. NICE Evidence Services are designed to meet the needs of users from across the NHS and social care, including (but not restricted to) clinicians, nurses, pharmacists, public health specialists, social workers, information specialists, other practitioners and commissioners. The service is built on an 'open-access principle' – as much content and functionality as possible will be freely accessible. Access to some full-text content requires users to log on because of commercial arrangements with the information providers, although this is being kept to a minimum and the log-on process is as simple as possible. Patients, service users and carers and the wider public are able to search NICE Evidence Services and access content (commercial arrangements permitting). NICE Evidence Services also includes information for patients where this has been accredited by the Department of Health's Information Standard.

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

Engagement

59. *Communications:* The communications team explains what we do and why. It protects and enhances our reputation. Its role is to promote NICE's core aim of improving quality and productivity of healthcare, public health and social care. Over the past few years we have shifted our focus to digital platforms; a process that continues as technologies and ways of accessing information evolve.

60. Work continues to improve the NICE website to give users the opportunity to personalise and tailor information of most relevance to them; and we are developing ways to use new digital platforms, including social media and digital devices, to communicate with old and new audiences as people change the way they access information.

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

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

63. *Involving patients, services users and the public*: We have a service user and public-centred approach in the development of our methodologies across all our programmes. Our processes are designed to enable organisations that represent patients, service users, carers and the wider public to submit evidence, alongside health professionals and others, and to influence the formulation of guidance and other products and services. Individual patients, service users, carers and community members are involved in the development of each piece of NICE guidance, and other products. In addition, patients, service users and the public and the organisations representing their interests, are increasingly supporting the implementation of our guidance and advice. We are committed to seeking improvements in how we can better incorporate the views of lay people into our work and in disseminating our recommendations to a public audience. To this end, we reviewed of our approach to engaging with the public and service users and consulted on proposals to improve how patients and the public can help develop NICE guidance and standards. Subject to comments from the consultation we will begin implementing the proposals during 2017-18.

64. We are committed to involving the public, patients, service users and their carers and organisations that represent their interests, such as Patients Involved in NICE (PIN), in developing our methods, our guidance and the NHS Evidence service, and we will continue to develop our capacity and our methodologies to do so.

65. We are also committed to encouraging and advising voluntary and community sector organisations to support the use of NICE guidance and standards. We will continue our work to refer people to appropriate patient and voluntary sector organisations' as part of our guidance to provide readers with additional sources of support. Voluntary and community sector organisations have formal agreements with NICE to support the use of NICE quality standards and we will continue to work with NICE Implementation Programme and Healthwatch England to provide advice to local Healthwatch organisations on supporting the use of NICE guidance and standards

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

67. Organisations that commission and deliver services are important external partners in our work. We want to ensure that they are encouraged to become involved in the development of our guidance as well as its implementation.

68. *Science Policy and Research:* The Science Policy and Research Programme leads NICE corporate scientific affairs, and develops and maintains NICE's research governance infrastructure. The programme collaborates with the research community and participates in key research projects of strategic importance to NICE, including spearheading our involvement with national health research funders such as the Medical Research Council (MRC) and the National Institute for Health Research (NIHR). Good progress has been made in collaborating with the NIHR on research recommendations from NICE advisory bodies, including the implementation of a "NICE Key Priority" designation in 2015 to signal particular importance. So far, five research recommendations have been accelerated through NIHR using the new arrangements. In addition, there has also been a substantial increase in requests from committee Chairs and Centre Directors for NIHR advice relating to research recommendations across all areas of NICE guidance production. In collaboration with NIHR

colleagues, the Science Policy and Research team also tracks the NIHR spend on research resulting from NICE advisory body research recommendations.

69. The programme also leads on managing NICE's relationship with the MHRA. Good collaboration has been established through quarterly meetings and on-going engagement in several areas of mutual interest. We now have a much greater understanding of interactions between the two organisations. Real value is also derived from a key issues log which is kept up to date with review at the quarterly meetings. We also have clear agreement of the mechanisms and contacts for collaboration between NICE and the Commission on Human Medicine (CHM) as recommended in the Triennial Reviews of both organisations. These arrangements allow NICE to actively seek CHM input on NICE guidance and evidence summaries. We are currently working with MHRA and industry on mechanisms for sharing regulatory information with NICE to support the early appraisal of health technologies – this is particularly important in the context of cancer medicines where almost the entire appraisal process is completed in advance of Marketing Authorisation. Joint work to implement recommendations from the Accelerated Access Review and to consider potential implications of Brexit has also started. Through European collaborative activities, we are also developing strong links with the European Medicines Agency.

70. In recent years the Science Policy and Research programme has also focussed on playing a more direct role in delivering NICE's research needs through seeking funding to set up research projects within the programme. Strong progress has been made resulting in significantly increased research activities despite reduced grant in aid funding. We currently have a team of 7 staff working on research projects fully funded through research grant income. Current activities include collaborative research on Adaptive Pathways and the use of "real world" evidence which we are engaged in via 5 European Innovative Medicines Initiative (IMI) funded projects. We are also engaged in research on patient preferences through a research grant from Myeloma UK. Learning from these projects is translated to practice through the guidance producing teams and life sciences companies engaged in developments through the Office for Market Access and NICE Scientific Advice. The team is also engaged in exploring other research funding opportunities.

Adoption and impact

71. *Implementation*: NICE guidance and advice needs to be effectively implemented to have any impact on the health and well-being of the population and the quality of care provided. Our job is to produce what is needed, when it is needed and then do all we can to encourage and support those who are in a position to apply it. This is a complex, challenging task for which an understanding of the evidence for effective ways of overcoming obstacles is an essential prerequisite. There is a growing body of research evidence and an accompanying literature on not merely what change is desirable in health systems but how to achieve it so it is embedded and sustained. It is possible that the messages about how to effect change may not be getting across to policy-makers and managers in ways which help them or in terms they find

useful. NICE needs to be both a user of, and contributor to, the evidence on how to effect large-scale transformational change in complex health systems. To support this process, NICE has an ongoing programme of implementation support to ensure appropriate support is provided for uptake of guidance and quality standards, including specific support for the sustainability and transformation footprints (STPs).

72. The implementation strategy has five specific objectives, to: produce guidance and standards that are fit for the audience's needs; ensure relevant audiences know about the guidance recommendations; motivate and encourage improvement; highlight practical support to improve local capability and opportunity; and evaluate impact and uptake. NICE has an Implementation Strategy Group comprised of academic leaders in the field of health, care and social science who help us to achieve the aims of the implementation strategy. The Group advises on new areas of implementation science and engaging with the research community to stimulate evaluation of significant areas of implementation and improvement science to inform our work.

73. NICE provides or endorses relevant implementation support products for a range of purposes, including support for commissioning, support for service improvement and audit, and support for education and learning, all with the aim of making implementation more straightforward at a local level. Some examples of support from NICE include the web based 'Into practice' guide for organisations on how to put evidence into practice, a forward planner updated monthly to summarise our future work programme, provide indicative costs and highlight links with the tariff, and a Local Practice Collection which includes Shared Learning examples and Quality and Productivity case studies on the NICE website.

74. We also have a regional team that provide practical support and advice to NHS trusts, networks, CCGs, local authorities and social care providers, particularly in relation to effective processes for implementation and information about NICE. During 2017-18 we will be refocusing the work of the regional team, to align it with the regional structures of NHS England and Public Health England. This will facilitate a strategic approach of working more closely with partner organisations, and of using new technologies such as webinars, to increase the impact of the team.

75. We also have an active programme of strategic engagement at a national level, as well as locally and regionally. Progress in engagement – and its effect on use of NICE guidance and standards - will be reported against standard metrics in the 6 monthly Uptake and Impact report. This will also include information that NICE has about how our recommendations for evidence-based and cost effective care are being used.

76. *Adoption of Health Technologies:* We facilitate the adoption of selected guidance across the NHS through engagement with clinical teams, commissioners, patients groups and social care. Included in this is focused practical advice about how to measure impact. There are two types of practical adoption support: the first consolidates the learning that has taken place from a

significant number of NHS sites that have already adopted a technology; the second focuses on technologies that are not widely used in the NHS or where complex redesign to services is required to successfully implement a technology.

77. We also support the uptake of new technologies in conjunction with the Academic Health Science Networks (AHSNs), the Office for Life Sciences and NHS England including providing the secretariat for the NICE Implementation Collaborative Board and supporting the Innovation Scorecard.

78. ***Endorsement and accreditation***: To support users of NICE Evidence, we introduced a formal accreditation programme, enabling 'kite-marking' of high quality independent guidance producers. We now also have a process of formally endorsing externally produced implementation tools and resources, where these are in line with NICE recommendations. This process helps users of guidance to identify high quality resources, recognising the potential power of these channels and the lack of capacity to produce all that we might want to ourselves. Examples of new and existing collaborations to develop this approach include with the BMJ through their improvement and information platforms, and organisations or alliances representing the public, professional associations and networks such as AHSNs. In 2017-18 we will be considering whether these programmes can operate on a fee-for-service basis.

79. ***NICE Pathways***: NICE will continue to produce and promote access to a range of interactive Pathways based on NICE guidance to ensure integration across topics and with guidance and quality standards. Pathways now provide access to all NICE guidance, including guidelines and guidance on technologies, making them the most comprehensive route to identify related guidance on the NICE website.

80. ***Digital strategy:*** We will continue to implement the digital strategy approved by the Board in January 2013 and updated in September 2015. The strategy provides a frame of reference to guide the continued digital transformation of the organisation.

81. A key component of our digital strategy is to improve the efficiency and productivity of NICE guidance development processes. Over the next 3 to 5 years, NICE will transform the way its content is developed, written and managed with a view to produce much more structured guidance content. This will allow our recommendations, evidence statements, and the underpinning evidence to be queried, updated, shared and repurposed more effectively, with benefits to internal and external users of NICE's content alike.

82. Other key objectives of digital transformation include the need to widen and improve access and distribution of NICE guidance and evidence-based products and services to NICE core audiences using a range of digital channels. We will strive to continually improve our website, to ease the navigation of NICE's complex portfolio of products and services, and facilitate access to relevant and related content for users. We will continue to improve mobile access to our services and introduce some personalisation features for

our users. Finally, we will seek to identify partners for joint working on digital initiatives which support the distribution and re-use of NICE content in decision support and other third party systems.

83. In delivering its digital strategy NICE is creating important links with digital teams across the Arms' Length Body sector. NICE will continue to develop these connections and explore opportunities to inform, and where suitable, influence the design of system-wide digital information services and products. This will ensure that the effort invested by NICE in producing its information assets is not duplicated and that NICE material is used as source reference material in digital systems developed by the health and care sector wherever suitable.

Core principles for product development

84. In the development of guidance and other advice, NICE operates a set of core principles. These principles inform the development of any new work programmes as well as the delivery of existing programmes. These principles state that:

- A comprehensive evidence base, subject to rigorous assessment and analysis, will be used to inform the development of evidence summaries and guidance recommendations;
- Input from the public, patients, people who use social care services and health and social care professionals will form part of all guidance development;
- Independent advisory bodies will develop recommendations on behalf of the Board;
- Transparent process and methods will underpin the development of all evidence summaries and guidance recommendations;
- A consultation or process of contestability will enable external stakeholders to comment on and inform the development of our guidance;
- A process of regular review and updating will ensure guidance recommendations are of continuing value.

85. These principles are supplemented by advice to NICE's advisory bodies on our approach to the application of social value judgements, and on the requirements to promote, within our guidance, equality of opportunity and to seek to eliminate unlawful discrimination on the grounds of any characteristic protected by equality legislation. It will be important for us to hold onto these principles during the changes facing us.

Resource assumptions

86. NICE receives most of its funding directly from the Department of Health. This funding is known as grant-in-aid (GIA) and is split into two key components, Administration and Programme funding. Administration costs are defined as non-frontline activities and support activities such as the provision of policy advice, business support services and technical or scientific advice and support.

Programme costs are defined as costs incurred in providing frontline activities such as direct patient care.

87. The majority of NICE's activity (and Department of Health funding) is classified as Administration – the exceptions are funding for supplying the British National Formulary (BNF) publications to the NHS and some costs associated with Medical Technologies Evaluation. NICE receives other funding from Health Education England and NHS England which is also treated as Programme.

88. The table below shows the planned sources of funds for 2017-18 and how they will be applied. It also shows how these compare with the 2016-17 plan.

Table 1: Sources and application of funds

	2016-17 £m	2017-18 £m
Sources of Funding		
Administration - GIA	49.4	46.0
Programme - GIA	8.7	8.5
Income from Devolved Administrations	2.0	1.8
Income from Health Education England	3.8	4.0
Income from NHS England	5.9	6.4
Other operating income	2.8	3.0
Non-Cash Funding - Depreciation	1.0	1.0
Total Sources of Funding	**73.6**	**70.7**
Application of Funds		
Guidance and Advice	58.3	56.1
Corporate	12.8	12.7
Reserves	1.5	0.9
Depreciation Charges	1.0	1.0
Total Applications of Funding	**73.6**	**70.7**

Sources of funds

89. It has been confirmed that the 2017-18 administration funding will fall by 7% (£3.3m) in cash terms. This is the second year of an overall straight line phased real terms reduction of 30% in our administration funding over the current Spending Review (SR) period to 2019-20. The programme budget will also reduce from £8.7m to £8.5m which gives a total reduction in GIA funding of £3.6m (6%). It has also been confirmed that the programme element will have a phased reduction over the SR period to £8m (10%).

90. In addition to GIA funding there are a number of other sources of income. In total these are projected to be £15.2m, an increase of £0.7m from 2016-17.

91. We anticipate that NHS England will continue to provide funding to support a number of existing programmes such as our work to support the Cancer Drugs Fund. There are also a number of new programmes that are proposed to begin in 2017-18. These are subject to confirmation and any potential income and expenditure associated with these are excluded from the Table 1 above. Details of funding received from NHS England is set out in the table below.

Table 2: NHS England funding

Funding from NHS England	2017-18 £m
Ongoing activity	
Cancer Drugs Fund	3.0
Evidence based treatment pathways in mental health	1.5
Commissioning Support Programme	0.8
Commissioning Through Evaluation	0.6
MedTech Innovation Briefings	0.5
Rapid Evidence Summaries	0.1
Total confirmed activity	**6.4**
Proposed / planned work (funding to be confirmed)	
Shared Decision Making support (Patient decision aids)	0.7
Develop new MedTech Horizon Scanning Database	0.5
Produce evidence summaries for Regional Medicines Optimisation Committees	0.1
Evaluation of digital therapies within the IAPT programme	0.4
Total proposed activity	**1.7**

92. Other income sources are expected to rise to £3.0m. These sources include the Scientific Advice programme which is self-funding. Scientific Advice provides early advice to the pharmaceutical and medical technology industries. These activities will generate £1.2m to cover direct costs and contribute to overheads where appropriate.

93. Rental income is also included in other income and will remain around £0.8m for 2017-18. Our London office will continue to host the Human Fertilisation and Embryology Authority (HFEA) and we will continue to generate income from the sub-lets in our Manchester office to the Homes and Communities Agency and the Care Quality Commission.

94. Funding of £4m will come from Health Education England under the service arrangements in place whereby NICE procures and provides the national core content for the NHS.

95. NICE receives income from the devolved administrations in Wales, Scotland and Northern Ireland. This contributes to the cost of selected guidance

production, producing the BNF and some supporting services depending on which products and services they make use of locally. Service level agreements set out the level of funding that will be provided and which outputs can be used by each country or support to be provided. It is expected that this income will reduce from £2.0m to £1.8m as Scotland have indicated they no longer require Multiple Technology Appraisals and QOF from NICE.

96. In addition to the grant-in-aid funding that we receive from the Department of Health, we also bid for capital funding on an annual basis. Although subject to confirmation, the assumed capital requirement for 2017-18 is £0.5m as per previous years. It is anticipated this will be used to upgrade office facilities (Manchester toilet refurbishment) and IT hardware and software.

97. There is also a non-cash limit of £1m associated with depreciation of assets. These capital and depreciation budgets and resource limits are over and above the grant-in-aid funding set out above.

98. There are also small amounts of funding from other sources anticipated to contribute £0.7m for income generating activities within Science Policy and Research, the Office for Market Access (OMA) and IP and Business Content. Science Policy and Research have secured a number of European research grants to help fund on-going projects and staff resource spanning over a number of years.

How we apply our resources

99. The proposed reduction in GIA funding over the spend review period presents significant challenge to the organisation. The Senior Management Team and Board agreed a strategic savings programme to deliver these savings in the four financial years from April 2017. The Board also agreed a strategic vision for NICE that seeks to retain the broad scope of NICE's offer at the end of this period.

100. The pay budget for 2017-18 is currently £35.7m, excluding contingency reserves and inflationary pressures (see appendix 3.1 for full breakdown). This is a reduction of £1.4m (3.7%) compared to 2016-17. The budgeted wte is 645, down from 656 wte in 2016-17. This has been achieved by restructuring within Evidence Resources in September 2016 and the Centre for Guidelines, Health and Social Care and Communications directorates in the final quarter of the 2016-17 financial year.

101. The non-pay budget for 2017-18 is £34.2m, a reduction of £0.8m (2.3%). This is due to a reduction in the number of External Assessment Centres working with the Medical Technologies programme (reduced from four to three centres) and reductions in the budget for the NCC Social Care contract in the Centre for Guidelines. This contract will be closed at the end of 2017-18 as work is being brought in house.

102. The reserve balance for 2017-18 is currently £0.9m. Of this, £0.4m is set aside to cover potential cost pressures such as the pay award increases and the

apprentice levy. The balance £0.5m has arisen due to front-loading of some savings programmes, this will be used to fund any non-recurrent cost pressures and transition costs arising in 2017-18.

Human Resources

103. There are two members of staff expected to earn more than £142,500 during 2017-18. Overall, the ratio of staff on the executive senior managers (ESM) pay framework to total staff complement is 1 ESM for 86 staff.

104. The Board approved a three year workforce strategy in July 2015 which we will continue to implement in 2017-18. This was developed in the context of the anticipated workforce challenges associated with the funding reductions expected. The strategy recognises the staffing issues associated with such significant change and has been developed to provide the support that managers will need. We will undertake a mid-term review in the summer of 2017 to ensure that we remain on track and that the objectives arising out of the strategy remain fit for purpose.

105. As part of the implementation of our workforce strategy, each Centre and Directorate has been developing workforce plans which have helped with our programme of organisational change and will continue to help us achieve more efficient resourcing and enable us to better direct our training and development resources.

106. We have also started to roll out a talent management programme, successfully completing career conversations with all staff at 8d level and above. We will progress this work in 2017-18 by rolling out career conversations to all staff at Band 8 level with the ultimate aim that by the end of the 2018-19 we will have talent management embedded at NICE and in operation for all staff groups.

107. In 2017-18 we will design and build the system infrastructure that will enable us to translate the information obtained from our talent management programme into succession plans, strategic resourcing, targeted development programmes (such as the Department of Health and Civil Service Leadership programmes and Reach Higher leadership programmes for BAME staff) and the creation of opportunities for "stretch" projects, both internal to NICE and external across the sector for staff who are looking to develop into their next role.

108. We have been developing our apprenticeship programme and this will continue in 2017-18. We currently have 10 wte apprentices in post, 6 of whom were recruited in 2016-17 and count towards our annual recruitment target, with several more posts in recruitment. We aim to achieve our target of 14 wte apprentices during 2017. We will be developing an apprenticeship strategy to ensure we continue to use apprenticeships as part of our talent and succession plans, maximise the use of the apprenticeship levy, and achieve the national recruitment target that requires us to ensure that apprentices form 2.3% of our workforce.

109. We are committed to staff engagement and will build on the excellent relationship with staff side partners by developing staff partnership strategies, health and well-being at work and improving staff involvement and communication for non-unionised staff. In particular NICE will review how it listens to its staff and responds to concerns and complaints that are raised.

110. In 2016 the Senior Management Team approved an investment in an online learning management system (LMS). The LMS provides a central point for online learning and enables managers and staff to record and maintain all their learning and development activities. In 2017-18 we will be continuing to embed, tailor and improve the system and will launch our new e-appraisal system.

Estates

111. All NICE's office facilities now operate on a totally flexible working model with ratios that achieve or exceed the Government Property Unit (GPU) metrics. Since April 2016, the Human Fertilisation and Embryology Authority is co-located in our London office. This provides an income stream to offset against our savings targets.

112. The lease on the London office runs through to the end of 2020 when it is expected that the freeholder will redevelop the site. At that point NICE would expect to move to one of the London public sector 'hub' sites. The lease on our Manchester office comes up for renewal at the end of 2017. The GPU has given us permission to renew the lease for a 10 year term with a break opportunity at year 7 for which we have negotiated favourable terms. In the longer term, but no earlier than 2024, the GPU is planning a North West hub, which is why the break at 7 years in our new lease was negotiated.

Procurement

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

Sustainable development

114. We are committed to supporting and promoting sustainability and climate change resilience issues.

115. We will continue to consider our own direct impact, focusing our efforts on areas where carbon impact is most significant. These include: electricity use, staff and non-staff business travel, printing of guidance and the British National Formulary (BNF), office waste and recycling.

116. In addition, we intend to explore ways in which the sustainability of health interventions we are asked to consider might feature in the guidance we produce. A sustainability steering group has been established that will develop a generic statement on sustainability to be incorporated in NICE products. It will also consider how sustainability factors (social and environmental) can be incorporated into the cost impact analysis work. We will do this in conjunction with the Centre for Sustainable Healthcare and the Sustainable Development Unit. Any changes to our methods or for the presentation of guidance would need to be the subject of discussion and consultation. We will also develop a Board-approved, Sustainable Development Management Plan (SDMP).

Equality

117. As part of NICE's compliance with the Public Sector Equality Duty there is an equality analysis process for each item of NICE guidance (which includes quality standards and indicators for the Quality and Outcomes Framework and Clinical Commissioning Group Outcomes Indicator Set). This seeks to ensure that, wherever there is sufficient evidence, NICE's recommendations support local and national efforts to advance equality of opportunity and narrow health inequalities.

118. NICE meets the Equality Act's specific duty on publication of information through its annual equality report on the impact of its equality programme. In March 2016 the Board agreed equality objectives for the period 2016 to 2019 in accordance with the Public Sector Equality Duty.

Risk management

119. We actively consider the risks associated with the achievement of our strategic and business objectives. The senior management team regularly review risks to ensure that appropriate mitigating action is being taken. The Audit and Risk Committee receives regular assurance on behalf of the Board concerning the identification and management of risks. The main vehicle for this assurance is the risk register but the Audit and Risk Committee also receives reports on significant incidents resulting from unforeseen or unmitigated risks.

120. The Board receives assurance on these from a number of sources but primarily through the Chief Executive's regular report. The Department of Health regularly assesses the extent to which NICE has met its statutory obligations at accountability meetings.

Principal business objectives 2017-18

Objective	Actions
Guidance, standards, indicators and evidence	
Publish guidance, standards and indicators, and provide evidence services against the targets set out in the Business Plan and in accordance with the metrics in the balanced scorecard	• Deliver guidance, standards, indicators and evidence products and services, in accordance with the schedule set out in the Business Plan • Ensure performance meets the targets set in the balanced scorecard
Implement changes to methods and processes in the technology appraisal programme	• Obtain stakeholders' perspectives on methods related to managing uncertainty and structured decision making • Deliver further improvements to the operation of Committee decision making • Subject to the outcome of consultation, implement the joint NICE-NHSE proposals for changes to the technology appraisal and highly specialised technologies programmes, introducing more flexible, rapid, risk-based appraisal processes • Develop methodological guidance, and internal capacity and capability for 'real world' data development and analysis
Refine and implement new methods and processes to accelerate the development of updated clinical, public health and social care guidelines	• Establish 6 internal capacity slots for updating guidelines, using new accelerated methods and processes • Implement new staffing structure and functions in the Centre for Guidelines • Review and revise methods and processes for accelerated update outputs • Develop and implement new scoping and post-consultation validation methods and processes to support the development of guideline updates in-house.

Objective	Actions
	• Establish pre-development recruitment of guideline committee chair and expert members to support scoping
Enhance methods for developing and maintaining guidelines	• Continue to develop the methods and processes of guideline development to maintain and enhance NICE's reputation for methodological quality and efficiency in guideline development. • Establish and maintain links and networks with external research initiatives, organisations and projects to address our methodological needs and ensure our methods continue to reflect internationally-recognised best-practice. • Establish new staffing structure and functions to support health economics across the Centre for Guidelines • Develop a NICE GP Reference Panel to advise on the scoping of guidelines. • Implement any changes agreed following the consultation on the NICE approach to patient and public engagement
Deliver the suite of NICE evidence services, which meet the evidence information needs of health and social care users and partner agencies	• Maintain and make measurable improvements to the component services of NICE Evidence Services • Procure and maintain the underpinning Link Resolver and Identity Management services • Manage content procurement contracts (CKS, Cochrane), including those on behalf of HEE (National Core Content), to plan
Implement the relevant aspects of the Government's industrial strategy for the life sciences industries, taking account of the recommendations in the final report of the Accelerated Access Review	• Assess and report to the Board on the financial, operational and reputational implications of the Accelerated Access Review and the Government's life sciences strategy, for NICE guidance programmes • Develop an implementation plan and report to the Board on progress

Adoption and Impact

Deliver a programme of strategic and local engagement	• Work with local health and care systems to promote the use of NICE guidance and quality standards, measured against agreed standard metrics • Support the use of NICE guidance and standards through the work of other national organisations in health, public health and social care, measured against agreed metrics
Evaluate the impact and uptake of Health and Social Care products and services and ensure that guidance and standards meet the needs of our audiences	• Produce a twice yearly uptake and impact report • Consult with the research community through the Implementation Strategy Group to stimulate evaluation of implementation and improvement science
Promote NICE's work and help users make the most of our products by providing practical tools and support, using innovative and targeted marketing techniques. Contribute to demonstration of impact though regular evaluation	• Develop the use of graphics and images to help explain guidance and related products • Building on the new Social Care Quick Guides, develop new online summaries for other forms of guidance which are short, concise and use infographics and multimedia techniques • Redesign the current resource used by practitioners to help make savings, improve productivity and promote optimal use of interventions • Support shared decision making within NICE through delivery of commitments in the action plan of the Shared Decision Making Collaborative • Develop the resource impact support team to enable it to deliver the budget impact assessments required as part of the changes to the TA and HST programmes
Promote collaboration on digital initiatives and content strategy across ALBs and with academic establishments and other external stakeholders	• Support NHS Digital in the development and adoption of common standards, taxonomies and language across ALBs • Maintain an ongoing relationship with the nhs.uk project (re-development of NHS Choices) • Identify partners for joint working on digital initiatives which support the distribution and re-use of NICE content in decision support and other third party systems. This may involve academic and regional collaborations • Fully capitalise on existing relationships with specialists in the evidence management field and extend to other potential partners

	- Support NHS England to deliver the digital IAPT pilot programme (Improving Outcomes in Psychological Therapies)
Create a structured and coordinated approach for working with and listening to stakeholders	- Roll out a customer relationship management (CRM) system to support and monitor engagement with stakeholders and to help deliver tailored communications - Develop a new interactive online newsletter with content tailored for key audiences - Explore opportunities to develop personalisation functionality on the NICE website (working with the digital services team) that allows visitors to tailor content to their needs - Implement a social media strategy to increase engagement and drive traffic to corporate content - Further develop a system to capture audience insights (including Twitter and Website analytics) and provide regular reports to senior management - Develop metrics to measure the extent and impact of our engagement with social care audiences
Deliver new digital service projects, maintain NICE's existing digital services and implement service improvements based on user insights and service performance	- Deliver digital service projects in line with the agreed investment priorities for 2017-18 - Maintain the NICE Digital Services to agreed service levels (service availability and time to defect resolution) - Maintain digital services performance indicators in line with business priorities and user insights - Translate data and observations about the performance of NICE Digital Services into actionable improvement proposals and implement in line with business priorities
Operating efficiently	
Operate within resource and cash limits in 2017-18. Actively manage the appropriate application of any non-recurrent funding as early as practicable in the financial year.	- Deliver performance against plan for all budgets monitored and reported to the Senior Management Team and the Board

Implement the second year of a three year strategy to manage the reduction in the Department of Health's Grant-In-Aid funding and plan for a balanced budget in 2017-18	• Centres and directorates identify the savings expected from them in order enable the Institute to manage within the reduced Grant in Aid funding received from DH, by April 2018 • Management of change exercises completed in accordance with the schedule determined by the Senior Management Team
Subject to Ministerial approval put in place arrangements to charge the cost of the technology appraisal programme to industry users, from April 2018	• Obtain DH and HM Treasury decisions on cost recovery by June 2017. • If approved, put in place designed and tested financial and operational arrangements by December 2017 • If approved, ensure that charging arrangements are able to go live from April 2018
Actively pursue revenue generation opportunities associated with international interest in the expertise of NICE and the re-use of NICE content and quality assurance	• Articulate and promote NICE's value propositions associated with the re-use of NICE content outside of the UK, including permissions to use content overseas, adaptation of guidance, quality assurance services and syndication services • Articulate and promote NICE's value propositions involving knowledge sharing with international organisations interested in NICE's expertise and experience
Enthuse and enable staff to deliver on the Institute's objectives, ensuring that every member of staff has a clear set of personal objectives, a personal development plan and an annual appraisal	• All staff have clear objectives supported by personal development plans • Put in place implementation plans for relevant NICE workplace guidance • Actively manage staff with the objective of ensuring that the global job satisfaction index in the annual staff survey is maintained or improved from its 2016 level • Put in place resources to support staff through Management of Change exercises

Promote a culture of continuous improvement within the organisation and uphold the ambition to remain a world-renowned organisation, benchmarking where possible its systems, processes and outcomes against best players internationally	• Identify the programmes which might be suitable for benchmarking and assess what, if any, international benchmarking is possible by September • Identify 10 publications in peer reviewed international journals which assess and provide an opinion on one or more aspects of NICE's work and submit to the Board for consideration in December

APPENDICES

1. **Balanced Scorecard for 2017-18**

2. **Activity Analysis for 2017-18**

3. **Revenue budget allocations for 2017-18**

4. **Board and Senior Management Team**

5. **Organisational Chart**

Appendix 1 - Balanced Scorecard 2017-18

The balanced scorecard is structured into three domains reflecting NICE's strategic objectives:

- Delivering guidance, standards, indicators and evidence, helping to achieve high quality, sustainable services, supporting the health and care system to use its resources efficiently, and contributing to a thriving life sciences industry;

- Supporting adoption and impact by working with others to provide practical tools and support to help people make the most of our work and to measure its use;

- Operating efficiently, by using our resources productively and sustainably, and by supporting our staff to deliver on their full potential.

Guidance, standards, indicators and evidence

Success Criteria	Key Measures	Target
Development and publication of guidance and evidence outputs		
Publish 34 guidelines • Clinical areas, including updates (25) • Public health (3) • Social care (3) • Management of common infections (3)	Publication within stated quarter	80%
Publish 55 technology appraisals guidance	Publication within stated year	100%
Publish 30 interventional procedures guidance	Publication within stated quarter	80%
Publish 6 diagnostics guidance	Publication within stated quarter	80%
Publish 3 highly specialised technologies guidance	Publication within stated year	100%

Success Criteria	Key Measures	Target
Publish 7 medical technologies guidance	Publication within stated quarter	80%
Publish 36 medtech innovation briefings (MIBs)	Publication within stated quarter	80%
Submit advice to Ministers on up to 30 Patient Access Schemes	Publication within stated year	100%
Deliver up to 25 Commissioning Support Documents to NHS England	Publication within stated quarter	80%
Publish 56 evidence surveillance	Publication within stated quarter	80%
Publish 10 evidence summaries[1]	Publication within year	80%
Deliver 7 quick guides for social care	Publication within year	100%
Deliver 20 quality standards	Publication within stated quarter	80%
Deliver 1 indicator menu	Publication within year	100%
Deliver 4 Evidence Based Treatment Pathways (EBTP) to NHS England	Delivery to NHS England within stated quarter	100%
Deliver 30 endorsement statements	Publication within stated quarter	80%
Deliver 50 shared learning examples	Publication within stated quarter	80%
Publish 12 monthly updates of the BNF and BNF C content	Publication within stated quarter	80%
Deliver a regular medicine awareness service	Publication to regular schedule	90%
Deliver 16 medicines optimisation key therapeutic topics	Publication within stated quarter	80%
Deliver 25 medicines evidence commentaries	Publication within stated quarter	80%
Deliver 6 IAPT assessment briefings	Deliver within stated quarter	80%

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[1] This number may increase by up to 10 in a year, dependent on new work and funding to support NHS England Regional Medicines Optimisation Committees

Adoption and impact

Success Criteria	Key Measures	Target
Provision of support products for the effective implementation of guidance		
Complete a minimum of 5 adoption support products	Publication within year	80%
Publish 96 resource impact products	Publication within year	80%
Maintaining and developing recognition of the role of NICE		
NICE guidance and standards support the new STP Footprints	NICE products referenced in STP footprint implementation plans within year	80%
NICE products help to inform CQC inspections	NICE guidance and quality standards referenced in the new health and adult social care assessment frameworks for the CQC's key question around effectiveness	100%
Coverage of NICE in the media	% of positive coverage of NICE in the media resulting from active programme of media relations	80%

Operating efficiently

Critical Success Factors	Key Measures	Target
Delivering programmes and activities on budget		
Effective management of financial resources	Revenue spend	To operate within budget
Effective management of non-exchequer income	Net income received from non-exchequer income sources measured against business plan targets	90%
Produce the annual report and accounts within the statutory timeframe	Publications	100%

Critical Success Factors	Key Measures	Target
Maintaining and developing a skilled and motivated workforce		
Management of recruitment	Proportion of posts appointed to within 4 months of first advertisement	80%
Management of sickness absence	Quarterly sickness absence rate is lower than NHS average rate (3.7% Apr-Jun 2011) or general rate for all sectors (2.8%)	90%
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%
Staff involvement	Hold monthly staff meetings	80%
Staff well-being	Implementation of NICE's quality standard for healthy workplaces: improving employee mental and physical health and wellbeing in respect of own staff	80% of quality statements
Sustainable Development		
Recycled waste	% of total waste recycled	50%
Improving stakeholder satisfaction		
Improved satisfaction	Complaints responded to in 20 working days	80%
	Enquiries fully responded to in 18 working days	90%
	Number of Freedom of Information requests responded to within 20 working days	100%
	PQs contribution provided within requested time frame	90%
Ensuring stakeholders have access to our websites as the main communication channel	Percentage of planned availability, not including scheduled out of hours maintenance	98%

Critical Success Factors	Key Measures	Target
Interest in opportunities for lay people to sit on our advisory committees reflected by ratio of applications to positions	2:1 (or greater) each quarter	100%
Improving efficiency and speed of outputs		
Speed of production	% STAs for all new drugs issuing an ACD or FAD within 6 months of the product being first licensed in the UK	90%
	% of multiple technology appraisals from invitation to participate to ACD in 41 weeks, or where no ACD produced to FAD in 44 weeks	85%
	% of Appeal Panel decisions received within 3 weeks of the hearing	80%

Appendix 2 - Activity Analysis 2017-18

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

Programme	2016-17 published outputs	2017-18 planned outputs
Social care guidelines	1	3
Clinical guidelines, including updates	24	25
Public health guidelines	6	3
Management of common infections guidelines	0	3
Social care quick guides	2	7
Quality standards	33	20
Indicator menu	1	1
Technology appraisals guidance	TBC	55
Highly specialised technologies guidance	1	3
Medical technologies guidance	5 (expected)	7
Medtech Innovation Briefings	40 (expected)	36
Diagnostics guidance	5	5
Commissioning support documents	n/a	25
Patient Access Scheme advice	30 (expected)	Up to 30
Interventional procedures guidance	28	30
Evidence summaries	20	10
Medicines optimisation key therapeutic topics	16	16
Medicines evidence commentaries	25	25
Adoption support products	5	5
Resource impact products	80	96
Shared learning examples	50	50
Endorsement statements	30	30
Guidance surveillance reviews – clinical	45	45
Guidance surveillance reviews – public health	8	10
Guidance surveillance reviews – social care	0	1
IAPT assessment briefings	n/a	6
Medicine awareness service	50	50

Appendix 3.1 - Centre and directorate budget allocations 2017-18

	wte	Pay £'000	Non-pay £'000	Total £'000
		2017-18		
Guidance and advice				
Centre for Guidelines	117	6,625	13,640	20,265
Centre for Health Technology Evaluation	175	9,762	5,424	15,186
Health and Social Care Directorate	125	6,958	2,182	9,140
Evidence Resources Directorate	99	5,987	5,619	11,606
Corporate				
Communications Directorate	71	3,637	425	4,062
Business Planning and Resources Directorate	58	2,719	5,866	8,585
NICE International	0	0	0	0
Contingency Reserves	0	508	0	508
Inflationary pressures	0	373	0	373
Depreciation	0	0	1,000	1,000
Total Budget	**645**	**36,569**	**34,156**	**70,725**

Appendix 3.2 - Revenue projections in financial statements format

Statement of comprehensive net expenditure			
	2017-18 £'000		
Expenditure			
Staff costs	36,569		
Depreciation & Amortisation	1,000		
Other expenditure	33,156		
	70,725		
Income			
Income from activities	-15,280		
Other income			
Net Expenditure	55,445		

Note 3 – Staff numbers and related costs		Permanently	
	2017-18 Total £'000	Employed Staff £'000	Other £'000
Salaries and wages	28,710	27,510	1,200
Social security costs	3,503	3,503	
Employer contributions to NHSPA	4,456	4,456	
Other pension costs			
	36,669	35,469	1,200
Less recoveries in respect to outward secondments	-100	-100	
Total net costs	36,569	35,369	1,200

Appendix 3.3 - Balance sheet projection

Statement of Financial Position to 31 March 2018	
	Total
	31 March 2018
	£000
Non-current assets	
Property, plant and equipment	3,000
Intangible assets	200
Non Current Receivables	0
Total non-current assets	**3,200**
Current assets	
Trade and other receivables	2,000
Other current assets	1,500
Financial Assets	0
Cash and cash equivalents	1,500
Total current assets	**5,000**
Total assets	**8,200**
Current liabilities	
Trade and other payables	-2,000
Other liabilities	0
Provisions for liabilities and charges	0
Total current liabilites	**-2,000**
Non-current assets less net current liabilities	**6,200**
Non-current liabilities	
Provisions for liabilities and charges	-1,000
Other payables	0
Financial Liabilities	0
Total non-current liabilities	**-1,000**
Assets less liabilitites	**5,200**
Taxpayers' equity	
General fund	4,500
Non-exchequer trading reserves	700
	5,200

Appendix 3.4 - Cash flow projection

Projected cash flow statement for year ending 31 March 2018	
	£'000
Cash flows from operating activities	
Net surplus after cost of capital and interest	-55,445
Adjustments for non-cash transactions	1,000
(Increase)/Decrease in trade and other receivables	0
Increase/(Decrease) in trade and other payables	0
Use of provisions	-250
	-54,695
Cash flows from investing activities	
Purchase of property, plant and equipment	-400
Purchase intangible assets	-100
Proceeds of disposal of property,plant and equipment	0
Proceeds of disposal of intagibles	0
	-500
Cash flows from Financing Activities	
Payments in respect of finance leases and PFI contracts	0
Net Cash inflow/(outlow) before financing	-55,195
Net Parliamentary Funding	55,445
Net increase/(decrease) in cash equivalents	250
Cash and cash equivalents at the beginning of the period	1,250
Cash and cash equivalents at the end of the period	1,500

Appendix 4 - Board and Senior Management Team

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

Professor David Haslam CBE	Chair
Professor Sheena Asthana	Non-Executive Director
Dr Rosie Benneyworth	Non-Executive Director
Professor Angela Coulter	Non-Executive Director
Professor Martin Cowie	Non-Executive Director
Ms Elaine Inglesby-Burke	Non-Executive Director
Mr Tim Irish	Non-Executive Director
Dr Rima Makarem	Non-Executive Director
Mr Andy McKeon	Non-Executive Director
Mr Tom Wright CBE	Non-Executive Director
Sir Andrew Dillon CBE*	Chief Executive
Professor Mark Baker	Director: Centre for Guidelines
Mr Ben Bennett*	Director: Business Planning and Resources
Ms Jane Gizbert	Director: Communications
Professor Gillian Leng CBE*	Director: Health and Social Care
Professor Carole Longson MBE*	Director: Centre for Health Technology Evaluation
Ms Alexia Tonnel	Director: Evidence Resources

Note: * Executive Directors

Appendix 5 – Organisational Chart

	Centre for Guideines	Clinical, social care and public health guidelines, BNF
	Centre for Health Technology Evaluation	Technology appraisals, Interventional procedures, Medical devices and diagnostics, Scientific Advice, Science policy and research, Topic Selection, Highly Specialised Technologies, Office for Market Access
Chief Executive	**Health and Social Care**	Medicines and technologies, system engagement, quality and leadership, public involvement
	Business Planning and Resources	Finance and facilities, Human Resources, IT and procurement, business planning, corporate office
	Communications	Media relations, corporate communications, enquiry handling, website and editorial
	Evidence Resources	Information services, on-line evidence services, digital transformation, intellectual property and business management

National Institute for Health and Care Excellence

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

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

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

Ben Bennett

Director, Business Planning and Resources

March 2017

National Institute for Health and Care Excellence
NICE Standing Orders, Standing Financial Instructions and Reservation of Powers
Date: 15 March 2017
Reference: 17/025

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Background

1. NICE is required to review its Standing Financial Instructions, Standing Orders, and Reservation of Powers to the Board and Scheme of Delegation annually. This review has taken place and a number of relatively minor updates are proposed.

2. The proposed changes are summarised below. The full revised documents are available on request.

Changes to the documents

3. In addition to minor changes to update terminology the following changes have been made.

Standing orders (SOs)

4. The sections on the use of private finance and the competitive market testing of in-house services have been removed on the basis that these provisions are not relevant to NICE's circumstances.

Standing Financial Instructions (SFIs)

5. The authority to appoint staff and vary the funded establishment has been clarified.

Reservation of Powers to the Board and Scheme of Delegation

6. The following matter reserved to the Board *'the approval of management policies including personnel policies incorporating the arrangements for the appointment, removal and remuneration of staff'* has been amended to '*the approval of any policies which the Board may from time to time reserve itself responsibility'*. This better reflects the Board's role is strategic rather than managerial, and does not routinely agree management policies.

7. Removal of the references to the year-end responsibilities of reviewing the reports from the auditors (as this is undertaken by the Audit and Risk Committee on behalf of the Board).

8. Clarification that the requirement for Board approval of staff compensation payments over £50,000 relates to extra contractual payments. Also, that in such cases, the Board approval is subject to any permissions required from the Department of Health and HM Treasury.

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Senior Management Team deputies

9.   Since the last annual review of these documents, deputies have been appointed in each of the centres and directorates to help ensure the continuity of management arrangements in advance of any director's absence.

10. In absences of less than 4 weeks, the deputy will act for the director when necessary, supporting their senior directorate colleagues as required, enabling decisions to be taken at the appropriate level. The deputy will attend the Board, SMT and Guidance Executive, unless the director has previously indicated that other arrangements are more appropriate. In absences over 4 weeks, the deputy will assume the director's responsibilities, including line management of the senior team and will be paid an acting up allowance.

11. The Board is asked to consider the status of the deputies when attending Board meetings on behalf of a director, and whether the following sections of the Standing Orders should be revised.

  •   *An officer in attendance for an officer member but without formal acting up status may not count towards the quorum.*

  •   *An officer who has been appointed formally by the Board to act up for an officer member during a period of incapacity or temporarily to fill an officer member vacancy, shall be entitled to exercise the voting rights of the officer member and will count towards the quorum.*

12. The options include stating that a deputy will count towards the quorum (and have a vote) when attending any Board meeting on behalf of a director; or alternatively they only do so when taking on the broader responsibilities outlined above in absences over 4 weeks.

Conclusion

Issues for decision

13. The Board is asked to:

  a.   Approve the amendments to the governance documents.

  b.   Confirm the position of the SMT deputies when attending a Board meeting.

National Institute for Health and Care Excellence

March 2017

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National Institute for Health and Care Excellence

NICE uptake and impact report

This report gives details of the NICE uptake and impact report presented to the Board for information in March 2017, and provides options for the format of future reports for consideration.

The Board is asked to consider options for the future and agree a preferred format.

Gill Leng

Director, Health and Social Care

March 2017

National Institute for Health and Care Excellence
NICE uptake and impact report
Date: 15 March 2017
Reference: 17/026

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Introduction

1. This paper introduces the NICE uptake and impact report for March 2017. The paper also considers options for the format of future updates and asks the Board to agree a preferred format.

Background

2. The NICE uptake and impact report is produced twice a year, and the March 2017 report accompanies this paper. The report uses published data from national audits, reports, surveys and indicator sets to provide a picture of the uptake of NICE recommendations. Information about national, regional and local engagement is also collected to consider the wider impact of NICE across the health and social care system.

3. The contents of the report have increased over the last year, in part following a steer from the Board. In September 2016, the report was revised to incorporate the NICE field team biannual report and other information about the wider impact of NICE. In addition, we have worked with partners to identify new sources of uptake data and further aligned national audits with NICE guidance and quality standards. This has resulted in twice as many national audits, reports and surveys being available for analysis in the March 2017 report than previously. This work is ongoing, which may continue to increase the volume of uptake data available for future reports.

4. The report is produced primarily for the NICE Board, but may also be of interest to a wider range of stakeholders. Following Board review, the report will be published on the uptake page of the NICE website. The increasing volume of information in the report may, however, mean we should consider a more accessible presentation, both for the NICE Board and for the potential wider audience.

Future options

5. Options for the future presentation of information about uptake and impact are set out in the table below, taking into account potential future audiences.

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Table: Future options

Option	Benefits	Limitations
1. Continue with comprehensive 6 monthly board report	• Allows for a review of all available data and information • Allows for analysis of overarching trends and patterns across sectors or topics	• Results in lengthy report in which key information may be less accessible • Timeliness of information affected by time to produce report and 6 month gap between reports.
2. Provide a shorter 6 monthly report, with topic based updates at intervening meetings	• Continues to provide a detailed overview of uptake and impact • Topic based updates can be aligned with national audit publication schedule, allowing for rapid updates in these areas	• Comprehensive document will no longer be available
3. Augment the complete 6 monthly report with a short, web-based version for a wider audience	• Provides a high-level and publically accessible picture of uptake and impact for a wider audience • Would allow for the development of different presentations such as videos and interactive charts	• Cost implications to develop and update, and may require resource from the external communications team and/or an external contractor

Issues for decision

6. The Board is asked to consider the options presented above, with the recommendation that in future we produce a shorter 6-monthly report with topic-based updates at intervening meetings (option 2).

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NICE uptake and impact report

March 2017

*A biannual report on the uptake of NICE products
and NICE's impact on health and social care*

Contents

Foreword

NICE guidance on effective, appropriate practice helps those working in health and social care to make better decisions with patients, service users and their families. This is particularly important as the NHS faces the challenges of increasing demand and the added complexities of dealing with an aging population. It aligns well with NHS Improvement's priority of improving the quality and sustainability of services.

This report reviews the impact of NICE guidance, standards and advice on the health and care system, and highlights how evidence-based recommendations are contributing to strategic change and quality improvement. It highlights the benefits of organisations across the health and care system working together to create the safest, highest quality health and care service. The use of NICE guidance, standards and indicators is key to enabling commissioners and provider organisations to keep improving the quality and efficiency of the care they provide.

This report clearly shows that while good progress is being made in some areas, there is still room for improvement in others. The challenges facing the system require a joined-up approach and ever closer working between national bodies. NHS Improvement and NICE are already working closely together, and this is a process that we want to continue. Only by aligning our approach, moving towards shared goals, can we best support the health and social care system improve for patients.
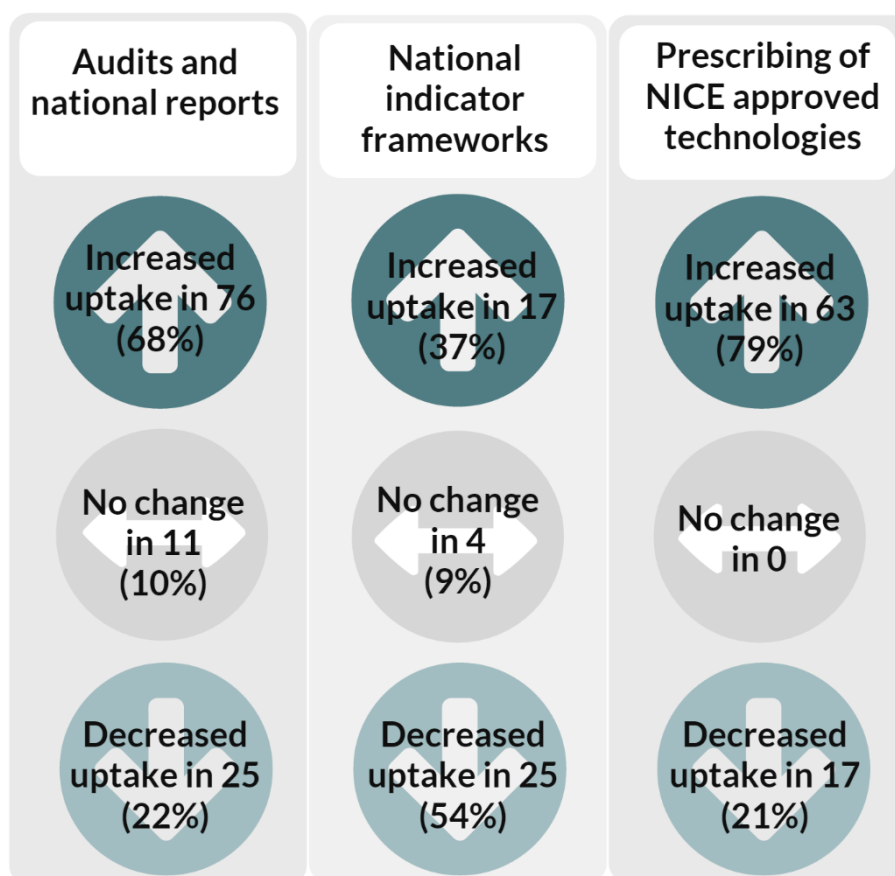
Dr Kathy McLean

Executive Medical Director, NHS Improvement

Executive summary

The biannual NICE uptake and impact report provides information on the uptake of NICE products and the wider impact of NICE on the health and care system. This report covers the period April to October 2016.

The report uses data collected from national audits, reports, surveys and indicator frameworks to review the uptake of NICE guidance recommendations and quality statement measures. The report also considers the wider impact of NICE on the health and social care system by reviewing engagement at a national, regional and local level.

A high level overview of the trend in uptake of NICE recommendations over the last 6 months, by type of information, is shown in the graphic below.

Audits and national reports	National indicator frameworks	Prescribing of NICE approved technologies
Increased uptake in 76 (68%)	Increased uptake in 17 (37%)	Increased uptake in 63 (79%)
No change in 11 (10%)	No change in 4 (9%)	No change in 0
Decreased uptake in 25 (22%)	Decreased uptake in 25 (54%)	Decreased uptake in 17 (21%)

Key findings throughout the report are presented in separate health, public health and social care sections. More information is available about the uptake of our guidance and quality standards in the health sector than for public health and social care. Some topics, however, such as dementia, antimicrobial stewardship and discharge from hospital cover more than one sector, reflecting a move towards greater integration. We continue to seek more information that will give us greater insight into the uptake and impact of NICE guidance and standards in social care, and across public health.

Health: clinical practice

Almost all of the national data collected for the report gave us information about the uptake of our products for the health sector. The report focuses on 3 areas related to priorities in clinical practice: diabetes, maternity and patient experience.

- In diabetes care, more patients with type 2 than type 1 diabetes received NICE recommended care, and a higher proportion achieved recommended blood sugar targets. There was evidence that improvements in recorded delivery of care processes appeared to be associated with inclusion in the Quality and Outcomes Framework (QOF).

- In maternity services, there was an association between quality standards and a steady improvement in outcomes such as the proportion of babies born at less than 30 weeks receiving a 2 year follow-up as recommended by NICE.

- For patient experience, patients in both hospital and general practice were satisfied overall with their care. Compared with other inpatients, more patients with cancer reported being involved in decisions about their care as recommended by NICE. However, there was some variability in the information and support offered to people with different types of cancer.

Health: medicines and technology

Prescribing data from the innovation scorecard showed rapid uptake of many medicines newly appraised by NICE, including those recommended for treating hepatitis C and diabetes.

We are involved in national medicines optimisation strategies, including the use of biosimilar medicines. Potential cost savings when switching to biosimilar versions are significant, and NICE medicines and prescribing associates reported large savings in their local health economies after using NICE resources to support a change in prescribing.

Public Health

Data on the use of NICE public health guidance is limited, but some information was available for the 6 month period of this report. Data from the NHS staff survey was used to determine the uptake of recommendations from the NICE guidance on workplace health: most respondents felt that their organisation took positive action on health and wellbeing; but less than half were satisfied with the extent to which their work was valued.

National indicator and audit data show that a high proportion of people who smoke and who have underlying health conditions were offered assistance to quit, in line with NICE recommendations.

At a local level, work to support NICE guidance on antimicrobial stewardship resulted in reductions in the proportion of broad-spectrum antibiotics prescribed as a total of all antibiotic prescribing.

Social care

Data from the Public Health Outcomes Framework showed that, while the NICE guideline on home care recommends that the potential negative effect of isolation should be addressed, less than half of adult social care users have as much social contact as they would like. National audit data showed that most inpatient wards have dedicated discharge coordinators, as recommended in the NICE guideline on transitions between home and hospital.

At a local level, the NICE medicines and prescribing associates reported that implementing NICE's guidance on managing medicines in care homes led to cost savings and improved safety. The NICE field team reported that initiatives to improve transfer of care in line with NICE's transition guidelines showed a reduction in readmissions, and dementia guidance is being used to inform local practice and service specifications.

1. Introduction

NICE's purpose is to help improve the quality, sustainability and productivity of health and social care by producing guidance and information on effective, appropriate practice. However, NICE guidance and advice needs to be effectively implemented to have any impact on the health and wellbeing of the population and the quality of care provided.

Evaluating uptake and impact is a key objective of our implementation strategy. This twice-yearly report aims to provide an overview of the information that NICE has gathered about how our recommendations for evidence-based and cost effective care are being used. The report is produced primarily for the NICE Board, but may additionally be of interest to our commissioners, our partners in the health and social care system, and to those working in the system who use our guidance.

How we developed this report

Gather 1 — We gathered information that was newly available between April and October 2016. This included national data, local practice examples and information about NICE's communication activities.

Review 2 — We reviewed the data and established whether it measured the uptake of NICE recommendations or quality standard measures.

Result 3 — We analysed the resulting data and reported the trends and patterns that we identified. We used further supporting information to provide context to our findings.

In this report we have gathered data about the uptake of our recommendations which were newly available to us between April and October 2016. These routinely collected data come from a range of sources and were initially collected for a variety of reasons across the complex health and social care system. Where possible we have synthesised and interpreted the data to look for trends and patterns which might help us identify areas of particularly high, low or variable uptake of our recommendations.

To give us the broadest possible picture of the impact of NICE products on the health and social care system, we have considered these data alongside information about our engagement and communication activities between the same dates. We have looked at how we engage with the system at a national, regional and local level to understand how we might have influenced policy and practice.

We recognise throughout the report that the health and social care system is enormously complex and there are many factors which influence changes in practice and outcomes. Increased uptake of NICE recommendations is just one of these factors. Demographics, constrained resources, public expectation and a wave of new technologies are combining to present the system with both challenges and opportunities. The sustainability and transformation plans drawn up to meet the 'triple challenge' identified in the NHS Five Year Forward View recognise that, while some of what is needed can be done by the NHS, much will require collaboration with local government, voluntary organisations and employers.

In this report we have looked at the findings by sector in separate sections for health, public health and social care, although we recognise the increasing extent of integration across sectors. Much of the regional and local engagement work we have reported on involves supporting new models of integrated care and many of the topic areas in the report cover the health and social care interface, such as dementia and prescribing in care homes.
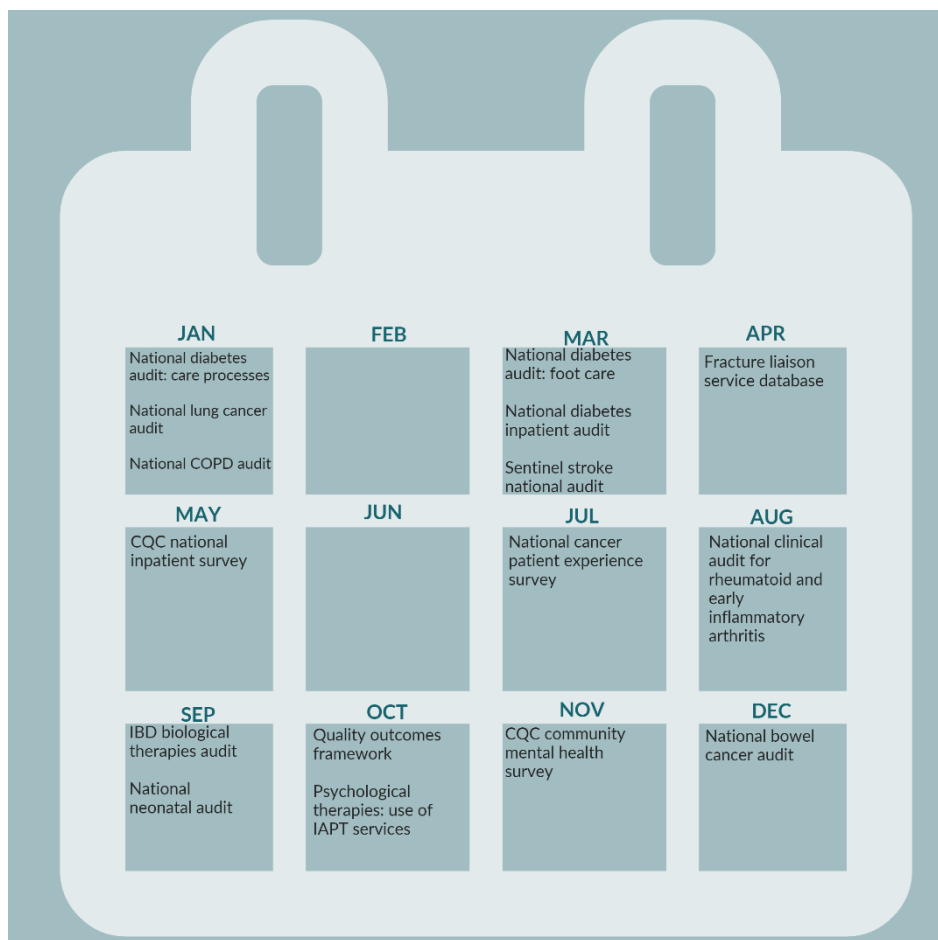
2. Information sources used in this report

To develop this report, we considered information that was newly available between April and October 2016. We collected newly published data which gave us information about the uptake of NICE guidance and standards. We also collated feedback from users of our guidance and information about NICE's engagement activities to examine the wider impact that NICE is having on the health, public health and social care sectors.

2.1. *Uptake of NICE recommendations*

The best available information to examine the uptake of NICE recommendations is published national data. This is because it gives us the most accurate and representative picture of how our recommendations are being used in practice.

Because the uptake and impact report publishes twice a year, and many of the data sources it is based on are published annually or less frequently, the amount and type of data included in each report will vary. This report includes data which were collected between April and October 2016, allowing us to include the 2015/16 Quality and Outcomes Framework data release, published in October 2016. The graphic below highlights some of the major audits and data releases which are expected to be available for inclusion in future reports.

JAN	FEB	MAR	APR
National diabetes audit: care processes		National diabetes audit: foot care	Fracture liaison service database
National lung cancer audit		National diabetes inpatient audit	
National COPD audit		Sentinel stroke national audit	

MAY	JUN	JUL	AUG
CQC national inpatient survey		National cancer patient experience survey	National clinical audit for rheumatoid and early inflammatory arthritis

SEP	OCT	NOV	DEC
IBD biological therapies audit	Quality outcomes framework	CQC community mental health survey	National bowel cancer audit
National neonatal audit	Psychological therapies: use of IAPT services		

National audits, reports, surveys and indicators

Data about the uptake of NICE recommendations are routinely collected from national audits, reports, surveys and indicators. The full list of audits, surveys and reports used in this report is included in Appendix A. These include:

- National clinical audits commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP)

- Patient experience surveys published by the Care Quality Commission (CQC)

- Data on indicators such as those included in the Quality and Outcomes Framework (QOF) and the Public Health Outcomes Framework (PHOF)

- Routine data collections, such as smoking statistics, published by NHS Digital

- Regular or one-off reports such as those produced by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), the NHS Benchmarking Network, NHS England, patient groups, royal colleges, all-party parliamentary groups and other national health and care organisations.

Audits, reports and surveys are identified by monthly searches of relevant organisations' websites, via newsletters and alerts and by developing relationships with organisations who commission and publish data. When identified, sources are included in NICE's audit publications planner, which provides details of current and future national audit publications and is published quarterly on the NICE website.

Each published source is reviewed by a NICE analyst to identify data which provide information about the uptake of a NICE recommendation or quality statement measure. The criteria for inclusion are that the publication or audit must:

- contain new and original work

- have findings and results that relate to populations resident in England, Scotland, Northern Ireland or Wales

- include quantitative data (reported as a compliance measure) which gives us information about a specific recommendation or measure published in NICE guidance.

Following a peer-review process, data which meet the criteria are uploaded to the NICE uptake database and made available to users of our products. The database can be used by people working in health, public health and social care to find audits relevant to NICE recommendations and to compare local or regional uptake with national data.

National audit, report and survey data used in this report

Between April and October 2016, **348 new data points from 32 national audits, reports and surveys were added to the uptake database** (see Appendix A). These data gave us information about the national uptake of 212 recommendations or quality statements from 60 of our guidelines, quality standards and technology appraisals. During this period, major publications such as the National Diabetes Audit and the CQC National Inpatient Survey were analysed. Most of the uptake data collected from these (335 data points) gave us information about our recommendations in the health sector.

Chart 1: Data points added to the uptake database from national audits, reports and surveys, April to October 2016, by sector

● Health   ● Public health   ● Social care
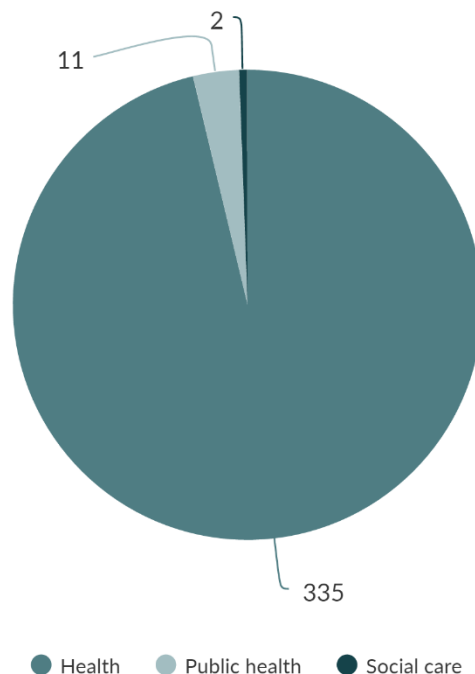
Indicators data used in this report

Between April and October 2016, we identified **53 indicators from 2 national frameworks** which gave us information about 45 recommendations or quality statements in 30 of our guidelines or quality standards. Most of the indicators (47) gave us information about the uptake of our clinical guidelines.

Chart 2: Indicators added to the uptake database from national indicator frameworks, April to October 2016, by sector
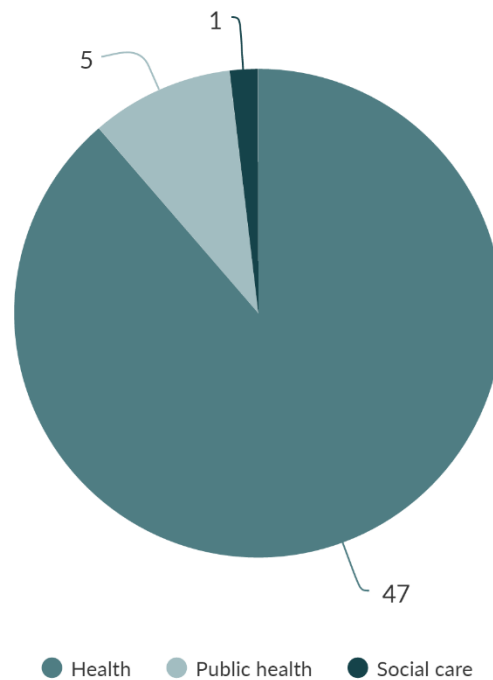
The **Quality and Outcomes Framework** (QOF) contains national data from general practice about user achievement against groups of indicators, many of which are from the NICE menu of indicators. This menu is developed by NICE and provides a range of evidence-based indicators to support national and local measurement of quality improvement. The indicators are underpinned by a robust evidence base and have been through a rigorous process, which includes development by an independent committee, testing and piloting, and public consultation. They are regularly reviewed to ensure they are in line with the latest guidance.

We analyse the QOF data release annually to identify which indicators give us uptake information about a specific recommendation or quality statement measure in a NICE guideline or quality standard. From the 2015/16 data release, we identified **47 indicators** which measure the uptake of our recommendations or quality statement measures.

For the first time this year we have analysed the data published by Public Health England in the **Public Health Outcomes Framework** (PHOF). These data give information about health improvement, factors that affect health and wellbeing, health protection and mortality. Many of the indicators are broad outcome measures, such as life expectancy or mortality rates, which cannot be linked directly to a specific NICE recommendation or quality statement measure. However, these indicators can help to build an overall picture of outcomes in areas of health and care which are related to our guidance. It should be noted that, while the indicators are

published as public health outcomes, many of them measure outcomes in areas, such as breastfeeding initiation, which are covered by NICE's clinical guidelines.

We have identified **6 indicators** from the framework which gave us information about the uptake of specific recommendations or quality statement outcome measures.

Prescribing data in this report

The prescribing data in this report comes from the innovation scorecard and the medicines optimisation dashboard, which give information about the uptake and use of positively appraised NICE medicines.

The **innovation scorecard** reports on the use of medicines in the NHS in England which have been positively appraised by NICE since January 2012. NHS Digital publishes this information every three months on behalf of the Office for Life Sciences. October 2016's report contained prescribing data for **85 medicines** with usage data to the end of March 2016.

The **medicines optimisation dashboard** contains national data on medicines use that aim to help clinical commissioning groups improve and understand how well patients are being supported to use their medicines. NICE have identified 15 key therapeutic topics where there are potential opportunities for maintaining or improving quality and improving value from the use of medicines. The dashboard currently contains data for 8 key therapeutic topics: type 2 diabetes, non-steroidal anti-inflammatory drugs, biosimilar medicines, anticoagulants, asthma, hypnotics, antibiotic prescribing and antidepressants. We have considered the data on biosimilar medicines further as part of a medicines and technologies case study in the health findings section of this report.

2.2. Wider impact of NICE

Assessing the wider impact of NICE is not an exact science and is inevitably influenced by other activity across the wider health and care system. To help us understand how NICE and its products are used and valued, we collected as much information as possible from teams across NICE which told us about our activities between April and October 2016. We collated information about NICE's influence on and contributions to national policies to help understand our wider impact on the system. We considered feedback from NICE's engagement with health and care professionals, to show how well NICE products are used and understood.

We also collected and analysed data about our website and communication activities, to help us identify popular themes among health and care professionals and the wider public. We looked at our newly published guidance to identify which topics have resulted in most press and user interest, and we analysed the enquiries NICE received and the shared learning examples we published. We will continue to collect and analyse this information in future reports to look for any patterns.

Engagement activities

National engagement

NICE aims to develop and foster productive and sustainable relationships with those in the health and care system to ensure that our guidance is used to its full potential. Much of our engagement with national partners aims to ensure that their work, such as NHS England's Right Care programme or the Care Quality Commission's inspection programme, is aligned to our guidance. For this report, we reviewed strategic and national activities carried out by teams across NICE to identify areas of impact.

NICE field team

The NICE field team of implementation consultants provide practical support and advice to NHS trusts, networks, CCGs, local authorities and social care providers, particularly in relation to effective processes for implementation and information about NICE. Each implementation consultant works with NHS, local authority and other organisations in their area, ensuring regular interaction with NICE stakeholders. For this report, we looked at the field team success criteria and gathered examples of their work in each sector.

Medicines and prescribing associates

The NICE medicines and prescribing associates are a community of associates who work within their own organisations and health economies to help us support and promote high quality, safe, cost-effective prescribing and medicines optimisation. In this report, we've reviewed their activities in the data collection period and gathered examples of their work to support NICE guidance in priority areas.

Conferences and events

The NICE external communications team manages NICE's presence at conferences and events, promoting the work of NICE and contributing to a greater awareness and understanding of NICE's role. The team also coordinates NICE's programme of speaking arrangements, proactively seeking out opportunities for NICE staff to speak at key conferences and responding to speaker requests. All upcoming events and speaker engagements are highlighted to users of NICE on the events page of NICE's website. For this report, we collated details of the events which NICE either exhibited at or contributed to between April and October 2016 to help us identify topics and themes of greatest interest.

We have also considered feedback from NICE's regional stakeholder events. These were held in September and October 2016 and focused on integration in Manchester, public health in Birmingham, the NHS in London and social care in Bristol. In total, 97 people attended these facilitated round-table discussions which explored the views of the attendees on how they work with NICE and what more we can do to support their role.

Audience engagement

NICE website

The NICE website is the main route to our guidance and advice for health and social care professionals and the wider public. For this report we looked at which guidance and quality standards our users viewed most in the data collection period, to help us identify topic areas which might be of most interest to the health and care system. We gathered Google Analytics data from nice.org.uk/guidance and pathways.nice.org.uk, as these are the 2 ways our recommendations on the NICE website are accessed. Between April and October 2016, **NICE guidance pages received over 20 million page views and NICE Pathways a further 3 million**.

Enquiries received by NICE

The NICE enquiry handling team responds to users of NICE products, including the public, healthcare professionals, patient groups, charities and professional bodies. The team also coordinates responses to Parliamentary questions, HM Coroners letters and Freedom of Information requests. The team received 5,185 enquiries between April and October 2016, with 1,515 of these directly related to specific guidance or quality standards. In this report, we looked at these in more detail to identify any patterns or common themes.

Press and media activity

The NICE media relations team promotes our new and existing products, organises press conferences and interviews, briefs NICE spokespeople and issues comments

on relevant media stories. To help us identify the topics and themes which were of most interest to the press and media during the period covered by this report, we looked at both the coverage generated by our press releases and the media enquiries we received.

Shared learning examples

[Shared learning examples](#) are case studies submitted by users of NICE products, showing how our guidance and standards have been put into practice in the NHS, local authorities, the voluntary sector and a range of other organisations. While some of these examples are submitted as a result of the organisation contacting us, others are identified as possible examples by teams within NICE who work to support implementation, such as the [NICE field team](#) and the [adoption team](#). Organisations are then encouraged and supported to submit their example. For example, the field team have been working to try and increase the number of shared learning examples from the social care sector, and the adoption team often identify potential examples as part of the work they do to support adoption of guidance. In the data collection period, we published 34 shared learning examples.

2.3. How we used these data in the report

After gathering all of the available uptake data and information on the wider impact of NICE, the data were grouped by topic area, such as diabetes or smoking cessation. We had much more data and therefore many more potential topics relevant to the health sector than public health or social care. The topics were reviewed by an editorial board made up of NICE colleagues representing the teams who have contributed to the report. The board also provided clinical oversight and specialist expertise in areas such as resource impact. The board identified those topics which should be highest priority for analysis in the report, using the following criteria as a guide:

- the topic is a national priority

- the topic is of significant media or public interest

- more than 1 information source is available, including a source of uptake data

- the topic allows for discussion of uptake, quality improvement or cost savings associated with disinvestment.

After grouping and prioritising the data we looked for trends and patterns; where possible we looked at data over an extended period of time to identify how uptake in an area of health or care has changed. Where data over time were not available we looked for different patterns, such as differences in patient experience between people with different conditions.

We then looked more closely at the available information about the wider impact of NICE for each sector. We collected practice examples to demonstrate how teams across NICE engage with colleagues across the health and care system and we considered how NICE influences and contributes to national policies.

Finally, we developed case studies in each sector, which bring together uptake data with information about the wider impact of NICE to give a broad overview of our work in key priority areas.

2.4. Data limitations

The data used in this report were gathered from a variety of sources and were originally collected for a range of different purposes. There are often limitations in what the data can tell us and what further analyses are possible.

In addition, the health and social care system is complex and there are multiple initiatives that drive, improve or influence the quality of care. The data we have gathered may tell us about increases in the use of NICE products or better uptake of specific recommendations, which could be one reason why outcomes change over time. However, we have recognised throughout this report that there may be many other reasons for observed changes in outcomes.

Audit data

National audits, reports and surveys can provide valuable information about the uptake of NICE recommendations. Many of these are well-established programmes which regularly publish results and can help us identify changes over time. However, the audit criteria or survey questions are developed by national organisations to meet their own requirements and may reflect priorities which are not included in any NICE guidance, or are based on recommendations from other sources. The limitations of using these data include:

- Some audit criteria or survey questions can provide insight but do not exactly match our recommendations, or provide information about only one part of a multi-part recommendation. For example, the NICE guideline on diabetes in children and young people covers people aged under 18 but the National Paediatric Diabetes Audit looks at the treatment of young people up to the age of 24.

- Some audits or surveys have changed since they were previously reported, with new or updated audit criteria or new analyses applied to the data before publication. This means that direct comparisons over time are not possible or may be misleading. For example, the Cancer Patient Experience Survey has been completely redesigned for 2015, with new questions added and changes made to the data collection methods for existing questions.

- We often have no access to the raw data, meaning that no further analyses are possible or comparisons over time may be misleading. Some results are reported as a proportion only, or they have been weighted or otherwise adjusted. For example, the quality and methodology report which was published with the CQC Inpatient Survey states, "Due to the nature of statistical comparisons and weighting calculations, comparisons between years of data should be undertaken with caution, as weights are recalculated every year for statistical

comparisons and minor percentage differences may lead to changes in rounding."

- The audit may be a one-off publication. While this gives us useful information about uptake at a point in time, it means that no changes over time can be considered.

- Our guidance may have changed. NICE guidelines and quality standards are regularly updated to reflect new evidence. The lead-times for making changes in audit programmes vary, so the measures in national audits do not always align with what NICE currently says.

- Some audits and reports are based on small sample sizes or have poor response rates. This means that results should be treated with caution, particularly any attempt to consider changes over time.

- Methodology statements are not always available, meaning that we cannot be confident in the quality of the data and do not know if any weighting or other adjustments have been applied.

- There is a well-established programme of national audits in the health sector but we have far less of the same type of information available for public health and social care. This means that it is difficult to understand uptake of NICE's recommendations in these areas by using national data.

Indicators data

In this report we have used data collected and published in the Quality and Outcomes Framework (QOF) and the Public Health Outcomes Framework (PHOF). There are some of the same limitations as discussed above when using these data, such as indicators not matching our recommendations exactly or measuring only part of a recommendation.

Prescribing data

The Innovation Scorecard is an Official Statistics publication, which means that it complies with the UK Statistics Authority's code of practice. Limitations of using these data include:

- Although trends can be determined, not all of the medicines in the scorecard are reported in the same units, which means that direct comparisons of use are not always possible.

- Hospital prescribing data is not centrally collected in the NHS. The information included in the scorecard is collected and collated on a commercial basis by an external organisation. These data are incomplete for medicines delivered via the homecare route or purchased through routes outside the pharmacy systems, such as pre-mixed medicines

purchased from specialist companies. This means that there may be higher uptake of some medicines than is reported in the scorecard.

- Many of NICE's technology appraisals recommend a new medicine as an option for treatment of a condition, and prescribing data for other treatment options may not be included in the scorecard. This means that low or variable uptake of one medicine can be as a result of people choosing an alternative which is not measured in the scorecard.

- Many of NICE's technology appraisals are for medicines which are licenced to treat multiple conditions, although each appraisal is for the treatment of only one condition. It is not possible to split prescribing by condition, which means that it can be difficult to understand overall changes in prescribing.

- The scorecard includes medicines which have had a positive NICE appraisal but does not include medicines which are recommended in NICE clinical guidelines. When a medicine which has previously had a positive technology appraisal is added to a clinical guideline, it is no longer eligible for inclusion in the scorecard. This means that we have limited information about prescribing for conditions such as diabetes, where most of the medicines which NICE recommends are included in the NICE clinical guideline.

- The scorecard does not currently provide any information about the uptake of NICE medical technology or diagnostics guidance so we have very limited uptake information in these areas. Because of difficulties in accessing data, a decision was made to remove these from the scorecard in 2016. NICE is working with NHS Digital and the Office for Life Sciences to test a new approach to including these products in future scorecards.

Wider impact of NICE

Local and regional practice examples and feedback often give us a deeper insight into the drivers and barriers to implementing NICE guidance and provide practical examples of how recommendations are put into practice. However we recognise that these findings may not apply to people working in different settings or in areas of the health and care system which are configured differently.

3. Findings

After gathering the available uptake and activity data, we reviewed these to identify any trends or patterns. In this report, we have first considered the findings overall, and have then looked in more detail at uptake and impact in each of the health, public health and social care sectors.

3.1. *Uptake of NICE recommendations*

National audits, reports and surveys

Between April and October 2016, 348 new data points from 32 national audits, reports and surveys were added to the uptake database. Where possible, the uptake database shows changes over time. When we looked at the data points we identified in this period, we were able to consider **changes in uptake over time for 112 of our recommendations or quality statement measures**. We have calculated these changes only where the same data point was reported in a previous audit, and where the methodology of the audit and the recommendation it measures have not changed (see data limitations).

A summary of these changes over time are shown below. The same information from the September 2016 NICE uptake and impact report is shown here for reference. It should be noted that these data relate to the uptake of different guidelines or quality standards, so this does not represent a direct like-for-like comparison. **Two-thirds show increased uptake since the previous audit, one-fifth decreased uptake and one-tenth no change.**

March 2017		
Increased uptake in 76 (68%)	No change in 11 (10%)	Decreased uptake in 25 (22%)

September 2016		
Increased uptake in 36 (47%)	No change in 16 (21%)	Decreased uptake in 24 (32%)
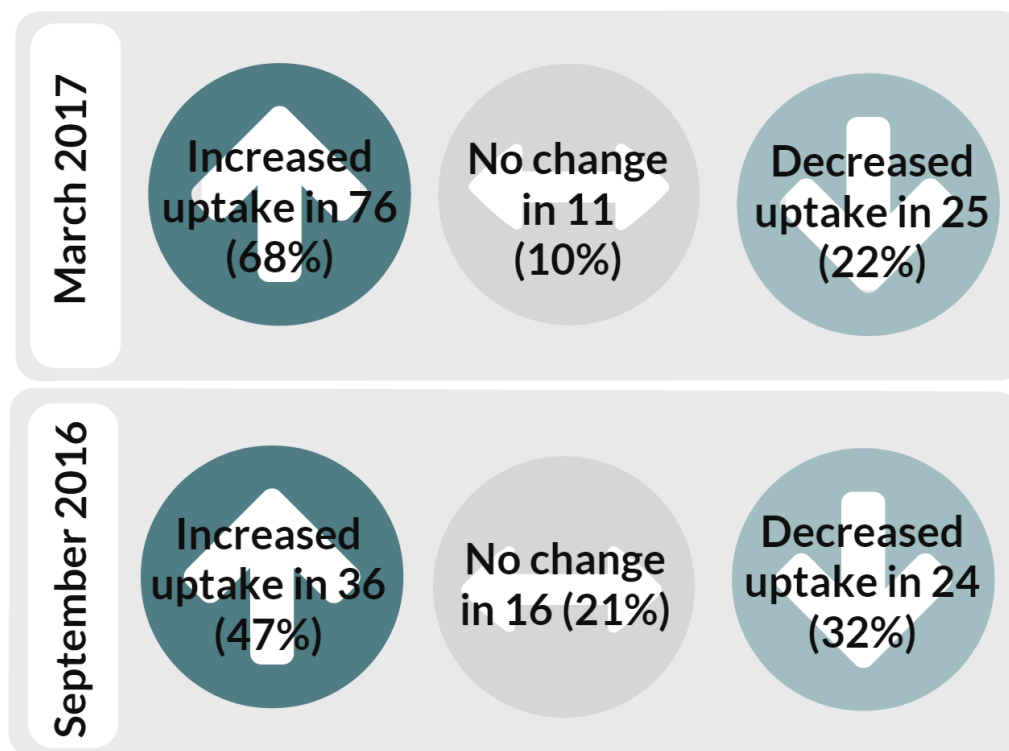
Some of these changes over time are very small and some may not be statistically significant. We are unable to calculate this without access to raw, unweighted data, but we do record when the audit publication reports significance. Of the changes in this report, **19 were reported as statistically significant increases and 2 as statistically significant decreases**.

Indicators

From the 2015/16 **Quality and Outcomes Framework** (QOF) data release, we identified 47 indicators which measure the uptake of our recommendations or quality statement measures. Of these, 40 were included in the previous year's QOF so we were able to look at changes over time; a summary is shown below. **One-third increased, one-tenth were unchanged and the remainder showed a decrease,** although it should be noted that most of the changes over time for these indicators were very small**.**

Increased uptake in 13 (33%)   No change in 4 (10%)   Decreased uptake in 23 (57%)
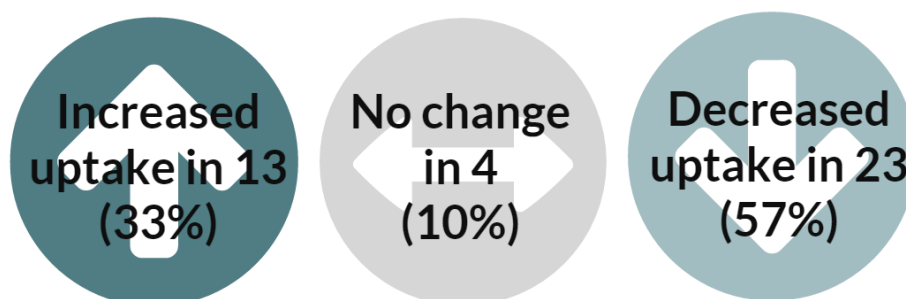
From the **Public Health Outcomes Framework** (PHOF), we identified **6 indicators** which give us information about the uptake of specific recommendations or quality statement outcome measures. Although we had not previously analysed these indicators, data from previous years were available so we were able to look at changes over time. **Two-thirds showed an increase, one-third a decrease.**

Increased uptake in 4 (67%)   Decreased uptake in 2 (33%)

Prescribing data

The innovation scorecard published in October 2016 contained uptake data for 85 medicines, of which 80 had prescribing data available for more than a year. For these medicines we compared the volume dispensed in 2014/15 with that dispensed

in 2015/16 and found that **63 (79%) showed an increase in the volume dispensed** and the remainder a reduction.

Since the suspension of medical technologies from the innovation scorecard in 2016, we have no uptake information for our medical technologies or diagnostics guidance available for inclusion in this report. We hope that a new, robust process for including medical technologies in the innovation scorecard will mean that we can report on these in future uptake and impact reports.

3.2. *Wider impact of NICE*

Engagement activities

> Much of our engagement in this period has been cross-sector, working at a national, regional and local level to influence the new models of care which aim to integrate health and care services.
>
> Of the sector-specific engagement we have tracked in this report, the largest proportion is relevant to the health sector.

National engagement

A key current driver of change in the system is the Five Year Forward View, which sets out a new vision for the future of the NHS based on new models of care. Over the period covered by this report, NICE has continued to play an active role in developing and supporting the implementation of the vision. NICE is represented on the national programme boards which are responsible for developing programmes and policies to deliver the Five Year Forward View.

NICE guidance and standards are embedded throughout the Five Year Forward View task force reports, developed to support quality improvement in the 3 clinical priority areas:

- Achieving World-Class Cancer Outcomes: Taking the strategy forward

- Better Births

- The Five Year Forward View for Mental Health

The National Quality Board (NQB) shared commitment to quality framework was developed during the data collection period for this report and published in December 2016. NICE is a member of the NQB and the working group which developed the framework. The shared commitment recognises NICE's importance in improving quality across the system, highlighting that:

- NICE quality standards bring clarity to quality

- our indicators measure outcomes that reflect the quality of care, and

- our developmental quality statements set out an emergent area of cutting-edge service delivery or technology currently found in a minority of providers and indicate outstanding performance.

During the period covered by this report, NICE engaged in a number of ways to support the development of Sustainability and Transformation Plans (STPs). These are place-based plans for the future of health and care services in a footprint area. Draft plans were submitted in June 2016 and final plans in October. NICE guidance was an important element of a number of resources produced by NHS England to support the development of STPs, including:

- Quick Guides, which were developed to help local leaders work together in tackling the big system questions, and build on existing efforts to make progress on some of the most challenging priorities. Each guide starts by setting out what success would look like in 2020, and gives suggestions about how areas could approach implementation. NICE commented on all of the guides and highlighted the relevant NICE products to be included in each.

- A library of resources document, which was intended to be a useful resource for sustainability and transformation footprints seeking to quantify and address their care and quality and health and wellbeing gaps. For ease of reference, it pulled together in one place much of the previously published guidance relevant to these gaps. The document included a dedicated section for NICE quality standards and indicators, which mapped selected NICE standards against key national topics such as urgent and emergency care, elective care, cancer care and maternity care.

We have looked at how the NICE field team supported these plans at a regional and local level in the sector-specific sections of this report. We have also highlighted further policies and programmes which we have worked with system partners to develop and influence.

Field team

Performance against the NICE field team success criteria between April 2016 and January 2017 is reported in full in appendix B. In this period, the field team recorded 27 engagements with sustainability and transformation footprints. The team have been working to increase engagement with the social care sector and have collected 52 examples of NICE social care guidance being used by local authorities or provider networks.

In this report, we've looked at more detail at the field team's work to embed NICE guidance and quality standards into new models of care and integrated services, including supporting the development of the Nottinghamshire Sustainability and

[Transformation Plan](#) and the [Greater Manchester Health and Social Care Partnership](#). We've also looked at topic-specific support, where the field team have worked with local and regional partners to support implementation of NICE's [workplace health](#) and [dementia](#) guidance.

Medicines and prescribing associates

In the data collection period, the medicines and prescribing associates supported a range of medicines practice and clinical topics:

- NICE clinical guidelines: [multimorbidity](#), [type 2 diabetes in adults](#), [medicines optimisation](#), [atrial fibrillation](#), [cardiovascular disease](#)
- NICE medicines practice guideline: [antimicrobial stewardship](#), [controlled drugs](#)
- NICE social care guideline: [managing medicines in care homes](#)
- [NICE position on biosimilar medicines](#)
- Key therapeutic topics: [high-dose inhaled corticosteroids in asthma](#), [hypnotics](#)

In this report, we have looked in more detail at the associates' work to support the NICE guidelines and quality standards on [antimicrobial stewardship](#) and [managing medicines in care homes](#), and our position on [biosimilar medicines](#).

Conferences and events

In this period, NICE speakers contributed 96 presentations, panel discussions, workshops or keynote addresses at 80 conferences or events.

Chart 3: NICE speaker contributions to conferences and events, April to October 2016, by sector

● Health ● NICE overall ● Public health ● Social care
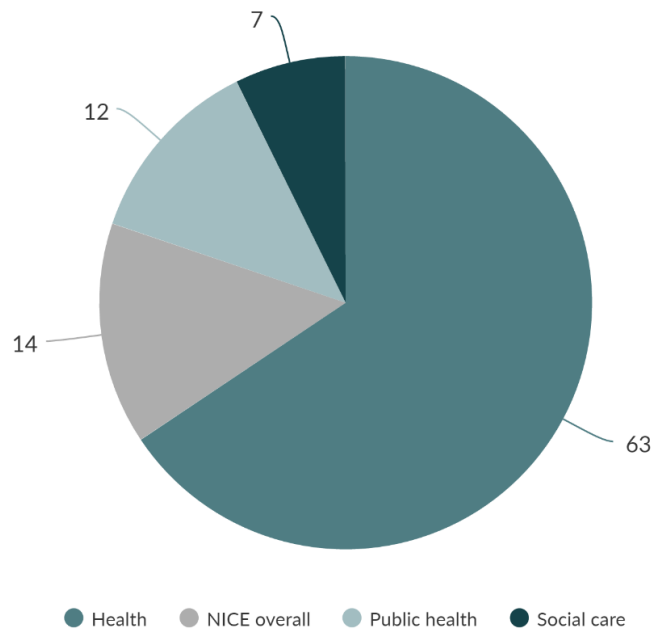
The largest proportion (66%) of speaking engagements were health-related. Of the 63 in this sector, 30 were about NICE health related programmes or activities, such as good practice in health technology assessment or the role of NICE products in supporting service transformation.

- Of the 33 topic-specific speaking engagements in the health sector, **6 were about diabetes** and 5 were to promote and discuss NICE's new guideline on care of the dying adult.

- Of the 12 public health related speaking engagements, **3 were related to our workplace health guidelines**.

- There were 7 social care related engagements; 2 were about our transition topics and 2 were related to the social care of people with dementia.

In addition to these speaking engagements, **NICE exhibited at 13 conferences or events between April and October 2016**. These included the Royal College of Nursing (RCN) and the Royal College of GPs (RCGP) annual conferences and NHS England's Innovation Expo. We exhibited at Public Health England's annual conference and the Society of Local Authority Chief Executives (SOLACE) summit. To promote our social care guidelines, we exhibited twice at Community Care Live, in London and Birmingham. We have looked at the feedback collated from NICE colleagues who spoke to delegates at these conferences and this is considered further in the sector-specific results sections of this report.

Audience engagement

The 5 most viewed guidance topics on the NICE website are all clinical and likely to be most used in primary care.

Diabetes and hypertension featured in top 5 most viewed guidance and pathways and enquiries received.

The NICE guideline on sepsis was the most enquired about of all guidance, the 2nd most viewed of new guidelines and resulted in the 2nd highest number of articles in response to a press release.

In this period, members of the public were most likely to contact us to seek information about how to access treatments NICE has recommended, particularly IVF and mental health treatments.

NICE website

When we reviewed the 20 million guidance page views in the data collection period, we found that **93% were of health topics**, with **clinical guidelines and quality standards accounting for 77%** of the total, and medicines and technology guidance accounting for 16%.

Chart 4: NICE guidance and quality standard page views, April to October 2016, by sector

Legend: Health: clinical   Health: medicines and technologies   Social care   Public health   Cross sector quality standards

0.8 %
4.8 %
1.4 %
16.3 %
76.7 %
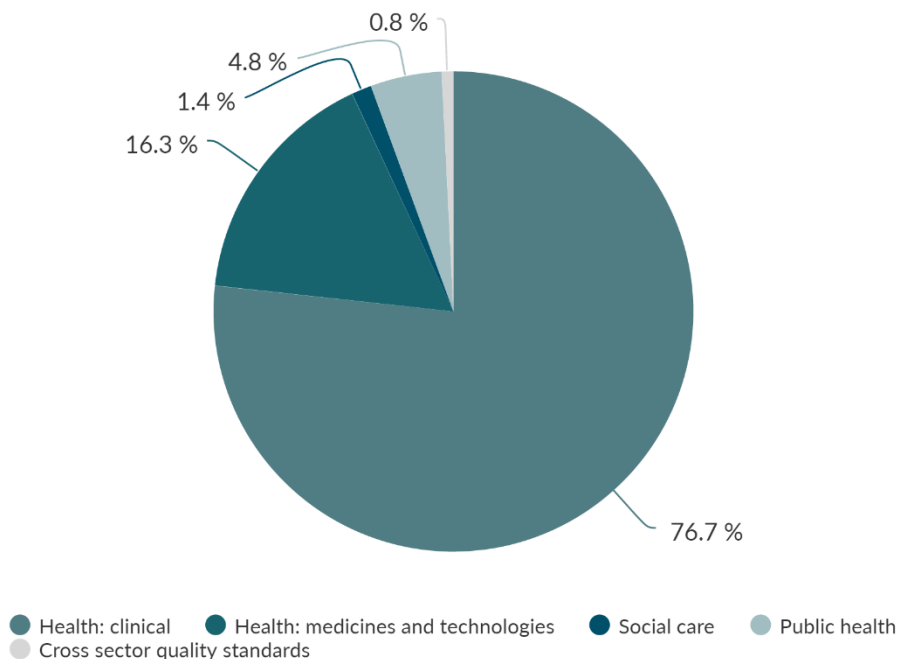
The top 5 products by page view between April and October 2016 were **all clinical guidelines, on topics with a primary care focus.**

Guideline	Publication date	Page views April to October 2016
Hypertension in adults	August 2011	468,036
Type 2 diabetes in adults	December 2015	392,202
Suspected cancer	June 2015	320,755
Chronic obstructive pulmonary disease	June 2010	281,185
Depression in adults	October 2009	247,274

Each of the top 5 most viewed **quality standards** in the period were also clinical topics. Of these, the asthma, end of life care for adults and urinary tract infections in adults quality standards are topics which do not currently have underpinning NICE guidance, which suggests that our users are keen to find information from NICE even in the absence of a guideline.

Quality standard	Publication date	Page views, April to October 2016
Asthma	February 2013	125,903
End of life care for adults	November 2011	102,041
Infection prevention and control	April 2014	84,974
Urinary tract infections in adults	June 2015	78,907
Chronic obstructive pulmonary disease	July 2011	59,939

NICE Pathways present everything NICE says on a topic in an interactive flowchart, including guidelines, technology appraisals, medical technology and diagnostics guidance and quality standards. The most viewed pathways in the period are shown below; in line with the most viewed guidelines, diabetes, hypertension and COPD are popular topics.

The NICE pathways on diabetes is the most viewed and brings together all of NICE's clinical and public health guidelines and quality standards alongside guidance on medicines for treating diabetes and its complications, and interventions such as insulin pump therapy. The third most viewed is the NICE pathway on patient experience in adult NHS services, which is included in every other relevant pathway.

NICE pathway	Page views, April to October 2016
Diabetes	189,608
Hypertension	126,355
Patient experience in adult NHS services	84,754
Chronic obstructive pulmonary disease	69,209
Acute coronary syndromes	61,554

New guidance

We also reviewed the data for new guidance and quality standards published in this report's data collection period and for the preceding 6 months (October 2015 to October 2016), to help us identify which of our most recently published products might be generating most interest. **All of the top 5 most viewed are clinical guidelines.**

Guideline	Publication date	Page views, April to October 2016
Type 2 diabetes in adults	December 2015	392,202
Sepsis	July 2016	181,888
Menopause	November 2015	162,629
Care of dying adults in the last days of life	December 2015	98,841
Tuberculosis	January 2016	86,664

The most viewed new social care guideline was **transition from children's to adults' services for young people using health or social care services**, and the most viewed new public health guideline was **oral health for adults in care homes**. We have looked in more detail at the most viewed guidance and quality standards by sector in the results sections of this report.

Enquiries received by NICE

When we analysed the 1,515 guidance or quality standard-related enquiries received in the data collection period, we found that **39% came from the public and 29% from the NHS**. The rest of the enquiries came from sources such as professional and educational bodies, patient groups, pharmaceutical companies, health regulators, private healthcare providers, public relations firms and Parliamentary questions.

We found that **92% of the enquiries were about our products for the health sector**. Clinical topics accounted for the majority (67%), followed by medicines and technologies (25%).

Chart 5: NICE guidance and quality standard-related enquiries, April to October 2016, by sector

- Health: clinical
- Health: medicines and technologies
- Social care
- Public health

78
35
386
1,016
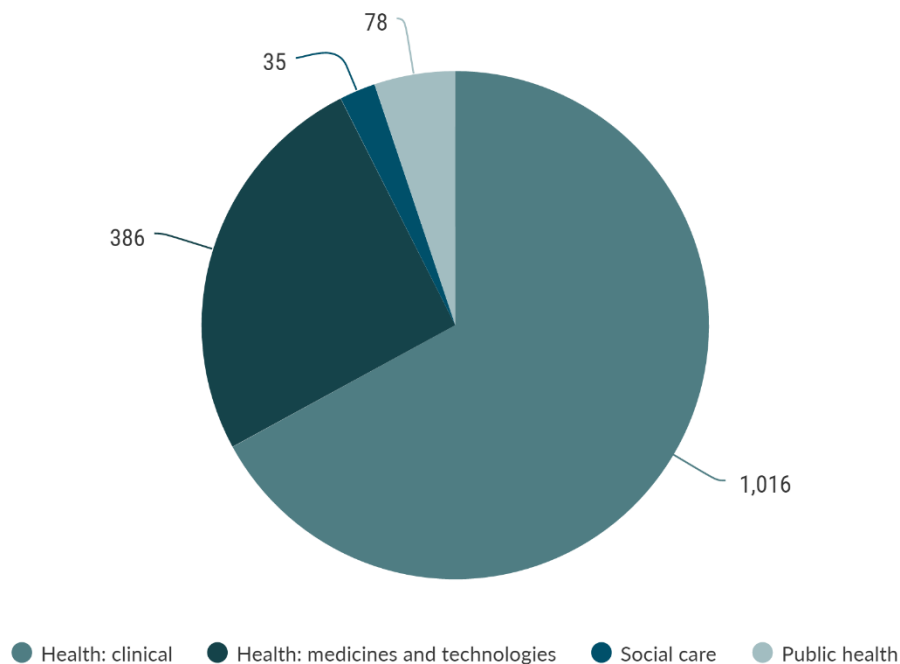
We identified that the top 5 most enquired about guidance and quality standards in the period were **all clinical guidelines**.

Guideline	Publication date	Enquiries
Sepsis	July 2016	39
Fertility problems	February 2013	35
Low back pain	May 2009	25
Hypertension in adults	August 2011	24
Type 2 diabetes in adults	December 2015	23

The types of enquiries received varied considerably for these 5 guidelines.

- Most of the enquiries about the sepsis guideline came from health professionals and were related to the guideline launch, particularly about the content and presentation of the algorithms.

- Most enquiries about the older fertility problems guideline were from members of the public who wanted to know how to access IVF treatment as recommended by NICE.

- The updated low back pain guideline (now NG59) was published in November 2016 and all of the enquiries received during the data collection period relate to this review, particularly about how evidence for the use of acupuncture had been considered by the committee.

The enquiry handling team allocates each enquiry to a category, which we used to further analyse the 1,515 guidance-related enquiries. The largest category (370) were from health and care professionals and members of the public seeking further information about our recommendations. These enquirers contacted us to clarify definitions used in our guidance, ask for the evidence behind recommendations and check if local practice was in line with what NICE has said.

The next largest group of enquiries (198) were from members of the public, contacting NICE about how our recommendations relate to the care they have received or, more often, have not been able to access. Many of these were from people seeking our help to get treatments which we have recommended, with IVF and mental health conditions such as anxiety featuring regularly. This may suggest that uptake of our recommendations in these areas is low or particularly variable.

Press and media activity

Between April and October 2016 **our press releases generated 725 pieces of coverage**, such as articles in national and regional press and coverage on television and radio. The top 5 press releases by number of articles are listed below. We have looked in more detail at the communication campaigns to promote our new guidance

on [ataluren for Duchenne muscular dystrophy](#), [sepsis](#) and [harmful sexual behaviour](#) in the sector-specific findings sections of this report.

Press release	Resulting coverage
Ataluren for Duchenne muscular dystrophy	88
Sepsis	81
Nivolumab in combination with ipilimumab for advanced melanoma	45
Pertuzumab for breast cancer	32
Harmful sexual behaviour	31

As well as proactively promoting our guidance, the media relations team responds to enquiries received from the press and media. Between April and October 2016 they received 590 enquiries, with the top 5 topic areas listed below.

Enquiry area	Enquiries April to October 2016
Lung cancer	50
Cancer Drugs Fund	40
NICE remit	33
Respiratory conditions	31
Obesity and diet / urology cancer / breast cancer	28 each

The most enquired about topic in this period was lung cancer. These enquiries were related to 3 separate appraisal decisions; the positive appraisals of [osimertinib](#) and [pembrolizumab](#) and the draft appraisal of [nivolumab](#), which did not recommend this medicine for the treatment of non-small-cell lung cancer. The enquiries about respiratory conditions relate to the appraisal of [lumacaftor–ivacaftor](#) (Orkambi) which was not recommended for use in the treatment of cystic fibrosis, and the draft [asthma diagnosis](#) guideline.

Subjects which the team are regularly contacted about, such as the Cancer Drugs Fund (CDF) and NICE's remit, are featured on the dedicated [press and media page](#) of NICE's website. This includes frequently asked questions and sets out NICE's stance on potentially controversial topics such as statins and hormone replacement therapy.

Shared learning examples

In the data collection period, we published 34 shared learning examples. Of the 20 which gave us information about the uptake or impact of our guidance, 12 were primarily related to health topics, 6 to public health and 2 to social care. However, as highlighted in the introduction to this report, many of the examples cross over sectors and show the benefits of integrated working.

4. Findings by sector

4.1. *Health: clinical practice*

This section includes information looking at the uptake and impact of NICE's clinical guidelines and quality standards. Most of the available uptake information from national audits, reports and surveys relates to this sector. Prioritisation identified 3 key areas which align with national priorities: **diabetes, maternity, and patient experience**, with a focus on shared decision making and cancer patient experience. We have analysed the audit and indicator data available for these topic areas in more detail to look for trends and patterns in the uptake of our recommendations.

We have then looked at the wider impact of NICE in the health sector, including our impact on national policies and initiatives, and a focus on how our field team are working to embed NICE guidance in the development of Sustainability and Transformation Plans (STPs). We also looked at another national priority area, mental health, by considering the uptake and implementation of our guideline on psychosis and schizophrenia at a national and local level.

Uptake of NICE guidance: overall

Between April and October 2016, we added 364 data points from audits, reports, surveys and indicators to the uptake database measuring the uptake of our clinical guidelines and standards. Of these, we were able to measure changes over time for 141 data points.

Increased uptake in 85 (60%)

No change in 10 (7%)

Decreased uptake in 46 (33%)
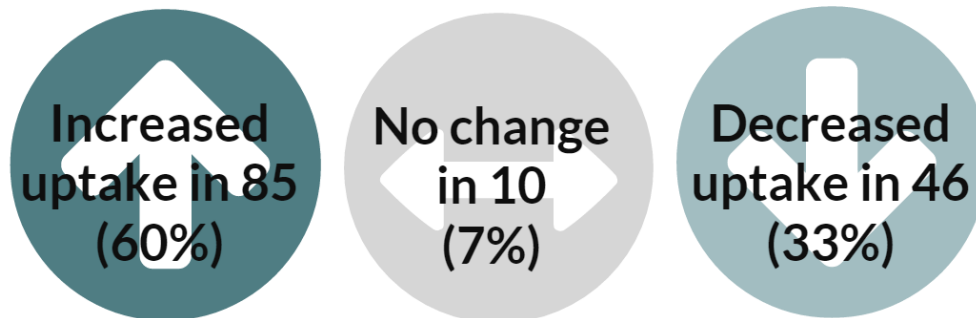
Uptake of NICE guidance: Diabetes

> The proportion of adults with type 2 diabetes who achieve HbA1c targets, receive the NICE recommended care processes and are offered structured education is higher than those with type 1 diabetes.
>
> While the delivery of most NICE recommended care processes remains steady, those which have been retired as QOF indicators have reduced.
>
> The number of people with newly diagnosed diabetes offered structured education increased following inclusion in the QOF, but the number of people taking this up remains very low at about 5%.
>
> Despite foot protection services appearing to be in place, only a small proportion of people received a foot risk assessment within 24 hours of admission to hospital.

Our diabetes guidance is amongst the most widely viewed of all our products, with the NICE pathway on diabetes having 50% more visitors than the next most viewed pathway. In this period, data measuring the uptake of NICE guidance recommendations for people with diabetes were collected from 4 national audits and 1 national report. These information sources provided uptake data for 4 diabetes guidelines and 1 quality standard. We have looked at more diabetes data, giving us information about prescribing and the use of insulin pumps, in the health: medicines and technologies section of this report.

A number of diabetes related guidelines were updated during 2015 and the table below provides a summary of which guidance was updated and replaced by the current version.

Current guideline	Guideline(s) updated and replaced
Type 1 diabetes in adults: diagnosis and management (NG17)	• Diagnosis and management of type 1 diabetes in children, young people and adults (CG15), published July 2004
Diabetes (type 1 and type 2) in children and young people: diagnosis and management (NG18)	• Diagnosis and management of type 1 diabetes in children, young people and adults (CG15), published July 2004
Diabetic foot problems: prevention and management (NG19)	• Type 2 diabetes foot problems: Prevention and management of foot problems (CG10), published January 2004 • Diabetic foot problems: Inpatient management of diabetic foot problems (CG119), published March 2011
Type 2 diabetes in adults: management (NG28)	• Type 2 diabetes (CG66), published May 2008 • Type 2 diabetes: The management of type 2 diabetes (CG87), published May 2009

Achievement of blood glucose treatment targets

To minimise the risk of long-term vascular complications, NICE guidance recommends blood glucose treatment targets for people with type 1 and type 2 diabetes. While the guidance recommends specific targets for HbA1c, a measure of average blood glucose levels over weeks/months, an individualised approach is also recommended. Information about the achievement of treatment targets by diabetes type was taken from the national diabetes audit report.

Key findings:
A larger percentage of people over 12 with type 2 diabetes achieved HbA1c target measures compared to people with type 1 diabetes. **For both types of diabetes, over the last three audit periods an increasing proportion of people achieved an HbA1c of 48 mmol/mol or lower**.

Chart 6: Achievement of HbA1c target levels in adults with type 1 and type 2 diabetes, 2009/10 to 2014/15
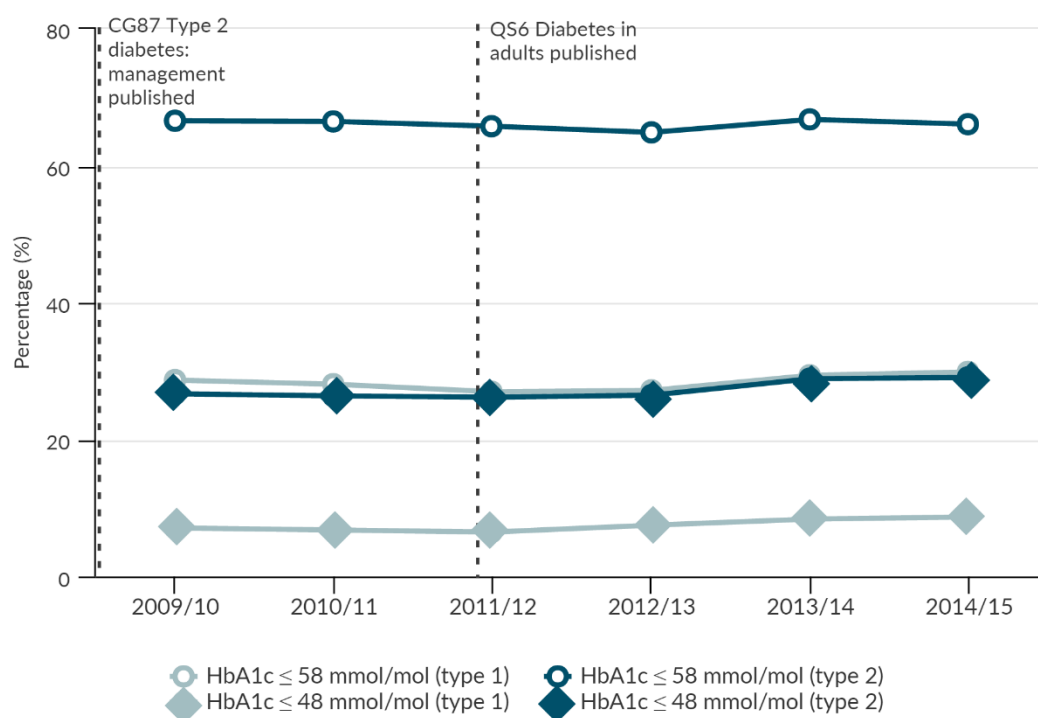
Source: National Diabetes Audit

Blood pressure readings

For people with type 2 diabetes NICE guidance recommends that blood pressure should be controlled to reduce the risk of adverse outcomes such as cardiovascular risk, diabetes eye damage and renal disease. Information about the uptake of these recommendations were taken from the Quality and Outcomes Framework (QOF). The QOF indicator measures the proportion of people over 17 years of age on the register with blood pressure readings at or below 150/90 mmHg or at and below

140/80 mmHg. Individualised blood pressure targets will depend on a number of factors including the presence of kidney, eye or cerebrovascular damage.

Key findings:
The proportion of people with diabetes over 17 years of age achieving the stated blood pressure levels is stable. Around 86% of people with diabetes achieve a blood pressure reading of 150/90 mmHg or less and around 70% achieve 140/80 mmHg or less.

Diabetes care processes: people aged over 12

NICE recommends that all adults with diabetes should receive key processes of care to ensure that the risk of diabetes related complications are kept to a minimum. Blood glucose (HbA1c) and blood pressure measurements are 2 of the 8 key care processes. The national diabetes audit provides information about the percentage of people over 12 with diabetes recorded as receiving these care processes.

Key findings:
Overall, most of the data show a steady position. Approximately 84% of people with type 1 diabetes and 95% of those with type 2 had their HbA1c checked. For cholesterol checks, the figures are similar for people with type 2 diabetes (93%) but slightly lower for those with type 1 (79%). Overall, a **larger proportion of people with type 2 diabetes are receiving the recommended care processes than those with type 1 diabetes**. This difference was lowest for the recording of smoking status and highest for recording albumin:creatinine ratio.

Chart 7: Recording of smoking status and albumin:creatinine ratio for people with diabetes, 2009/10 to 2014/15
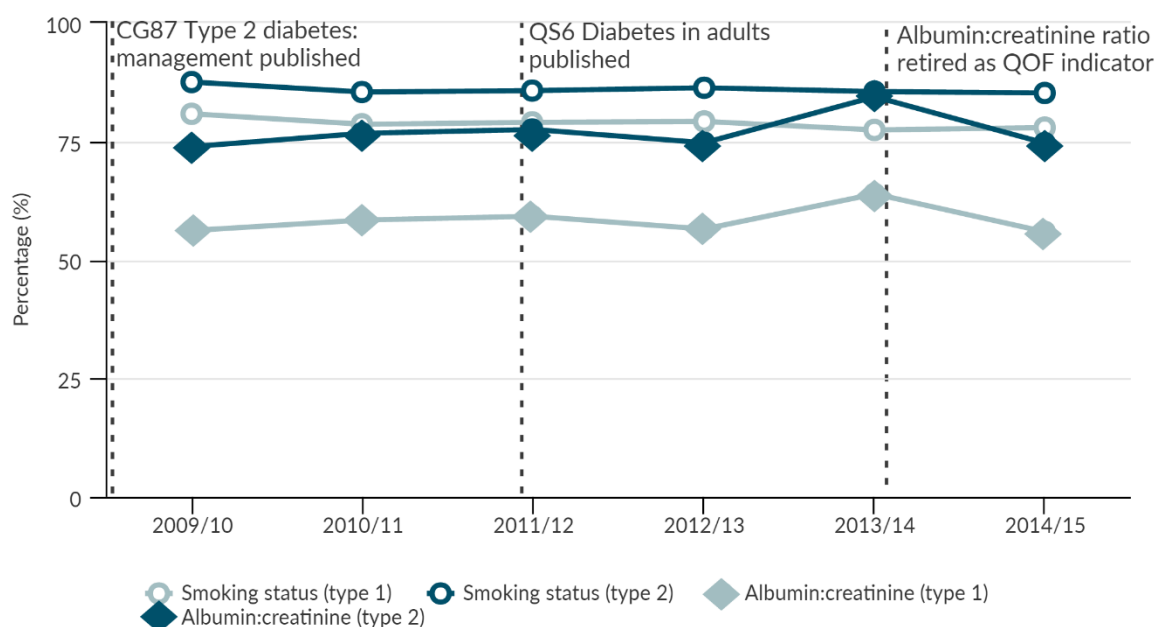
Source: National Diabetes Audit

The recording of body mass index (BMI) and albumin:creatinine ratio are the only care processes which have not maintained a relatively steady position. Recording of BMI was retired as a QOF indicator in 2013/14 and albumin:creatinine ratio in 2014/15. As can be seen in charts 7 and 8, **the recorded delivery of both care processes dropped following removal from the QOF.**

Chart 8: Recording of BMI status of people with diabetes, 2009/10 to 2014/15
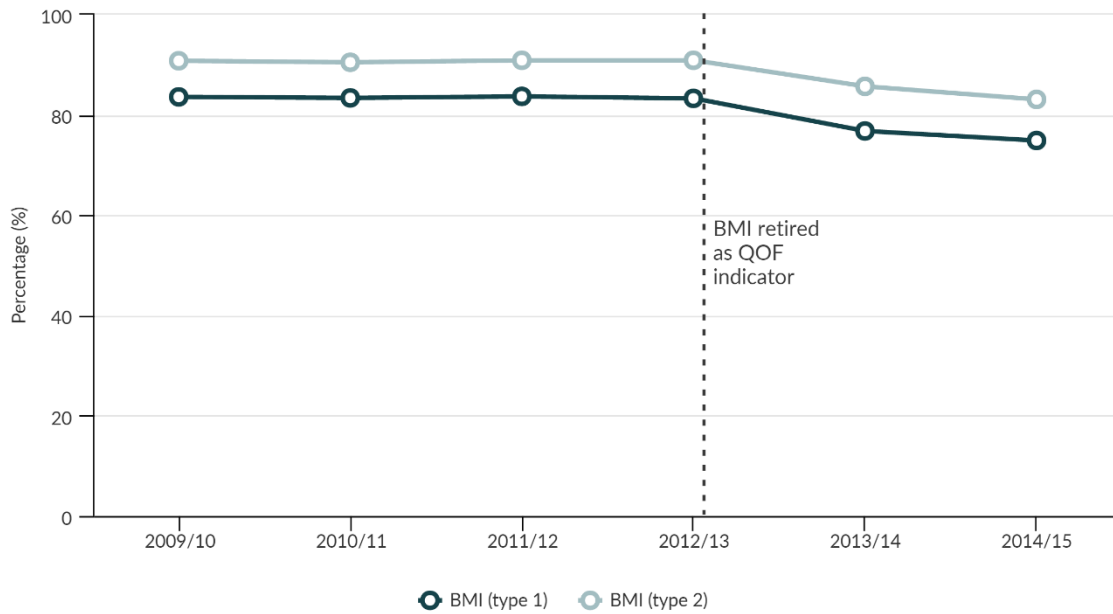
Source: National Diabetes Audit

Diabetes care processes: people aged 12 to under 25

NICE recommends that children and young people with diabetes should also receive key care processes to ensure that the risk of diabetes related complications are kept to a minimum. The national paediatric diabetes audit provides information about the percentage of children and young people with diabetes recorded as receiving these care processes. The 7 key care processes reported in the audit are shown in chart 9.

Key findings
Overall there was an **increase in the proportion of children and young people receiving the recommended care processes**. The recording of HbA1c was consistently higher than for the other care processes and the recording of eye screening saw the largest increase over the 5 audit periods.

Chart 9: Children and young people with diabetes receiving NICE recommended care processes, 2010/11 to 2014/15
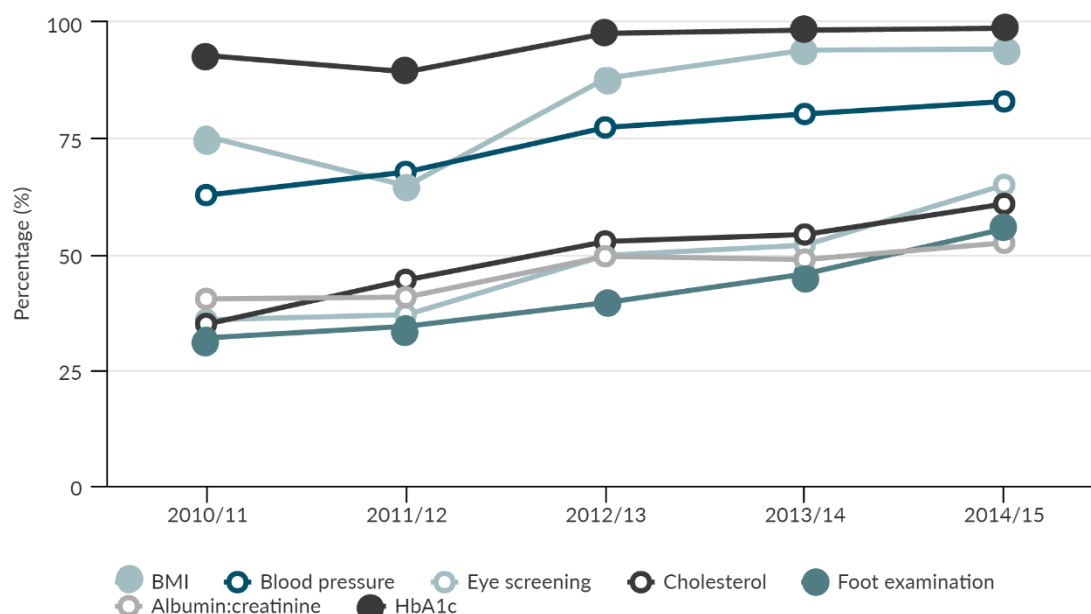
Source: National Paediatric Diabetes Audit

Thyroid and coeliac testing: people aged 12 to under 25

NICE guidance recommends that children and young people diagnosed with type 1 diabetes are monitored for thyroid disease at diagnosis and annually thereafter. The NICE guideline on coeliac disease recommends that people diagnosed with type 1 diabetes should also be tested for coeliac disease.

Key findings:
For all children and young people with type 1 diabetes, **screening for thyroid function increased from 50% in 2013/14 to 70% in 2014/15**. The increase in screening for those newly diagnosed was similar, from 36% to 57%. The gains made for coeliac disease screening were smaller, from 47% to 55%.

Structured education

NICE recommends that adults with diabetes receive structured education programmes to help improve their knowledge and skills, and also to help motivate them to take control of their condition and self-manage it effectively. Data measuring the uptake of these recommendations were taken from the national diabetes audit and the QOF.

Key findings:
Large gains appear to have been made in the proportion of people with diabetes being offered structured education. Referral into patient education was not routinely well recorded in primary care systems until this became an indicator in

the QOF in 2013/14. This resulted in a large increase in the number of people recorded as being offered patient education. **However, the percentage of people attending such courses appears to remain low at about 5%**. In addition, a much larger proportion of people with type 2 diabetes are being offered structured education than those with type 1 diabetes.

Chart 10: Proportion of people with diabetes offered and attended structured education, 2009/10 to 2014/15
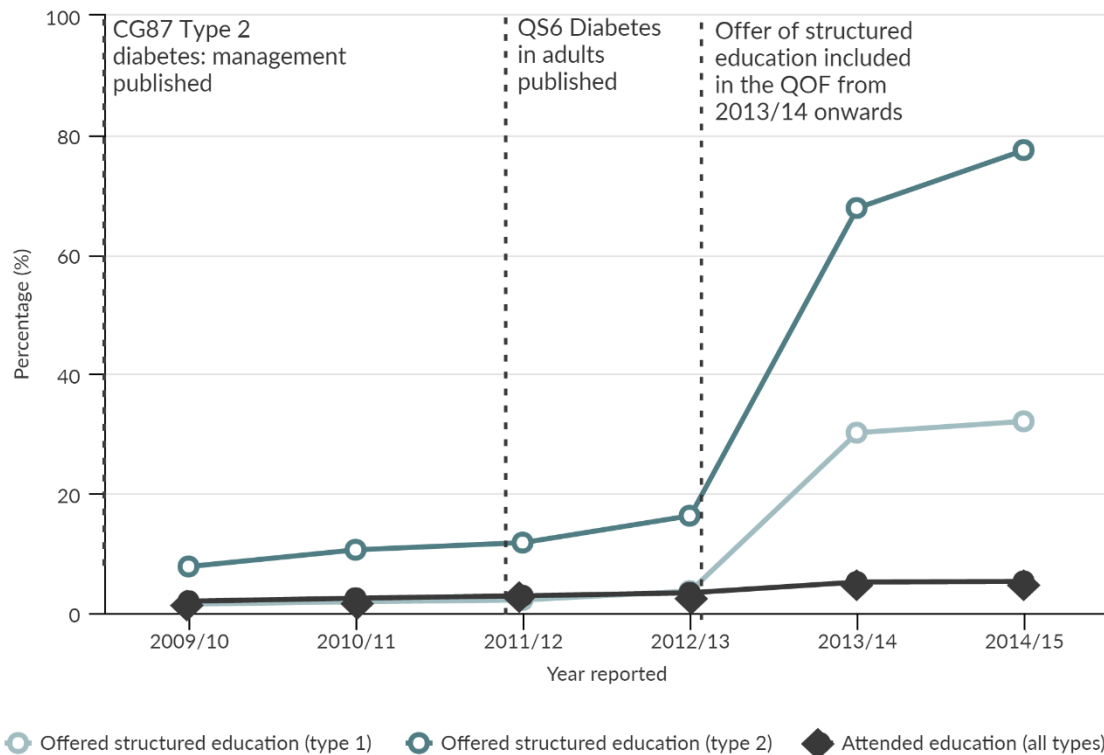
Source: National Diabetes Audit

The QOF data appear broadly consistent and show that **about 70% of people with diabetes are offered structured education in primary care.** The national diabetes audit report recommends that commissioners and providers of care should investigate the reasons for the difference between structured education offers and structured education attendances.

Inpatient diabetes team

NICE recommends that adults with type 1 diabetes in hospital receive advice from a multidisciplinary team with expertise in diabetes. The specialist multidisciplinary team has the knowledge to help the person understand how to best adapt management of their diabetes when in hospital. Input from a multidisciplinary specialist team can reduce the length of hospital stay for adults with type 1 diabetes and improve their experience of hospital.

Key findings:
The proportion of inpatients seen by the diabetes team has remained low but stable. Data were taken from the national diabetes inpatient audit.

Chart 11: Percentage of inpatients seen by the diabetes team, 2010 to 2015
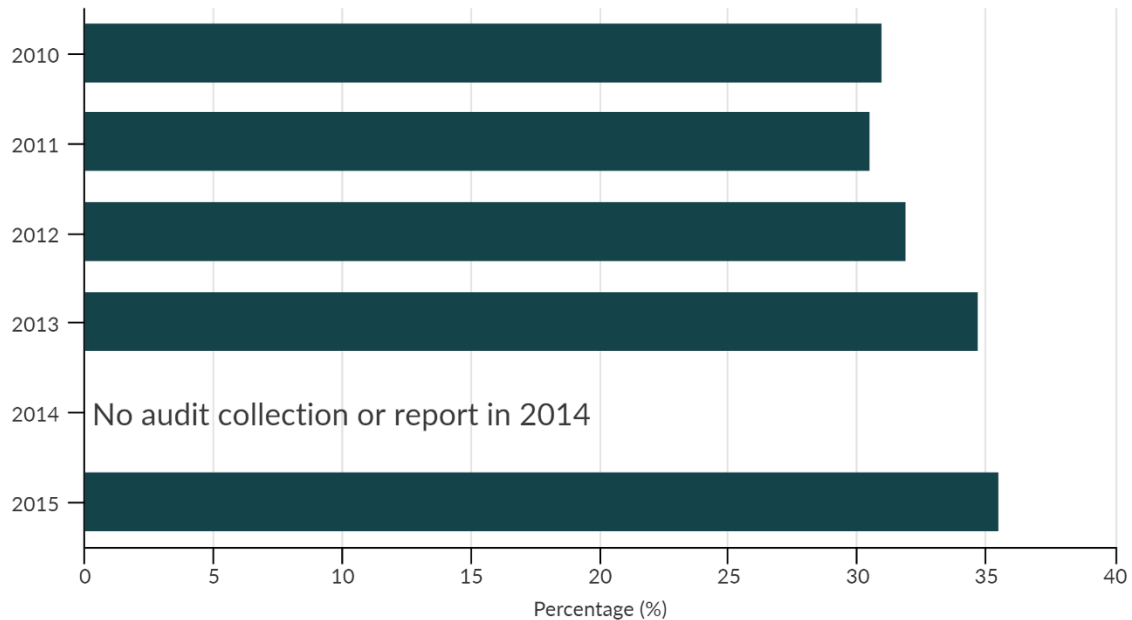
Source: National Diabetes Inpatient Audit

Foot protection services and foot assessment

NICE has made a number of recommendations to help prevent and manage foot problems in people with diabetes. This is because the risk of foot problems in people with diabetes is increased, largely because of diabetic neuropathy (nerve damage or degeneration) and peripheral arterial disease (poor blood supply due to diseased large- and medium-sized blood vessels in the legs). Data for these recommendations were collected from the national diabetes inpatient audit and the national diabetic foot care audit.

Key findings:
Due to funding issues there was a break in the national diabetes inpatient audit between 2013 and 2015. Over this time **the proportion of patients receiving a diabetic foot risk assessment for ulceration within 24 hours of admission reduced** and the gains made in previous years were reversed to the level seen in 2010. Whether this is due to the break is speculative but it is quite possible.

Chart 12: Proportion of inpatients receiving a diabetic foot risk assessment for ulceration within 24 hours of admission, 2010 to 2015
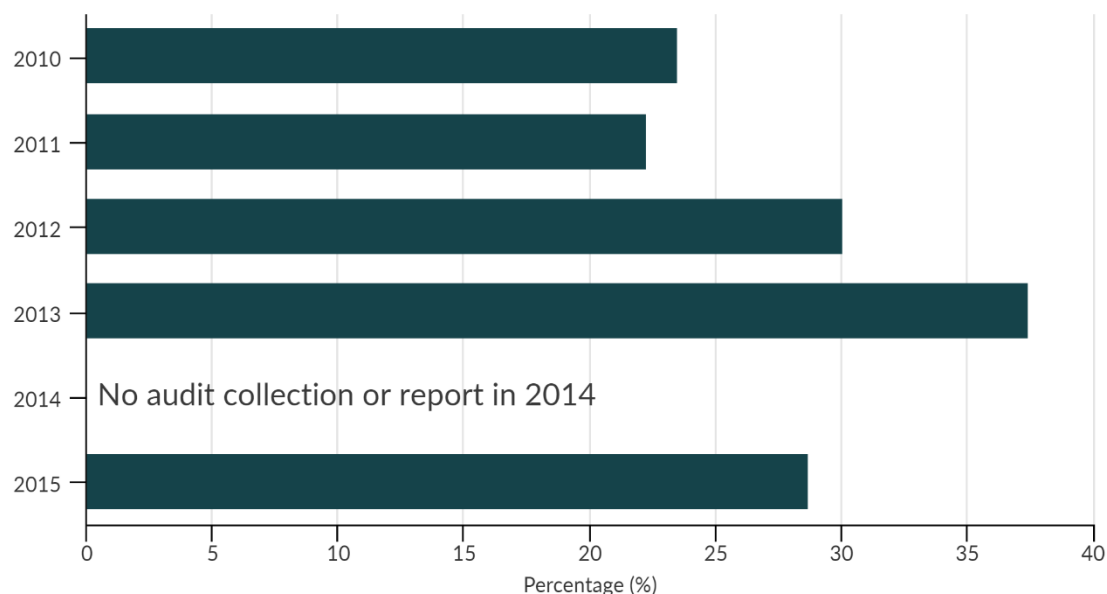
Source: National Diabetes Inpatient Audit

Uptake data from the first annual national diabetic foot care audit were also collected. The findings are presented below.

Key findings:
Just over 3 quarters of CCGs and local health boards reported having a foot protection referral pathway for patients identified as higher risk during annual foot examinations, and just **over half reported that they had a referral pathway for expert assessment of patients with new, deteriorating or recurrent foot disease within 24 hours**. Despite foot protection pathways being in place, the proportion of patients being assessed within two days was low. These findings should be interpreted with caution since less than 60% of commissioners participated in the survey. In addition, just under 40% were unable to give a definitive response (yes or no) to one or more of the questions.

	Proportion meeting the audit criteria
Proportion of CCGs and local health boards providing a foot protection referral pathway for patients identified as higher risk during annual foot examination.	77.4
Proportion of CCGs and local health boards providing a referral pathway for expert assessment of patients with new, deteriorating or recurrent foot disease within 24 hours.	54.1
Proportion of people with diabetes with an active foot problem (not self-presenting) referred to the multidisciplinary foot care service or foot protection service within one working day and triaged within one further working day.	14.4

Uptake of NICE guidance: maternity

> The proportion of parents of babies receiving specialist neonatal care who have met with a senior member of the neonatal team within 24 hours of admission has increased, from 68% in 2011 to 88% in 2015.
>
> The proportion of babies who have their temperature recorded with an hour of admission to a neonatal unit continues to increase, from 63% in 2009 to 94% in 2014.
>
> The proportion of babies born at less than 30 weeks gestation who receive a 2 year follow-up has increased steadily since 2011 to a peak of 60% in 2015. The proportion of these babies found to have no neurodevelopmental impairment has dropped, from 50% in 2011 to 43% in 2015.

A review of maternity services was identified as one of the clinical priorities in the delivery of the Five Year Forward View and NICE guidance is referenced throughout Better Births, the resulting report of the maternity taskforce. In this period, information about the uptake of NICE guidance recommendations covering components of neonatal care were collected from the National Neonatal Audit Programme (NNAP), produced by the Royal College of Paediatrics and Child Health and commissioned by HQIP. The NNAP provided uptake information on 2 quality standards: neonatal specialist care, published October 2010, and neonatal infection, published December 2015.

Participation

The quality standard on neonatal specialist care states that providers of specialist neonatal services should maintain accurate and complete data, and actively participate in national clinical audits and applicable research programmes. The proportion of neonatal units (NNUs) that submit data to the NNAP has been consistently high, rising from 95.9% in 2011 to 100% in 2015.

Transfer services

In the UK, neonatal care is provided by three different levels of unit and there are times where a baby may need to be transferred to a unit that has a level of care that is more appropriate to his or her needs at the time. NICE recommends that, where a transfer to a more appropriate level of unit is required, the transfer should, wherever possible, be within the same neonatal network. Babies and families should have access to the neonatal services their baby needs as close to home as possible.

Key findings
Between 2011 and 2015, the percentage of transfers that have stayed within the same neonatal network has remained **static at around 82%. This falls below the 95% standard set out in the DH** Toolkit for High Quality Neonatal Services (2009).

The toolkit states 'Each network should have the capacity to provide all levels of neonatal care for at least 95% of babies born to women booked for delivery in the network (i.e. no more than 5% of babies born to booked women should be transferred out of network for inappropriate reasons).

Temperature on admission

NICE recommends neonatal transfer services should provide safe and efficient transfers to and from specialist neonatal care. One of the quality measures of safe and efficient transfers is the admission temperature of the newborn baby. Low admission temperature has been associated with an increased risk of illness and death in pre-term infants. If recognised, hypothermia is easily preventable, even in vulnerable newborns, therefore it is important to take a baby's temperature on admission to the neonatal unit.

Key findings
The NNAP reports year on year increases for babies whose temperature was recorded within the first hour of admission to a neonatal unit, from **63% in 2009 to 94% in 2014.**

The 2010 neonatal specialist care quality standard suggests recording the proportion of newborn babies who receive specialist neonatal care who have an admission temperature of less than 36°C. The percentage of newborn babies in England and Wales at a gestational age of less than 29 weeks found to be less than 36°C within an hour of birth has reduced from 18% in 2011 to 12% in 2014.

In the 2015 NNAP the percentage of newborn babies with a low temperature fell again to 9%, although the measured gestational age changed to less than 32 weeks and additional NNUs in Scotland were included.

Year	Percentage of babies at gestational age <29 weeks whose temperature was recorded within an hour of admission (%)	Percentage of temperatures that were <36°C (%)
2009	63	Not recorded
2010	77	Not recorded
2011	90	18
2012	89	15.6
2013	93	12.4
2014	94	12.4

Parental involvement

NICE recommends that parents of babies receiving specialist neonatal care should be encouraged and supported to be involved in planning and providing care for their baby, and regular communication with clinical staff should occur throughout the care

pathway. This can be measured through evidence of local arrangements to involve parents in decision-making processes.

Key findings
The NNAP measures documented consultation with parents by a senior member of the neonatal team within 24 hours of admission. **Parent consultation has increased from 68% in 2011 to 88% in 2015.**

Chart 13: Percentage of episodes of care with a documented consultation with parents by a senior member of the neonatal team within 24 hours of admission, 2011 to 2015
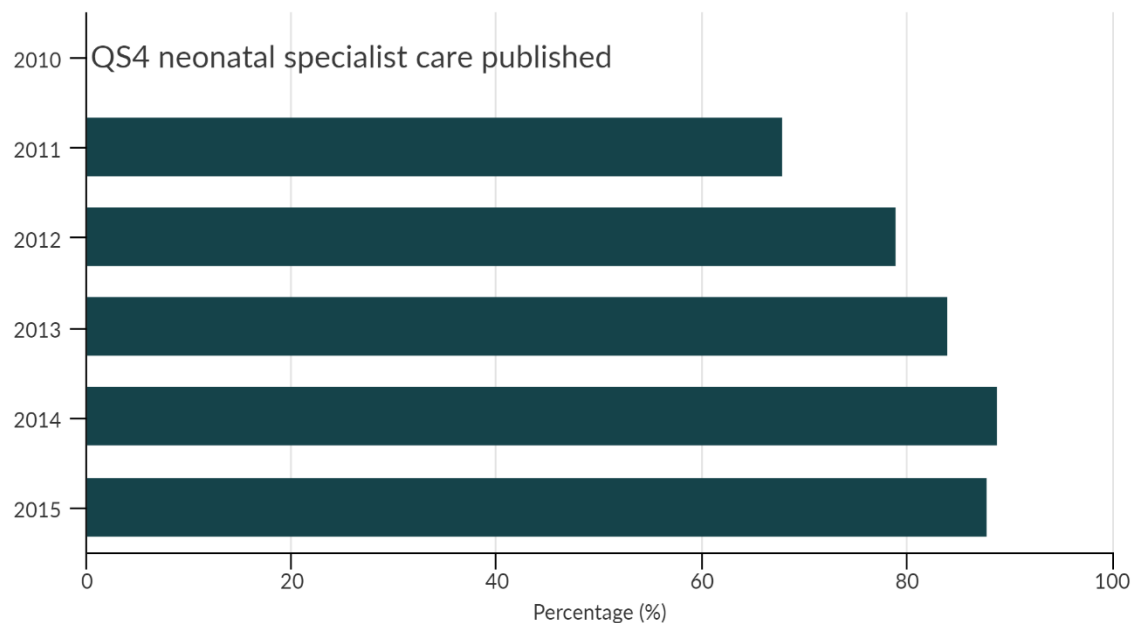
Source: National Neonatal Audit Programme

Breastfeeding

Premature babies are especially vulnerable to infection, and mother's milk provides an important line of defence through the protective antibodies that it provides. As well as a reduction in infection and gut pathologies, breast milk improves longer-term health and neurodevelopmental outcomes. The quality standard on neonatal specialist care states that mothers of babies receiving specialist neonatal care should be supported to start and continue breastfeeding, including being supported to express milk.

Key findings
Since 2012, the proportion of babies who are receiving any of their own mother's milk at discharge has remained steady at around 58%.

Infection

The quality standard on neonatal infection states that rates of early‑onset neonatal infection should be measured as an outcome. The NNAP includes measures on the percentage of babies admitted to a neonatal unit who have:

a) one or more episodes of a pure growth of a pathogen from blood;
b) one or more episode of a pure growth of a pathogen from CSF

Key findings
In 2015, 71,181 blood and CSF cultures were recorded, an increase from 11,998 blood cultures recorded in 2011. The data suggest that infection rates have remained steady since 2012; about 0.01% of all babies had a positive CFS culture result recorded and about 0.5% of babies had a pure growth of a pathogen. However, these data should be interpreted with caution as there are concerns about the completeness and quality of the data for this audit question.

Health outcomes

Babies born prematurely do not always reach key developmental milestones so clinical follow-up checks at age 2 provide a valuable opportunity to identify any potential issues at an early stage. The neonatal specialist care quality standard states that babies receiving specialist neonatal care should have their health outcomes monitored. Functional impairment, for example neurodevelopmental impairment, should be assessed as part of the follow-up and all outcomes should be recorded.

Key findings
The proportion of babies born before 30 weeks gestation for whom a 2 year health status follow-up has been partially or fully completed **increased from 39% in 2011 to 60% in 2015**. The proportion of babies born before 30 weeks gestation reported to have no neurodevelopmental impairment has decreased from 50% in 2011 to 43% in 2015.

Chart 14: Percentage of babies born 2 years previously, who were < 30 weeks gestation, survived and were discharged from a NNU who had some/all health data recorded at a 2 year health status follow-up, 2011 to 2015
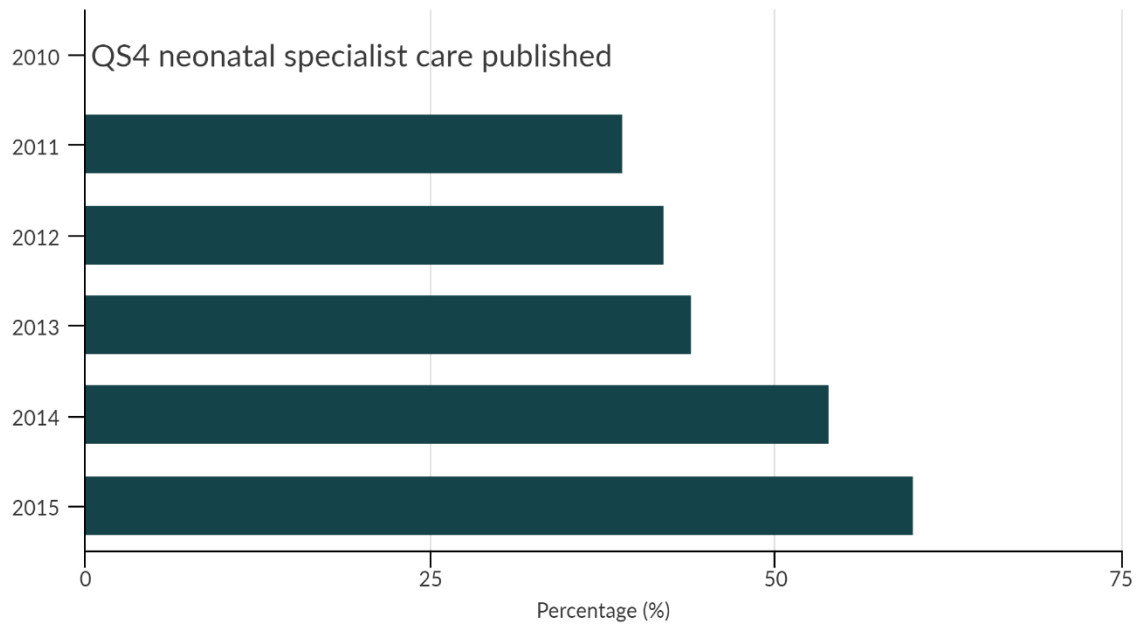
Source: National Neonatal Audit Programme

Chart 15: Percentage of babies born 2 years previously, who were < 30 weeks gestation, survived and were discharged from a NNU who had no neurodevelopmental impairment recorded at 2 year health status follow-up, 2011 to 2015
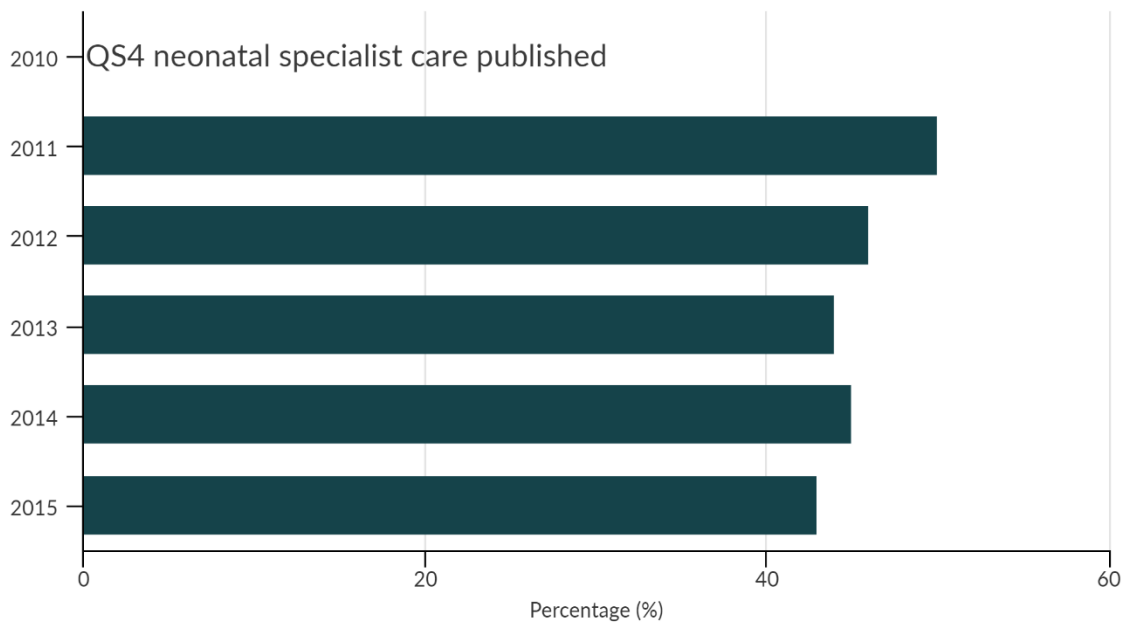
Source: National Neonatal Audit Programme

Uptake of NICE guidance: patient experience

> Overall, key measures of good patient experience are relatively high and show little change over time. The proportion of inpatients who felt they were always treated with dignity was 84% and, in primary care, 83% of respondents felt that their GP was good at treating them with care and concern.
>
> Findings related to shared decision making are generally positive, particularly for cancer patients. More than two thirds reported being as involved as they wanted to be in decisions about their care compared to 59% of all inpatients, although this figure is showing an upwards trend.
>
> There appears to be variation in the amount of information and support offered to people with different cancer types. People with prostate cancer report being less satisfied with information about their treatment options and side effects than people with all cancers.

The Five Year Forward View identifies that patient experience is one of the 3 key aspects which define quality in healthcare, alongside patient safety and clinical effectiveness. In this period, information about the uptake of NICE guidance recommendations on the components of a good patient experience in adult NHS services was collected from 3 national reports; the CQC's adult inpatient survey and NHS England's national cancer patient experience survey and GP patient survey. These data sources provided uptake information for 5 guidelines and 5 quality standards. Most of these data provide information about the uptake of NICE's guideline on patient experience in adult NHS services which was published in February 2012 so, where possible, we have looked at change over time since 2011.

Patient experience
NICE recommends that all people who use adult NHS services are treated with dignity, kindness, compassion, courtesy, respect, understanding and honesty.

Key findings:
The CQC adult inpatient survey reported that **84% of patients felt they had always been treated with dignity while they were in hospital**, which is an increase from 80% in 2011. Similarly, a large proportion (91%) of patients reported they had always been given enough privacy when being examined, although this was lower for patients in the accident and emergency department (80%) than for all patients. Finally, **the proportion of patients who reported that doctors or nurses talked in front of them as if they weren't there showed an encouraging downwards trend**, although this is still higher for doctors than nurses.

Chart 16: Proportion of inpatients who reported that doctors and nurses talked in front of them as if they weren't there, 2011 to 2015
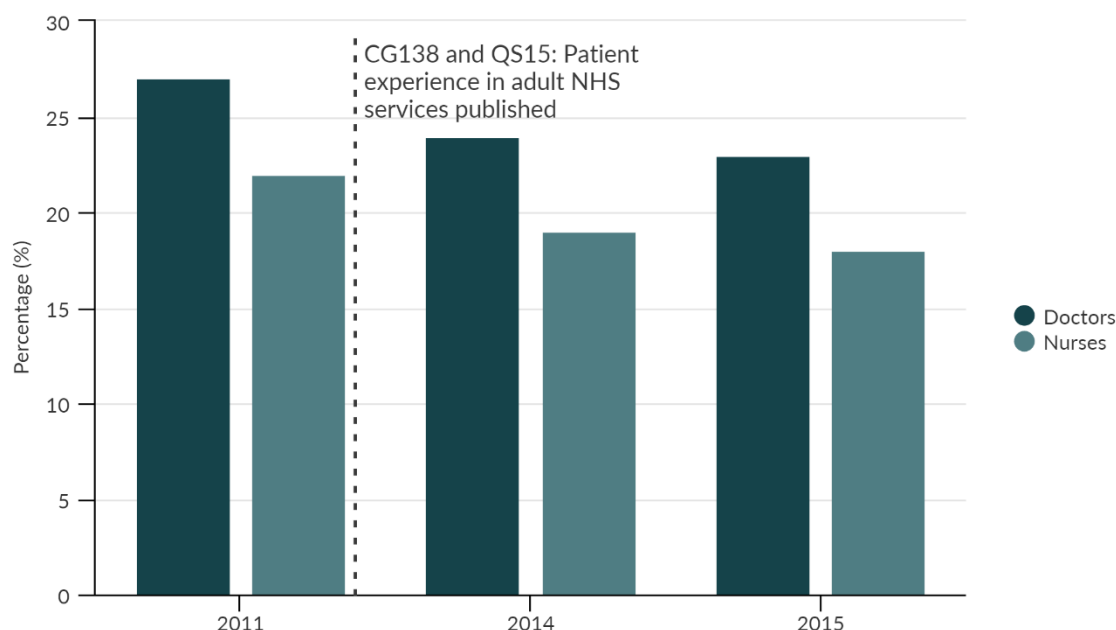
Source: CQC adult inpatient survey

Key findings:
NHS England's GP patient survey reported that **9 out of 10 patients had trust and confidence in the GP they saw.** About 87% felt that their GP was good at listening and 83% felt that their GP treated them with care and concern, and these proportions have remained stable since 2011.

Shared decision making

NICE recommends that patients are actively involved in shared decision making and are supported by healthcare professionals to make fully informed choices about investigations, treatment and care that reflect what is important to them. We recognise the importance of shared decision making in all of our guidance, we have produced patient decision aids and tools to support people receiving and delivering care and we work with partner organisations in the shared decision making collaborative to support the wider health and care system to embed shared decision making into routine practice.

Key findings:
The CQC adult inpatient survey reported that 59% of respondents felt that they were definitely involved as much as they wanted to be in decisions about their care and treatment. This result **shows an upwards trend**, from 52% in 2011 and 57% in 2014.

The NHS England national cancer patient experience survey reported that **78% of all cancer patients felt that they were definitely involved as much as they wanted to be in decisions about their care and treatment.** No results are

available for previous years. This is a much higher proportion than reported in the CQC inpatient survey, which may suggest differences in the way cancer patients are treated from inpatients with other conditions and diseases. However, while the question is the same, the methodology of these surveys is different so it should be noted that the results cannot be directly compared.

The NHS England GP survey asks a slightly different question; **74% of respondents reported that their GP was good at involving them in decisions about their care**. This result has been generally stable since 2011.

Understanding treatment

Information about the aims, risks, benefits and consequences of treatment options is a prerequisite for the patient's involvement in shared decision making, and is also required to help patients make sense of their health. NICE recommends that patients are supported by healthcare professionals to understand relevant treatment options, including benefits, risks and potential consequences.

Key findings:
The CQC inpatient survey found that **83% of respondents reported that, before their operation or procedure, they received an explanation of the risks and benefits in a way they could understand completely**. This finding shows a small upwards trend, from 80% in 2011. These survey findings suggest the majority of people are clear about the risks and benefits of the treatment they are having.

The national cancer patient experience survey found that, when compared to all cancer patients (83%), a higher proportion of people with lung cancer (84%) reported having their treatment options explained to them. However, these proportions were lower for people with prostate cancer (80%).

In primary care, the GP patient survey reported a slight increase in the proportion of patients that felt that their GP was good at explaining their tests and treatments, from 78% in 2011 to 82% in 2016.

Information

NICE recommends that patients are given information, and the support they need to make use of the information, in order to promote their active participation in care and self-management. The information should be both oral and written, and given in an accessible format. NICE also recommends that patients are made aware of who to contact, how to contact them and when to make contact about their ongoing healthcare needs.

Key findings
The CQC inpatient survey found that **81% of respondents felt they had been given the right amount of information about their condition or treatment**. This is about the same as the 79% reported in 2011.

The survey also asked a number of questions about information given at discharge. While **a large proportion (72%) of patients answered "completely" when asked if they had been given clear written information about their medicines, only 40% answered "completely" when asked about whether they had been given enough information about side effects to look for when at home**. Reassuringly, 78% of respondents reported that hospital staff had told them who to contact if they were worried about their condition or treatment after they left hospital. These results have remained stable since 2011.

Physical and psychological needs

NICE recommends that patients have their physical and psychological needs regularly assessed and addressed, including nutrition, hydration, pain relief, personal hygiene and anxiety. Preventing and managing pain and ensuring that nutritional requirements are met are core components of a good patient experience.

Key findings:
The CQC inpatient survey found that just under **two thirds of people reported they had always received enough help from staff to eat their meals**. Just under three quarters (72%) of inpatients said they thought hospital staff definitely did everything they could to help control their pain. However the proportion reporting that they always got enough emotional support throughout their stay was lower at 59%. These results have remained stable since 2011.

Support

NICE recommends access to a key worker for people with cancer, to provide information and support throughout their care. This can help to improve patient experience because people know they have someone who they can discuss their care with, and it also helps to ensure that any care takes the person's needs into account. Key workers can also provide information about support services.

Key findings:
The cancer patient experience survey found that **the majority of people with cancer were given the name of a specialist nurse who would support them through their treatment**. This proportion was highest for people with breast cancer and lowest for people with sarcoma.

	Were you given the name of a Clinical Nurse Specialist who would support you through your treatment?
People with breast cancer	94.4%
People with lung cancer	93.4%
People with all cancers	**89.9%**
People with prostate cancer	89.1%
People with sarcoma	87.4%

Source: NHS England cancer patient experience survey 2015

Wider impact of NICE

> Much of our engagement in this period has been with new care models and sustainability and transformation footprints, with the aim of embedding our guidance into new ways of working. NICE has successfully engaged with the development of Sustainability and Transformation Plans (STPs) at a national level and, through our field team, at a regional and local level.
>
> Topic-specific engagement is ongoing at all levels, with NICE speakers in demand at health-related conferences and events.
>
> The overall awareness of NICE in the health sector appears to be good, and the majority of visitors to our website are interested in clinical topics.

Engagement activities

In addition to the cross-system engagement highlighted in the overall findings section of this report, topic-specific engagement continues to take place at a national and regional level, working with partners to encourage uptake of our recommendations. Examples in this period include:

- The NICE implementation support team engaged with NHS England, the Royal College of Surgeons and specialist organisations such as the British Association of Oral and Maxillofacial Surgeons, among many others, to support the implementation of a recommendation in NICE's guideline on cancer of the upper aerodigestive tract. Sentinel lymph node biopsy (SNLB) is recognised to improve patient experience when offered as an alternative to neck dissection, which is very invasive and has a number of side effects. NICE has worked with stakeholders to support the development of a quality assurance framework, and has engaged with the providers of the national head and neck audit to encourage measurement of the use of SNLB.

- NICE are members of and contributors to the Citizen Insight Network, bringing together the Department of Health, other arm's length bodies and national organisations such as Healthwatch and the Health Quality Improvement Partnership (HQIP). Our involvement in this network during the period of this report allowed us to highlight our recommendations relating to patient experience and shared decision making, and to share expertise on topic-specific work such as how best to include the voice of patients in dementia care.

- NICE speakers promoted and discussed our recommendations by delivering 33 topic-specific presentations, panel discussions, workshops or keynote addresses on health topics at conferences and events

between April and October 2016. Topics included diabetes, care of the dying adult and dementia.

- NICE attended 4 audit specification development meetings hosted by HQIP, covering topics such as diabetes, paediatric intensive care and heart conditions. These meetings are the first step in the commissioning of each national clinical audit. By highlighting NICE recommendations and quality statements at the specification stage it is hoped that future national audits will align more closely with NICE recommendations and therefore encourage uptake.

Field team focus: Sustainability and Transformation Plans (STPs) and devolution

As well as NICE's national role in supporting the development of STPs, at a regional and local level the NICE field team of implementation consultants are seeking to work with their local STPs to embed NICE guidance. In the north of England, NHS England convened an Arm's Length Body STP Oversight Group on which the local implementation consultant represents NICE. This group supported the regional review of submitted plans and continues to provide oversight and support to STP development and delivery. During plan submission, the NICE implementation consultants supported plan review locally wherever possible and proposed key lines of enquiry to help build use of NICE guidance and quality standards into the plans.

In the North West, the local implementation consultant is supporting one of the local STP footprints, Lancashire and South Cumbria, as they begin to put the plan into practice. This work is at an early stage, and the implementation consultant is working to ensure that NICE guidance and quality standards are reflected in the detailed plans which are being developed. The implementation consultant sits on the quality sub-group of the overall steering group, and is supporting a piece of work on regulated care by helping to weave NICE guidance recommendations and quality standards into service specifications and performance assurance frameworks which are being developed.

In the [Greater Manchester Health and Social Care Partnership](#) (GMHSCP) system, the [five-year plan](#) was developed to support devolution and integration, and technically is their STP. In the preparatory year for devolution, the local implementation consultant developed and maintained relationships with key individuals and the evolving structures and systems in order to position NICE as a key and enabling partner for when the formal Partnership was established and the Executive team appointed, and also to ensure that that NICE guidance and standards were central to the new ways of working. This included working with an Academic Health Science Network (AHSN) to embed quality standards into data collection, feeding in NICE indicators to the development of performance dashboards, working with Public Health England to support the development of

worklessness population profiles, and supporting the savings and disinvestment agenda.

By supporting the development process and connecting across the system, the implementation consultant was able to ensure that the system leaders understood the importance of NICE guidance and standards. As a result, she has been invited to sit on the GMHSCP Quality Board, where she continues to highlight the importance of NICE guidance and quality standards.

Audience engagement

The NICE regional stakeholder events, held in autumn 2016, identified that the group of attendees from the NHS were the most familiar with NICE, and used our guidance more regularly than either public health or social care professionals. We know that, between April and October 2016, **77% of guidance page views on the NICE website were of clinical practice guidelines and quality standards** and **67% of our guidance-related enquiries were about clinical guidelines** so it is unsurprising to hear that people working in clinical practice are those who most routinely use our guidance.

In this period, our guideline on sepsis was the 2nd most viewed of our newly published guidelines, and the most enquired about. The following example shows how our external communications team successfully promoted this guideline on the NICE website and twitter feed and in the national and regional media.

Communications highlight: sepsis

> **Following guidance launch, the sepsis news story was the most viewed story on the NICE website between April and October 2016, with 13,113 views.**

The National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) report Just Say Sepsis, published in 2015, estimated that 37,000 people die with sepsis in the UK each year, and highlighted the importance of early recognition and diagnosis.

NICE published its guideline on the recognition, diagnosis and early management of sepsis in July 2016. Our news story about the guideline launch was the most viewed story on the NICE website between April and October 2016 with 13,113 views. The media team produced three videos explaining the guideline and its recommendations and personal experiences of the disease that were viewed more than 2,000 times on YouTube.

Tweets on the subject from the NICE account were seen more than 120,000 times in the week of publication, with input from NCEPOD, Royal Colleges, NHS

organisations and the public. The press release generated 81 pieces of news coverage, in national newspapers, broadcast and regional press. NICE spokespeople appeared on BBC Breakfast TV, Radio 4 Today programme, GMB and regional radio. We produced a Storify of the coverage.

Data from the Just Say Sepsis enquiry, carried out before the guideline publication, have given us useful baseline information about our recommendations. For example, we recommend that all healthcare professionals involved in triage or early management are given regular appropriate training in identifying, assessing and managing sepsis, which should include local protocols for early treatment. However, the report identified that only 66% of hospitals reported having a specific protocol or care pathway for identifying and managing patients with sepsis.

The identification and early treatment of sepsis has been identified by NHS England as a national Commissioning for Quality and Innovation (CQUIN) goal, and data will be collected on the timely identification and treatment of sepsis in emergency and inpatient settings. We hope to be able to look at improvements in this area in future reports.

Clinical practice case study: psychosis and schizophrenia

> The number of people experiencing a first episode of psychosis being treated with a NICE approved care package within 2 weeks of referral has increased from 59% to 77% in the last year.

In the UK, mental illness is the single biggest cause of disability. Each year around 25% of people live with a mental health problem and only approximately 1 in 4 of those people receive treatment. The NHS five year forward view states that people with severe or prolonged mental illness die on average 15 to 20 years earlier than others. Despite the link between physical and mental health, they have historically been treated as two separate matters, with mental health often ignored or stigmatised.

In February 2011, the Department of Health published No health without mental health, which outlined the Coalition Government's overall approach to improving mental health outcomes. One of the stated aims was to intervene early in psychosis, as a growing body of evidence suggested that early intervention could aid faster recovery, reduce the likelihood of relapse and reduce the risk of suicide.

As detailed in the NICE psychosis and schizophrenia in adults quality standard, early intervention in psychosis can improve clinical outcomes. In October 2014, NHS England and the Department of Health jointly published Achieving better access to mental health services by 2020. This document detailed mental health access and waiting time standards for introduction during 2015/16, and the planned investment of £80 million. As part of the standard, one of the deliverables was for more than 50% of people experiencing a first episode of psychosis to be treated with a NICE approved care package within two weeks of referral.

NHS England collect statistics on early intervention in psychosis waiting times; these data are also reported as a CCG Improvement and Assessment Indicator Framework (CCGIAF) indicator. The **proportion of people in England experiencing a first episode of psychosis who were treated with a NICE approved care package within 2 weeks of referral has steadily increased over the last year, from 59% in December 2015 to 77% in October 2016.** While 91% of CCGs were achieving or overachieving the 50% target by the end of 2016, there was wide variation in waiting times for treatment of psychosis across CCGs, with some CCGs achieving treatment within 2 weeks for 100% of patients and others for a little as 3.1% of patients.

Chart 17: Number of CCGs achieving the 50% target for patients receiving a NICE approved care package within 2 weeks of referral, October 2016
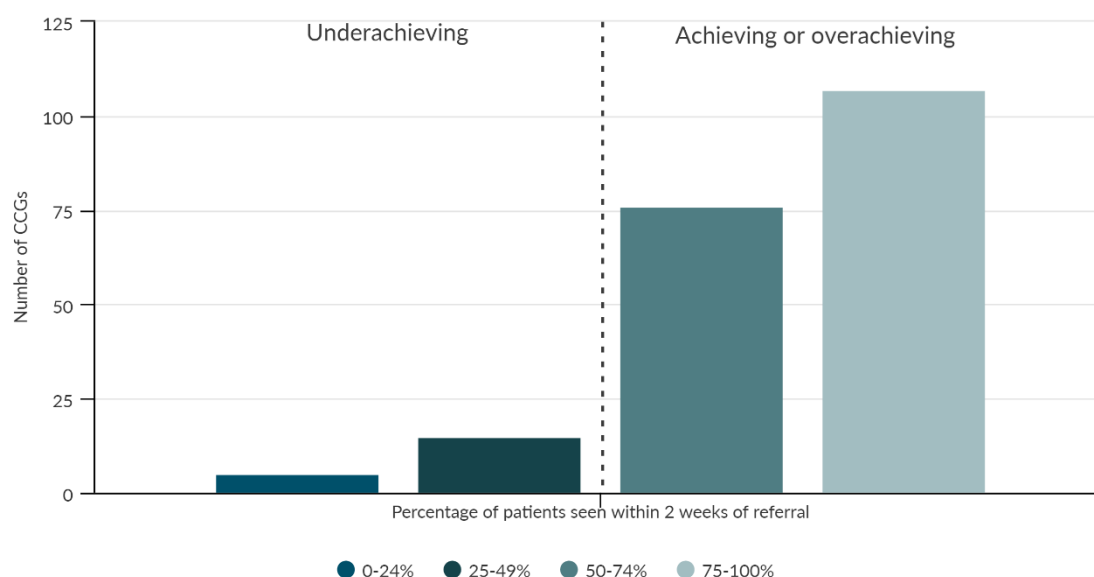
Source: NHS England, Early Intervention in Psychosis Waiting Times statistical release

[Implementing the Early Intervention in Psychosis Access and Waiting Time Standard: Guidance](#), published by NICE and NHS England in April 2016, describes the essential components of a NICE-approved care package. The publication brings together recommendations from the [psychosis and schizophrenia in children and young people](#) and [psychosis and schizophrenia in adults](#) guidelines as well as the psychosis and schizophrenia in adults quality standard, and groups them in to packages depending on patient age and mental state. Key elements of the packages include: assessment, cognitive behavioural therapy for psychosis (CBTp), family intervention, medication, monitoring physical health and support programmes.

In July 2016, the Royal College of Psychiatrists published their first audit on [Early Intervention in Psychosis](#) (EIP) in England. The audit collected data up to June 2015 and focused on several NICE recommendations from the psychosis and schizophrenia in adults guideline and measures from the psychosis and schizophrenia in adults quality standard.

- The psychosis and schizophrenia in adults quality standard recommends that adults with psychosis or schizophrenia are offered CBT for psychosis as CBT can help to improve psychotic symptoms. The EIP audit reported that 41% of patients with a first episode of psychosis or suspected psychosis were offered CBT for psychosis.

- Family intervention can improve coping skills and relapse rates of adults with psychosis and schizophrenia. The NICE guideline recommends that it is offered to family members of adults with psychosis or schizophrenia.

The EIP audit reported that the families of 31% of psychosis or schizophrenia patients were offered family intervention.

- As clozapine is the only drug with established efficacy in reducing symptoms and the risk of relapse for adults with treatment‑resistant schizophrenia, the NICE guideline recommends that clozapine should be offered to people with schizophrenia whose illness has not responded adequately to treatment despite the sequential use of adequate doses of at least 2 different antipsychotic drugs. The EIP audit reported 36% of people were prescribed clozapine according to this criteria.

- Due to the negative effect that unemployment can have on the mental and physical health of adults with psychosis or schizophrenia, the NICE guideline recommends that people with psychosis or schizophrenia who wish to find or return to work be offered a supported employment programme. In the EIP audit, 63% of psychosis or schizophrenia patients recorded as unemployed and seeking work were offered one or more supported employment or education programmes.

- To try and improve carers, quality of life and to reduce carer burden and psychological distress, the NICE guideline recommends that carers of people with psychosis or schizophrenia are offered carer‑focused education and support programmes. According to the EIP audit, the identified carer of 50% of patients aged 17 years or over were offered a carer-focused education and support programme.

A [shared learning example](#), published in September 2016, describes how Lancashire Care NHS Foundation Trust (LCFT) devised a governance and assurance framework for the implementation of the waiting time standard and NICE approved care package. As well as participating in the EIP audit, LCFT assessed their performance against the NICE psychosis and schizophrenia in adults quality standard and recorded the challenges they faced and actions taken to improve the service against each statement. A best practice pathway was agreed based on the NICE guidelines and made available via a SharePoint site.

In order to meet the waiting time standard for early intervention in psychosis and the first quality statement of the psychosis and schizophrenia in adults quality standard, LCFT redesigned their service through newly appointed assessment leads. This included the development of a referral to treatment live dashboard from the electronic waiting list recording system. The dashboard allowed teams to monitor time to treatment and monthly targets were achieved.

Analysis of the Trust's delivery of other elements of the NICE approved care packages resulted in further steps being taken, including:

- hiring 3 additional CBTp qualified staff

- supporting more staff to attend a range of family intervention training so that a variety of family intervention could be offered

- reviewing the barriers to prescribing clozapine and agreeing clear approaches to reporting and a pathway for medication management

- developing a web based education programme which will be made available to all carers of individuals under the care of the trust for psychosis or schizophrenia.

Overall, LCFT fully or partially met 6 of the 7 objectives defined in their project and highlighted the importance of the best practice pathway in achieving these goals.

4.2. Health: medicines and technologies

This section includes information looking at the uptake and impact of NICE's medicines practice guidelines, technology appraisals and medical technology and diagnostic guidance. We have looked at the wider impact of NICE in the medicines and technologies sector, including our impact on national medicines optimisation policies and initiatives.

We have then looked at the uptake of NICE recommendations. The principal source of information about the uptake of medicines and technologies recommended in NICE guidance is the innovation scorecard and we have analysed the October 2016 publication. National audits and reports are also a limited source of information and we have analysed the available data in this section.

Finally, we have looked at a national priority area, biosimilar medicines, by analysing prescribing and audit data and highlighting some notable resource savings achieved in local health economies with the support of our medicines and prescribing associates.

Wider impact of NICE

> **NICE continues to influence and lead national policies on medicines and technologies, confirmed by the recommendations in the Accelerated Access Review.**
>
> **We have continued to successfully support both national policy and local medicines optimisation, and in priority areas such as antimicrobial stewardship and biosimilar prescribing.**
>
> **About 16% of our guidance page views are of medicines and technology topics, but they accounted for a quarter of our enquiries and most of our press coverage in the period covered by this report.**

Engagement activities

The Accelerated Access Review published in October 2016. This review makes several recommendations about how NICE should contribute to the aim of speeding up access to innovative healthcare and technologies. It includes the recommendation that NICE should be part of a proposed Accelerated Access Partnership with other key national bodies. The review recognises NICE's key role in the process of supporting innovation, and recommends that NICE should support improved accountability and transparency around uptake. Engagement with the Office for Life Sciences and other national partners to more clearly understand the implications of the review's recommendations is underway.

NICE continues to work with partners in several ways to support topic-specific or policy initiatives.

- NICE and NHS RightCare held a joint pop-up university session at NHS England's Expo in September 2016, focusing on how medicines optimisation is being embedded in the RightCare approach. RightCare have advised that the session helped shape their strategy on medicines optimisation.

- NICE has contributed to the development of NHS England's Regional Medicines Optimisation Committees (RMOCs) through membership of the steering committee and the evaluation, membership and topic selection working groups.

- NICE are members of and contributors to the national biosimilars steering group, helping to develop national policy in this area.

- Work with local NHS organisations to identify practical solutions to potential adoption barriers resulted in 3 adoption support products being

published in the report period: GreenLight XPS, sacubitril valsartan and PIGF-based testing.

Audience engagement

Medicines and technologies guidance accounted for **16% of all guidance page views** between April and October 2016. Of our **medicines practice guidelines**, the guideline on patient group directions was most viewed. Both this and the second most viewed guideline, controlled drugs, cover topics with a regulatory aspect, which may suggest that our users want to ensure they are following best practice in these areas.

Guideline	Publication date	Page views, April to October 2016
Patient group directions	February 2014	78,686
Controlled drugs: safe use and management	April 2016	56,778
Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes	March 2015	54,505
Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use	August 2015	34,976
Developing and updating local formularies	March 2014	5,094

Of our **technology appraisals, medical technologies and diagnostics guidance**, our guidance on the use of faecal calprotectin tests was by far the most viewed in the period.

Guidance	Publication date	Page views, April to October 2016
Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel (DG11)	October 2013	100,654
Alzheimer's disease - donepezil, galantamine, rivastigmine and memantine (TA217)	March 2011	41,975
Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (TA388)	April 2016	37,847
Guidance on the Extraction of Wisdom Teeth (TA1)	March 2000	34,944
Myocardial infarction (acute): Early rule out using high-sensitivity troponin tests (Elecsys Troponin T high-sensitive, ARCHITECT STAT High Sensitive Troponin-I and AccuTnI+3 assays) (DG15)	October 2014	31,775

Although the Alzheimer's disease technology appraisal was originally published in March 2011 it was updated during the data collection period, and the appraisal of sacubitril valsartan was newly published in the period. However, the fourth most viewed guidance, on extraction of wisdom teeth, is the oldest of all of NICE's

published technology appraisals, dating back to March 2000. This guidance is currently being [updated](#).

While accounting for 16% of our web views, medicines and technologies accounted for **a quarter of all NICE enquiries** in the data collection period. **Of the 5 press releases which resulted in most coverage, 3 were medicines topics**, and most of the incoming press enquiries were about technology appraisals or related topics, such as the Cancer Drugs Fund. The following example highlights the press interest in one of our appraisals.

Communications highlight: ataluren for Duchenne muscular dystrophy

> The press release on the decision to approve ataluren generated the most press coverage of any release between April and October 2016.

NICE published its guidance recommending the use of [ataluren for the treatment of Duchenne muscular dystrophy](#) in July 2016, through our Highly Specialised Technologies Programme. This is a rare condition, with only 35 people expected to receive treatment in the first year following NICE approval. However, a very well-organised campaign by charities [Muscular Dystrophy UK](#) and [Action Duchenne](#) meant that there was lots of press interest in our guidance.

The press release on the decision to approve ataluren generated the most press coverage of any release between April and October 2016, with **88 articles across national, regional, broadcast and radio.** This was followed by another 5 stories when additional time to reach an agreement was given and final guidance was issued in July. The press release and news story in July on the NICE website received 4,419 views. Our tweet about the final guidance in July was seen 24,657 times and engaged with 146 times.

Uptake of NICE guidance: overall

In the October 2016 innovation scorecard, we identified changes over time for 80 medicines.

Increased uptake in 63 (79%)

Decreased uptake in 17 (21%)
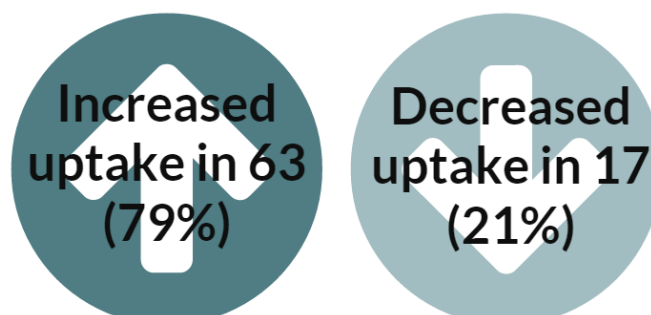
Between April and October 2016, we added 14 data points to the uptake database measuring the uptake of our medicines and technology recommendations. Of these, we were able to measure changes over time for 6 data points.

Increased uptake in 3 (50%)

No change in 1 (17%)

Decreased uptake in 2 (33%)
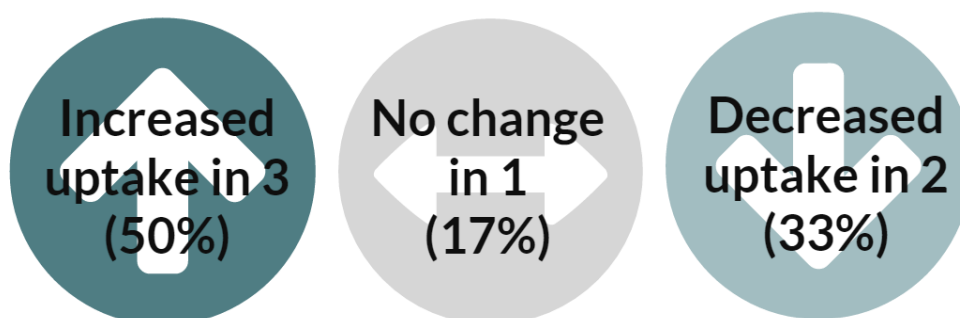
Uptake of NICE guidance: prescribing data

Overall, the uptake of scorecard medicines included in the October 2016 publication increased year on year.

Newly appraised medicines for the treatment of diabetes and hepatitis C showed rapid uptake in this period.

Some medicines in the scorecard have seen a decline in uptake over the period. The reason for this decline can be complex, but a common theme is displacement, where alternative treatment options for the treatment population have been positively appraised by NICE.

The innovation scorecard published in October 2016 contained uptake data for 85 medicines, and presented prescribing data to the end of March 2016. Medicines are eligible to be included in the innovation scorecard once 6 months has elapsed following publication of a technology appraisal. 80 of the 85 medicines had

prescribing data available for more than a year. For these medicines we compared the volume dispensed in 2014/15 with that dispensed in 2015/16; **63 (79%) showed an increase in the volume dispensed and the remainder a reduction**. Given the large number of medicines included in the innovation scorecard, uptake information has been grouped by the following diseases/conditions:

- diabetes

- hepatitis C

- acute coronary syndrome

- cancer

- relapsing-remitting multiple sclerosis.

When NICE recommends a treatment 'as an option', the NHS must make sure it is available within 3 months (unless otherwise specified) of its date of publication. It is important to note that the innovation scorecard reports on positively appraised medicines with a technology appraisal published after January 2012, and so prescribing data for other treatment options, either appraised by NICE or not, may not be included.

It should also be noted that a calculated percentage change is indicative of an increase or decrease in prescribing only and does not suggest that optimum levels of prescribing have been reached.

Newly added medicines

13 new medicines were added to the innovation scorecard in October's quarterly publication. The percentage change in prescribing was calculated by comparing the volume of medicine prescribed in the quarter they were added to the scorecard to the volume of medicine prescribed in the previous quarter.

Key findings:
Of the 13 medicines added in October the volume dispensed increased for 10 (77%). For 5 of these medicines the percentage increase was over 100%, showing rapid uptake, although in some cases this is distorted by the small volume of medicine dispensed.

Chart 18: Medicines newly added to the scorecard October 2016, percentage change in prescribing between October–December 2015 and January–March 2016
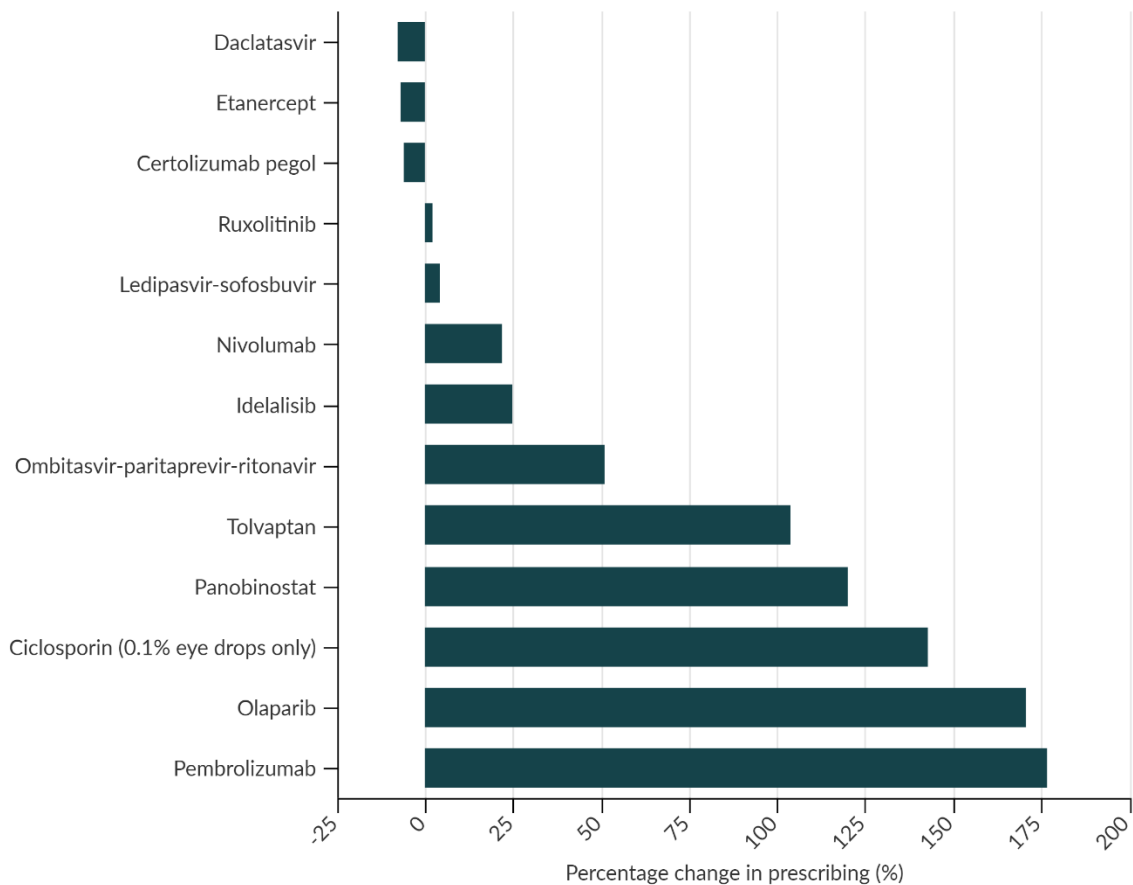
Source: Innovation Scorecard

Type 2 diabetes: SGLT2 inhibitors

SGLT2 inhibitors work by increasing the amount of glucose excreted in urine by the kidneys. These medicines have been appraised by NICE for the treatment of type 2 diabetes in combination with other treatment options, or in some circumstances as a monotherapy.

Key findings:
Uptake of all the SGLT2 medicines increased. Dapagliflozin was the most dispensed medicine and empagliflozin the least. Dapagliflozin was first appraised by NICE in June 2013 and empagliflozin in March 2015. Although this shows rapid uptake, the SGLT2 medicines account for a small proportion (less than 3%) of the prescribing for all antidiabetic medicines.

Chart 19: SGLT2 inhibitors for the treatment of type 2 diabetes included in the October 2016 innovation scorecard, percentage change in prescribing between 2014/15 and 2015/16
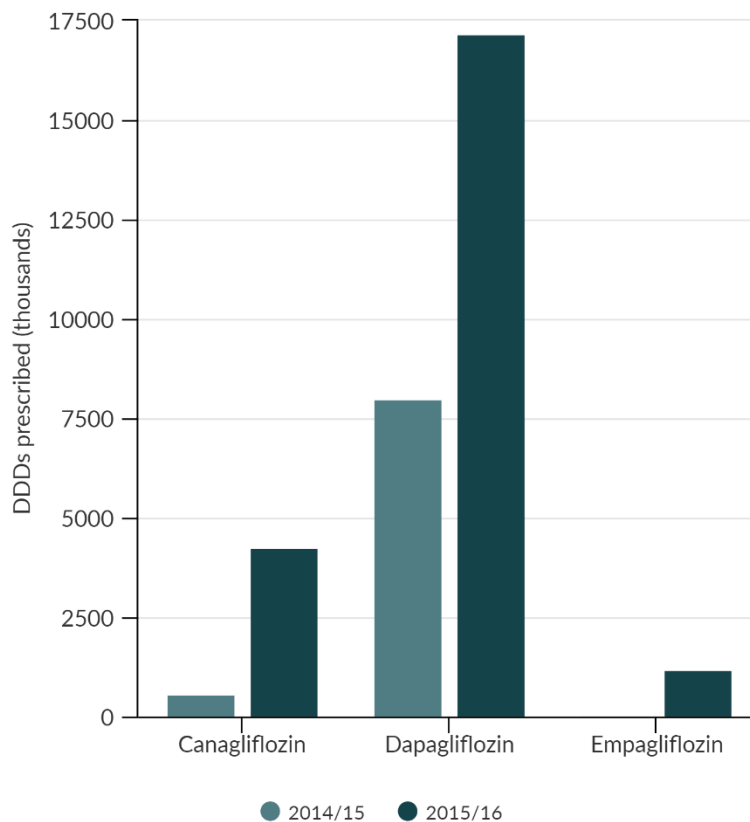
Source: Innovation Scorecard

Hepatitis C

An estimated 160,000 people in England are chronically infected with hepatitis C. Historically, treatment has consisted of pegylated interferon (a weekly injection) and ribavirin (a capsule or tablet). By using newer, more effective medicines, up to 90% or more of people with hepatitis C may be cured. Uptake data for these new medicines are shown in chart 20.

Key findings:
With the exception of telaprevir and boceprevir uptake (discontinued in August 2014 and January 2015) **uptake of these medicines has increased considerably and rapidly.**

Chart 20: Hepatitis C medicines included in the October 2016 innovation scorecard, percentage change in prescribing between 2014/15 and 2015/16
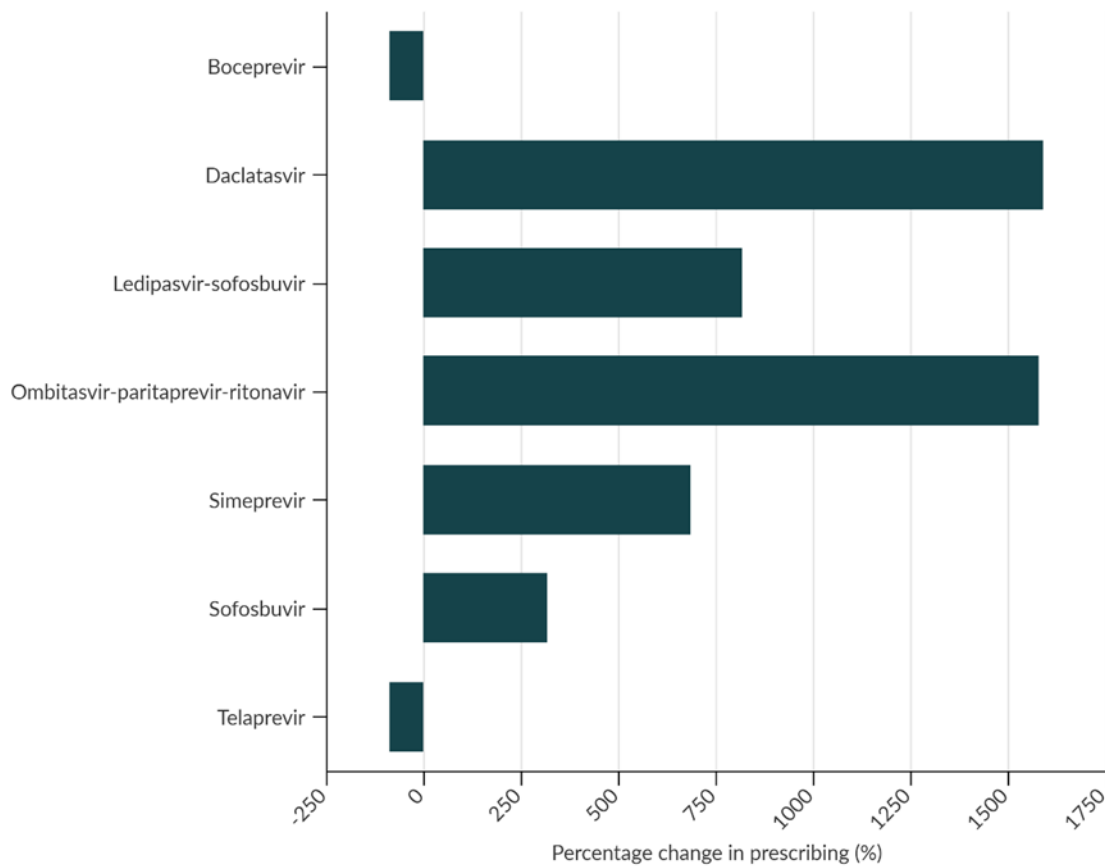
Source: Innovation Scorecard

Acute coronary syndrome

Three medicines for the treatment of acute coronary syndrome (ACS) were included in October's innovation scorecard as a grouping. These medicines have been appraised by NICE as treatment options for preventing artherothrombotic events in adults with acute coronary syndrome.

Key findings:
Ticagrelor was the most prescribed of the three ACS medicines included in the grouping. Rivaroxaban was the least prescribed and is not included in the chart because the volumes were so small. These medicines have been appraised by NICE as options for treatment but there are other options which have not been appraised by NICE.

Chart 21: Acute coronary syndrome medicines included in the October 2016 innovation scorecard, percentage change in prescribing between 2014/15 and 2015/16
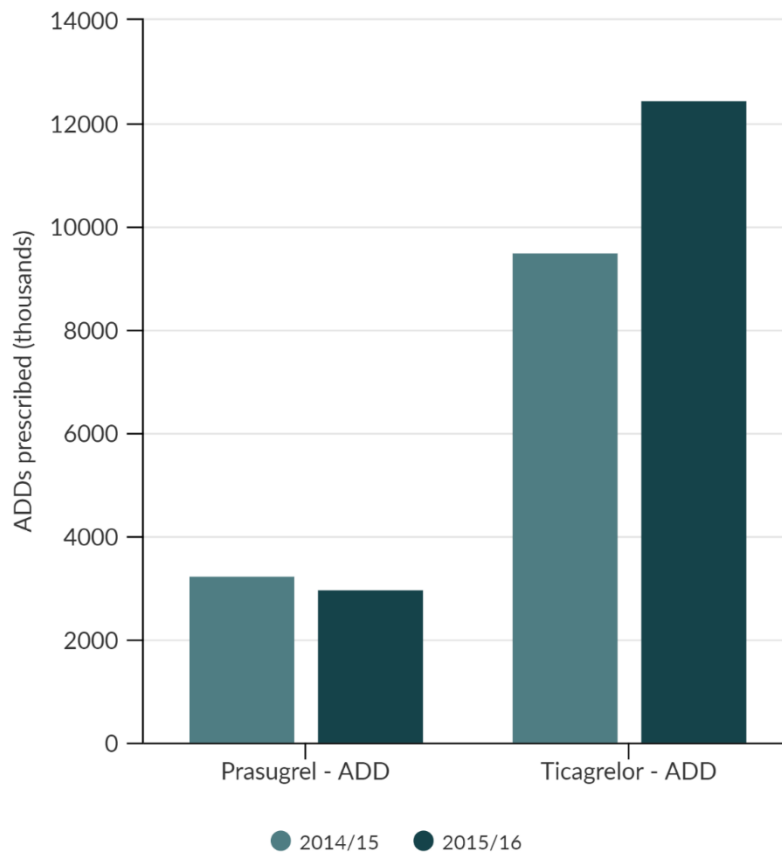
Source: Innovation Scorecard
Actual daily dose (ADD) assigns a unique value for each presentation of a drug based on units (tablets, capsules, patches etc.) and the recommended frequency of daily use (e.g. one a day, three times a day) for a particular indication.

Cancer

Twenty seven of the 85 medicines included in October's innovation scorecard are used to treat cancer. These medicines are used to treat a wide variety of cancers and some medicines are used to treat more than one type of cancer. For 25 of these medicines, prescribing data for more than 1 year is included in the scorecard. Of those, 17 saw an increase in the volume dispensed and the remainder a decrease.

Key findings:
Metastatic hormone-relapsed prostate cancer
- Prescribing of enzalutamide for treating metastatic hormone-relapsed prostate cancer increased by 164% during this period. Abiraterone acetate, also indicated for metastatic hormone-relapsed prostate cancer, saw a fall in prescribing (-23%).

Non-small-cell lung cancer
- Prescribing of afatinib for treating epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer increased by 179%. Prescribing of other treatment options for this patient group fell; erlotinib by 29% and gefitinib by 15%.

Chronic lymphocytic leukaemia
- Idelalisib for the treatment of chronic lymphocytic leukaemia saw an increase in prescribing (+480%) while ofatumumab, indicated for the treatment of patients with chronic lymphocytic leukaemia who have not received prior therapy and who are not eligible for fludarabine-based therapy, saw a decrease in prescribing (-53%).

Melanoma
- Dabrafenib for treating unresectable or metastatic BRAF V600 mutation-positive melanoma and pembrolizumab for treating advanced melanoma saw large increases in prescribing. Vemurafenib for treating locally advanced or metastatic BRAF V600 mutation-positive malignant melanoma prescribing fell by -41% during this period. It should be noted that these medicines have small volumes of prescribing.

Relapsing-remitting multiple sclerosis

Five medicines for the treatment of relapsing-remitting multiple sclerosis (RRMS) were included in October 2016's innovation scorecard. These medicines were presented as a grouping. Although the technology appraisal for natalizumab was published before the January 2012 cut-off date for inclusion in the innovation scorecard, this medicine was included for completeness.

Key findings
Across the grouping **all the medicines saw an increase in prescribing**. The increase was lowest for natalizumab and highest for dimethyl fumarate. Relative to the other medicines included in the group, teriflunomide was prescribed least. This might be due to the need for frequent blood tests to monitor for problems with liver function in the early months of treatment and the potential for this medicine to cause birth defects when administered during pregnancy.

Chart 22: Relapsing-remitting multiple sclerosis medicines included in the October 2016 innovation scorecard, percentage change in prescribing between 2014/15 and 2015/16
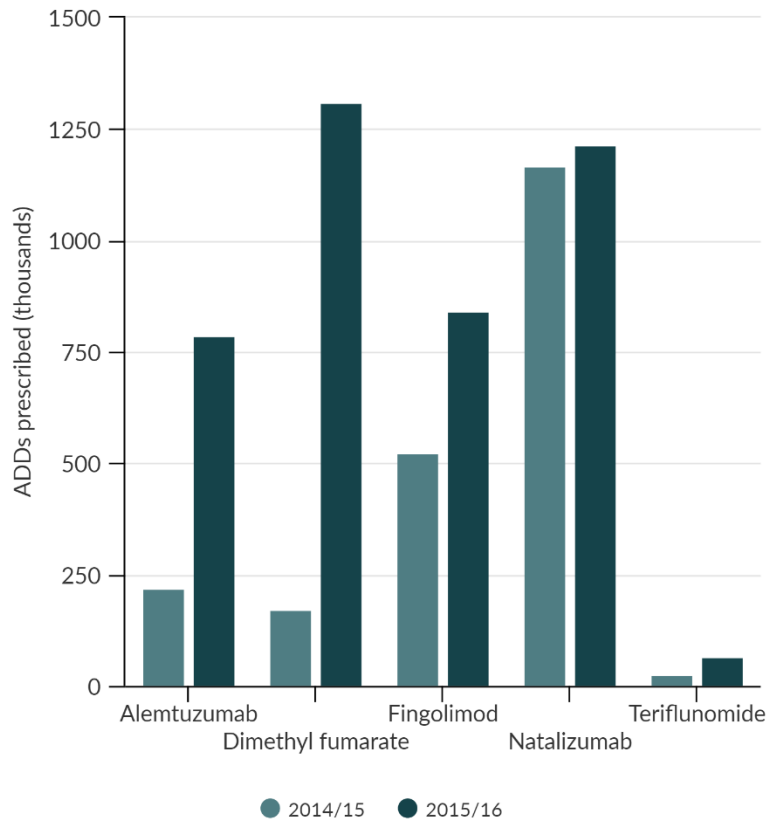
Source: Innovation Scorecard

Uptake of NICE guidance: national audits and reports

Type 1 diabetes

NICE recommends subcutaneous insulin infusion (CSII or 'insulin pump') therapy as a treatment option when attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections result in the person experiencing disabling hypoglycaemia or when HbA1c levels have remained high (that is 69 mmol/mol or above) on multiple daily injection therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care (see TA151). Data about the uptake of this recommendation were collected from the national diabetes insulin pump audit.

Key findings:

In 2014-15, the proportion of people with Type 1 diabetes attending participating specialist services and treated with an insulin pump was 11.7%. The audit was completed as a feasibility study and so the data should be treated with some caution. The audit findings also suggested that people with type 2 diabetes were being treated with insulin pumps outside of NICE guidance, although the report raised the possibility that people with type 1 diabetes may be incorrectly classified as type 2. The audit found that the mean HbA1c reading was lower in people on an insulin pump compared to those not on a pump.

Medicines and prescribing case study: biosimilar medicines

> **Data from the inflammatory bowel disease audit demonstrated that infliximab biosimilars are as effective as infliximab originator with a similar adverse event profile.**

A biosimilar is a biological medicine that is developed to be highly similar to an existing biological medicine in physicochemical and biological terms. NHS England supports the appropriate use of biosimilar medicines to increase commercial competition and create increased choice for patients and clinicians and enhanced value propositions for individual medicines. A collaborative guide to biosimilars produced by NHS England and partners including NICE states that this increased competition will release cost efficiencies to support the treatment of an increasing number of patients and the uptake of new and innovative medicines.

Following the publication of NICE's position statement on biosimilar medicines in January 2015, several NICE technology appraisals state that recommendations also apply to biosimilar versions of the appraised medicines. Recommendations are supported by an adoption support resource to provide practical information and advice on the use of biosimilar versions. A key therapeutic topic was published in February 2016, and updated in January 2017, to support the use of biosimilar medicines in general.

The national clinical audit of biological therapies UK inflammatory bowel disease audit provides data on infliximab originator and infliximab biosimilar adverse reactions to treatment. NICE's inflammatory bowel disease (IBD) quality standard includes a statement and measure on the number of adverse events reported because of drug treatment for IBD. The audit data reports that, at initial treatment, 4% of adults and 1% of children receiving treatment with biological therapies had an adverse reaction recorded. At 3 month follow up, 10% of adults and 5% of children receiving treatment with biological therapies had an adverse reaction recorded. Data on adverse reactions to biological therapies in adults and children by infliximab originator and biosimilar are presented in the table below. These figures appear to be low and similar across originator and biosimilar prescribing.

	Initial treatment		3 month follow up	
	Infliximab biosimilar	Infliximab originator	Infliximab biosimilar	Infliximab originator
Adult adverse reactions	5%	5%	11%	7%
Paediatric adverse reactions	0%	2%	5%	5%

The IBD audit also provides outcome data on infliximab biosimilars (Inflectra and Remsima) compared with infliximab originator (Remicade). Data in the tables below show disease severity at initial treatment and at 3 month follow up for adults with Crohn's or ulcerative colitis, with biosimilar and originator treatments.

Crohn's disease				
Disease severity	Initial treatment		3 month follow up	
	Infliximab biosimilars	Infliximab originator	Infliximab biosimilars	Infliximab originator
Remission	2%	0.8%	33%	27%
Mild	6%	9%	31%	36%
Moderate	59%	61%	31%	33%
Severe	33%	29%	4%	4%

Ulcerative colitis				
Disease severity	Initial treatment		3 month follow up	
	Infliximab biosimilar	Infliximab originator	Infliximab biosimilar	Infliximab originator
Remission	No data	1%	32%	21%
Mild	No data	3%	34%	28%
Moderate	No data	49%	30%	37%
Severe	No data	48%	5%	15%

The data demonstrate that **infliximab biosimilars are as effective as infliximab originator**. A response was seen at 3 months in 84% of adult and 86% of paediatric patients treated with infliximab biosimilar and 85% of adult and paediatric patients treated with infliximab originator.

Biosimilar prescribing information is included in NHS England's medicines optimisation dashboard. The data show that the **use of biosimilar infliximab (Inflectra, Remsima, Flixabi), is increasing in England**. In the quarter July to September 2015, 13% of all infliximab purchased was infliximab biosimilar. This **increased to 56% in the most recent July to September 2016 quarter.**

Chart 23: Biosimilar infliximab prescribing as a percentage of all infliximab prescribing, July 2015 to September 2016
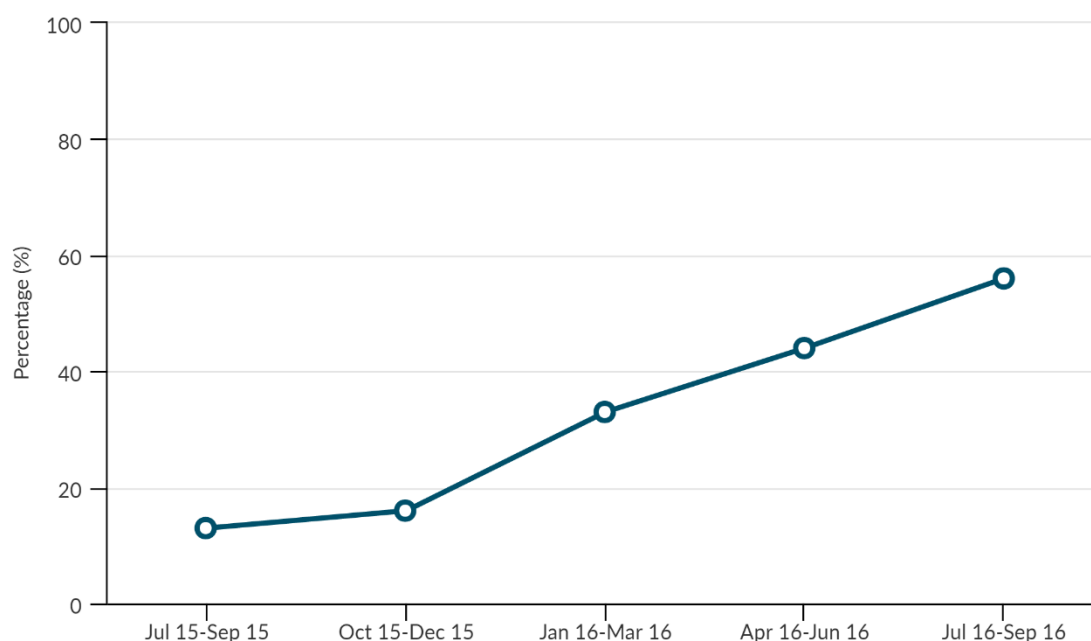
Source: Medicines Optimisation Dashboard

The availability of biosimilar infliximab provides an opportunity for substantial cost savings; the IBD audit highlights that its use **reduces the cost of treatment from approximately £10,000 per patient per year to less than £5,000.** Data from the NICE medicines and prescribing associates provides information on local initiatives that have increased the use of biosimilars, reducing the cost burden of expensive biological therapies on the NHS.

In many areas, local policies have been developed to support the managed introduction of biosimilar medicines into care pathways safely and effectively as they become available, taking into account relevant regulatory advice, national guidance, patient factors and cost. Data from associates shows that, where switching from originator to biosimilar infliximab has begun to take place, this varies from 15-100%, although there are still some areas where biosimilar medicines are not being used. This may be provider-led, or because commissioners do not support a gain share agreement, which is an arrangement in which commissioners share a proportion of any financial savings made by NHS trusts as a result of more cost-effective use and procurement of medicines. In some areas, uptake of biosimilar etanercept has been slow because of supply chain difficulties or creating agreements with different providers.

Approaches taken in local health economies have included employing a biosimilar or high cost drugs pharmacist to work with clinicians and patients, creating a biosimilar committee to review requests for exemptions from switches, and gain share agreements. Associates have provided local training on biosimilar medicines and

facilitated the production of local policies, patient information leaflets, and fact sheets for clinicians.

In one large teaching hospital in the North West, the NICE medicines and prescribing associate was the author of the Trust biosimilar policy. The approach includes discussion of all new biosimilars at the medicines management group as they appear. Timescales for transition of new patients are included, with the aim of achieving a 3 month target. The associate network was a useful resource during policy development, providing examples of successful approaches. A 50:50 gain share for all new biosimilars is now in place. Over **53% of patients have been switched to biosimilar infliximab, with an estimated cost saving of around £830,000.**

Similarly, in Oxford, the practical support of the associate programme, including providing materials on biosimilar medicines, technology appraisals and the NICE compliance statement, examples of letters to patients, and highlighting the importance of the patient perspective, helped shaped the local template for biosimilar medicines. In the period March to October 2016, **80% of patients were using biosimilar infliximab, representing a saving of £124,000**. Savings for etanercept were approximately £70,000.

4.3. Public health

This section includes information looking at the uptake and impact of NICE's public health guidelines and quality standards. We have very little public health uptake information available for this edition of the report. Although we analysed the Public Health Outcomes Framework (PHOF) during the data collection period, only one of the indicators gave us information about a specific recommendation in a public health guideline. We have looked at the routinely collected data on smoking and stop smoking services and information about the uptake of our workplace health guidance in this section.

We have then looked at the wider impact of NICE in the public health sector, including our impact on national policies and initiatives, and a focus on how our field team have worked with a local authority to support our health in the workplace guidance. We have considered work that our medicines and prescribing associates are doing locally to support antimicrobial stewardship. Finally, we have looked at 2 shared learning examples which demonstrate the benefits of implementing our guidance on excess winter deaths.

Uptake of NICE guidance: overall

Between April and October 2016, we added 17 data points to the uptake database measuring the uptake of our public health guidelines and standards. Of these, we were able to measure changes over time for 10 data points.

Increased uptake in 6 (60%)   Decreased uptake in 4 (40%)
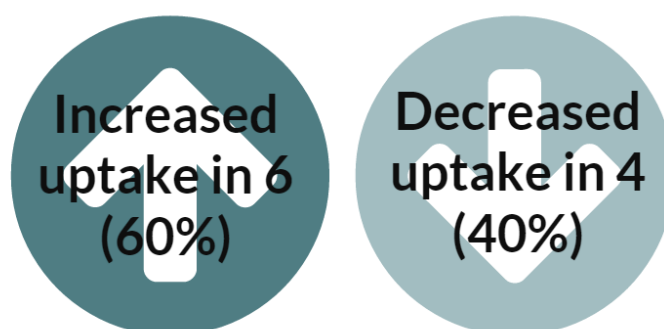
Uptake of NICE guidance: smoking

The Five Year Forward View focuses on the need to get serious about prevention as a key element of delivering a sustainable NHS. The report highlights that smoking-related diseases remain England's number one killer. NICE has produced a suite of public health guidelines and quality standards with the aim of reducing the number of people who smoke. These include guidance on stop smoking services and quality standards on supporting people to stop smoking and reducing and preventing tobacco use. In this period, data measuring the uptake of recommendations from these guidelines and standards was available from a routine data collection and the Quality and Outcomes Framework (QOF).

Recording of smoking status and offering support

To enable interventions to be offered, NICE recommends that health professionals should proactively ask people if they smoke. If they do, they should be offered advice on how to stop.

Key findings
The QOF records whether people with underlying health conditions (chronic heart disease, peripheral arterial disease, stroke or transient ischaemic attack, hypertension, diabetes, chronic obstructive pulmonary disease, chronic kidney disease, asthma, schizophrenia, bipolar affective disorder or other psychoses) have their smoking status recorded, and if they are smokers whether they have a record of an offer of support and treatment. **Both measures are relatively high at around 94%** and have remained stable over recent years.

Stop smoking services

NICE recommends that people who smoke should be offered therapy or a combination of treatments that have been proven to be effective. When people who smoke have set a quit date with an evidence‑based smoking cessation service, they should be assessed for carbon monoxide levels 4 weeks after the quit date.

Key findings
The QOF records that **over 99% of practices support patients who smoke to stop using a strategy which includes providing literature and offering appropriate therapy**. The routinely collected NHS Digital statistics on NHS stop smoking services record whether people who reported that they had quit smoking were validated with a carbon monoxide test, as recommended by NICE. This figure remains steady at around 70%.

Uptake of NICE guidance: workplace health

The Five Year Forward View highlights the importance of a healthier workforce to reduce NHS demand and lower long term costs. The report states that the NHS as an employer should set a national example in the support it offers its own 1.3 million staff to stay healthy, and recommends that implementation of NICE guidance on promoting healthy workplaces should be a priority in the NHS, particularly for mental health. Improving the support available to NHS Staff to help promote their health and wellbeing in order for them to remain healthy and well has been identified as a national Commissioning for Quality and Innovation (CQUIN) goal. NHS England has produced guidance to support this goal, which references NICE guidance throughout.

In this period, data measuring the uptake of the guideline on workplace health: management practices were available from the NHS staff survey.

Organisational priorities

The workplace health: management practices guideline highlights that there is a positive association between wellbeing, job satisfaction and an employee's job performance, and that work-related illness and workplace injury led to the loss of an estimated 28.2 million working days in 2013/14. NICE recommends that health and wellbeing should be a core priority for the top management of an organisation, and that employers should employ a consistent, positive approach to all employees' health and wellbeing. The guidance recommends valuing and acknowledging employees' contribution across the organisation.

Key findings
The NHS staff survey asked about wellbeing for the first time in 2015. **90% of respondents stated that their organisation definitely or to some extent takes positive action on health and wellbeing**. However, when asked how satisfied they were with the extent to which their organisation values their work, only **46% answered satisfied or very satisfied.**

Leadership style

The workplace health: management practices guideline highlights that many studies have shown a relationship between supportive supervision and job satisfaction, and that good line management has been linked with good health, wellbeing and improved performance. NICE recommends that line managers should adopt a positive leadership style that includes offering help and encouragement and recognising the contribution of each employee. Line managers should also encourage creativity and new ideas and explore new ways of doing things and opportunities to learn.

Key findings

The NHS staff survey asked about the support that respondents received from their direct line manager; 69% of respondents reported being satisfied or very satisfied. When asked if they were able to make suggestions to improve the work of their team or department, 76% of respondents answered positively.

Wider impact of NICE

NICE continues to work closely with Public Health England (PHE) at a national level, focusing on joint priorities and working. NICE contributed to PHE's Local Health and Care Planning: Menu of preventative interventions which outlines evidence-based, preventative public health interventions that can help improve the health of the population and reduce health and care service demand in the short to medium term.

At a regional level, NICE continues to seek opportunities to work with PHE's regional teams and local authority public health teams to embed our guidance into regional and local practice and policies.

Field team focus: health and wellbeing in the workplace

NICE has produced a suite of guidelines to support health and wellbeing in the workplace, including guidance on mental wellbeing at work and management practices. In Devon, the local implementation consultant mapped recommendations from these guideline to the Workplace Wellbeing Charter, originally developed by NHS Liverpool and now championed by Public Health England. This prompted a request for NICE to formally develop this work.

The implementation consultant subsequently delivered a workshop to colleagues from Public Health England, the Department for Work and Pensions, a CCG, a mental health partnership, County and District hospitals and an acute trust. The implementation consultant used NICE resources such as the local government briefing on workplace health to make the case for improving health in the workplace. The session covered the impact on providers of the workplace Commissioning for Quality and Innovation (CQUIN) goal, and local workplace health activity such as programmes on brisk walking, mental health, stress at work and musculoskeletal issues.

The CQUIN guidance produced by NHS England recommends using the assessment and accreditation process in the Workplace Wellbeing Charter to fully implement NICE's guidance on workplace health. Having identified the NICE recommendations which map to this charter, the implementation consultant was able to highlight and lead a discussion on the relevant guidance.

Antimicrobial stewardship

The UK Five Year Antimicrobial Resistance Strategy, published in 2013, states that "there are few public health issues of greater importance than antimicrobial resistance in terms of impact on society" because "the rapid spread of multi-drug resistant bacteria means that we could be close to reaching a point where we may not be able to prevent or treat everyday infections or diseases." One of the 3 aims of the UK strategy is to conserve and steward the effectiveness of existing treatments.

The NICE guideline on antimicrobial stewardship, published in 2015, aims to change prescribing practice to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection. NICE has also published a key therapeutic topic on antimicrobial stewardship which summarises the evidence base and advises on options for local implementation.

While antimicrobial stewardship work has always been part of medicines optimisation, the NICE guidance was seen by our medicines and prescribing associates as a tool to enable change and focus on these issues. Between April and October 2016, the associates built on the training they had received on the NICE antimicrobial stewardship guideline to facilitate implementation of the guidance in their local areas.

The associates used resources produced by NICE, including slide sets for associates, the baseline assessment tool and medtech innovation briefings, along with resources signposted to in the guidance such as the TARGET antibiotics toolkit, and shared examples of good practice. Implementation activities included local workshops for primary and secondary care clinicians, patient education including a local radio campaign, education events for patient groups, leaflets, posters and GP waiting room videos, antimicrobial prescribing analysis, feedback and peer support, and financial incentives to meet prescribing targets.

NICE recommends that prescribers should take into account the risk of antimicrobial resistance for individual patients and the population as whole, and that local or national guidelines should be followed. National policies such as Public Health England's managing common infections in primary care recommend that simple generic antibiotics should be used if possible when antibiotics are necessary. Broad-spectrum antibiotics such as co-amoxiclav, quinolones and cephalosporins should be reserved to treat resistant disease. Prescribing of these broad-spectrum antibiotics is reported in the medicines optimisation dashboard and, in 2015/16 ranged from 4% to 14% as a percentage of all antibiotic prescribing across CCGs in England.

In Southampton CCG, providing one to one support had the biggest impact in changing prescribing behaviour. Specific patient examples were discussed with individual prescribers. Data for 12 months up to July 2016 showed that **cephalosporins, quinolones and co-amoxiclav prescribed as a percentage of all antibiotic items reduced from 13% to 11%.**

In Northamptonshire, GPs received a large number of co-amoxiclav prescription requests from podiatrists. This was addressed by training podiatrists on antimicrobial stewardship, and including antibiotics in their toolkit as independent prescribers. This encouraged ownership of the prescribing and resulted in a **reduction in the prescribing of co-amoxiclav, cephalosporins and quinolones as a percentage**

of antibiotics from 11% to 8% (Nene and Corby CCGs, March to October 2016), which the GPs largely ascribed to the medicines optimisation work with podiatrists.

In secondary care, a number of associates have targeted **reviewing antibiotics within 48 hours of being prescribed**. Barking, Havering and Redbridge University Hospitals NHS Trust and North Middlesex University Hospital NHS Trust have redesigned drug charts to facilitate this, and figures from Western Sussex Hospitals NHS Foundation Trust showed that **this was achieved in 88% of antibiotic prescriptions** between March and October 2016.

Audience engagement

The NICE stakeholder engagement workshops, held in autumn 2016, revealed that public health professionals had a good overall understanding of the role of NICE and were relatively regular users of our guidance and standards in their everyday work. A review of NICE website statistics from April to October 2016 reveals that our guideline on increasing vitamin D supplementation in at-risk groups was the most viewed. As was the case with our clinical guidelines, where diabetes was a popular topic, the public health guideline on preventing type 2 diabetes was also popular in this period.

Guideline	Publication date	Page views, April to October 2016
Vitamin D: increasing supplement use among at-risk groups	Nov-14	49,497
Type 2 diabetes: prevention in people at high risk	Jul-12	39,360
Behaviour change: the principles for effective interventions	Oct-07	37,077
Maternal and child nutrition	Mar-08	36,388
Smoking cessation services	Feb-08	34.013

Communications highlight: harmful sexual behaviour among children and young people

NICE published our guideline on harmful sexual behaviour in September 2016. The NICE press release generated 31 pieces of press coverage at publication, which was **the fifth highest of any press release in the data collection period**. Publications including the Mail, Telegraph, Sun and BBC carried advice about sexting and spotting the difference between normal experimentation and harmful behaviour.

The news story on the NICE website received 2,232 views and an accompanying blog by Jon Brown from the NSPCC received 429 views. On Facebook our posts reached 348 people and on Twitter our tweets were seen more than 36,000 times, with combined 100 retweets and 53 favourites. The NSPCC and the Children's Commissioner were supportive in the media.

Public health case study: excess winter deaths

Public Health England's 2016 Cold Weather Plan notes that winter weather has a direct effect on the incidence of heart attack, stroke, respiratory disease, flu, falls and injuries and hypothermia. Indirect effects include mental health problems such as depression, and the risk of carbon monoxide poisoning if boilers, cooking and heating appliances are poorly maintained or poorly ventilated.

The Office for National Statistics estimates that, in England and Wales in 2015/16, there were 24,300 excess winter deaths, where 15% more deaths occurred in winter months than non-winter months.The Public Health Outcomes Framework includes a fuel poverty indicator which reports that 10.6% of households in England experienced fuel poverty in 2014. This is a 1.4% increase since 2013.

NICE's excess winter deaths guideline, published in March 2015, recommends the use of a strategy to address the health consequences of cold homes. A shared learning example discusses an Affordable Warmth Partnership in Middlesbrough that delivers a programme of help and support to vulnerable people throughout the winter months. The Partnership created an Affordable Warmth Action Plan with the aim of tackling fuel poverty and the health impacts related to living in cold homes. The action plan used the NICE guideline as a framework and included the following specific actions:

- enhance a referral process into a single point of access hub

- deliver a range of training to front-line staff

- further develop a housing database to include both health and home energy efficiency data to strengthen the links between cold homes and ill health

- to begin to establish a data sharing protocol between relevant partners.

Following implementation of the housing database, outreach events and one to one advice sessions with vulnerable people, **over 2,600 people accessed the initiative during winter 2015/16**, successfully raising awareness of fuel poverty issues, energy efficiency and staying healthy and warm at home. The initiative also provided practical help to improve household income and access boiler replacement/home insulation grants, thus helping to reduce carbon and make homes easier to heat.

A second shared learning example focuses on the Warmth for Wellbeing Service in Leeds, which aims to establish a co-ordinated and complementary service to support households with their affordable warmth needs. The newly commissioned service aims to align with the NICE excess winter deaths outcomes on:

- reduction of preventable, excess winter death and illness rates

- improvement of health and wellbeing among vulnerable groups

- reduction of pressure on health and social care services

- reduction of 'fuel poverty' and the risk of fuel debt or being disconnected from gas and electricity supplies (including self-disconnection)

- improvement of the energy efficiency of homes.

The new service for vulnerable people living in cold homes provides tailored solutions to identified needs, including:

- face to face advice

- low-cost energy saving improvements

- heating serving or repairs

- referrals to relevant support such as large-scale energy efficiency improvements to properties.

The preliminary findings show an increase in telephone contact with vulnerable people, alongside household savings on utility bills mainly as a result of successful Warm Homes Discount applications and switching suppliers.

It appears that local initiatives implementing the NICE excess winter deaths guideline recommendations are finding an increase in the number of vulnerable people benefitting from advice and help to keep their homes warm. In time this should yield future cost savings by contributing to reducing heart attacks, strokes, respiratory diseases, flu, falls and injuries and hypothermia. Continuing to implement and measure these initiatives will help to establish valuable outcomes data in the future.

4.4. Social Care

This section includes information looking at the uptake and impact of NICE's social care guidelines and quality standards. We have very little social care uptake information available for this edition of the report. We have looked at the available audit data on discharge from acute settings and the indicator on social contact in this section.

We have then looked at the wider impact of NICE in the social care sector, including our impact on national policies and initiatives, and a focus on how our medicines and prescribing associates have supported the use of the NICE guideline on managing medicines in care homes. We have taken another look at field team work to support an STP, with a particular focus on the NICE guideline on transition from hospital to care homes with the aim of reducing readmission. Finally, we have looked at our dementia guideline and considered how our recommendations, though a product of the clinical guideline programme, are supporting better care in the social care sector.

Uptake of NICE guidance: overall

There is very little national data available to demonstrate the uptake of NICE guidance in the social care sector. Between April and October 2016, we added 4 data points to the uptake database measuring the uptake of our clinical guidelines and standards. Of these, we were able to measure changes over time for 1 data point.

Increased uptake in 1

Uptake of NICE guidance: discharge from hospital

NICE's guideline on the [transition between inpatient hospital settings and community or care home settings for adults with social care needs](#) recommends that health and social care organisations should agree clear discharge planning protocols and that a single health or social care practitioner should be responsible for coordinating the person's discharge from hospital.

Key findings
The Older People's Care in Acute Settings Benchmarking Report reported that **86% of acute trusts or local health boards had a documented supported discharge protocol across all wards**. The report also found that 79% of inpatient wards had dedicated discharge coordinators.

Uptake of NICE guidance: social contact

In NICE's [home care](#) guideline, it is recommended that the potential negative effect of social isolation on people's health and wellbeing should be addressed. In the guideline on [older people with social care needs and multiple long-term conditions](#), it is recommended that health and social care practitioners should support people to maintain links with their friends, family and community, and identify if people are lonely or isolated.

Key findings
The [Public Health Outcomes Framework](#) records the proportion of adult social care users who have as much social contact as they would like. This has remained steady since 2014 at around 44%.

Wider impact of NICE

NICE continues to work with national partner organisations such as the CQC and Ofsted, with the aim of agreeing key areas of mutual interest and embedding our work in inspection regimes and national policies.

The development of an Adult Social Care Quality Strategy is now underway and NICE is engaging with the group of national organisations working to produce this, with the aim of including our recommendations as a recognised measure of quality. It is hoped that this may ultimately lead to more information becoming available about the uptake of our social care guidance.

In this section, we have looked at how our medicines and prescribing associates and the NICE field team are working at a local and regional level to support the implementation of NICE guidance and encourage uptake of our recommendations in the social care sector.

Managing medicines in care homes

The NICE guideline on [managing medicines in care homes](#) was published in 2014, and was followed by a [quality standard](#) in 2015. The recommendations cover the prescribing, handling and administering of medicines for all people living in care homes, and the provision of care or services relating to medicines to those people. The NICE medicines and prescribing associates have worked in their local health economies to support implementation. Links with care homes pharmacists and local authorities have been particularly important as a multidisciplinary approach to implementation of the guidance has been taken in many regions, involving care homes, local authorities, the CQC and safeguarding teams. Care home staff training, medication reviews and patient reviews by pharmacists and GPs have been carried out.

In Wigan, using a multidisciplinary approach, medication reviews have been performed by CCG pharmacists, who made recommendation to the patients' GPs. Data is available for the 12 month period from September 2015 for 479 medication reviews across 52 care homes. Overall **there was an approximately 16% reduction in the number of prescribed medications, reducing the average number of medications to from 9.4 to 7.9 per person**. 57% of people reviewed had medication stopped, 20% had a dose adjustment and 23% had treatment initiated. Annual savings were approximately £380,000.

In Swindon CCG, a care home pharmacist has been employed, and data for the period March to October 2016 showed 241 patients across 7 care homes were reviewed, leading to 581 interventions (stopping, changing, and instigating monitoring of doses), saving approximately £36,000.

In Cardiff, a pilot was carried out in 3 care homes. Processes for medicines ordering and administration were aligned to the NICE guidance, and pharmacist-led medication reviews were performed. Here, 121 medication reviews were undertaken and 116 discrepancies between GP practice and medicines administration charts were identified. 139 medications were stopped, and 47 medications were changed in terms of timing, dose or formulation. The main objective of this project was improving patient safety through the use of medication reviews, but savings of nearly £2,000 over 6 months were also made. The pilot has now been rolled out locally.

Field team focus: transition between inpatient hospital settings and community or care home settings for adults with social care needs

Nottingham and Nottinghamshire Sustainability and Transformation Plan (STP) footprint comprises of several organisations including 2 unitary Local Authorities, 6 CCGs, 2 acute trust providers, 1 mental health and community services trust, 2 community service providers and numerous independent and third sector providers of health and care services. There are 6 new care models being established including an acute care collaborative (East Midlands Radiology Consortium), an integrated primary and acute care system, an urgent and emergency care vanguard, an enhanced health in care home vanguard, a multispecialty community provider and an integration pioneer. NICE is a sponsor for the integrated primary and acute care system (Mid Nottinghamshire: Better together) and support has been provided to the various vanguards in a number of ways, including signposting to key NICE resources and demonstrating how they can be used to identify high impact areas for quality improvement and evaluate impact.

The STP outlines high impact areas for improving services and the health and wellbeing of the population and the local implementation consultant has been supporting this work in a number of ways.

The implementation consultant has collaborated with colleagues at PHE East Midlands to provide 2 workshops to support public health staff involved in developing the local STPs. The first workshop focused on 'making the case for prevention' and the second was more general and focused on 'evaluating return on investment'. Prevention is a priority area for the STP and is underpinned by the East Midlands report Meeting the prevention challenge: a call to action. The implementation consultant contributed to this report by signposting the author to key NICE guidelines and quality standards and also highlighting practical tools and resources produced or endorsed by NICE.

The STP recognises the ongoing need to engage with and develop the marketplace for third sector providers. There has already been a great deal of work in the area aiming to develop the capacity of voluntary and community services organisations to provide evidence based services that meet local need. The 'Better data project' led by PHE East Midlands in collaboration with the local implementation consultant

resulted in a programme of workshops for third sector organisations and the publication of [Better data: an introductory guide](#).

Good progress is already being made towards ensuring evidence-based pathways of care. The implementation consultant has worked with the main health providers in the footprint to establish systematic approaches to implementing NICE guidance. Nottinghamshire Healthcare NHS trust recently held a [NICE conference](#) aimed at sharing good practice and celebrating successes in the organisation.

The next step for the STP footprint is to implement the plan. The implementation consultant recently provided workshops for the social care commissioning and transformation leads at the 2 local authorities and has agreed to provide a further session exploring how NICE resources can support the teams with implementing the STP.

As a member of the patient safety collaborative 'discharge and transfer of care cluster' (a network of 9 patient safety collaboratives working on improving transfer of care for people requiring a hospital admission, chaired by the Director of the East Midlands Patient Safety Programme), the implementation consultant was able to raise awareness of the NICE guideline on [transition between inpatient hospital settings and community or care home settings for adults with social care needs](#). The patient safety collaboratives have gone on to share [several case studies](#) describing how they have improved transfer of care in their local organisations.

The NICE guideline recommends that health and care multidisciplinary teams should work together to identify and address factors that could prevent a safe, timely transfer of care from hospital. A project focused on [reducing readmissions](#) highlights the benefits of integrated care across the health and social care system in Nottingham and reported 80 fewer people readmitted each month when compared with the previous year. A project focusing on developing community services to [support people after discharge](#) reported a reduction in the time between being declared medically safe for discharge and actual discharge taking place. This project notes that full integration between health and social care is due to take place with a joint hub delivering integrated care pathways, which is in line with NICE recommendations.

Audience engagement

The NICE regional stakeholder events, held in autumn 2016, identified that the group of professionals from social care were the least familiar with our guidance and referred to it less often than health or public health professionals. This is unsurprising as social care guidance is our newest programme of work, with the first guideline published in March 2014. That guideline, [managing medicines in care homes](#), was the most viewed of our social care guidelines between April and October 2016.

Guidance	Publication date	Page views, April to October 2016
Managing medicines in care homes	Mar-14	98,131
Transition from children's to adults' services for young people using health or social care services	Feb-16	27,221
Transition between inpatient hospital settings and community or care home settings for adults with social care needs	Dec-15	23,843
Home care: delivering personal care and practical support to older people living in their own homes	Sep-15	18,509
Older people with social care needs and multiple long-term conditions	Nov-15	18,363

NICE's audience insight team carried out research about our products among social care professionals during 2016. This identified that structural issues in the care home sector, such as low staffing levels and high staff turnover, may be contributing to difficulties in implementing NICE guidance. The target audiences for our guidance suggested that the length of guidelines may be an obstacle to people working in social care.

To respond to this audience feedback, NICE published two quick guides in October 2016. These short, visual guides are intended to present key information from the full guideline. One is aimed at care home managers and the other at people who arrange their own care. A programme of assessment is now underway, and we will review the findings in the next uptake and impact report.

The audience insight research also highlighted that face-to-face promotion of our products was particularly important for the social care audience, particularly because there is low awareness overall of our role in producing social care guidance when compared to our reputation in the health sector. We exhibited at Community Care Live in Birmingham (May 2016) and London (September 2016) to promote our guidance and quality standards. The feedback collected was very positive, with delegates commenting that our recommendations were much needed and really helpful. Many delegates reported that they did not know we produced so much for social care.

We further promoted NICE products for the sector at 2 workshops for social care students. The workshops provided an introduction to NICE and familiarised the students with NICE Evidence search. Again, the feedback was positive, particularly from postgraduates who felt that the resources would be useful in their practice.

Communications highlight: transition between inpatient mental health settings and community or care home settings

NICE's transition guideline for mental health settings published in August 2016. To promote it, the media team hosted a live #NICEchat Twitter discussion. Tweets related to the chat were seen over 230,000 times, with over 1,600 interactions (retweets, likes and clicks to the NICE profile/website). Organisations and influencers including SCIE, MIND, Together Mental Health and The Mental Elf helped to spread the news and joined discussions on the day. We produced a Storify of the chat. We also produced 2 videos explaining the guideline and its recommendations which were viewed more than 300 times on Facebook and YouTube.

Our communications highlighted that mental health staff should build good relationships as early as possible with people moving between services, raising awareness of the detrimental impact poor transitions can have on people. The story gained no traction in mainstream media but was well received on the NICE social channels, showing the success of promoting under-reported stories via organisational channels.

Social care case study: dementia

Dementia is a term used to describe the progressive decline in cognitive function in which people may experience a range of symptoms including: memory loss, language impairment, disorientation and changes in personality.

In recent years, there have been a number of national dementia strategies published. The Department of Health's Living well with dementia: a National Dementia Strategy (2009) and the Prime Minister's challenge on dementia 2020 (2015) set out plans to improve awareness, diagnosis and quality of care in dementia. Dementia typically affects older people and with the aging population the prevalence of dementia will also increase.

Over the past 10 years, the reported prevalence of dementia has almost doubled, seeing an increase from 1 person in 253 to 1 person in every 129. Using data from the Quality and Outcomes Framework (QOF), chart 24 illustrates the trend in dementia diagnosis over the past 10 years. From October 2014 to March 2015, NHS England introduced a £55 incentive for new diagnoses of dementia, which may explain the sharp rise.

Chart 24: Reported dementia prevalence, 2006/07 to 2015/16
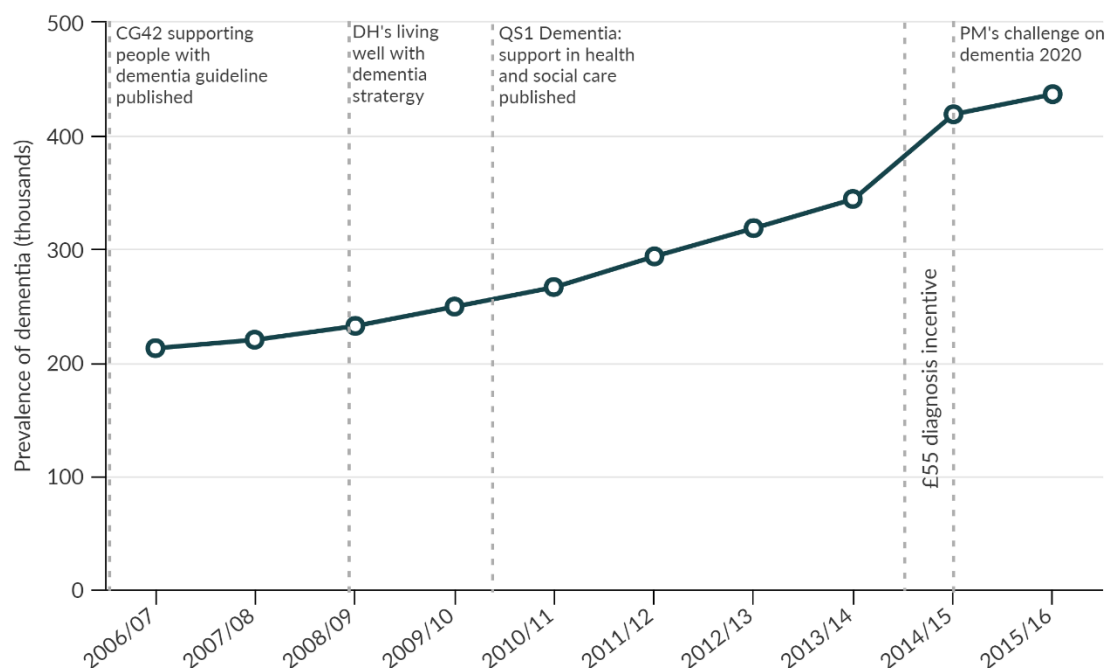
Source: QOF

Although the QOF data indicate a significant increase in the number of people diagnosed with dementia, it is thought that there is still an issue with under-

diagnosis. The Prime Minister's challenge on dementia 2020 estimated that only 42% of people living with dementia have been diagnosed.

NICE has produced a suite of guidance relating to the diagnosis and care of dementia. The NICE guideline on supporting people with dementia and their carers in health and social care and the quality standard on dementia: support in health and social care recommend that all staff working with people with dementia should have access to dementia-care training. In March 2016, the NHS Benchmarking Network published Older People's Care in Acute Settings. This publication reported that, in October 2015, 89% of acute trusts had specific dementia training for all staff caring for older people.

The quality standard on dementia: support in health and social care recommends that people with suspected or known dementia using acute and general hospital inpatient services or emergency departments have access to a liaison service that specialises in the diagnosis and management of dementia and older people's mental health. NHS England collect and report data on dementia assessment and referral, which includes the number of patients aged 75 and over admitted as an emergency for more than 72 hours in England who have been identified as potentially having dementia, and the associated assessment and referral data.

These data show that, over the past 3 years, **the proportion of patients who are asked the dementia case finding question or who have a known diagnosis of dementia or clinical diagnosis of delirium has increased from 72% to 90%.** The proportion of patients who are reported as having had a dementia diagnostic assessment including investigation has also steadily increased, from 86% to 94%.

Chart 25: Proportion of patients who are asked the dementia case finding question or have had a diagnostic assessment, June 2013 to September 2016
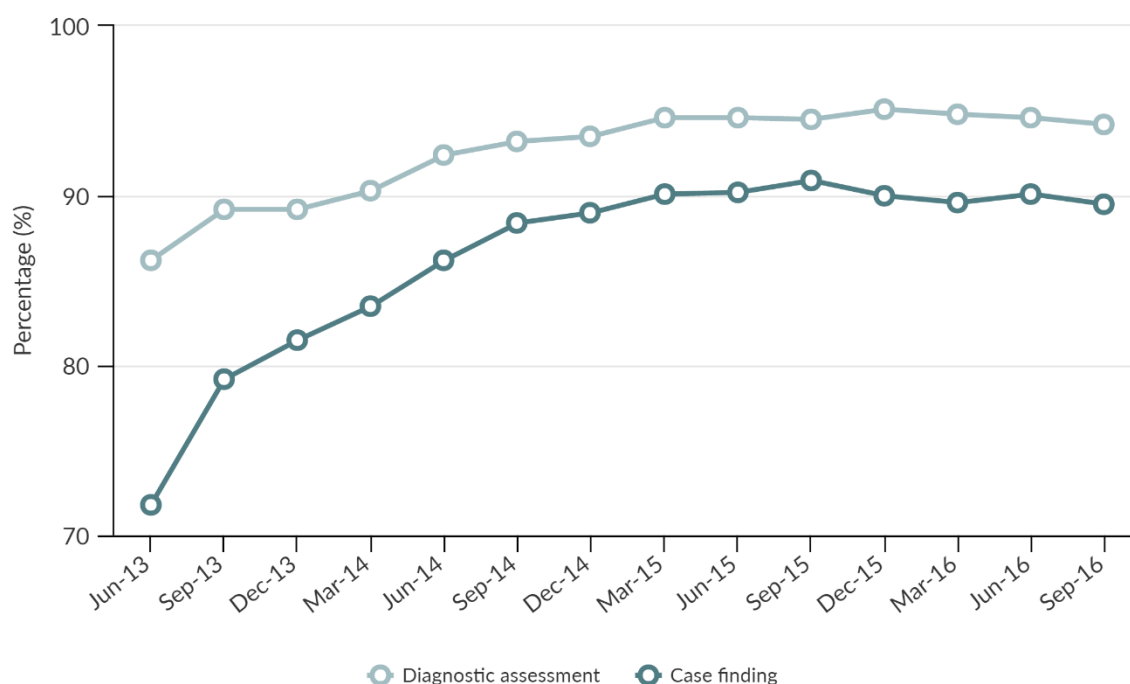
Source: NHS England dementia assessment and referral

The Prime Minister's challenge on dementia 2020 estimates that the number of dementia diagnoses are set to double in the next 30 years. The Alzheimer's society Dementia UK report states that the average cost of dementia care in the UK is £32,250 per person and the majority of the spend is on social care, with an estimated 90% of people in elderly mentally infirm (EMI) homes and around 73% of people in nursing homes having dementia.

At a local level, NICE guidance has been used in social care settings to improve dementia care. A statement from the quality standard on dementia: independence and wellbeing recommends that people with dementia should be enabled, with the involvement of their carers, to take part in leisure activities during their day based on individual interest and choice. A shared learning example describes how the charity Alive! developed innovative activity sessions for older people living in care, with particular focus on those with dementia. Alive! train presenters to connect with participants, enabling them to shape the content of sessions and stimulate memories and discussions. The personalised, dementia friendly sessions often use iPads, music, film clips, poems and images. An external assessment of their work by researchers from the University of the West of England stated that the activities positively impact on the mental and emotional wellbeing of those who participate.

The NICE guideline on dementia: supporting people with dementia and their carers in health and social care recommends that health and social care managers should ensure that the design of built environments meets the needs of people with

dementia. The environment should enable and aid orientation and specific attention should be paid to: lighting, colour schemes, floor coverings, assistive technology, signage, garden design, and the access to and safety of the external environment. Attention should also be paid to the size of units, the mix of residents, and the skill mix of staff to ensure that the environment is supportive and therapeutic. In September 2016, an implementation consultant from the NICE field team held a learning session with Solihull Metropolitan Borough Council (MBC) to help them start the process of working with NICE guidelines. The recommendations in our guidance were used by the MBC to underpin specifications for their new build facilities.

The recorded prevalence of dementia is likely to continue to increase due to the aging population and improved recognition, diagnosis and recording. Dementia is of concern in both clinical practice and social care, where these shared learning examples show how NICE guidance can be used to deliver improved standards of care. With increasing prevalence, cost savings in dementia care would be welcomed. NICE has identified several areas that may result in a cost savings, including the promotion of healthy lifestyles to reduce modifiable risk factors that could prevent or delay the onset of dementia, and improving the transition between hospital and social or home care to reduce the length of hospital stays and admissions to care homes.

5. How can we improve data collection for future reports?

We have identified many more sources of routine data for inclusion in this report than in previous reports, including twice as many national audits and reports than were available for inclusion in the September 2016 report. We will continue to work closely with partners such as the Healthcare Quality Improvement Partnership (HQIP) to encourage alignment of these audits with NICE guidance and standards.

Despite the increase in audits and reports, we still have very little national data to tell us about the uptake of NICE guidance and standards in the public health and social care sectors. We have analysed the Public Health Outcomes Framework in this report and will continue to engage with Public Health England to identify any further datasets which might help us understand how our public health guidance is used. It is hoped that development of the Adult Social Care Quality Strategy will lead to more information becoming available for this sector. We continue to look for information in these sectors and would encourage national organisations to share any suitable data with us.

Future reports will be able to draw on metrics developed to support NICE's strategic engagement plan to inform the wider impact sections. In addition, this report is the first which analyses audience engagement and we will therefore be able to consider trends over time in future reports.

6. Appendices

Appendix A: National audits, reports and surveys (n=32) added to the uptake database between April and October 2016, providing uptake data on 60 NICE guidelines and quality standards

Topic area	National audit or report	NICE guidance and quality standards
Arthritis	The British Society for Rheumatology. National Clinical Audit for Rheumatoid and Early Inflammatory Arthritis 2nd Annual Report 2016.	QS33 Rheumatoid arthritis in over 16s
Cancer	Royal College of Surgeons. National Bowel Cancer Audit Report 2015.	QS20 Colorectal cancer
Cardiac	National Institute for Cardiovascular Outcomes Research. National Audit of Percutaneous Coronary Interventional Procedures Public Report. National Institute for Cardiovascular Outcomes Research. National Audit of Cardiac Rhythm Management. National Institute for Cardiovascular Outcomes Research. National Heart Failure Audit.	TA71 Guidance on the use of coronary artery stents TA324 Dual‑chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block QS68 Acute coronary syndromes in adults CG108 Chronic heart failure in adults: management
COPD	Pulmonary Rehabilitation: Steps to breathe better. National Chronic Obstructive Pulmonary Disease (COPD) Audit Programme: Clinical audit of Pulmonary Rehabilitation services in England and Wales 2015	QS10 Chronic obstructive pulmonary disease in adults CG101 Chronic obstructive pulmonary disease in over 16s: diagnosis and management
Dementia	Older People's Care in Acute Settings Benchmarking Report NHS Benchmarking Network March 2016 NHS England. Dementia assessment and referral.	QS1 Dementia: support in health and social care CG42 Dementia: supporting people with dementia and their carers in health and social care CG162 Stroke rehabilitation in adults NG27 Transition between inpatient hospital settings and community or care home settings for adults with social care needs
Diabetes	National Diabetes Audit 2014-2015: Report 1, Care Processes and Treatment Targets National Diabetes Inpatient Audit (NaDIA) – 2015 National diabetes foot care audit report 2014-15	QS6 Diabetes in adults NG17 Type 1 diabetes in adults: diagnosis and management NG18 Diabetes (type 1 and 2) in children and young people: diagnosis and management NG19 Diabetes foot problems: prevention and management NG20 Coeliac disease: recognition, assessment and management

	National diabetes insulin pump audit 2013-2015 National Paediatric Diabetes Audit Report 2014-15	NG28 Type 2 diabetes in adults: management PH10 Stop smoking services PH53 Weight management: lifestyle services for overweight or obese adults TA151 Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus
End of life care	Royal College of Physicians. End of life care audit - dying in hospital: National report for England 2016.	QS13 End of life care for adults NG31 Care of dying adults in the last days of life
Falls and fractures	Royal College of Physicians. Fracture Liaison Service Database (FLS-DB) Facilities audit Royal College of Physicians. National hip fracture database	CG124 Hip fracture: management CG146 Osteoporosis: assessing the risk of fragility fractures CG161 Falls in older people: assessing risk and prevention QS16 Hip fracture in adults TA204 Denosumab for the prevention of osteoporotic fractures in postmenopausal women
Inflammatory bowel disease	Royal College of Physicians. National Clinical Audit of Biological therapies: UK Inflammatory Bowel Disease Audit.	TA187 Infliximab (review) and adalimumab for the treatment of Crohn's disease TA329 Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262) QS81 Inflammatory bowel disease
Idiopathic pulmonary fibrosis	British Thoracic Society. Interstitial Lung Disease Registry Programme Annual Report 2014/15.	QS79 Idiopathic pulmonary fibrosis in adults CG163 Idiopathic pulmonary fibrosis in adults: diagnosis and management
Kidney disease	The Renal Association. UK Renal Registry 2015.	TA48 Guidance on home compared with hospital haemodialysis for patients with end-stage renal failure NG8 Chronic kidney disease: managing anaemia
Neonatal care	Royal College of Paediatrics and Child Health. National Neonatal Audit Programme.	QS4 Neonatal specialist care
Parkinson's	Parkinson's UK. 2015 UK Parkinson's Audit.	CG35 Parkinson's disease in over 20s: diagnosis and management
Patient experience	Quality Health. National Cancer Patient Experience Survey. Care Quality Commission. National inpatient survey. NHS England. National GP patient survey	QS12 Breast cancer QS15 Patient experience in NHS services QS17 Lung cancer in adults QS78 Sarcoma QS91 Prostate cancer CG80 Early and locally advanced breast cancer: diagnosis and treatment CG121 Lung cancer: diagnosis and management

		CG138 Patient experience in adult NHS services: improving the experience of care for people using adult NHS services
		CG175 Prostate cancer: diagnosis and management
		NG5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes
Patient safety	NHS Digital. NHS Safety Thermometer: Patient Harms and Harm Free Care	QS61 Irritable bowel syndrome in adults: diagnosis and management
		CG92 Venous thromboembolism: reducing the risk for patients in hospital
		CG161 Falls in older people: assessing risk and prevention
		CG179 Pressure ulcers: prevention and management
Postnatal care	NHS England. Statistical release breastfeeding initiation and breastfeeding prevalence 6-8 weeks.	QS37 Postnatal care
Psychosis & schizophrenia	Royal College of Psychiatrists. Early Intervention in Psychosis Audit.	QS80 Psychosis and schizophrenia in adults
		CG178 Psychosis and schizophrenia in adults: prevention and management
Sepsis	National Confidential Enquiry into Patient Outcome and Death. Just Say Sepsis! A review of the process of care received by patients with sepsis.	NG51 Sepsis: recognition, diagnosis and early management
Smoking	NHS Digital. Statistics on Women's Smoking Status at Time of Delivery: England.	PH26 Smoking: stopping in pregnancy and after childbirth
	NHS Digital. Statistics on NHS Stop Smoking Services: England, April 2015 to March 2016	QS43 Smoking: supporting people to stop
Stroke	Royal College of Physicians. Sentinel Stroke National Audit Programme.	QS2 Stroke in adults
		CG162 Stroke rehabilitation in adults
Workplace health	Picker Institute Europe. NHS staff survey 2015.	PH41 Physical activity: walking and cycling
		QS84 Physical activity: for NHS staff, patients and carers
		NG13 Workplace health: management practices

Appendix B: Performance against agreed process measures and success criteria by the NICE field team of implementation consultants from April 2016 to January 2017, and their relevance to health, public health and social care sectors

Measure type	Measure	Audience	2016/17 Target	Achieved	Health	Public Health	Social Care
Process measure	Engage with 52 (80%) of NHS England Vanguard sites and Primary Care Home Test sites (previously called NAPC Rapid Test Sites)	Vanguards, New Care Models, Primary Care Home Test Sites & GP Federations	52	33	☑		☑
Success criteria	An example recorded from each Vanguard and Primary Care Home Test site engaged, with outlining their current use of NICE guidance, quality standards or indicators	Vanguards, Primary Care Home Test Sites	52	16 It is expected that a number of visits to some sites will need to take place before an example is generated	☑		☑
Success criteria	Initial engagement with 30 GP Federations and intelligence obtained from each on their use, or planned use, of NICE guidance, quality standards or indicators	GP Federations	30	2 Engagement commenced autumn 2016	☑		
Process measure	Contribute to design and delivery of the STP regional development days	Sustainability and Transformation Footprints	4	27 Despite attempting to, the team did not contribute to the events specified in the process measure. All engagements with STPs have been recorded.	☑		☑

Measure type	Measure	Audience	2016/17 Target	Achieved	Health	Public Health	Social Care
Success criteria	20 examples of working with STP footprints to embed the use of NICE guidelines and quality standards in local plans	Sustainability and Transformation Footprints	20	7	✓		✓
Process measure	Minimum of 1 collaborative project between NICE and PHE established with each of the 9 PHE centres	Public Health England	9	6		✓	
Success criteria	40 examples of NICE public health related guidelines or quality standards being used to inform local authority health and wellbeing policies or commissioning agreements	Public Health England	40	10 Engagement commenced autumn 2016		✓	
Process measure	Engagement with 120 (80%) of local authority social care commissioners	Local authority social care commissioners	120	102			✓
Success criteria	For all local authorities visited, a practice example outlining how they are implementing, or have challenges with recommendations from either, the NICE guideline on transition between inpatient hospital settings & community or care homes settings for adults with social care needs or, transition from children's to adults services	Local authority social care commissioners	120	42			✓

Measure type	Measure	Audience	2016/17 Target	Achieved	Health	Public Health	Social Care
Process measure	Engagement with 10 county/regional social care provider networks	Social Care provider networks	10	8			☑
Success criteria	For all networks visited, a practice example outlining how they are implementing, or have issues, with recommendations from the NICE guideline on transition between inpatient hospital settings and community or care homes settings for adults with social care needs	Social Care provider networks	10	10			☑
Process measure	Engagement with 120 (80%) of acute and specialist trusts	NHS acute and specialist trusts	120	111	☑		
Success criteria	For all trusts visited, a practice example outlining how they are using (or reasons for not using) NICE guidelines, quality standards and associated resources to deliver value for patients and demonstrate improvements in quality	NHS acute and specialist trusts	120	74 The team is looking for examples not previously recorded.	☑		
Process measure	An assessment of the cost effectiveness of the webinar	NHS mental health trusts	1	Planned for winter 2016/17	☑		
Success criteria	An evaluation of the webinar from the attendees' perspective	NHS mental health trusts	1	Planned for winter 2016/17	☑		

National Institute for Health and Care Excellence

Appropriate investment and disinvestment offer from NICE: update

This report gives details of progress with the redesigned offer from NICE to support appropriate care and disinvestment.

The Board is asked to review the report.

Professor Gillian Leng

Director, Health & Social Care Directorate

March 2017

National Institute for Health and Care Excellence
Appropriate investment and disinvestment offer from NICE: update
Date: 15 March 2017
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Introduction

1. This paper provides an update to the Board on progress with redesigning NICE's offer to support appropriate care and disinvestment.

Background

2. At its meeting on 16 November 2016, the Board approved next steps to meet the NICE 2016-17 business plan objectives to redesign and promote a comprehensive resource for commissioners and providers on the use of NICE guidance to help make savings, improve productivity and promote optimal use of interventions. This objective is carried forward into the 2017-18 business plan.

3. NICE's support for disinvestment is currently found on a 'Savings and Productivity' page on the NICE website. The offer (the 'Collection') includes:

   - Do not do recommendations

   - Cost saving guidance (including the resource planner)

   - Return on investment tools linked to public health guidance

   - Medicines optimisation key therapeutic topics

   - Cochrane topics

   - Quality and productivity (formerly QIPP) case studies of local cost savings

4. A screenshot of the current collection is shown below:

Figure 1 Screenshot of current NICE savings and productivity collection
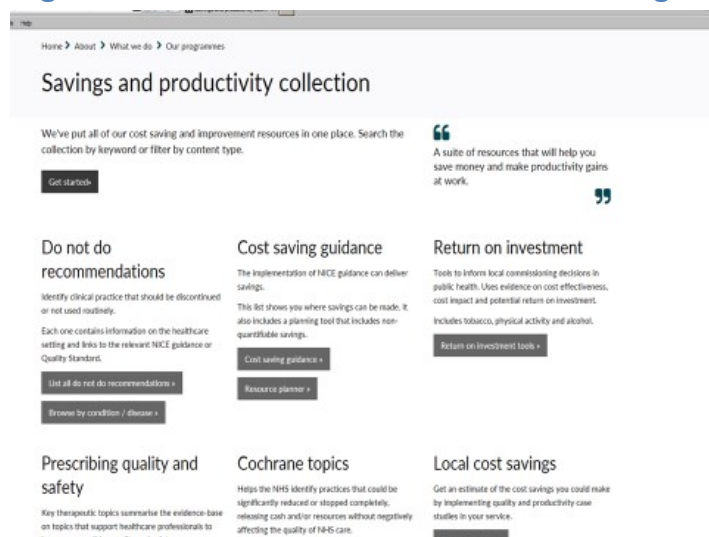
5. NICE also works with external partners to encourage use of these resources. We are aware, however, that the collection needs to be more relevant to end users, and more accessible, so we are in the process of making some changes.

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6. We know there is an expectation from stakeholders and system partners for NICE to take a greater role in supporting potential disinvestment in healthcare, and to use our reputation to demonstrate how disinvestment in services can result in better clinical outcomes and patient experiences. This role was emphasised in the *Accelerated Access Review* (October 2016), which recommended that NICE, NHS Improvement and NHS England should have a greater focus on opportunities for disinvestment in products and procedures that are not cost effective.

7. In November 2016, the NICE Board agreed a number of proposals to improve our support for disinvestment. This included: reframing our 'do not do' recommendations; redesigning the Savings and Productivity collection on the NICE website; developing a clearer narrative and messages for different audiences (clinical, commissioning and financial); explaining NICE's support for appropriate disinvestment; and working with system partners to align with NICE's offer. This paper provides an update on progress to achieving these objectives.

Reframing do not do recommendations

Agreed development

8. The do not do collection represents a comprehensive set of advice, but the majority of content - over 90% - is not associated with any cost savings. Those that do produce savings, cannot be currently be identified by the user. It was therefore agreed that maintaining the set as it is unhelpful, both for those wishing to identify savings, and for practitioners who recognise that there are very few 'never' do's on the grounds of effectiveness or cost effectiveness.

9. To identify do not do recommendations with potential savings, the proposal agreed by the Board in November was to encourage the development of 'disinvestment recommendations' during – rather than after – guideline development. This means we are more likely to identify suitable disinvestment opportunities. The new approach builds on work in the Centre for Guidelines to incorporate consideration of cost impact earlier in the process. We agreed to have new methods and processes in place for guideline development by March 2017

Progress

10. The Centre for Guidelines is scheduled to publish an interim update to its methods manual in April 2017, which will include amendments to the section on developing and wording recommendations. The proposed wording states that guideline committees should make a negative recommendation (i.e. 'do not offer') if they believe that the vast majority of practitioners or commissioners or people using services would not choose a particular intervention, for example if harms clearly outweigh benefits or if the intervention is not cost effective. In

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circumstances where there may be some benefit but not for the majority, committees should be as specific as possible (i.e. 'do not offer unless…').

11. It has been agreed that the criteria for highlighting 'do not offer' recommendations are: where a practice is unsafe; where there is strong evidence that the practice is absolutely ineffective in terms of quality and/or cost; and where there is strong evidence that a practice is relatively ineffective in terms of quality and/or cost, compared with alternatives. These changes will be reinforced to guideline developers and committees during scoping, updating and development of guidelines.

12. We will cease the current process of identifying do not do recommendations post-publication from 1 April 2017. It should be noted that the digital transformation programme aims to develop guidance in a structured form that will in future enable the identification of recommendations on the basis of factors such as cost saving. The overall vision of the digital transformation programme is to manage our information as to allow them to be searched, reused and linked more effectively.

Redesign of the digital offer

Agreed development
13. The proposal agreed by the Board in November was a 2-stage redesign of the existing savings and productivity digital offer. Stage 1 involves simplifying the resources in the collection to make them more accessible. Stage 2 will be a new presentation of the resources, to be in place by the NICE conference in May 2017.

Progress
14. The new collection will be focused on a finance and commissioner audience and will comprise only our cost saving guidance and resource planner. The resource planner is produced each month to provide indicative costs or savings for upcoming guidance and the resource implications of published guidance in step with financial planning time frames. Cost saving guidance lists all NICE guidance that offer potential savings, and includes links to costing reports and templates.

15. The other elements of the current collection (see 3 above) will be removed. Work is underway to provide continued access to the resources, most of which are already accessible elsewhere on the NICE website (e.g. Key therapeutic topics under medicines and prescribing).

16. Presentation options for the collection are currently being developed. The amended online collection will be validated and tested by the adoption and impact reference panel (finance and commissioners who provide feedback to

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NICE) before it goes live, to ensure it works as an effective resource. This will inform stage 2 of the redesign.

17. The focus leading up to the NICE conference in May 2017 will be around communicating the changes, the rationale and NICE's position in relation to appropriate care and disinvestment.

A clear narrative

Agreed development

18. The Board agreed in November to identify new key messages for NICE's disinvestment offer, to resonate with all appropriate audiences. The new messages should build on our core purpose to help improve the quality, sustainability and productivity of health and social care. The new messages would form be part of a communication strategy to be in action by May 2017.

Progress

19. The narrative for our future work is: "NICE enables the NHS, local government and social care providers make the best use of resources by setting out the case for investment and disinvestment through our guidance programmes and our other advice. Our position is to work with system partners to realise the benefits from appropriate care and spending on the right things. This includes identifying specific recommendations that can save money, to enable conversations at a patient and population level on appropriate treatments and interventions".

20. The NICE communications team is developing a communications strategy based on this narrative, tailored for different audiences: clinicians, commissioners and finance professionals. This will be completed to support the simplified digital offer described above and the NICE conference in May, where we will host a session on spending on appropriate care as part of the innovation stream.

System alignment

Agreed development

21. The proposal agreed in November was to align our offer, and engage with, key partners including NHS England and NHS Improvement. The aim of this approach is to ensure better support across the system for disinvestment opportunities identified by NICE.

Progress

22. We have begun to explore opportunities to work with both NHS England and NHS Improvement on programmes related to appropriate care and disinvestment.

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23. NHS England has expressed a strong interest in exploring more robust links between commissioning policy and NICE guidance recommendations that support appropriate care and opportunities for disinvestment. We have established a joint working group across the CHTE, Medicines and technologies programme and centre for guidelines to progress this work

24. We are working closely with the NHS England RightCare team on its medicines optimisation strategy. NICE already produces the Key Therapeutic Topics, which summarise the evidence in areas where there are potential opportunities for maintaining or improving quality and improving value in medicines use. We are represented on the medicines optimisation dashboard steering group, and are contributing to the establishment of regional medicines optimisation committees (RMOCs) with NHS England. The purpose of the RMOCs is to ensure that medicine usage achieves optimal patient outcomes and best value, including identifying and making recommendations on medicines of unproven clinical value.

25. We are focusing on two key areas with NHS Improvement: the hospital pharmacy and medicines optimisation project (HoPMOp); and Getting it Right First Time (GIRFT). We are revising our partnership agreement with NHS Improvement, and aim to develop plans around these key programmes.

26. HoPMOp is part of the Hospital Pharmacy Transformation Programme (HPTP) fromthe Carter review. NHS Improvement has a key role in supporting trusts to implement this programme. We have used our associates network to provide feedback on draft proposals in support of the Carter recommendation to publish a top 10 list of opportunities for savings in medicines by March 2017.

27. The Getting It Right First Time (GIRFT) programme considers changes in orthopaedic surgery provisionto improve pathways of care, patient experience, and outcomes with significant cost savings. The programme is now expanding into other surgical specialties. One of the Carter recommendations was that a coordinated national clinical governance committee be established to ensure coordination and collaboration across NHS England, NHS Improvement, CQC and NICE. The committee met for the first time in August 2016 and is now working to align the many different work-streams that are in play across the system.

Conclusion

28. We are making progress on the steps agreed by the Board in November to redesign NICE's offer to support appropriate care and disinvestment. There will be a redesigned online offer with a clear narrative targeted at commissioners

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and finance professionals by May. In parallel, we are making the transition to strengthen our do not do recommendations, building on revised methods underway in the centre for guidelines. We are working with system partners, particularly NHS England, to raise awareness of our methods and processes and alignment with commissioning policies.

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A replacement for the Health Service Circular 2003/011 (The interventional procedures programme: working with the National Institute for Clinical Excellence to promote safe clinical innovation)

This report gives details of the replacement for the Health Service Circular 2003/011 (The interventional procedures programme: working with the National Institute for Clinical Excellence to promote safe clinical innovation).

The Board is asked to consider and approve the replacement for the Health Service Circular 2003/011.

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Programme Director – Devices and Diagnostic Systems

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Programme Director and Clinical Advisor – Interventional Procedures Programme

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March 2017

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A replacement for the Health Service Circular 2003/011
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Background

1. The arrangements for the UK wide application of guidance from the Interventional Procedures Programme were previously outlined in the Health Service Circular 2003/011 (The interventional procedures programme: working with the National Institute for Clinical Excellence to promote safe clinical innovation).

2. When the draft Interventional Procedures Programme Manual was approved for consultation by SMT in March 2015, it was noted that this circular was no longer current and there was no way of replacing it centrally because of discontinuation of Health Service Circulars. At that stage, SMT suggested that that there was a need for a meeting with senior policymakers and clinical leaders from England and the devolved administrations to discuss and agree a new approach.

Proposed changes

3. Representatives from the Interventional Procedures programme met with senior NHS policymakers in September 2016 to discuss the arrangements for NICE's Interventional Procedures programme in England, Wales, Scotland and Northern Ireland.

4. The attendees supported the need for a UK-wide approach for reviewing the safety and efficacy of new surgical procedures and for highlighting the importance of the NICE Interventional Procedures Programme.

5. The group discussed and proposed amendments to the original Circular to make it applicable to current conditions across the four nations. An updated document was drafted by the Interventional Procedures Programme.

6. That document has been considered and approved by the Senior Management Team and the relevant NHS policymakers from the four nations of the UK.

7. Each jurisdiction has agreed to reinforce to its providers and commissioners, the need to have due regard to this document (where applicable).

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Conclusion

8. The document has been considered and approved by the Senior Management Team at NICE and the relevant NHS policymakers from the four nations of the UK.

Issues for consideration

9. The Board is asked to:

- Consider and approve the replacement for the Health Service Circular 2003/011 (The interventional procedures programme: working with the National Institute for Clinical Excellence to promote safe clinical innovation).

- Note that once approved this document will be circulated to senior policymakers from England and the devolved administrations for implementation.

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The National Institute for Health and Care Excellence (NICE) Interventional Procedures Programme

Purpose of the Programme

1. NICE's Interventional Procedures Programme assesses the safety and efficacy of interventional procedures to determine whether they work well enough and are safe enough for use in the NHS. The programme's aims are to protect the safety of patients and to support doctors, other clinicians, Clinical Governance Committees, healthcare organisations and the NHS as a whole in managing clinical innovation responsibly.

2. The process and methods of the Interventional Procedures Programme are designed to ensure that robust guidance is developed for the NHS in an open, transparent and timely way, with appropriate input from consultees and other stakeholders, including patients, from across the UK.

Definitions and scope

3. An *interventional procedure* is one used for treatment or diagnosis that involves incision, puncture, entry into a body cavity, electromagnetic or acoustic energy.

4. An interventional procedure may be assessed by the Interventional Procedures Programme if it is not yet generally considered established clinical practice in the NHS or UK independent sector, or if it is an established clinical procedure, the efficacy or safety of which has been called into question by new information or advice.

Summary of requirements of medical practitioners and NHS or independent health care providers

5. Individual provider organisations will wish to have a process in place for the introduction of any new procedure into their organisation. Health care professionals planning to undertake in the NHS a new interventional procedures or an established clinical procedure, the efficacy or safety of which has been called into question by new information or advice must, before doing so, obtain approval using the appropriate governance structures of the organisation in which the procedure is to be performed. The Medical Director (or nominated deputy) of the organisation should ensure any new procedure falling within the scope of the Interventional Procedures Programme at the National Institute for Health and Care Excellence (NICE) is notified to NICE.

6. The only exception to this process is when the procedure is being used solely within a protocol approved by a Research Ethics Committee (REC).

What the NHS should do

7. The safe introduction of procedures into the NHS is dependent on the effective engagement of all NHS organisations with the operation of the Interventional Procedures Programme.

8. All NHS providers of healthcare should ensure they have governance structures in place to review, authorise and monitor the introduction of new interventional procedures or the use of established clinical procedure, the efficacy or safety of which has been called into question by new information or advice. These structures should ensure that any health care professional considering using a new interventional procedure which he/she has not used before, or has only used outside the NHS, seeks prior approval to do so using the appropriate governance structures of the organisation in which the procedure is to be performed. This also applies to procedures which may be used in an emergency.

9. If the procedure is the subject of published NICE interventional procedures guidance, the organisation should consider whether the proposed use of the procedure complies with that guidance before allowing it to be undertaken in the organisation.

10. If the procedure is not the subject of published NICE interventional procedures guidance as listed on NICE's website but falls within the definition and scope of the Interventional Procedures Programme, the Medical Director of the organisation (or nominated deputy) should notify the procedure to NICE, if the health care professional has not already done so.

11. Health care professionals wishing to carry out a new interventional procedure or an established clinical procedure, the efficacy or safety of which has been called into question by new information or advice must always obtain approval to do so using the appropriate governance structures within the organisation in which the procedure is to be performed.

12. If NICE is in the process of developing guidance on the procedure, the organisation should only approve its use if:

    a. The health care professional has appropriate experience and training.
    b. All patients offered the procedure are made aware of the special status of the procedure in the NHS. This should be done as part of the consent and shared decision-making process, and should be clearly recorded. Health care professional should ensure that patients understand that the procedure's safety and efficacy are uncertain. They should inform patients about the anticipated benefits and possible adverse effects of the procedure and alternatives, including no treatment.
    c. The organisation is satisfied that the proposed arrangements for clinical audit (which may include comparative or multicentre audit) are sound, and will capture data on clinical outcomes that will be used to review continued use of the procedure.

13. Once NICE has published its guidance on the procedure, the organisation should consider whether the proposed use of the procedure complies with the guidance before approving its continued use in their organisation, bearing in mind that NICE's final published guidance recommendations may need different arrangements to be put in place from those set out in section 12.

14. The organisation must ensure that any procedure on which there is

interventional procedure guidance is coded using the coding provided by NICE in the published guidance.

15. When the recommendation about a procedure from NICE includes collecting data on outcomes and safety, health care organisations should ensure systems are in place to support health care professionals to supply the information requested on every patient undergoing the procedure. The data on the outcomes and safety of that procedure should be reviewed by the organisation. The individual undertaking the procedure should also be expected to discuss their outcomes as part of their annual appraisal to allow reflection, learning, and individual improvement.

16. The only exception to the above process is when the procedure is being used only within a protocol approved by a Research Ethics Committee (REC). Once the research is completed, the procedure should be notified to the NICE Interventional Procedures Programme in the normal way. If an adverse incident occurs in association with a new interventional procedure, this should be reported, investigated and escalated in line with local policies. Device-related incidents should be reported to the competent authority.

17. This process does not mandate commissioning of specific procedures. Cost-effectiveness evaluation is not within the scope of the NICE Interventional Procedures Programme.

18. An outline description of the programme is set out in the Annex to this document.

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How the NICE Interventional Procedures Programme works

Any individual may notify a procedure to the NICE Interventional Procedures Programme by completing the online interventional procedures notification form.

A new notification will initiate the following process:

NICE will decide whether to develop guidance on the procedure, seeking more information from its specialist advisers and checking for a CE mark if needed.

The interventional procedures programme team will prepare a brief to initiate the assessment of the procedure. This is a short internal document covering key aspects of the procedure. The programme team seeks advice from appropriate specialist Committee members and the programme's specialist advisers when preparing the brief. Once the brief has been reviewed by the Committee, developing guidance on the procedure becomes part of the formal work of the programme.

NICE will prepare an overview of the evidence on the procedure's safety and efficacy. Specialist advice, patient commentary and evidence from device companies if available will elicited and taken into consideration as outlined in the IP programme manual.

The NICE interventional procedures advisory committee consisting of members who are independent of NICE will make draft recommendations on the efficacy and safe use of the procedure.

The NICE interventional procedures advisory committee may ask questions of Specialist Advisors and device companies before formulating its draft recommendations.

NICE publishes a consultation document consisting of the draft recommendations on the NICE website for four weeks.

At a further Committee meeting, the NICE interventional procedures advisory committee reviews the consultation document, and considers all the comments received during consultation, responds to them and makes any appropriate changes to the draft guidance.

Before guidance publication, there is a three week resolution stage. This process is a final quality assurance step where stakeholders who commented during the consultation period and who have completed a confidentiality statement are sent the final recommendations. NICE considers any requests for resolution and makes a formal response. The resolution process is not needed when no consultation comments are received or if stakeholders who provided consultation comments do not return their confidentiality statement.

Guidance is published on the NICE website once the resolution process is complete or sooner if there was no requirement for a resolution stage.

In some circumstances, NICE does not produce guidance on a procedure after receiving a notification. The most common reasons for this are that the procedure:

a. does not fit the programme's remit;
b. is not new;
c. involves a modification to an existing procedure whose safety and efficacy are sufficiently well understood;
d. relies on using a medical device but no device is available that has regulatory approval for the intended purpose.

Further information about the interventional procedures programme, including the programme manual can be found on the NICE website:

- *Process manual*
- *Interventional Procedures – further information about the programme*

NICE and NHS England consultation on changes to the arrangements for evaluating and funding drugs and other health technologies assessed through NICE's technology appraisal and highly specialised technologies programmes

NHS England and NICE recently consulted publicly on proposals to change the arrangements for evaluating and funding drugs and other health technologies assessed through NICE's technology appraisal (TA) and highly specialised technologies (HST) programme.

In light of this consultation, the Board is invited to consider and comment on the recommendations for making changes to the arrangements.

NHS England's Specialised Services Commissioning Committee considered the response to consultation at its meeting on Wednesday 22 February. The recommendations in this paper are consistent with the position adopted by NHS England.

NOTE: The response to proposals relating to the Highly Specialised Technologies programme is the subject of a separate paper.

Professor Carole Longson

Director of the Centre for Health Technology Evaluation

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Purpose of this paper

1. For the Board to consider the comments received in consultation on the joint proposals of NICE and NHSE for changes to the TA programme;

2. For the Board to consider and approve amendments made to the original proposals;

3. For the Board to consider and approve plans for implementation and next steps;

4. For the Board to note that proposals relating to the HST programme will be considered in a separate paper, in due course.

Background

The proposals

5. NICE and NHS England held a public consultation on proposals to change the arrangements for evaluating and funding drugs and other health technologies assessed through NICE's technology appraisal and highly specialised technologies programme, that would seek to provide:

   - rapid access for patients to the most cost-effective new treatments;

   - more flexibility in the adoption of technologies into the NHS which are cost effective but high in budget impact; and

   - greater clarity for patients and companies about the point at which treatments for very rare conditions appraised by NICE will automatically be routinely commissioned.

The consultation

6. In October 2016, NICE published a joint consultation with NHS England containing proposals to change aspects of the NICE Technology Appraisal and Highly Specialised Technologies programmes.

7. In summary, the proposals covered:

   - **Introduction of 'budget impact threshold' of £20m**. For those technologies that pass the NICE value assessment (applying NICE's published methods) and where the budget impact is below the threshold set, there would be no need to conduct a commercial negotiation. Should the budget impact exceed the set threshold in any of the first three years, a commercial negotiation would be triggered. Should this negotiation fail

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to conclude or not fully resolve the budget impact issues, NHS England would be able to apply to NICE to vary the funding requirement in order to phase introduction of the product over a longer period to help manage its impact on the NHS.

- **Linking NICE and NHSE processes for evaluating highly specialised technologies**. We consulted on introducing quality adjusted life years (QALY) as a measure of value in the HST programme, and on the application of a 'limit' of £100k per QALY below which the legal funding directive would apply (either immediately if there are no budget impact concerns or phased in over a period of time if the budget impact threshold of £20 million is triggered). For those technologies for which the cost per QALY calculation exceeds £100,000, there would be an opportunity to be considered for funding through NHS England's Clinical Priorities Advisory Group (CPAG) relative prioritisation process. This opportunity for a second consideration recognises the special position of very small groups of patients for whom new treatments are exceptionally expensive.

- **Introduction of a new 'Fast Track Appraisal'**. The consultation set out a proposal that appraisals in which we can be confident that a reliable judgement about value for money can be made at an early stage in the appraisal, would be able to enter a new Fast Track Appraisal, which would have lighter touch methods and a shorter process. In addition, where a positive recommendation is made, a shorter period of deferred funding - 30 days instead of 90 days, would be applied. The consultation proposed to use a cost per QALY level of £10,000 as one of the criteria for routing into fast track, as at that level it could, with a high degree of certainty, be predicted at an early stage in the evaluation that a technology would be cost effective. The budget impact threshold would still apply to products qualifying for the Fast Track Appraisal process.

8. The public consultation, which closed on 13 January 2017, having received 150 responses. In addition, four webinars for stakeholders (350 people registered to attend in total) and two face-to-face events in London and Manchester (63 attendees in total) were held, along with a number of individual meetings with key stakeholder groups.

9. The consultation report at Appendix A includes details of the number of responses by stakeholder type and responses to each consultation question. The published consultation document is included for reference at Appendix B.

10. **NICE's response to the comments on the proposals specific to the Highly Specialised Technologies programme will be the subject of a separate paper, in due course.**

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Budget impact

Questions asked in consultation

11. The following questions were included in consultation:

- Question 1: Do you agree that NHS England should set a budget impact threshold to signal the need to develop special arrangements for the sustainable introduction of cost effective new technologies?

- Question 2: Do you agree that £20 million is an appropriate level? If not, what level do you think the threshold should be set at and why?

- Question 3: Do you agree that NHS England should enter into a dialogue with companies to develop commercial agreements to help manage the budget impact of new technologies recommended by NICE?

- Question 4: Do you agree that NICE should consider varying the funding requirement for technologies it recommends, for a defined period, in circumstances where NHS England makes a case for doing so, on the grounds that the budget impact of the adoption of a new technology would compromise the allocation of funds across its other statutory responsibilities?

Summary of comments received

12. Much of the discussion at the events and webinars focused on the proposal in the consultation to introduce a net Budget Impact Threshold. As shown in the consultation analysis (see Appendix A), respondents had mixed views on the proposal.

13. There was a strong challenge from large pharmaceutical companies and industry representative bodies that the proposal was not needed at all. They felt that questions of affordability, whilst of valid concern, are addressed already through the Pharmaceutical Price Regulatory Scheme (PPRS). Indeed many, including academics and patient groups, questioned why the PPRS, which reduces the amount of money the NHS pays for new drugs, had not been referenced in the consultation document. Some smaller biotech firms, some patient groups and academics did, however, support the principle of introducing an affordability test for those products which have a high net budget impact.

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14. A number of respondents warned about the potentially disproportionate impact on first to market products, and that the proposal looks to be at odds with the ambition for England to remain an attractive launch market for innovative products; as set out in the Accelerated Access Review (AAR) and expected to be an important element of the Life Sciences Strategy.

15. There was also concern from many respondents about the proposed level of the net budget impact threshold. Pharmaceutical companies who disagreed with the principle also disagreed with the proposal to set the threshold at £20 million level, in any of the first three years of NHS use. Some respondents (for example the Association of the British Pharmaceutical Industry (ABPI) felt that £20 million was too low, and that only very high budget impact products should trigger a commercial discussion. They therefore suggested raising the threshold to £100 million, considered over the first two years of introduction. The ABPI also suggested that, if implemented, the proposal should be reviewed after one year to consider what impact it has had. There were other respondents who said that they felt unable to comment on the proposed level of the net budget impact threshold, as they did not feel there was sufficient exploration of the rationale or economic modelling in the consultation document.

16. Some of the challenges revealed a misunderstanding about how the budget impact threshold would work, which may relate to the language used to describe the proposal. Some consultees had interpreted the 'threshold' as an absolute expenditure limit meaning that NHS England would only ever routinely commission those products that have a net budget impact of £20m or less in any one year. Some respondents also interpreted the commercial discussion for products over £20 million as having the sole purpose of bringing the price down, so that the product would 'get under' the £20m threshold. Although the consultation document made it clear that £20 million was not "necessarily the maximum amount that the NHS would commit to funding a new technology in any one financial year", some respondents did interpret it that way.

17. Another key area of concern was in relation to the impact of this proposal on patients' access to new treatments, both in general and in terms of potential inequity for some patient groups; for example, those with rare/ultra-rare diseases, those with significant unmet need, those receiving curative treatments such as gene therapy that require a short term investment but deliver longer term benefits. Respondents wanted to know if there would be exceptions to the potential delay to the process and the funding, or example, treatments that fulfil the end-of-life criteria. Other potential exceptions suggested included treatments for populations with an unmet need, treatments recommended with managed access agreements, including those

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recommended for use in the cancer drugs fund, treatments considered 'transformational' and fast-track products. Some stakeholders also suggested that there should be an upper limit to the variation of the funding timeframe (for example 200 days) and also to consider a shorter period than 3 years over which to assess the net budget impact.

18. A further concern was that the proposal may be at odds with the commitments in the NHS Constitution that patients have "the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you". Some also suggested that the proposal threatens the independence of NICE.

19. Most stakeholders including companies supported the principle of discussing commercial arrangements with NHS England during the NICE appraisal. However, others felt that this discussion would come too late to be of value. One company noted that an arbitrary net budget impact threshold would not allow companies enough flexibility in commercial negotiations. Stakeholders nevertheless accepted that commercial discussions were important and should happen anyway, regardless of whether the budget impact proposal is implemented.

20. Stakeholders noted the difficulty in accurately estimating net budget impact. It was suggested that the uptake of high budget new medicines should be closely monitored after launch, with commercial agreements potentially being based on actual rather than predicted uptake, or that a commercial discussion should only need to be undertaken when the actual uptake of the technology reaches an agreed threshold. There was also the question of how net budget impact should be assessed for a technology with multiple indications.

21. NHS England can, if it chooses to, conduct commercial discussions at a national level on behalf of CCGs. Further detail of the governance for this arrangement will be worked up prior to implementation. NICE will accept a request for variation to the timescale for the funding requirement from NHSE on behalf of CCGs. No specific arrangements have been made for technologies that are, in rare circumstances commissioned by local authorities.

Response, including amendments to the proposals

22. Consultees raised a range of relevant and reasonable concerns about the proposals, challenging both the need for and the nature of the threshold. However, other than suggesting that the PPRS should negate the need for phased funding or that threshold should be set at a much higher level, no practical alternative, which addressed NHS England's assessment of the acuity of its financial position was put forward. The financial effect of the

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PPRS rebate mechanism has already been taken into account in NHS budgeting and so is not available as a solution to significant in year surges in the demand for resources to fund new treatments. A higher threshold and especially one set as a high as £100 million would materially fail to provide NHS England with the tools it needs to pursue the orderly management of its budgets.

23. The consultation document did not contain any information about how NHS England would frame its requests for a variation to the funding requirement, or how NICE would consider its requests. Consultees were concerned about this and so we have provided more detail in this response.

24. In light of the responses received we propose:

- To alter the terminology used for the consideration of net budget impact to **'budget impact test'** in order to clarify to stakeholders and the public that it is not a funding maximum;

- To **confirm £20m, in any of the first 3 years, as the budget impact test**, on the basis that no alternative solutions, which would provide NHS England with the facility we consider it urgently needs to manage significant in year demands on its budget, have been put forward;

- To **review the impact of the proposals** three years after its introduction.

25. NICE has developed a procedural statement to support the proposed arrangements. This statement is set out at Appendix C. The procedural statement sets out the information that NHS England will be asked to provide when it applies for a variation to the funding requirement, in cases where the budget impact test has been triggered. It also sets out what NICE's Guidance Executive will take into account when considering the request. These considerations are set out below, for ease of reference:

Information required from NHS England

26. For products where the budget impact test is engaged, NICE Guidance Executive will consider applications to vary the funding requirement, normally for up to a maximum of 3 years. In exceptional circumstances, a longer period may be considered.

27. Regardless of the duration of the variation requested, all applications will need to contain proposals for a phased allocation of funding.

28. When submitting a request for a variation, NHS England will be asked to provide the following information:

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- The duration of the proposed variation;

- The relevant provisions of any commercial agreement reached with the company;

- In the case of a technology funded from the national specialised commissioning budgets, the amount and phasing of funding that will be made available and how it is intended that this should be applied to eligible patients;

- In the case of technologies funded by clinical commissioning groups, what direction NHS England intends to give about the phasing of funding during the deferred funding period;

- An assessment of the impact on patients, eligible for treatment under the guidance, but whose treatments will be delayed as a result of the funding variation;

- The measures proposed to ensure that the alternative timescale for the funding requirement is not exceeded.

NICE's consideration of the request

29. NICE's Guidance Executive will consider a request from NHS England to vary the timescale for the funding requirement, taking the following into account the extent to which:

- The budget impact test been met;

- All reasonable opportunities for commercial discussions been pursued;

- The request in proportionate to the magnitude of the budget impact;

- The request has taken account of the severity and acuity of the condition to which the guidance relates;

- A commissioning policy been developed for managing appropriate access to the technology during the funding variation period.

30. NHS England will be expected to submit any application for variation to the funding requirement, in time for it to be considered by NICE's Guidance Executive, at the earliest opportunity, and no later than when it receives the outcome of the meeting at which the final recommendations are agreed.

31. Where NICE agrees to a variation of the timescale for the funding requirement, it is required to seek comments from the consultees to the appraisal.

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32. The assessment of net budget impact will be undertaken by the NICE Resource and Impact (RI) team at NICE. The RI team have recently completed a targeted consultation exercise with key stakeholders who have been invited to comment on their process and methods statements. The RI process and methods statement is included in Appendix D.

33. Applications to vary the funding requirement are specific to each topic. However, in the case of treatments with indications for which a funding variation is already in place, NICE will take into account the total budget for all relevant technologies, when considering an application for a funding variation for the second (and subsequent) technologies.

34. NICE and NHS England intend to put in place the arrangements for managing the budget impact test from 1 April 2017, for topics for which a first evidence submission is received after this date.

Decision

35. The Board is asked to:

- Approve the proposals for the budget impact test and for managing requests for variations to the funding requirement, as amended;

- Approve the process and methods statement for varying the duration of the funding requirement, as set out at Appendix C and D;

- Approve the implementation plan for consideration of varying the timescale for the funding requirement, as set out in paragraph 34;

- Note the proposal to review the application of the budget impact test after three years.

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Fast track appraisal

Questions asked in consultation

36. The following questions were included in consultation:

- Question 5: Do you consider that the criteria for the fast track process are appropriate? If not, what other criteria do you suggest?

- Question 6: Do you agree that NICE should 'fast track' new health technologies with a maximum incremental cost effectiveness ratio of £10,000 per QALY and whose costs are estimated to fall below the budget impact threshold?

- Question 7: Do you agree that NHS England should commit to accelerating funding for technologies approved under the fast track process from 90 days to 30 days?

- Question 8: Do you agree that NICE should absorb its proposed 'abbreviated' technology appraisal process into the proposed fast track process?

Summary of comments received

37. The Fast Track Appraisal (FTA) proposal was originally developed in order to find a way to provide faster access to those treatments which are highly cost-effective. The £10,000/QALY level was chosen to reflect the situation where a product could be deemed highly cost effective and where the risk of decision-error was minimal; i.e. the risk that a technology is over the £30,000/QALY upper limit.

38. Respondents broadly supported the concept of FTA, recognising that there was merit in speeding up the appraisal approach and implementation of treatments that are particularly cost-effective.

39. Some respondents expressed concern that net budget impact, as defined in the proposals, should not be used as an entry criterion for the FTA, as it would filter out products that may be extremely cost-effective but could have a high budget impact.

Response, including amendments to the proposals

40. Respondents broadly supported the FTA proposal, recognising that there was merit in speeding up the appraisal approach and implementation of treatments

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that are particularly cost-effective. They identified and offered varying views on the materiality of the risks associated with the proposals, which had been identified in the consultation document. No substantive additional risks were put forward and no alternative options, beyond in the case of some responses, the need for the proposal in the first place.

41. Since publishing the consultation document, it has become clear that expanding the fast track approach to cover more appraisals could help address an emerging challenge. This is that the NICE technology appraisal programme is facing a significant increase in the number of treatments it will need to consider, beyond the level at which the current process will be able to accommodate. This increase, of around 30%, rising to as much as 50% is due to the increasing numbers of products being assessed by the regulators, with some products requiring multiple licences, with some cancer products aiming for in excess of 20 indications for a single drug. This capacity challenge could, in part, be addressed through a less intensive appraisal process of the kind described in the fast track option.

42. Such a broadening of the scope of the proposed 'fast track' appraisal fits with the ambitions set out in the Accelerated Access Review and is also likely to be consistent with the emerging Life Sciences Strategy.

43. Nevertheless, in the short term, we intend to **introduce the FTA process** as proposed in consultation for products with a base case cost effectiveness of £10,000/QALY. A proposal to extend the fast track concept to a wider group of treatments will be brought to the Board in due course.

44. The new process will require a commitment from companies to ensure that the evidence underpinning their value proposition meets NICE's expectations at the start of their engagement. Companies will have the opportunity to engage in commercial conversations before and, in exceptional circumstances, during NICE's process, with NHS England. It is essential that system wide arrangements are in place to ensure commercial discussions can take place, on time, at pace, and with the necessary flexibilities in place, brokered by NICE. NICE will need to establish a team to support these commercial conversations.

45. The introduction of a fast track process will require judgements to be made about the evidence to be made earlier in the process. Decision makers will have to rely on much of the scrutiny having been applied before they meet, and so will be asked to accept that the scrutiny applied provides the basis on which to make a decision. NICE, and those working in the evidence review groups, will have to apply the experience and skills required to do this at an

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earlier stage in the process, and will need to build enough senior capacity to deal with this.

46. The consultation document referred to the fast track process potentially applying to medical technologies and diagnostics that meet the eligibility criteria. The relevant industry bodies and a number of medtech and diagnostics companies responded with comments. The exploration of a broader scope for fast track appraisals, and the longer term development of the new technology appraisal process, will explicitly address non-pharmaceutical technologies. This is consistent with the report of the Accelerated Access Review, which recommended that there should be a single set of clear national and local routes to get medical technologies, diagnostics, pharmaceuticals and digital products to patients.

47. As proposed in consultation, the fast track process will subsume the previous proposal for an 'abbreviated technology appraisal' (ATA). In drafting the process statement for the fast track process, comments received in consultation on the ATA process have been incorporated. The methods proposed for ATA have been set out as a 'cost comparison' addendum to the guide to the methods of technology appraisal (see Appendix F).

48. Consultees argued that excluding technologies, with a net budget impact of more £20 million, risked extending unnecessarily the time it will take to evaluate otherwise important new treatments. NICE and NHS England agree with this and so now propose to remove this restriction to entry into the fast track process.

49. NHS England has committed to ensuring that funding is available within 30 days from NICE having published guidance for products that go through FTA at £10,000 per QALY or less. NHS England is already making the same commitment for products that have gone through the Early Access to Medicines Scheme (EAMS).

50. A procedural statement to support the FTA process has been developed and is set out at Appendix E.

51. The consultation proposed that the fast track proposals would be introduced for topics referred to NICE from 1 April 2017. Considering the need to capture more topics than originally planned we propose to change this to topics with a first evidence submission from 1 April 2017.

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Decision

52. The Board is asked to:

- Approve the introduction of fast track appraisals, as proposed in consultation, from 1 April 2017;

- Approve the process, as set out at Appendix E;

- Approve the removal of the budget impact test as a criterion for entry into the fast track process;

- Approve the methods for cost comparison as set out in Appendix F;

- Note that a proposal to extend the fast track concept to a wider group of topics will be brought to the Board in due course;

- Approve the implementation plan, as amended as set out in paragraph 51.

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List of Appendices

Appendix A – Consultation analysis

Appendix B – Consultation on proposals for changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE's technology appraisal and highly specialised technologies programmes; analysis of responses to the consultation.

Appendix C – Budget impact and varying the time for statutory funding; procedural statement

Appendix D – Resource and Impact process statement

Appendix E – New fast track appraisals; process statement

Appendix F – Cost comparison; methods statement

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Consultation on changes to technology appraisals and highly specialised technologies

Analysis of responses to the consultation

Contents

1. Introduction

This report covers the responses received to the consultation on changes to technology appraisals and highly specialised technologies which ran from 13 October 2016 to 13 January 2017.

The use of quotes throughout the document is to illustrate some of the main issues raised. They do not necessarily reflect a balance of opinions.

2. The consultation in numbers

The consultation received responses from 150 stakeholders. We are aware that some organisations have collaborated in developing responses which have been submitted individually, therefore there is some duplication within the responses.

Summary of responses by question:

		Yes	Maybe	No	No response
1	Should there be a budget impact threshold (BIA)?	32%	12%	48%	8%
2	Should the BIA be set at £20m?	13%	21%	53%	13%
3	Should NHSE and companies negotiate where the BIA is exceeded?	47%	29%	17%	7%
4	Should NICE vary the Funding Directive where the BI threshold is exceeded?	23%	16%	50%	11%
5	Do you agree with the criteria for the NICE fast track process?	24%	36%	27%	13%
6	Should NICE fast track technologies anticipated to be less than £10,000 per QALY?	31%	28%	28%	13%
7	Should NHSE fund recommended fast track technologies within 30 days?	49%	13%	23%	15%
8	Should NICE merge its 'abbreviated' process into the fast track process?	40%	13%	22%	25%
9	Should there be an ICER cut off for automatic funding in the NICE HST programme?	23%	9%	47%	21%
10	Should the ICER cut off for HSTs be set at £100,000 per QALY?	11%	11%	53%	25%

11	Should HST topics above £100,000 per QALY go into the NHSE CPAG process?	18%	8%	50%	24%
12	Do you agree that the proposals for the HST programme mean that NICE would not need to take budget impact into account?	11%	10%	49%	30%
13	Do you think any of the proposals put NICE or NHSE at risk of failing to meet their statutory obligations under equalities legislation?	45%	7%	23%	25%

3. Who responded to the consultation?

STAKEHOLDER GROUPS

Research organisations, 6
Acadaemia, 6
Professional societies, 11
Companies, 40
Patient/Carer organisations, 39
Company trade associations, 9
Individuals, 6
NHS organisations, 2
Other, 7
NHS Trust's, 2
NHS commissioning bodies, 21
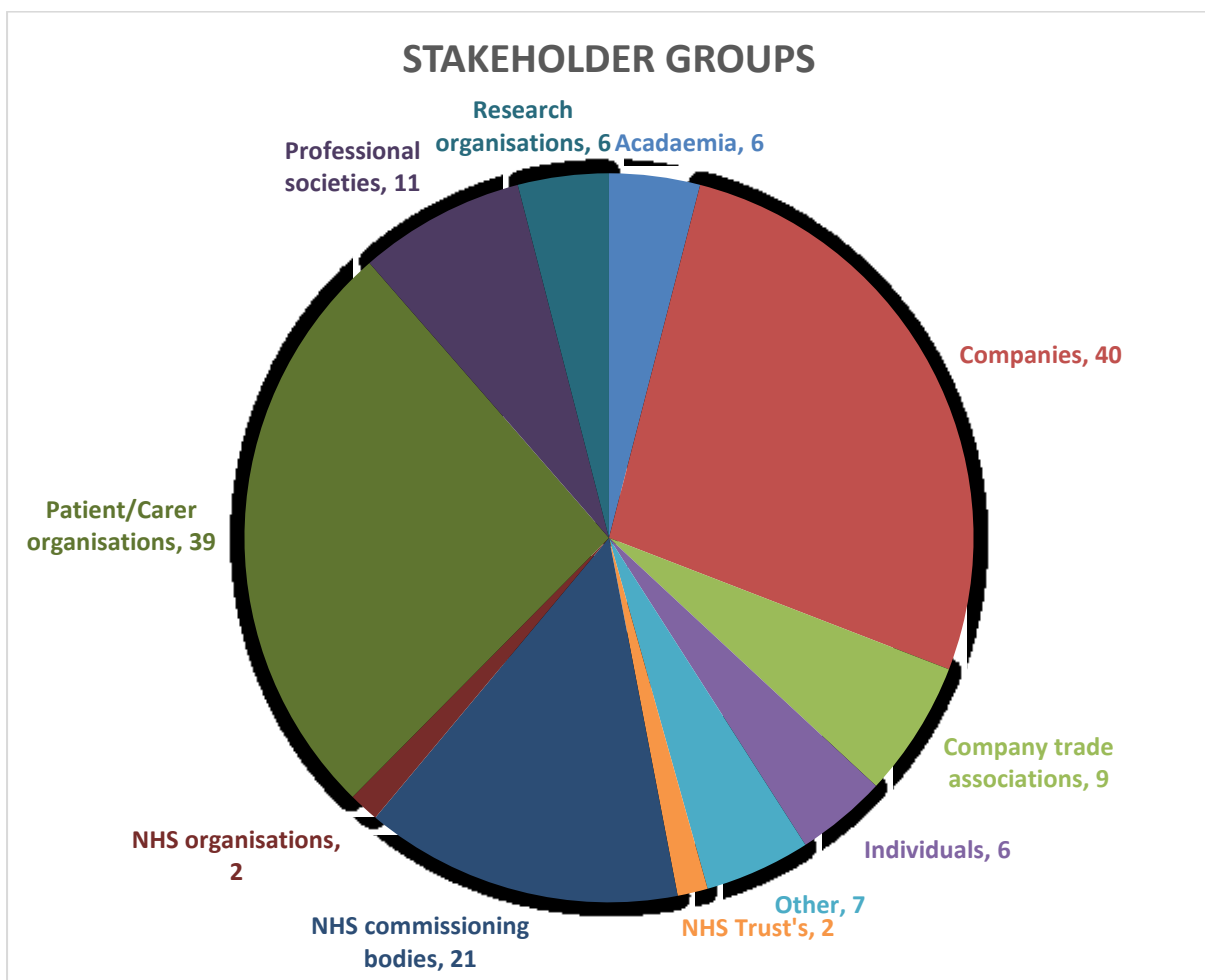
Responses were received from:

o 40 companies

o 39 patient carer organisations

- 21 NHS commissioning organisations

- 11 professional societies

- 10 Research organisations

- 9 Trade associations

- 24 other organisations and individuals

4. Analysis of responses to the questionnaire by question

Stakeholders were asked whether they agreed, disagreed or partially agreed with 13 questions based on key areas of the consultation document. Where stakeholders did not explicitly state 'Yes/No/Partially' in their response NICE staff selected the most relevant option based on their response. Because of time constraints, NICE staff did not follow up with these respondents to confirm their interpretations were correct. Where a stakeholder did not state 'Yes/No/Partially' and their response does not appear to answer the question, a 'no-response' has been allocated.

The following section shows the breakdown of stakeholder responses by question. The responses of the larger stakeholders groups (Companies, Patient/Carer organisations, NHS Commissioning organisations and Professional societies) have also been shown separately. Highlighted comments have been presented to give a general overview of the comments received for each question.

Section1 – Budget impact

Question 1: Do you agree that NHS England should set a budget impact threshold to signal the need to develop special arrangements for the sustainable introduction of cost effective new technologies?

Q 1

	All stakeholders	Companies	Patient/Carer organisations	NHS Commissioning bodies	Professional societies
■ Yes	48	4	4	17	7
■ Partially	18	5	4	2	2
■ No	72	27	31	1	0
■ No response	12	4	0	1	2
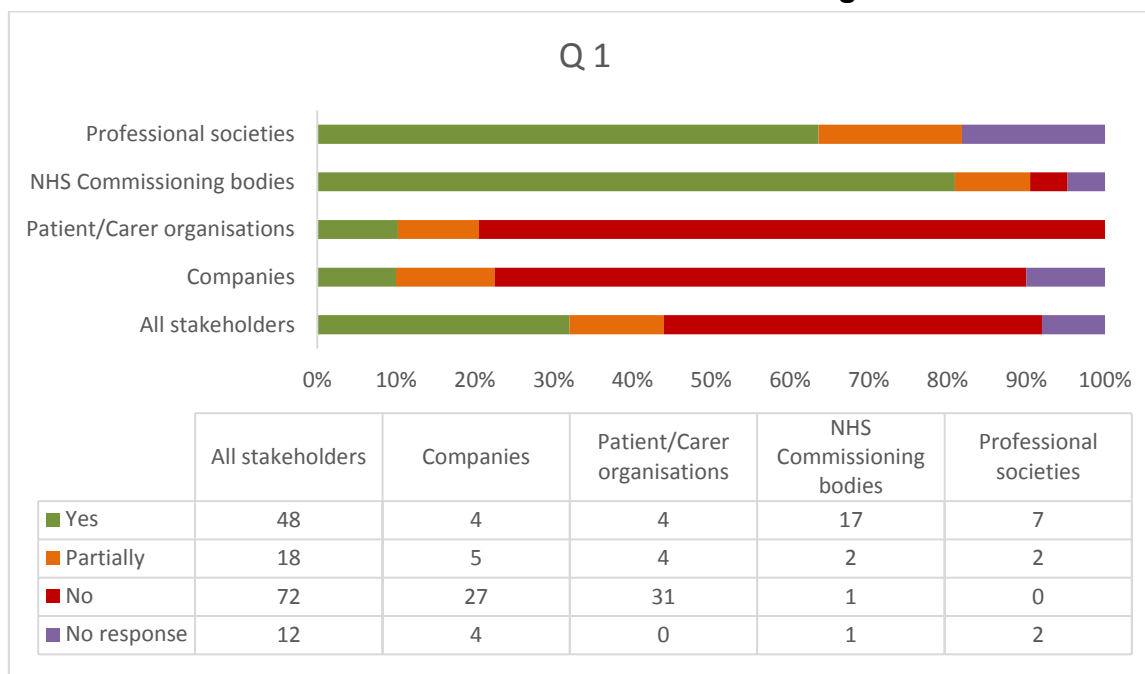
32% (48) of respondents agreed with the proposal, 12% (18) partially agreed and 48% (72) did not agree.

A general theme amongst responses was a recognition of the financial pressures that the NHS is currently facing.

Company responses

40 companies responded to this question. A clear majority of companies (68%) did not agree with the proposal. Less than a quarter (23%) agreed or partially agreed with the proposal.

These are some examples of the recurrent themes in responses that did not agree with the proposal:

- 'PPRS is the primary mechanism for managing affordability in the NHS' [Shire Pharmaceuticals]

- 'NHS England, NICE and the pharmaceutical industry must work constructively to ensure patient access to innovative medicines is not held up due to non-clinical considerations' [Bayer]

- 'Any threshold would hinder 1st to market products' [Amicus Therapeutics Ltd]

Companies that agreed with the proposals highlighted the following:

- 'it seems sensible to identify those technologies which will have the greatest impact on the health care budget' [Cook Medical Ltd]

- 'Recognising the economic challenges facing the NHS, Amgen agrees (in exceptional circumstances), with the principle of NHS England discussing with companies how best to manage the introduction of medicines that have an exceptionally high budget impact. However, the proposed threshold of £20m is inappropriate and we believe that this threshold should be £100m.' [Amgen Ltd]

Patient/Carer Organisation responses

39 patient/carer organisations responded to this question. Again, a clear majority (79%) did not agree with the proposals.

Themes in the responses that did not agree included:

- 'The introduction of a budget impact threshold could disadvantage innovative therapies especially where no other existing treatment exists.' [PHN Support]

- 'the solution to the affordable and sustainable introduction of new technologies should lie in better long-term planning and horizon scanning, as proposed in the Accelerated Access Review (AAR)' [Kidney Research UK]

- 'The addition of a budget impact threshold would add another layer of assessment and slow down the uptake of innovative medicines by NHS England' [Kidney Cancer Support Network]

Comments in agreement with the proposal included:

- 'we are all aware of the budgetary constraints and some mechanism is necessary at least to alert decision takers to the potential for new treatments to create budgetary dilemmas' [Leber's Hereditary Optic Neuropathy Society]

NHS commissioning bodies' responses

21 NHS commissioning bodies responded to this consultation. The vast majority (81%) agreed with the proposal. Whilst supporting the proposals they also wanted

clarity that the budget impact threshold would also apply to CCG's and Local authorities.

An example of a supportive comment from a commissioning body was:

- 'A budget impact based approach is also much more closely aligned to how the NHS operates in terms of financial planning.' [South East London Area Prescribing Committee]

Other responses

Comments that agreed with the proposal:

- 'In the context of an increasingly financially constrained health budget, this proposal provides a clear framework for industry, healthcare purchasers, clinicians and patients' [The Royal College of Opthalmologists]

Comments that did not agree with the proposal:

- 'The introduction of the budget impact (BI) threshold would likely lead to unjust inequalities arising between and within patient groups' [King's College London]

- 'this should be dealt with by adjusting the cost-effectiveness threshold conditional on budgetary impact' [University of Sheffield]

Question 2: Do you agree that £20 million is an appropriate level? If not, what level do you think the threshold should be set at and why?

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Professional societies
■ Yes	19	2	3	5	4
■ Partially	32	2	4	13	2
■ No	79	32	30	1	2
■ No response	20	4	2	2	3
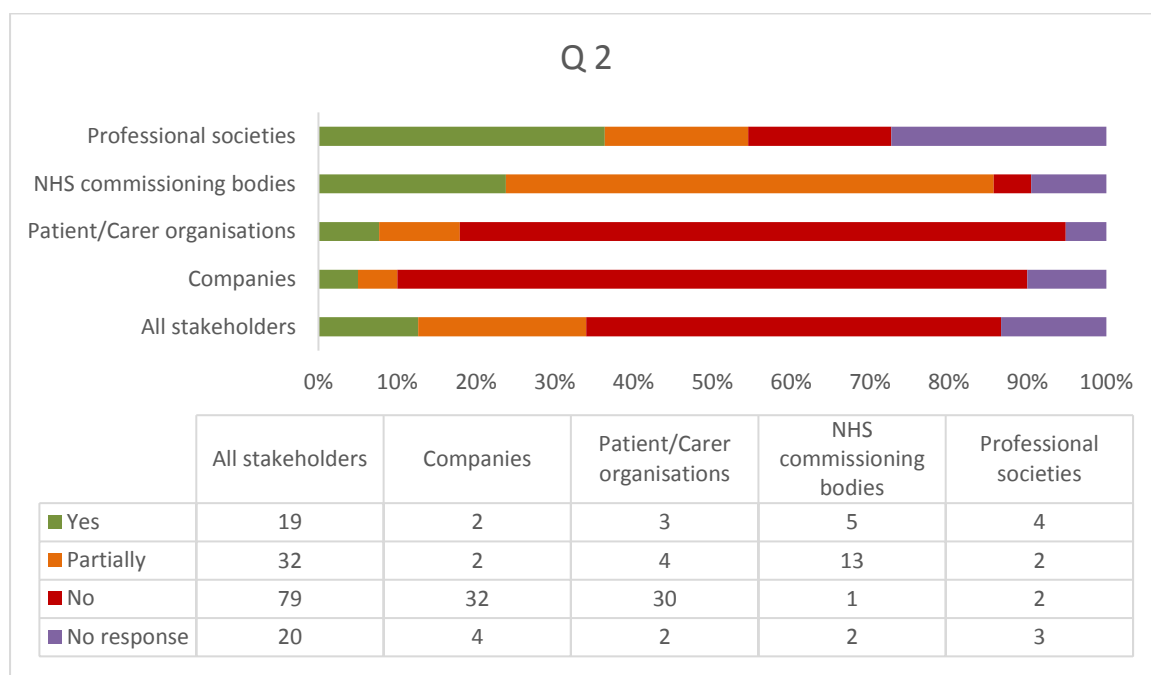
13% (19) of respondents agreed with the proposal, 21% (32) partially agreed and 53% (79) did not agree. Stakeholders felt that the £20 million figure had been arbitrarily selected, with a lack of rationale provided.

Company responses

80% of companies did not agree with this proposal whilst only 10% agreed or partially agreed. Comments suggested that if a threshold must be set it should be significantly higher, £100 million was frequently suggested.

Highlighted comments:

Disagreed

- 'It is concerning that 1 in 5 of NICE's technology appraisals over the last 12 months would have been affected, causing delayed or blocked access for large numbers of patients . If a threshold is to be set, this should be indicative and focused on exceptionally costly technologies, while taking account of other potential benefits arising (e.g. in moving care from hospitals to people's homes). A threshold which captures 1 in 5 recent technologies does not meet this description' [Shire Pharmaceuticals]

- 'The threshold proposed in this consultation has been put forward without substantive rationale, methodological detail, or consideration for impact on patient outcomes' [MSD UK Ltd]

Agreed

- 'This level appears appropriate in balancing the introduction of new innovation into the NHS with the ability of the NHS to afford these new innovations without compromising the availability of other treatments for patients' [Boston Scientific]

Patient/Carer Organisation responses

77% of patient/carer organisations did not agree with the proposals.

Highlighted comments:

Disagreed

'Any threshold is arbitrary and unhelpful because it will add a meaningless criterion to confuse more robust criteria. The introduction of a specific threshold would be completely arbitrary and furthermore it would undermine the right of patients (as set out the NHS Constitution) to access NICE-approved technologies.' [Tuberous Sclerosis Association]

- 'the proposal appears confused, conflicting with other proposed policy, coming as the Government introduces legislation to cap the overall cost of medicines, through the Health Service Medical Supplies (Costs) Bill. If the overall cost is capped to ensure spending is kept within defined budgets, why have an affordability test as well?' [Alzheimer's Society]

NHS commissioning body's responses

86% of NHS commissioning agreed or partially agreed with this proposal.

Highlighted comments:

Agreed

- 'Yes, although there is a slight concern companies may try and fast-track everything.' [Leeds North CCG, Leeds South & East CCG and Leeds West CCG, Leeds Teaching Hospital NHST, Leeds and York partnership FT]

Disagreed

- 'We feel this should be set lower as all parts of the system are struggling and any additional expenditure would need to find finance' [York and Scarborough medicines Commissioning Committee]

Other responses

Comments that agreed with the proposal:

- 'Based on current technologies undergoing HTA, a budget impact of £20 million should capture most technologies providing an important innovative advance in health care but which would also have a significant impact on financial planning' [All Wales Medicines Strategy Group]

- 'We are of the opinion that the value of the budgetary limit should be related to the proportional GDP spend on health rather than being set at a fixed value. This will maintain the relative priority attributed to new, innovative treatments.' [Faculty of Public Health]

Comments that did not agree with the proposal:

- 'If a new drug or intervention has a QALY of <£10,000 but affects commoner conditions such as heart attack, stroke, breast cancer, diabetes then clearly £20 million for the >55 million English population seems just too low to be workable. A link to patient volume seems a sensible approach' [UK Neurointerventional Group]

- 'a threshold of £20m is inappropriate and that a higher threshold of £100m in any of the first two years post-launch should be set as the trigger for dialogue. We propose that those medicines with a high net budget impact above £100m should be identified at 2-3 years prior to launch. Estimates would be based on best planning assumptions available at the time, and would be a "trigger" to signal formal dialogue to support the sustainable introduction of these medicines into the NHS.' [ABPI]

Question 3: Do you agree that NHS England should enter into a dialogue with companies to develop commercial agreements to help manage the budget impact of new technologies recommended by NICE?

Q 3

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Professional societies
■ Yes	70	9	19	14	9
■ Partially	43	14	16	4	0
■ No	25	16	3	2	0
■ No response	12	1	1	1	2
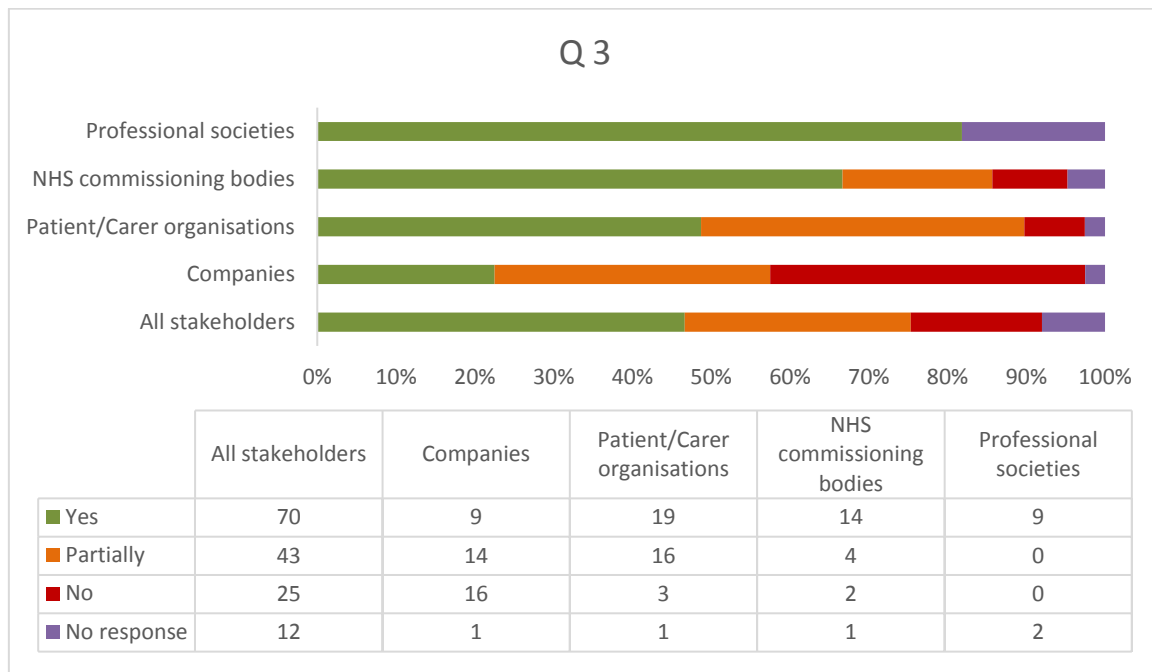
47% (70) of respondents agreed with the proposal, 29% (43) partially agreed and 17% (25) did not agree. There was full or partial support for earlier engagement between companies and NHS agreement across all stakeholders groups.

Companies

40% (16) of companies did not agree with the proposal, 23% fully agreed and 35% (14) partially agreed.

Highlighted comments:

Agreed/Partially agreed

- 'a clear framework and timeline for this process should be put in place. This would enable industry to gather relevant information earlier so that conversations could be held in parallel to the NICE TA process; this could avoid delays and enable rapid access close to market authorisation.' [MSD UK Ltd]

- 'early negotiation between all parties should take place that sets the commercial conditions for the entry of the new technology in the UK market. This negotiation should address both value for money (eg; cost-effectiveness, via NICE appraisal) and any 'exceptional' affordability issues (eg; managed entry arrangements to help NHSE with financial planning), and not introduce any further delays to approval, implementation and patient access' [Janssen and J&J Medical]

Disagreed

- 'we object in the strongest terms to any 'commercial agreements' that result in additional price cuts in order to make available a technology that has already successfully navigated a very stringent assessment by NICE' [Roche Products Ltd]

- 'we are of course supportive of the principle of commercial arrangements with NHSE, however a conversation with NHSE triggered by an arbitrary affordability threshold does not provide the flexibility we require and comes too late in the day to be of any value.' [Merck]

Patient/Carer organisations

49% (19) of patient/carer organisations agreed with this proposal, whilst only 8% (3) disagreed.

All comments in agreement highlighted the benefit of earlier engagement between NHS England and companies:

- 'dialogue between NHS England and pharmaceutical companies and manufacturers producing innovative treatments should be a usual part of preparation to deliver a medicine within the NHS' [Genetic Alliance UK]

NHS commissioning bodies

67% (14) of commissioning bodies agreed with this proposal, 10% (2) disagreed. Alongside this broad agreement was a desire for greater transparency over pricing:

- 'It is essential commissioners are informed of the detail of the agreements to ensure that costs charged to the NHS reflect the agreements made and the benefit to NHS is to be realised in practice' [Surrey Downs CCG]

Other responses

Comments that agreed with the proposal:

- 'We consider it reasonable for NHS England to negotiate further discounts with companies for technologies which are considered to be cost-effective by NICE but which have a substantial budget impact. We are however unsure what leverage could be applied by NHS England if the company knows that the NICE recommendation is to be positive and mandatory funding will eventually follow. A delay in funding may be insufficient to convince companies to provide additional discounts' [University of Sheffield]

Comments that disagreed with the proposal:

- 'It is also unclear why NICE needs to be involved in assessing budget impact if it is NHS England that will be using this information in negotiation with industry. Presumably the mandate and expertise to perform such an assessment also exists in NHS England, where it could be performed without any concerns about loss of independence or scientific integrity' [King's College London]

Section 2 – Varying timescales for the funding requirement

Question 4: Do you agree that NICE should consider varying the funding requirement for technologies it recommends, for a defined period, in circumstances where NHS England makes a case for doing so, on the grounds that the budget impact of the adoption of a new technology would compromise the allocation of funds across its other statutory responsibilities?

Q 4

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Professional societies
■ Yes	35	0	1	18	5
■ Partially	23	3	9	2	3
■ No	75	32	27	0	1
■ No response	17	5	2	1	2
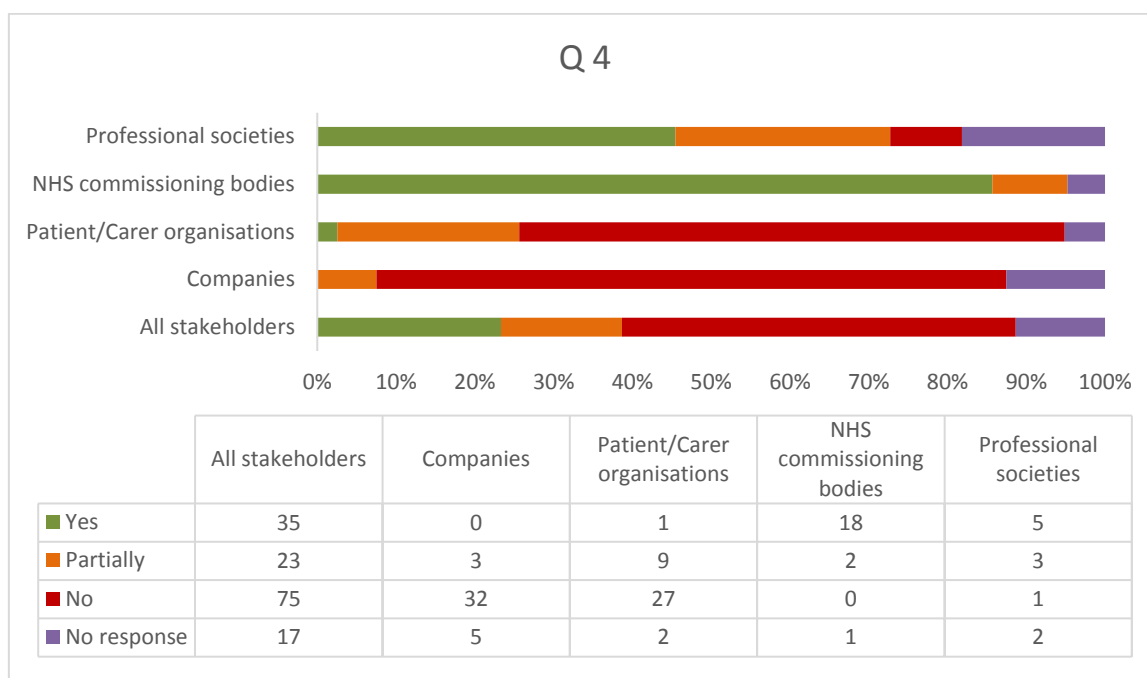
23% (35) of respondents agreed with the proposal, 16% (24) partially agreed and 50% (75) did not agree.

Companies

80% (32) of companies disagreed with this proposal, only 8% (3) partially agreed and none agreed.

Highlighted comments:

Disagreed

- 'Budget impact is only one of many considerations, so to use this as the single metric for varying recommendations would be inappropriate' [Medtronic]

- 'Where NICE has found a technology to be cost-effective, breaking the link to the funding requirement undermines the NICE process and is contrary to the current PPRS agreement. In particular, the lack of clearly defined timelines suggests NHSE could pursue delaying tactics via this mechanism to put

additional pressure on companies to drop prices further regardless of value or cost effectiveness' [Kyowa Kirin]

- 'Varying the funding requirement for a new technology by extending beyond 90 days denies patients access negating their rights enshrined under the NHS Constitution to treatments which have been deemed as cost effective by NICE. This goes against the recommendations of the AAR and the stated desire for patients to be able to benefit from new technologies faster' [Roche Products]

Partially agreed

- 'If this is based on the assumption that the initial years of implementation for a technology are likely to be more costly, then yes, particularly if this avoids directing funds away from other existing technologies' [Cook Medical UK]

Patient /Carer organisations

Similarly to company responses, a majority of patient/carer organisations, 69% (27), did not agree with this proposal. One organisation agreed with the proposal and 23% (9) were in partial agreement. Concerns with the proposal centred on the potential delayed access to new treatments.

Highlighted comments:

Disagreed

- 'This measure will create yet another barrier to the adoption of new technologies. It will make the process less transparent and has the potential to cause regular and significant delays in the availability of new treatments.' [Asthma UK]

- 'The purpose of NICE's appraisals in delivering assured patient access would be subverted were delay to become the norm. The emphasis should be on better horizon scanning and budgetary planning, with the onus on companies to provide timely guidance and on NHS England to make the most of its considerable purchasing power' [Specialised Healthcare Alliance]

Partially agreed

- 'If there is to be a variation it needs to involve the relevant patient organisations and clinicians, with a transparent process and adhere to a well-defined timescale, with a trigger for an appeal.' [Gauchers Association]

NHS commissioning bodies

In contrast to companies and patient/carer organisations there was broad support for this proposal amongst NHS commissioning bodies. 86% (18) agreed with the proposal with none disagreeing. Comments received were hopeful that the provisions should apply to CCG's as well.

- 'This should include any technologies which are the responsibility of CCGs' [NHS Dorset Clinical Commissioning Group]

Other responses

Example of comment in agreement:

- 'NICE approving new technologies for use in the NHS based on cost-effectiveness explicitly does not consider budget impact. As NHS England is the budget holder, it makes sense for the budget holder to be in a position to influence when mandatory funding should begin' [BMJ]

Examples of comments that disagree:

- 'there seems to be a contradiction of principles between the pursuit of obtaining faster NICE recommendations for new drugs and relaxing how long it takes before NHS Trusts must find the resources to fund these technologies. It would be somewhat perverse to introduce new processes that demand the rapid appraisal of new technologies but then to increase the lag between their positive recommendation and their availability on the NHS' [University of Sheffield]

- 'By seeking to avoid the legal funding requirements for NICE technology recommendations for some medicines, NHS England's proposals will irrevocably weaken guarantees within the NHS Constitution and will likely further limit patient access to new cost effective medicines.' [ABPI]

Section 3 – NICE Fast Track process

Question 5: Do you consider that the criteria for the fast track process are appropriate? If not, what other criteria do you suggest?

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Professional societies
■ Yes	36	5	5	11	5
■ Partially	54	15	13	8	4
■ No	40	17	14	1	0
■ No response	20	3	7	1	2
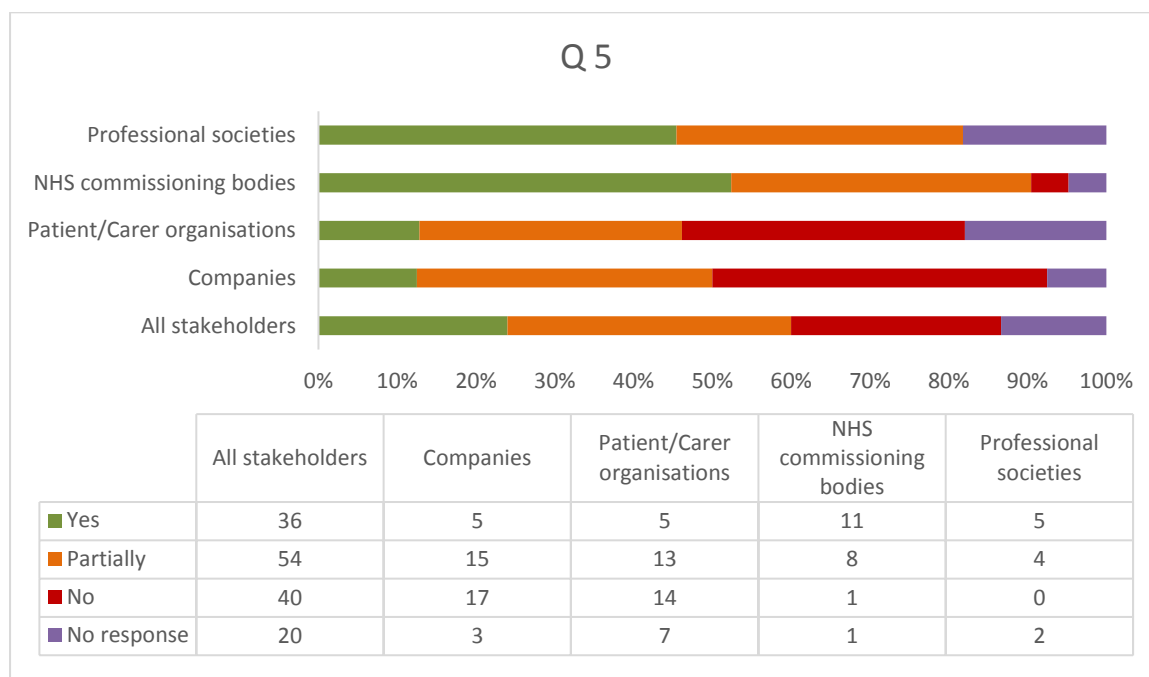
24% (36) of respondents agreed with the proposal, 36% (54) partially agreed and 27% (40) did not agree. There was a frequent misunderstanding that fast track topics would be prioritised for appraisal at the expense of carrying out standard appraisal topics.

Companies

There was a fairly even split between companies that agreed or partially agreed, 13% and 38% respectively, and those that disagreed, 43%. Companies welcomed the option of a streamlined appraisal route, whilst some felt the criteria were too narrow.

Highlighted comments:

Agreed

- 'We believe attempts to accelerate appraisal timelines would be in the interests of the NHS' [Alnylam Pharmaceuticals]

- 'if NICE and NHS England truly want to speed up access to the medicines that will have the greatest impact on patient outcomes then they need to apply

this process to all innovative new medicines that are a step change in care or offer significant efficiencies and improvements to the patient pathway and patient experience' [Bayer]

Disagreed

- 'As a principle, it is flawed. The industry supports NICE Guidance because a positive recommendation with the associated mandatory implementation and funding should be the fast track route to patient access, compared to those technologies not assessed by NICE. A fast track process implies an inconsistency with the NICE assessment process, when specific guidance (and the health of specific patients) is assigned greater importance over others simply due to upfront cost' [Akcea Therapeutics]

- 'we have concerns that the criteria outlined in the proposal are most likely to prioritise and accelerate access to those medicines where the unmet need is lower and where there are already established treatment options, thus creating perverse incentives for companies to disinvest in the most innovative therapies. This is in stark contrast to other government initiatives, such as EAMS and the Accelerated Access Review, which aim to ensure that acceleration is focused on areas of greatest unmet need' [Novartis]

Patient/Carer organisations

Patient/Carer organisations were also split evenly between agreeing/partially agreeing, 13% and 33% respectively, and disagreeing, 36%, with the suggested criteria for a Fast Track process.

Highlighted comments:

Agreed

- 'We are supportive of a faster and simpler process for very cost-effective medicines, whilst recognising that not many new medicines will fall into this category, so this new route will be of limited benefit to most patients.' [Breast Cancer Now]

- 'Any steps that aim to speed up patient access to medicines are to be welcomed' [Bloodwise]

Disagreed

- 'We take the view that the fast track appraisal process is inequitable and potentially discriminatory across the board for new technologies' [Society for Mucopolysaccharide Diseases]

- 'It is essential that NICE continues to focus on the development and implementation of robust processes for all new technologies, irrespective of price and taking into account the challenges of appraising technologies for ultra-rare diseases where patient numbers are very small.' [Niemann-Pick UK]

NHS commissioning bodies

There was a high level of support for the proposed Fast Track appraisal amongst NHS commissioning bodies, 19 out of 21 either agreed or partially agreed with the proposal. Only one organisation did not agree with the proposed criteria.

Highlighted comments:

Agreed

- 'Commissioners would want to be assured that the evidence provided to meet the criteria was robust' [Surrey Downs CCG]

- 'The criteria are appropriate but again, this process should be available for all eligible technologies not just those commissioned by NHS England' [Eastbourne Hailsham & Seaford CCG, Hastings and Rother CCG]

Other responses

Comments agreeing with proposed criteria:

- 'This is long overdue, and represents a valuable addition to the process where a quick & straightforward decision can be made.' [Individual]

- 'Timeliness is critically important and a fast track process for those technologies with a QALY less than £10,000 will result in earlier clarity on a larger number of technologies and provide patient benefit in areas of unmet clinical need at an earlier stage.' [All Wales Medicines Strategy Group]

Comments that did not agree with the proposed criteria:

- 'The criteria are fundamentally wrong – it's not a threshold issue, it's a matter of decision uncertainty. I also consider the biggest loss in health benefits from the NICE process is the de facto use of a £30K threshold for all appraisals and low levels of implementation. The potential benefits of getting a couple of drugs into the NHS three months quicker are negligible in comparison to these other issues.' [University of Sheffield]

- Requirements for strong evidence and low uncertainty could delay patient access as companies would have to conduct studies in larger populations and

for longer duration, discouraging early access to medicines which could bring value to patients [MAP BioPharma Limited]

Question 6: Do you agree that NICE should 'fast track' new health technologies with a maximum incremental cost effectiveness ratio of £10,000 per QALY and whose costs are estimated to fall below the budget impact threshold?

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Profesional societies
■ Yes	47	11	5	8	7
■ Partially	42	9	13	8	1
■ No	42	17	13	4	1
■ No response	19	3	8	1	2
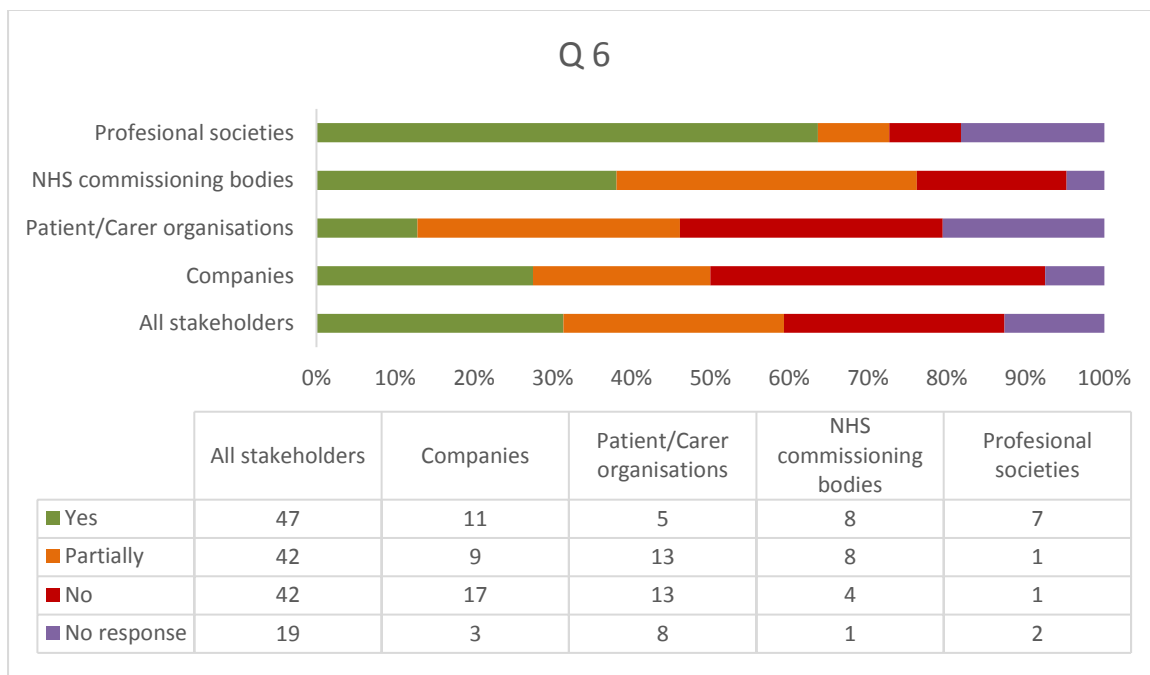
31% (47) of respondents agreed with the proposal, 28% (42) partially agreed and 28% (42) did not agree. There was widespread disagreement to include a budget impact above £20m as a criterion for the fast track appraisal process.

Companies

50% of company responses either agreed (27.5%) or partially agreed (22.5%) with the proposal. 43% of companies did not agree with the proposal, again showing a close split in opinions.

Highlighted comments:

Agreed

- 'the lower QALY removes a lot of the current gaming in the system to achieve current WTP thresholds' [Medtronic]

- 'Boehringer Ingelheim believes that a threshold of £10,000 per QALY gained for 'fast track' health technologies is reasonable for signalling cost-effectiveness; however, clarification is needed as to the definition of "a low degree of decision uncertainty"' [Boehringer Ingelheim]

Disagreed

- 'the challenge will be on whose methods are used. Every technology appraisal has had disagreement between the ERG and the manufacturer on the base case assumptions for the cost effectiveness models. Therefore if the fast track appraisal is going to work there has to be more standardisation of model frameworks for different diseases.' [Amicus Therapeutics Ltd]

- 'AstraZeneca does not support the Fast Track proposal being reserved for health technologies that meet the proposed budget impact threshold. Fast Track of a medicine should be based on ICER vs. primary comparator alone.' [AstraZeneca]

Patient/Carer organisations

33% (13) of patient/carer organisations disagreed with this proposal, mainly representing rare or ultra-rare diseases. Another 33% (13) partially agreed with the proposals, whilst 13% (5) fully agreed with the proposals.

Highlighted comments:

Agreed

- 'We are supportive of a faster and simpler process for very cost-effective medicines, whilst recognising that not many new medicines will fall into this category, so this new route will be of limited benefit to most patients' [Prostate Cancer UK]

- 'On the basis that these interventions are of sufficient interest anyway this seems like a good pragmatic approach' [The Cure Parkinson's Trust]

Disagreed

- 'It is a concern that companies will see this as an opportunity to concentrate R&D funding for those technologies under the £10,000 threshold' [Batten Disease Family Association

- 'It is also illogical to send the signal to pharmaceutical companies that drugs below the £10,000 threshold will be automatically approved, which may mean that the drug is extremely valuable to the NHS, but then to stop implementation if they exceed the budget impact threshold. More analysis is required into how many of drugs eligible for the fast-track process would breach the budget impact threshold.' [Myeloma UK]

NHS commissioning bodies

38% (8) of NHS commissioning bodies agreed with the proposal, another 38% (8) partially agreed with 19% (4) disagreeing.

Highlighted comments:

Agreed

- 'This will encourage companies to market costs below £10K which is good' [Guildford & Waverley Clinical Commissioning Group]

Disagreed

- 'No, the threshold should be lower. £10,000/QALY is still relatively high as the cost-effectiveness of the NHS is estimated to be £13,000/QALY (K Claxton et al.).' [North Central London Joint Formulary Committee]

- 'we do not feel that even this is affordable given the current financial situation' [York and Scarborough medicines Commissioning Committee]

Other responses

Comments in agreement:

- 'Yes, provided NICE can establish a process which mitigates the risks of reaching the wrong recommendation and minimises the proportion of cases where the appraisal is re-routed to the usual STA process' [University of Sheffield]

- 'this would also encourage more competitive pricing of new products' [British Society for Allergy and Clinical Immunology]

Question 7: Do you agree that NHS England should commit to accelerating funding for technologies approved under the fast track process from 90 days to 30 days?

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Professional societies
■ Yes	73	28	20	2	5
■ Partially	19	4	6	3	2
■ No	34	6	3	16	2
■ No response	24	2	10	0	2
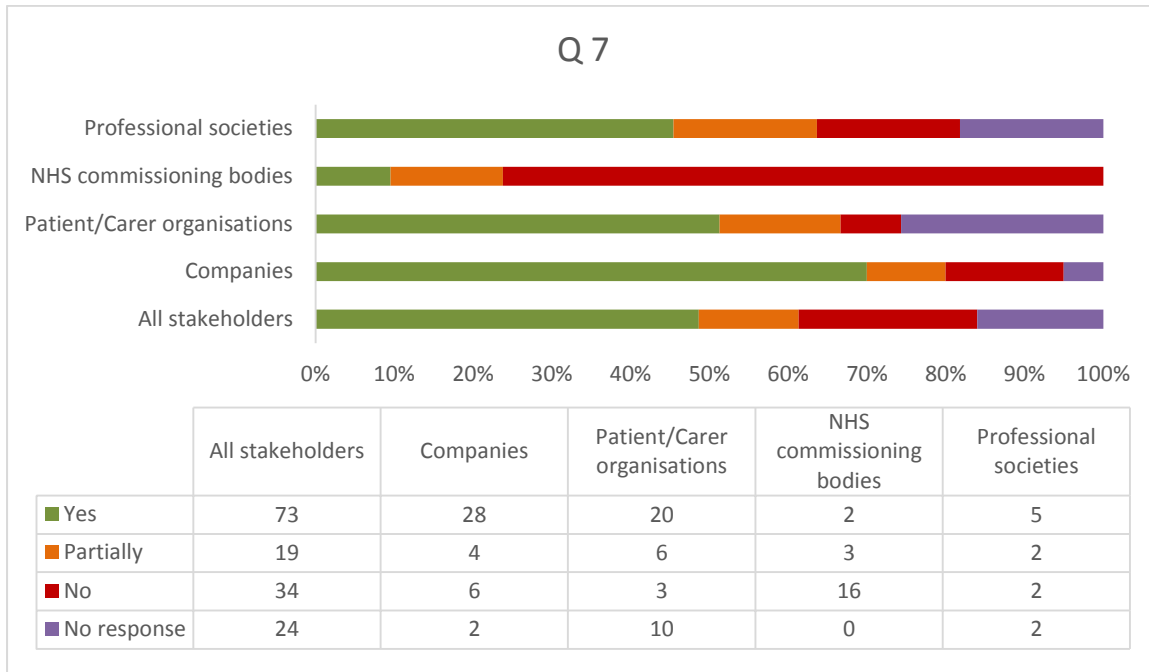
49% (73) of respondents agreed with the proposal, 13% (19) partially agreed and 23% (34) did not agree.

Companies

There was wide support for this proposal amongst companies; 70% (28) agreed with the proposal, a further 10% (4) partially agree and 15% (6) disagreed.

Highlighted comments

Agree

- 'We support this proposal and would encourage NHS England to ensure robust processes are in place and well communicated to ensure these timelines can be met, both for technologies which fall under specialised commissioning as well as those commissioned by CCGs' [Boston Scientific]

- 'This proposal however raises the question of why it is not possible, or even greatly preferable, for NHS England to commit to accelerating the funding for all technologies approved to 30 days. These therapies have been demonstrated to be cost-effective compared to the existing standard of care and so represent a more efficient use of NHS funding.' [Bristol-Myers Squibb]

Disagree

- 'As this proposal stands, it is counterintuitive that less innovative therapies with an ICER of £10K per QALY should benefit from faster implementation than more innovative medicines with an ICER of £10K-£20K per QALY, when both are considered by NICE to be cost-effective' [Novartis]

- 'Whilst NHS England may be able to promise funding within 30 days of TAG for Fast Track-approved technologies which sit within specialised services, many technologies assessed by NICE will ultimately be funded by CCGs, and it is unlikely that NHS England can commit to such rapid funding on behalf of CCGs, although we would welcome this if it were made possible' [Novartis]

Patient/Carer organisations

Patient/Carer organisations also welcomed this proposal; 51% (20) agreed, 15% partially agreed and only 8% disagreed.

Highlighted comments:

Agreed

- 'From a patient's point of view the faster we get access to treatment, the better. However perhaps it would be a more realistic aim to ensure that there is consistency in achieving the current 90 day period.' [PNH Support]

- 'If drugs are approved it is essential that patients have access to them as soon as possible so we agree that NHS England should commit to accelerating funding for approved technologies to 30 days' [Parkinson's UK]

NHS commissioning bodies

NHS commissioning bodies did not support this proposal. 76% (16) disagreed, with only 2 organisations agreeing and 3 partially agreeing. Concerns were raised over the levels of administration required to meet the 90 day implementation target, let alone 30 days.

Highlighted comments:

Agreed

- 'As this consultation also applies to CCGs, there would be a willingness from CCGs to fast track technology appraisals but the suggested 30 days in practice would be hard to achieve in CCGs' [Pharmacy Eastern Network]

Disagreed

- 'If CCGs are to be included in this arrangement then it will be important to keep the 3 month implementation rule. Clinical engagement and adjusting

local treatment pathways to accommodate the guidance followed by sign off by local medicines policy development committees are crucial steps to successful implementation. There is no indication that fast tracking a technology in this way will impact on any of the above steps and make the guidance quicker to implement.' [Eastbourne Hailsham & Seaford CCG, Hastings and Rother CCG]

- 'Current governance processes within CCGs are unlikely to allow for approval within 30 days' [East Surrey CCG]

Other responses

Highlighted comments in agreement:

- 'This would benefit patients and could incentivise companies to keep costs low and below the £10,000 threshold.' [Faculty of Public Health]

- 'It is essential that a formal 30 day implementation window does not lead to delays and uncertainty for those products that fall outside the fast-track process' [MAP BioPharma Limited]

Highlighted comments that disagree:

- 'The current 90 days is in place in order that appropriate health resources, including staff are in place. There is no evidence to suggest that, just because a new technology meets the criteria for fast tracking, that such resources can be put in place any more quickly.' [Ethical Medicines Industry Group (EMIG)]

- 'Not unless it can be established that it does not impose an additional administrative burden' [University of York]

Question 8: Do you agree that NICE should absorb its proposed 'abbreviated' technology appraisal process into the proposed fast track process?

Q 8

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Professional societies
■ Yes	60	16	11	12	7
■ Partially	20	4	4	4	3
■ No	32	16	6	2	0
■ No response	38	4	18	3	1
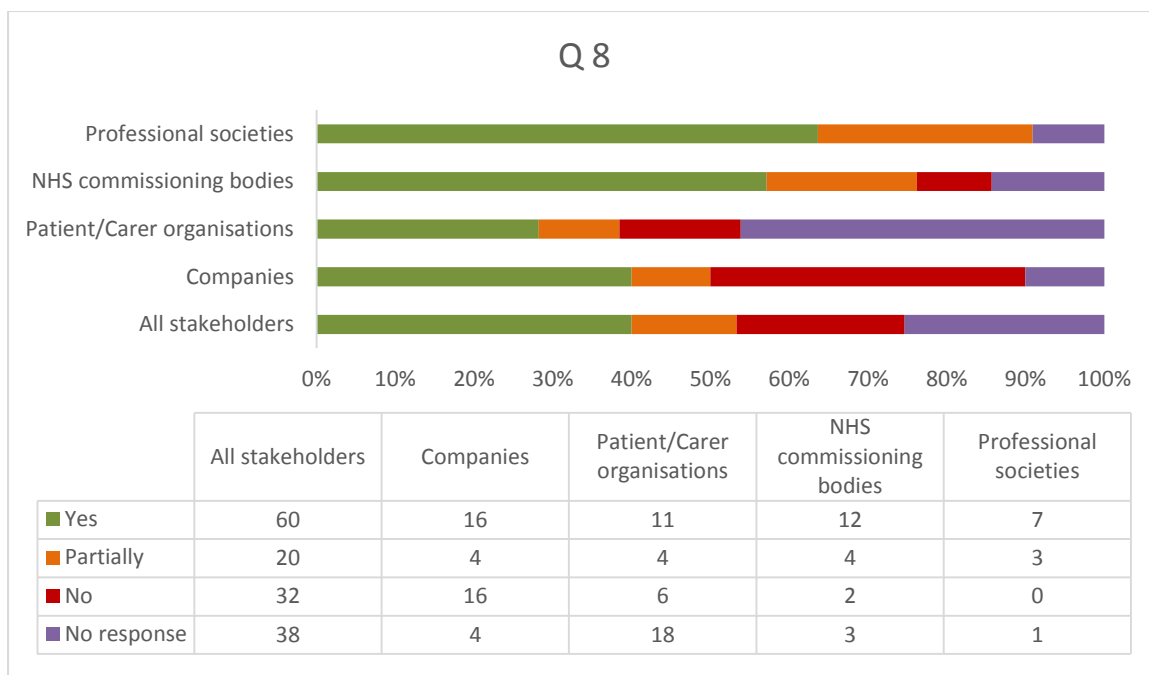
40% (60) of respondents agreed with the proposal, 13% (20) partially agreed and 22% (33) did not agree. The wording of this question caused confusion amongst stakeholders, with some stakeholders agreeing or disagreeing for the same reason – that the ATA/FTA processes should both be available as options.

Companies

Highlighted responses:

Agreed

- 'Yes, where the stages are in alignment. Although the 2 distinct routes (abbreviated and fast-track) should remain, given their slightly different objectives.' [Cook Medical UK]

- 'Bayer supports the development of a suite of appraisal processes or approaches to ensure the route used is proportionate to the intervention in question' [Bayer]

Disagreed

- 'These two processes should remain separate routes of appraisal, with differing criteria and outputs' [Chiesi]

- 'It is difficult to understand how either process is designed to work and the new proposals further confuse the already complex appraisal environment within the UK' [AbbVie]

Patient/Carer organisations

Highlighted comments:

Agreed

- 'it would be simpler to have one shorter process for very cost effective medicines. We understand from the consultation events that "integrate" is a more accurate description of the intention than "absorb" and it makes sense to align two schemes with similar objectives and scope.' [Prostate Cancer UK]

- 'We agree with this proposal and welcome any move to simplify and consolidate the process for assessing the most cost effective medicines' [The Brain Tumour Charity]

Disagreed

- 'No. The abbreviated technology appraisal should be used where there is a 2nd or successive generation drug where the budget impact creates a saving or is cost neutral and should apply across all new technologies including NICE HST.' [Association For Glycogen Storage Disease (UK)]

NHS commissioning bodies

The only comments received in response to this question are that this proposal would simplify the process.

Other responses

Comments in agreement:

- 'It is not clear what 'absorb its proposed 'abbreviated' technology appraisal process into the proposed fast track process' means. That these two processes should as far as possible be the same seems sensible' [University of York]

- 'As long as the consolidated process is equally or more efficient that its existing predecessors. The new absorbed appraisal process must also be appropriately explained to all levels of stakeholders so they can engage and monitor its effectiveness' [Brain Tumour Research]

Comments that did not agree:

- 'The criteria for each of the processes are different and they should remain separate' [European Medicines Group (EMG)]

Section 4 – Linking NICE and NHS England processes for evaluating highly specialised technologies

Question 9: Do you agree that NICE and NHS England should use a cost per QALY below which the funding requirement is applied for Highly Specialised Technologies?

Q 9

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Professional societies
■ Yes	34	4	2	11	6
■ Partially	14	2	2	5	2
■ No	71	31	23	3	0
■ No response	31	3	12	2	3
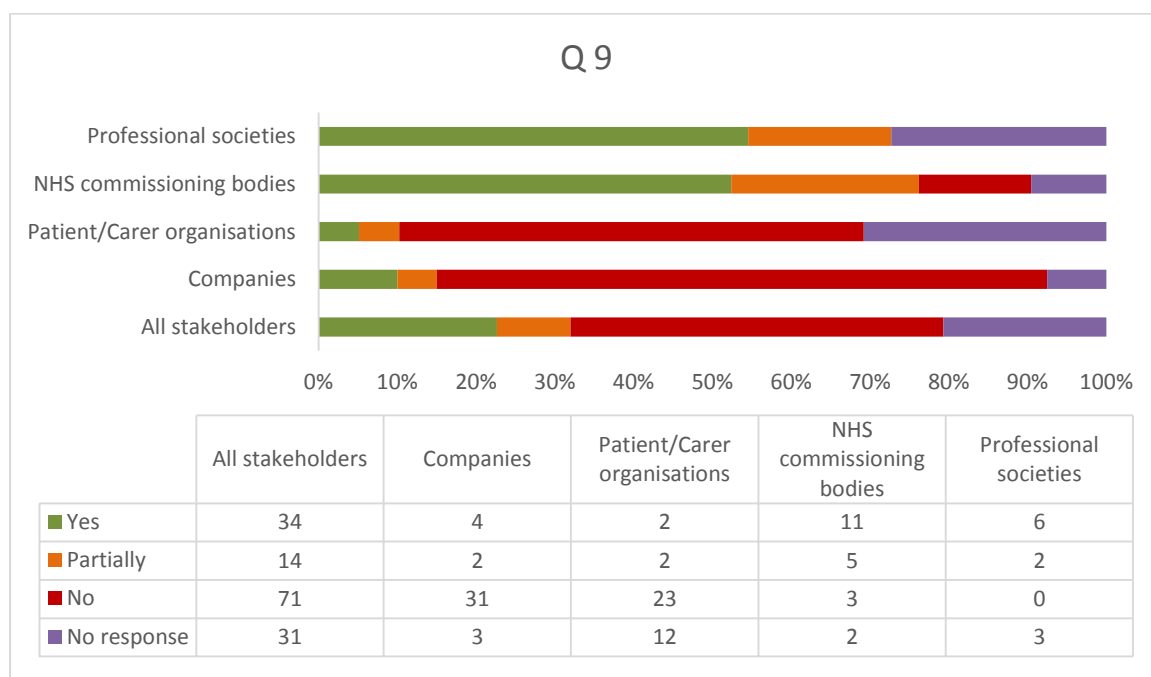
23% (34) of respondents agreed with the proposal, 9% (14) partially agreed and 47% (71) did not agree.

Companies

There was strong opposition to this proposal from companies, 78% (31) of whom did not agree with the introduction of cost per QALY for assessing highly specialised treatments. 10% (4) agreed with the proposal and 5% (2) partially agreed.

Highlighted comments:

Agreed

- 'We support this proposal to use a similar methodology to evaluate the applicability of funding requirements for Highly Specialised Technologies as for other technologies.' [Boston Scientific]

Disagreed

- 'No evidence has been presented as to why such a change of approach is needed. HST was established on the understanding from NICE that for ultra-orphan conditions a cost per QALY is an inappropriate metric to fully assess the benefit of such medicines' [Amicus Therapeutics ltd]

- 'We are strongly opposed to the introduction of a specific cost-effectiveness threshold into the HST process but we support further research to develop an appropriate structured decision making process for ultra-orphan medicines, as well as orphan medicines' [Shire Pharmaceuticals]

- 'the funding requirement should be based on unmet clinical need. A process that allows a holistic consideration of the clinical outcomes, unmet need and budget impact would appear to provide a much better indication of the value that a particular treatment might bring to patients and to the NHS. It can already be seen from the technologies that have been reviewed via the HST process that a cost per QALY threshold is inappropriate to assess and fully capture the value of these technologies' [PTC Therapeutics]

Patient/Carer organisations

Patient/carer organisations were also strongly opposed to this proposal. The majority of patient/carer organisations involved in the consultation represented rare diseases. 59% (23) disagreed with the proposal. Only 10% (4) either agreed or partially agreed, split evenly between the options.

Highlighted comments:

Agreed

- 'If this proposal helps more medicines to receive a positive recommendation then we would support this proposal' [Breast Cancer Now]

Disagreed

- 'We do not believe that cost per QALY should apply to Highly Specialised Technologies' [Batten Disease Family Association]

- 'There are significant problems in relation to QALYs and rare disease medicines. The implication of this proposal is that access to rare disease medicines above a threshold cost per QALY would be blocked' [Tuberous Sclerosis Association]

- 'Whilst QALY is a rational standard, there needs to be a movement to consider a more holistic approach and other health economic formulas and the involvement of healthcare professionals, economic specialists and most importantly patients and carers.' [Action Duchenne]

NHS commissioning bodies

Once again, the NHS commissioning bodies contrasted the views of companies and patient/carer organisations by supporting this proposal. 52% (11) agreed with the proposal, with a further 28% (6) partially agreeing. Only 3 NHS commissioning bodies disagreed with the proposal.

Highlighted comments:

Agreed

- 'This would seem appropriate from an equity perspective as all other treatments considered by NICE use a cost per QALY threshold' [NHS East and North Hertfordshire CCG]

Disagreed

- 'The cost/QALY needs to be equitable for all. I think if there are different cost/QALY for different things then the process could be up for challenge as to why?' [Chiltern and Aylesbury Vale Clinical Commissioning Groups]

Other responses

Highlighted comments in agreement:

- 'The healthcare system operates on a finite budget, money spent in one area is not spent in another. It should therefore all be treated with extreme care.' [Individual]

Highlighted comments that disagree:

- 'This could disadvantage patients with extremely rare diseases, and could deter manufacturers from developing innovative treatments for extremely rare conditions' [All Wales Medicines Strategy Group]

Question 10: Do you agree that £100,000 per QALY is the right maximum up to which the funding requirement would be applied? If not, what cost per QALY do you suggest, and why?

Q 10

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Professional societies
Yes	16	2	0	4	6
Partially	17	2	2	7	1
No	79	32	21	5	2
No response	38	4	16	5	2
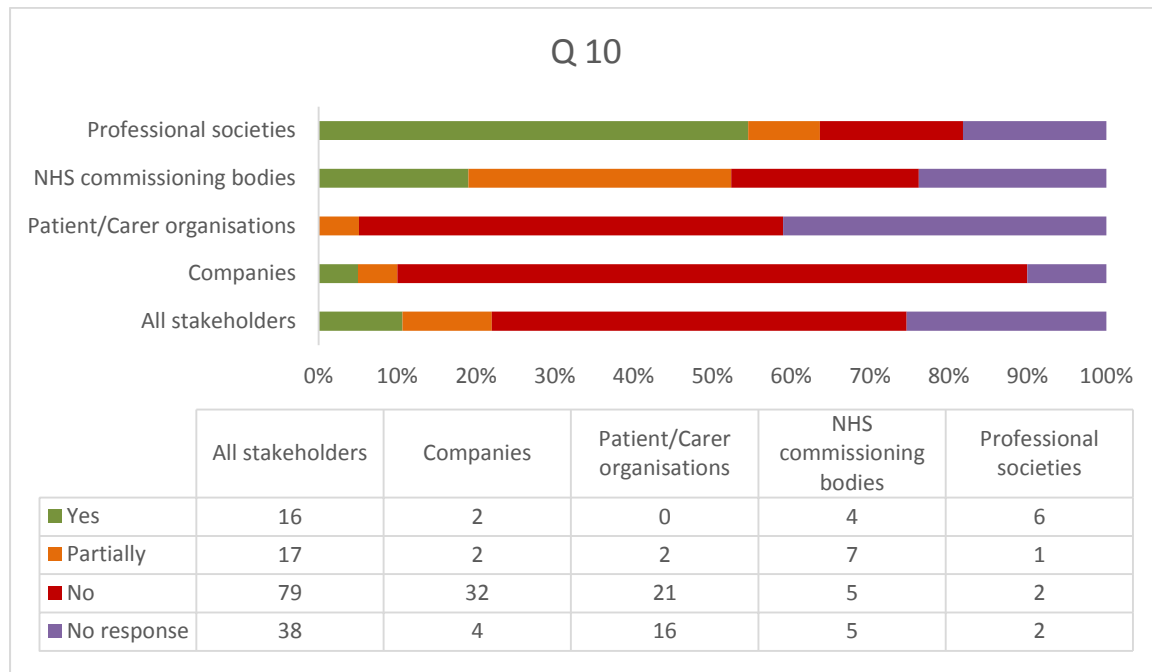
11% (16) of respondents agreed with the proposal, 11% (17) partially agreed and 53% (79) did not agree.

Companies

Again, companies were opposed with this proposal. 80% (32) disagreed with only a combined 10% (2, 2) either agreeing or partially agreeing.

Highlighted comments:

Agreed

- 'Boehringer Ingelheim believes that the proposed threshold of £100,000 per QALY gained for Highly Specialised Technologies is reasonable' [Boehringer Ingelheim]

Disagreed

- 'None of the 3 medicines that have gone through HST to date were close to being £100,000 per QALY and it is fair to say that it is unlikely for any ultra-orphan medicine to achieve and ICER below based on the incremental costs (especially if versus no treatment/palliative care) and incremental QALY gain seen for rare diseases' [Amicus Therapeutics Ltd]

- '£100,000/QALY is an arbitrary figure, not underpinned by validated methodology.' [Amgen Ltd]

- 'There is a lack of transparency reported within the consultation document as to how the cost effectiveness threshold of £100,000 has been derived. With no validated methodology underpinning the threshold presented it is not possible to comment as to whether it is the right maximum. Given the nature of the HST process, it seems unlikely that many medicines for rare diseases would fall under the proposed threshold of £100,000 per QALY. Therefore, the mandatory requirement for funding by NHS bodies would be lost, disadvantaging patients with limited/ if any treatment options' [MSD UK Ltd]

Patient/Carer organisations

Patient/Carer organisations were also opposed to this proposal. 53% (21) disagreed, 2 organisations partially agreed but none supported the proposal.

Highlighted comments:

Agreed

- 'Broadly yes, but there should be a degree of flexibility built into the threshold for special circumstances, eg for older patients where the cost of life-changing treatments are likely to be amortisable over fewer years than for younger patient' [Leber's Hereditary Optic Neuropathy Society]

Disagreed

- 'Going forward the £100,000 cost per QALY will without any doubt condemn children and adults with an ultra-rare disease to an early death by an arbitrary Government health policy' [Association For Glycogen Storage Disease (UK) Limited, Gauchers Association and the Society for Mucopolysaccharide Diseases]

- 'We do not understand how and why the £100,000 cost per QALY was chosen. NICE and NHSE must set out how they reached this estimate' [Cancer 52 and CML Support

- 'The HST QALY ceiling of £100,000 per QALY doesn't appear to be rooted in a rigorous methodology and it is unclear how this figure has been calculated. Inclusion of an arbitrary figure not rooted in evidence violates NICE's Charter' [Cystic Fibrosis Trust]

NHS commissioning bodies

33% (7) of NHS commissioning bodies partially agreed with this proposal, with a further 19% (4) agreeing. 24% (5) did not agree.

Highlighted comments:

Stakeholders that agreed with the £100,000 threshold did not provide any additional comments.

Disagreed

- 'should be less; the NHS cannot afford this' [South Worcestershire CCG, Redditch and Bromsgrove CCG and Wyre Forest CCG]

- 'if a more lenient threshold is given then funding will be needed from the government to implement this. It will be highly expensive' [Chiltern and Aylesbury Vale Clinical Commissioning Groups]

Other responses

Highlighted comments that agree:

- 'On balance, this is reasonable, given the potential development costs and small population to treat.' [The Royal College of Ophthalmologists]

- 'Agree that a much higher threshold is needed for these drugs' [Royal College of Paediatrics and Child Health]

Highlighted comments that disagree:

- 'There are very valid reasons why society may be willing to accept a higher cost effectiveness threshold for innovative technologies targeting rare and very rare diseases. However, NICE's appraisal committees have historically dealt with such considerations through deliberation and discretionary judgement rather than through the operation of a hard threshold' [King's College London]

- 'In the absence of a commissioning framework that establishes the special status of rare and ultra rare diseases, we consider that the threshold of £100,000 is too high as it will displace much more cost effective technologies for other conditions' [Faculty of Public Health]

- 'this appears to be an arbitrary sum, dependent on factors that have not been fully described' [Brain Tumour Research]

Question 11: Do you agree that if the cost per QALY level is exceeded, the technology should be considered through NHS England's specialised commissioning prioritisation process?

Q 11

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Professional societies
■ Yes	27	3	2	7	5
■ Partially	12	1	2	4	1
■ No	75	29	22	7	3
■ No response	36	7	13	3	2
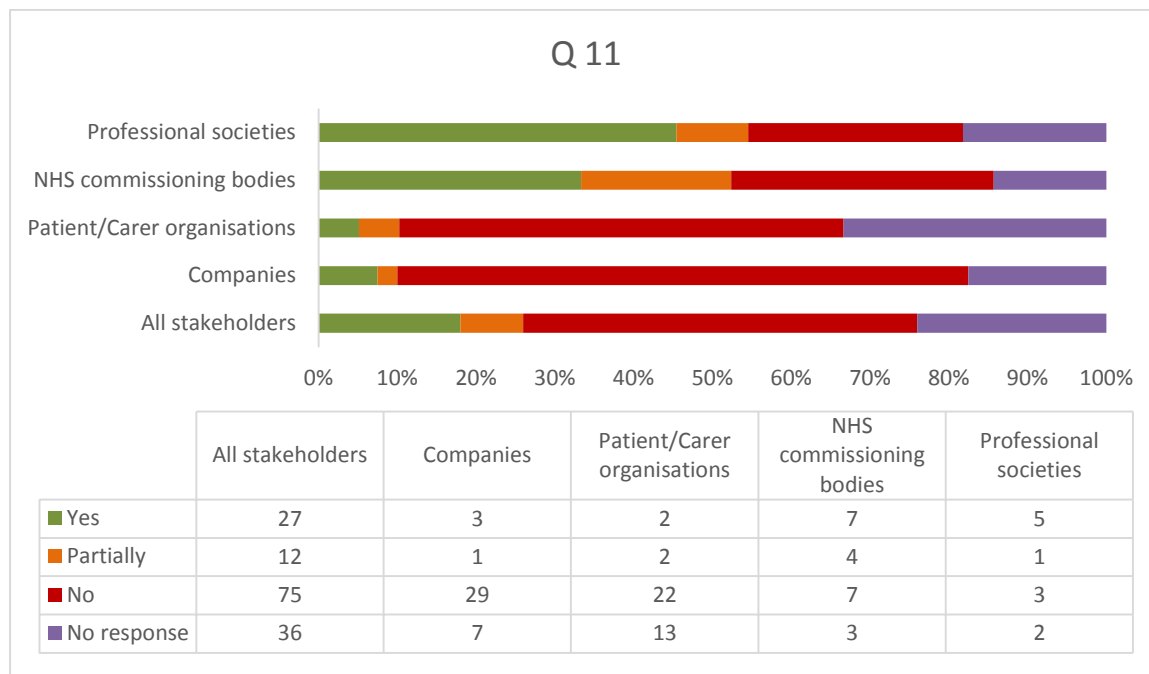
18% (27) of respondents agreed with the proposal, 8% (12) partially agreed and 50% (75) did not agree.

Companies

Reinforcing their opposition to the proposals on HST 73% (29) of companies did not agree with this proposal. 10% (4) either agreed (3) or partially agreed (1) with the proposal.

Highlighted comments:

Agreed

- 'Any opportunity for dialogue in these situations is welcome. However, any alternative "prioritisation process" for technologies which exceed the cost per QALY level for HST should be well-defined and subject to rigorous consultation and transparency, as is the case for all NICE appraisal methods' [Biogen]

Disagreed

- 'If technologies have to first go through NICE assessment to determine if they exceed what is clearly an arbitrary threshold, then this would cause lengthy

delays to access, particularly in cases where the timing of NICE assessment does not align with scheduled NHSE prioritisation rounds' [Amgen Ltd]

- 'The NHS England prioritisation process is not the optimal route for highly specialised technologies due to existing delays and a lack of transparency in the process by which decisions are made.' [MAP BioPharma Limited]

- 'Greater clarity, transparency of process and speed of process would be needed before this route for commissioning could be supported' [NAPP Pharmaceuticals]

Patient/Carer organisations

Again, patient/carer organisations did not support this proposal. 56% (22) did not agree with the proposal, 10% (4) either agreed (2) or partially agreed (2) with the proposal.

Highlighted comments:

Agreed

- 'if it seems that if this is a very special case it seems sensible to consider it under a different category and probably under different budget constraints' [The Cure Parkinson's Trust]

Disagreed

- 'It is surely mistaken for NICE and NHS England to propose directing Highly Specialised Technologies to an assessment and prioritisation route which has been acknowledged as deficient in that… The ultimate impact would be a discriminatory, slow moving system which failed to facilitate innovation for smaller patient groups, potentially creating a serious breach of trust' [Specialised Healthcare Alliance]

- 'CPAG's "one size fits all" prioritisation mechanism disfavours interventions for smaller patient populations. Furthermore, the sequential review of medicines would inevitably impede timely uptake of innovative medicines.' [Tuberous Sclerosis Association]

- 'The specialised commissioning prioritisation process is not currently fit for purpose with respect to its current remit. The process should be functional before its scope is expanded.' [Genetic Alliance UK]

NHS commissioning bodies

NHS commissioning bodies were divided in response to this proposal. 33% (7) agreed with the proposal whilst another 33% (7) disagreed. 19% (4) partially agreed with the proposal.

Highlighted comments:

No additional comments were provided by organisations that agreed with this proposal.

Disagreed

- 'The NHS should utilise one source of information that considers value for money and that should be NICE – if NICE do not accept that the technology meets that threshold then the NHS should not commission it' [South East London Area Prescribing Committee]

- 'As the process splits there is a danger that inconsistent appraisal methodologies are used and potential for lower access criteria for higher cost therapy' [East Surrey CCG]

Other responses

Highlighted comments that agree with the proposal:

- 'We would be supportive of this approach, as long as there is a robust, fair and transparent process for prioritising medicines that exceed £100,000 per QALY alongside all other technologies that enter the annual prioritisation process' [Welsh Health Specialised Services Committee]

Highlighted comments that disagree with the proposal:

- 'The cost-effectiveness threshold should be set at an appropriate level where this would not be required for new highly specialised technologies.' [BMJ]

- 'We do not consider this arrangement to be fair because it places a small (and poorly defined) subset of technologies at a significant advantage compared with others' [King's College London]

- 'The NHS England prioritisation process is not the optimal route for highly specialised technologies due to existing delays and a lack of transparency in the process by which decisions are made' [European Confederation of Pharmaceutical Entrepreneurs]

Question 12: Do you agree the proposed new arrangements mean that NICE would not need to take budget impact into account in its highly specialised technologies evaluations?

Q 12

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Professional societies
■ Yes	17	3	2	4	1
■ Partially	15	3	2	4	0
■ No	74	29	12	11	6
■ No response	44	5	23	2	4
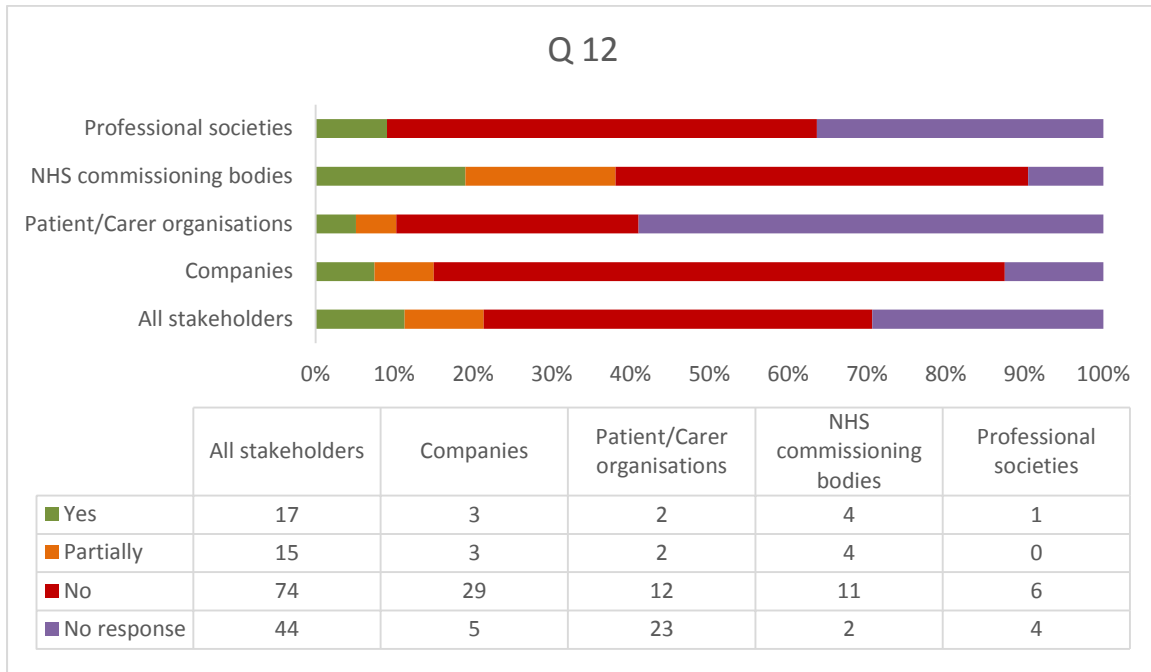
11% (17) of respondents agreed with the proposal, 10% (15) partially agreed and 49% (74) did not agree.

Companies

73% of companies did not agree that budget impact should not be considered for HST evaluations. 15% (6) either agreed (3) or partially agreed (3) with the proposal.

Highlighted comments:

Agreed

No substantive comments were received from companies that agreed with this proposal.

Disagreed

- 'The previous HST positive recommendations have, invariably, incorporated a managed access agreement, as such it would be potentially ill advised to suggest that budget impact will no longer be a key consideration with highly specialised treatments.' [Akcea Therapeutics]

- 'The "purity" of the NICE process should be maintained and its guidance should reflect the cost-effectiveness and benefit that the technology brings to

the NHS. There should not be change to the HST process.' [Napp Pharmaceuticals]

Patient/Carer organisations

58% (23) of patient/carer organisations did not respond to this question. 30% did not agree with the proposals and once again 10% (4) either agreed (2) or partially agreed (2) with the proposal.

Highlighted comments:

Agreed

- 'Budget impact threshold is unlikely to be exceeded due to the rarity of the diseases considered in the HST process' [Kidney Cancer Support Network]

Disagreed

- 'Budget impact should be considered, as long as it is done so in a fair, equitable and transparent way that does not discriminate against ultra-rare patient communities' [Niemann-Pick UK]

NHS commissioning bodies

In contrast to responses to the previous HST questions, NHS commissioning bodies did not agree that budget impact should not be considered. 52% (11) did not agree with the proposal, 21% (4) agreed and another 21% (4) partially agreed.

Highlighted comments:

Agreed

No substantive comments were received from NHS commissioning bodies that agreed with this proposal.

Disagreed

- 'This is assuming that budgetary impact is all placed on NHSE as opposed to CCGs. It may be determined that CCGs are the commissioners of the technology and if this is the case, the budget impact would be applicable as there is no singular prioritisation process for CCGs as there is for NHSE' [Bedfordshire Clinical Commissioning Group]

- 'any consideration should be a balance of value for money and affordability and therefore the proposed £20m threshold is equally applicable' [South East London Area Prescribing Committee]

Other responses

Highlighted comments that agree with the proposal:

- 'I expect so, as the population sizes are so small that the threshold is unlikely to be affected the size of spend' [University of Sheffield]

Highlighted comments that disagree with the proposal:

- 'Budget impact will always need to be taken into account' [Institute for Clinical and Economic Review]

- 'while budget impact is seldom significant for very rare conditions, some assessment would nevertheless continue to make sense as part of a financially aware approach to commissioning.' [European Confederation of Pharmaceutical Entrepreneurs]

Section 5 – General comments

Question 13: Do you consider that any proposals in this consultation would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation?

Q 13

	All stakeholders	Companies	Patient/Carer organisations	NHS commissioning bodies	Professional societies
■ Yes	67	25	22	7	1
■ Partially	10	1	5	3	0
■ No	34	5	3	8	6
■ No response	39	9	9	3	4
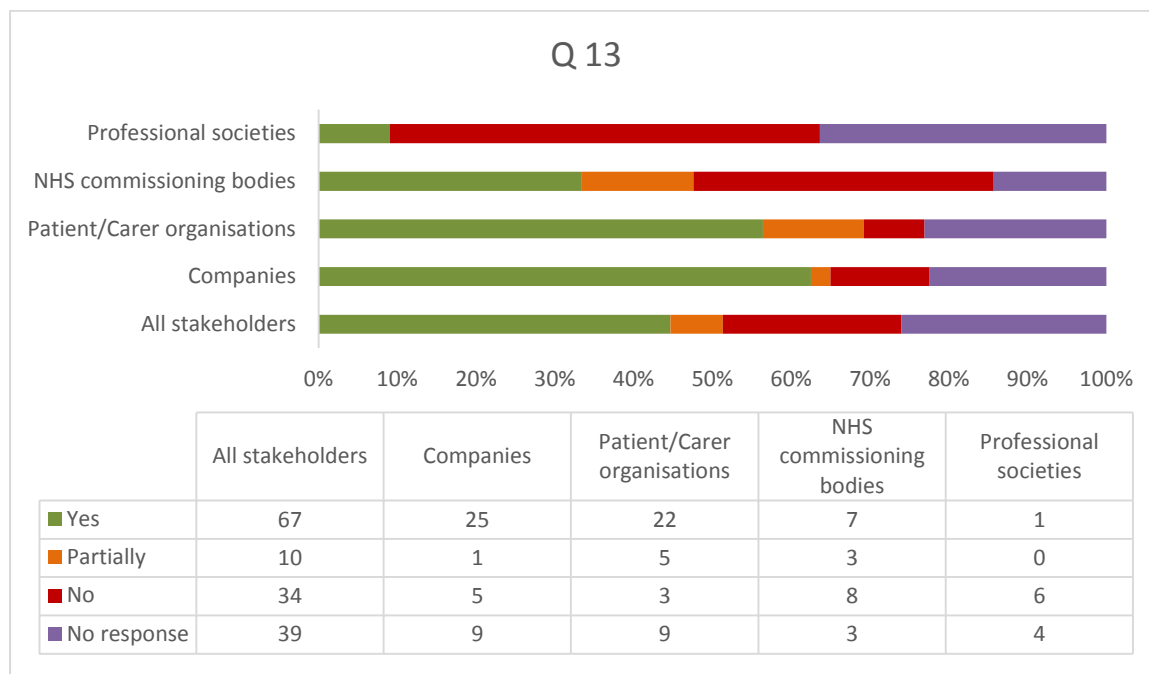
45% (67) of respondents agreed that the proposals would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation, 7% (10) partially agreed and 23% (34) did not agree.

Companies

63% (25) of companies agreed that the proposals would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation, 13% (5) did not agree and one organisation partially agreed.

Highlighted comments:

Yes

- 'we have some concern that the implementation of the budget impact threshold is likely to disproportionally affect technologies related to cancer treatment. This, in combination the decision to assess all cancer treatments and other measures now in place to assess promising cancer treatments earlier, suggests an inequitable concentration of resources around oncology' [Roche Diagnostics]

- 'There is a danger that the proposals for HSTs would in most cases prevent patients with very rare conditions from accessing clinically effective treatments, leaving them behind (and untreated) in a way which was not intended by the NHS Constitution' [Sobi Ltd]

No

No substantive comments were received from companies that did not think the proposed changes would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation.

Patient/Carer organisations

56% (22) of patient/carer organisations agreed that the proposals would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation, 13% (5) partially agreed and 8% (3) did not agree.

Highlighted comments

Yes

- 'there are substantial risks attendant to the proposals for Highly Specialised Technologies, which would systematically disadvantage people with rare conditions' [Specialised Healthcare Alliance]

- 'As civil servants involved in the health service, the priority should be patients and wider society. The whole premise of this consultation seems to be about cost and not approving the most innovative and promising new medicines that would benefit those of greater need.' [Action Duchenne]

- 'We are very concerned about how the budget impact threshold and the associated potential delays would impact on patients with terminal and end of life conditions. These patients cannot afford to wait longer for medicines to be introduced and are often relying on the next breakthrough treatment to become available so they can have another option of treatment. The higher accepted cost per QALY of £50,000 for end of life medicines, would in fact make these medicines more likely to be halted by the budget impact threshold proposals' [Prostate Cancer UK]

No

No substantive comments were received from patient/carer organisations that did not think the proposed changes would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation.

NHS commissioning bodies

33% (22) of NHS commissioning bodies agreed that the proposals would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation, 14% (3) partially agreed and 38% (8) did not agree

Highlighted comments:

Yes

- 'We have concerns that disease rarity is a very poorly defined basis for offering differing ICER thresholds. With the rapid advances in genotyping and personalised medicine it seems possible that even relatively common diseases such as breast cancer could be split into a series of rare diseases.' [South East London Area Prescribing Committee]

No

No substantive comments were received from NHS commissioning bodies that did not think the proposed changes would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation.

Other responses

Highlighted comments that feel that the proposals would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation:

- 'The use of arbitrary thresholds suggests that the sole purpose of NHS England and NICE is to control the financial impact of new medicines. There is not enough consideration given to the clinical and wider value of these treatments and the varied needs of the people who might benefit from them.' [European Confederation of Pharmaceutical Entrepreneurs]

- 'It is understood that no impact assessments have been conducted regarding how either the £20 million budget impact threshold or the £100,000 cost per QALY for HST will impact patient access and outcomes. This is of significant concern. With two out of three of the highly specialised technologies NICE has published final guidance on meeting the £20 million budget impact threshold, it is highly likely that patients with rare diseases would be adversely impacted by these changes' [British Society of Gastroenterology]

Highlighted comments that feel that the proposals would not result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation:

- 'The Faculty strongly supports this consultation as an important step in improving the equitable provision of effective healthcare' [Faculty of Public Health]

- 'No, however this may result in CCGs or providers failing to comply.' [Bridgewater Community Healthcare NHS Foundation Trust]

General comments

183 general comments were received in addition to responses to questions included in the consultation. Of these comments, 11 were further comments on budget impact, 2 on varying timescales, and 19 on the FTA process and 17 on HST.

Highlighted general comments:

- 'Going forward NICE and NHS England need to come up with a policy setting out their expectations on data they require in order to appraise new therapies for ultra-orphan diseases.' [Society for Mucopolysaccharide Diseases]

- 'The complexity of the language used in the consultation questions is a barrier to patient groups/representatives engaging with this consultation. The questions could have been put much more simply and perhaps accompanied by an example/diagram/process map where relevant.' [PNH Support]

- 'The circumstances for all the situations when technologies do or don't meet the cost/QALY and/or the budget threshold is confusing and inconsistent. It would help if it could be demonstrated as part of a pathway.' [South Worcestershire CCG, Redditch and Bromsgrove CCG and Wyre Forest CCG]

- 'Timescales for implementation proposed as April 2017 – this could have serious implications for CCGs financial and implementation planning who are planning for at least the next 2 years. A clear timetable of which drugs are involved in any of these processes should be published as soon as possible.' [Thames Valley and Wessex Commissioning Pharmacists Group]

- 'whilst the initiative is welcomed, BioMarin is concerned that the consultation does not specifically consider the clinical need of the patients. The overarching driver for prioritization of treatments in our view should be based on clinical need where clinical need should consider severity of disease, availability of alternative effective treatment options, potential for substantive improvement in health and quality of life. If a significant need exists for a patient and a treatment is potentially available, then the review of this treatment and any resulting mechanism that enables faster access should be accelerated.' [BioMarin Europe Limited]

- 'the proposals at issue here seem to be at odds with the AAR move to accelerate transformative technologies to create patient benefit sooner. In fact, with a budget threshold set to effectively delay implementation of a technology, for example where it could benefit a larger population, the proposals appear to run counter to the AAR altogether' [Kidney Research UK]

- 'Please can you clarify how this will impact on EAMs scheme' [Leeds North CCG, Leeds South & East CCG and Leeds West CCG, Leeds Teaching Hospital NHST, Leeds and York partnership FT]

- 'The proposals in the consultation document potentially represent that pragmatic way forward up to 2020. The two important caveats are that the costs of new drugs, both those that are fast-tracked and those that are above the cost impact threshold, should be tracked transparently in aggregate and by provider where necessary. This will ensure that the policy is having the intended effect to reduce new cost pressures and that individual providers are properly reimbursed. In the long run, and in the context of the UK's post-Brexit economy, it will be important that the NHS is properly funded to meet demand, that patients' access to new medicines and technologies is not constrained and that the NHS is able to remain a globally attractive partner for biomedical researchers and the life sciences industry.' [The Shelford Group]

Appendix A

List of stakeholders

Companies

- AbbVie
- Agendia NV
- Akcea Therapeutics
- Alexion Pharmaceuticals UK
- Alnylam Pharmaceuticals
- Amgen Ltd
- Amicus Therapeutics Ltd
- AstraZeneca

- Bayer
- Biogen
- BioMarin Europe Limited
- BlueBird Bio
- Boehringer Ingelheim
- Boston Scientific
- Bristol-Myers Squibb Company
- Celgene UK & Ireland

- Cell Medica, Ltd.
- Chiesi
- Cook Medical UK
- Eli Lilly and Company Ltd
- Genomic Health
- Gilead Sciences Ltd
- GSK
- Incyte Biosciences UK Ltd
- Janssen and J&J Medical
- Kyowa Kirin
- MAP BioPharma Limited
- Medtronic
- Merck
- MSD UK Ltd
- Napp Pharmaceuticals
- Novartis
- Novo Nordisk Ltd
- Pfizer
- PTC Therapeutics
- Roche Diagnostics
- Roche Products Ltd
- Servier Laboratories Ltd
- Shire Pharmaceuticals
- Sobi Ltd

Patient/Carer organisations

- Action Duchenne
- ALD Life
- Alzheimer's Research UK
- Alzheimer's Society
- Association For Glycogen Storage Disease (UK) Limited
- Asthma UK
- Batten disease family association
- Bloodwise
- Breast Cancer Care
- Breast Cancer Now
- Cancer 52
- Children's liver disease foundation
- CML Support Group
- Cystic Fibrosis Trust
- Diabetes UK
- Duchenne UK
- Gauchers Association
- Genetic Alliance UK
- Kidney Cancer Support Network

- Kidney Research UK

- Leber's Hereditary Optic Neuropathy Society

- Leukaemia CARE

- Lymphoma Association

- MS Society

- Muscular Dystrophy UK

- Myeloma UK

- National Aids Trust

- Niemann-Pick UK

- Pancreatic cancer UK

- Parkinson's UK

- PNH Support

- Prostate Cancer UK

- Society for Mucopolysaccharide Diseases

- Specialised Healthcare Alliance

- Target Ovarian Cancer

- The Brain Tumour Charity

- The Cure Parkinson's Trust

- The Haemophilia Society

- Tuberous Sclerosis Association

Professional Societies

- Association of Breast Surgery

- British Association of Dermatology

- British Society for Allergy and Clinical Immunology

- British Society of Gastroenterology

- British Society of Neuroradiologists

- Faculty of Public Health

- Royal College of Paediatrics and Child Health

- Royal College of Physicians

- The Royal College of Anaesthetists

- The Royal College of Ophthalmologists

- UK Neurointerventional Group

NHS Organisations

- Bedfordshire Clinical Commissioning Group

- Bridgewater Community Healthcare NHS Foundation Trust

- Chiltern and Aylesbury Vale Clinical Commissioning Groups

- Derbyshire Joint area prescribing committee

- East of England Priorities Advisory Committee

- East Surrey CCG

- Eastbourne Hailsham & Seaford CCG, Hastings and Rother CCG

- Guildford & Waverley Clinical Commissioning Group

- Leeds North CCG, Leeds South & East CCG and Leeds West CCG, Leeds Teaching Hospital NHST, Leeds and York partnership FT

- NHS Dorset Clinical Commissioning Group

- NHS East and North Hertfordshire CCG

- NHS England Specialised Commissioning (Midlands & East Region)

- Norfolk & Waveney Therapeutics Advisory Group

- North Central London Joint Formulary Committee

- Nottingham City CCG

- Oxfordshire CCG

- Paediatric Neurosciences Clinical Reference Group

- Pharmacy Eastern Network

- Salford Royal NHS Foundation Trust

- South East London are prescribing committee

- South Worcestershire CCG, Redditch and Bromsgrove CCG and Wyre Forest CCG

- Surrey Downs CCG

- Thames Valley and Wessex Commissioning Pharmacists group

- UK Genetics Testing Network

- York and Scarborough Medicines Commissioning Committee

Other organisations

- ABHI

- ABPI

- All Wales Medicines Strategy Group

- American Pharmaceutical Group

- Association of Medical Research Charities

- BioIndustry Association

- BIVDA

- Brain Tumour Research

- Cancer Research UK

- Device Access UK Ltd

- Ethical Medicines Industry Group (EMIG)

- European Confederation of Pharmaceutical Entrepreneurs

- European Medicines Group (EMG)

- Health Foundation

- Institute for Clinical and Economic Review

- King's College London

- Manchester Metropolitan University

- MAP BioPharma Limited

- Mapi Group

- Milliman - Health Actuarial Services

- The Institute of Cancer Research

- The Medical Technology Group

- The Shelford Group

- UK Medicines Information

- Universities Allied for Essential Medicines UK

- University of Edinburgh

- University of Leeds

- University of Sheffield

- Welsh Health Specialised Services Committee

Appendix B

Declaration of interest disclosures

Stakeholders were asked to declare whether they had received any payments, grants or other funding from the pharmaceutical industry in the last three years. Unfortunately, 53% (82) of stakeholders did not provide a response to this question.

Declarations of Interest

	Overall	Acadae mia	Compani es	Compan y trade associati ons	Individua ls	Other	NHS Trust's	NHS Commiss ioning bodies	NHS Organisa tions	Patient/ Carer organisa tions	Professio nal Societies	Research organisa tions
Yes	54	0	4	4	1	3	0	7	0	30	2	2
No	17	3	1	0	1	2	0	3	1	3	3	1
No response	79	3	35	5	0	2	2	11	1	6	6	4
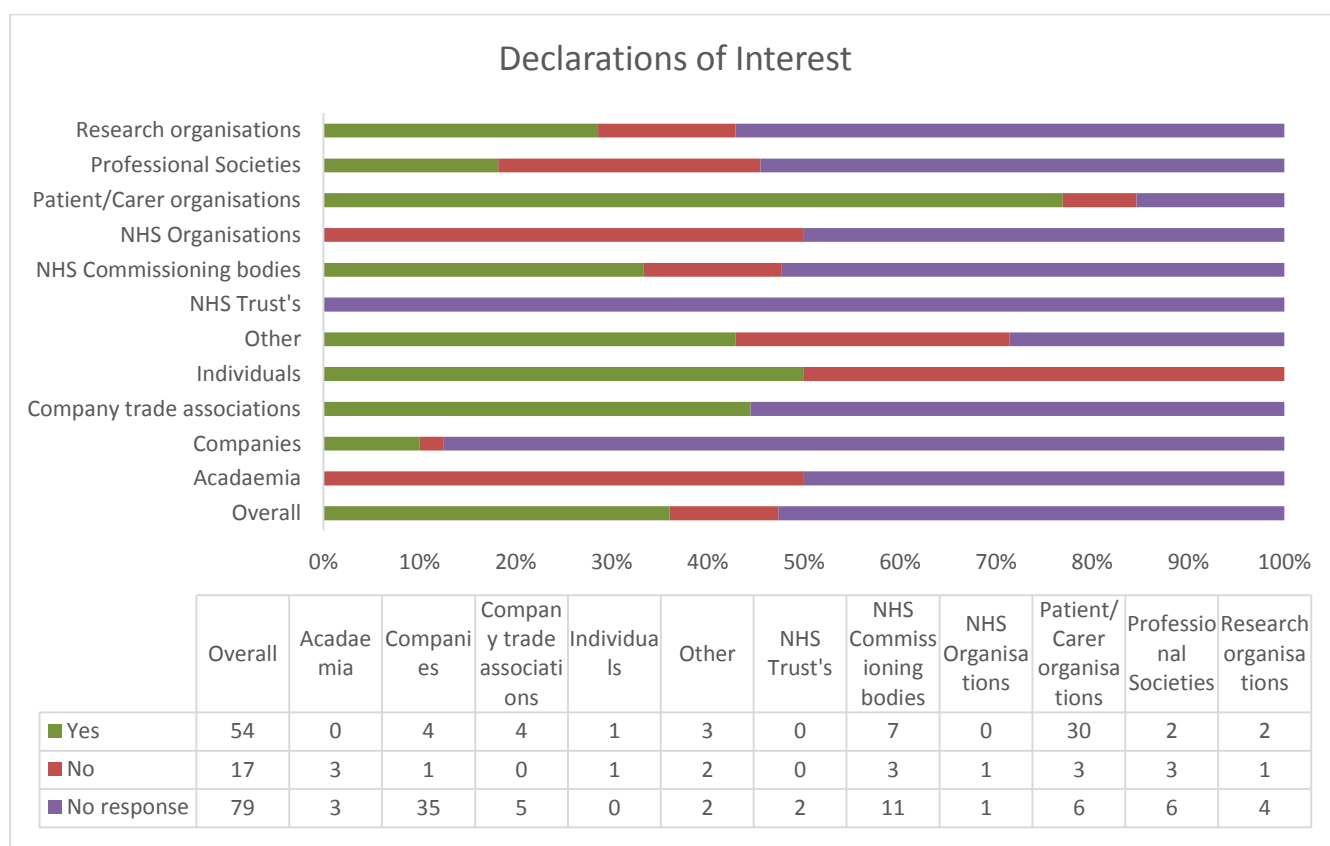
Overall, 36% (54) of stakeholders declared they had received payments from the pharmaceutical industry in the past 3 years. Of the non-company stakeholders 46% (46) declared a payment within the last 3 years.

The stakeholder group with the highest percentage of respondents affirming that they had received such payments were patient/carer organisations, 77% (30) of whom said they had received payments from industry.

National Institute for Health and Care Excellence (NICE) and NHS England

Proposals for changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE's technology appraisal and highly specialised technologies programmes

Version number: 1

First published: 13 October 2016

Prepared by: NICE and NHS England

National Institute for Health and Care Excellence (NICE) and NHS England

Proposals for changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE's technology appraisal and highly specialised technologies programmes

Why are NICE and NHS England proposing to make changes?

1. NICE and NHS England intend to work together more closely to better manage access to new drugs and medical technologies (devices and diagnostics) by simplifying and speeding up some appraisals, and by making the arrangements for funding others more clear. The proposed changes will benefit patients by providing access to the most effective and cost-effective new treatments more quickly and will help the life sciences industry by increasing the opportunities for companies to help manage the introduction of their new technologies into the NHS.

2. The NHS is committed to providing timely access to new treatments, but introducing new technologies in a way that is both good for UK business and, at the same time, optimises the financial sustainability of the NHS can be challenging. This consultation sets out a number of ways in which NICE and NHS England can provide an environment that encourages the life sciences industry and the NHS to work together in the best interests of patients. By facilitating collaboration and providing opportunities for early dialogue between innovators and the NHS, and by speeding up appraisal and adoption processes, NICE and NHS England can enable the development of arrangements that deliver the right outcomes for both patients and the life sciences industry.

3. The proposals set out in this document provide:

    *   Quicker access for patients to the most cost-effective new treatments.

    *   More flexibility in the adoption of cost-effective, high budget impact technologies into the NHS.

    *   Greater clarity for patients and companies about the point at which treatments for very rare conditions that are appraised by NICE will automatically qualify for funding from routine commissioning budgets.

What are the consultation proposals?

4. NICE and NHS England propose to:

- Introduce a 'fast track' NICE technology appraisal process for the most promising new technologies, which fall below an incremental cost-effectiveness ratio of £10,000 per QALY (quality adjusted life year), to get these treatments to patients more quickly.

- Operate a 'budget impact threshold' of £20 million, set by NHS England, to signal the need for a dialogue with companies to agree special arrangements to better manage the introduction of new technologies recommended by NICE. This would apply to a small number of technologies that, once determined as cost effective by NICE, would have a significant impact on the NHS budget.

- Vary the timescale for the funding requirement when the budget impact threshold is reached or exceeded, and there is therefore a compelling case that the introduction of the new technology would risk disruption to the funding of other services.

- Automatically fund, from routine commissioning budgets, treatments for very rare conditions (highly specialised technologies) up to £100,000 per QALY (5 times greater than the lower end of NICE's standard threshold range), and provide the opportunity for treatments above this range to be considered through NHS England's process for prioritising other highly specialised technologies.

Why is this a joint consultation between NICE and NHS England?

5. NICE appraises the clinical and cost effectiveness of new health technologies. In doing so, it takes account of the fact the NHS has fixed resources available to it. NHS England manages the budgets that enable care to be provided and has a statutory responsibility to ensure that its functions are exercised effectively, efficiently and economically within the funds provided to it by the Department of Health.

6. The importance of taking account of the financial impact when managing the introduction of new drugs and other technologies was highlighted by the Public Accounts Committee which recommended that *'The Department of Health and NHS England should, in collaboration with NICE, ensure affordability is considered when making decisions that have an impact on specialised services. For example, building in consideration of how the cost of implementing NICE recommendations can be kept affordable within available commissioning*

budgets, and by using national bargaining power to get best prices for high-cost drugs'.[1]

7. The independent Accelerated Access Review has also identified the general issue of affordability, as well as emphasising the importance of developing a collaborative framework through which transformative technologies can be moved quickly through development, evaluation and adoption.

8. NHS England and NICE have worked together to develop the best approach to implementing these proposals and this consultation sets out how both organisations propose to develop and coordinate their processes. Some of the proposals in this consultation relate to NICE's processes and methods and others to the way in which NHS England manages its budgets. In some cases, the changes that NICE is proposing to make are a consequence of the approach that NHS England wants to take. In others, the changes are being proposed by NICE. In all cases, the proposals have been agreed by both organisations, subject to the outcome of consultation.

The changes in more detail

NHS England budget impact threshold

9. NHS England, as the budget holder, is responsible for allocating funding for new technologies. Some new technologies that meet the NICE cost-effectiveness threshold also have a high budget impact. In order to balance value and affordability, NHS England believes that special arrangements should be put in place to manage the budget impact of the new treatment in order to avoid compromising access to other forms of care. NHS England proposes that these special arrangements would be triggered when a technology being appraised by NICE, through its technology appraisal and highly specialised technologies programmes, is estimated to exceed a 'budget impact threshold'.

10. It is important to note that budget impact and the application of a budget impact threshold will not influence NICE's consideration of the clinical and cost effectiveness of a technology. It will be used to inform the arrangements, described below, which NHS England will seek to put in place to help manage the impact of technologies, recommended by NICE, which have a very high budget impact.

11. Having considered the frequency and magnitude of high budget impact NICE-recommended technologies, NHS England proposes to set the threshold at £20 million per annum. NICE will assess the potential budget impact by estimating the net annual cost to the NHS. The threshold would be regarded as having been triggered if it is projected to be reached or exceeded in any of the first 3 financial years of its use in the NHS. NICE will take advice from the manufacturer and clinical experts in making this estimate. It should be noted that the budget impact threshold is not necessarily the maximum amount that the NHS would commit to funding a new technology in any one financial year.

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[1] Committee of Public Accounts' 10th report of the 2016-17 session

12. It is anticipated that only a small number of new technologies recommended by NICE would exceed this budget impact threshold. An analysis of positive technology appraisals published between June 2015 and June 2016 reveals that around 80% of new technologies recommended by NICE fell below the proposed budget impact threshold.

13. For those technologies that receive a positive NICE recommendation, but are above the budget impact threshold, NICE would signal the need for a commercial agreement between the company and NHS England. When agreement is reached and this brings the budget impact below the threshold, the standard 90-day funding requirement would apply.

14. When it is not possible to fully address the budget impact challenge, NHS England may ask NICE to vary the standard funding requirement and make a case for NICE to allow a longer period of phased introduction. The nature of NHS England's request to NICE to vary the funding requirement would reflect any commercial agreement that NHS England and the company have been able to reach. Patient access schemes would remain the main route to ensuring a product is considered cost effective during the NICE appraisal process.

15. Technologies recommended by NICE that fall below the proposed budget impact would be unaffected by these arrangements.

Varying the timescale for the funding requirement

16. NICE would consider requests from NHS England to vary the funding requirement when the budget impact threshold is expected to be exceeded in any of the first 3 years of the use of a technology in the NHS. The length of any variation and potential phasing of implementation of NICE guidance would necessarily depend on the individual circumstances for each technology and any commercial arrangements NHS England and the company are able to agree.

17. Under current regulations NICE can consider extending the standard 3-month period of deferred funding (the funding requirement) if it considers that one or more of the criteria it is allowed to apply is satisfied. One of these criteria indicates that NICE may vary the funding requirement if it considers that*: 'the health technology cannot be appropriately administered until other appropriate health services resources, including staff are in place'*. This applies in both the technology appraisal and highly specialised technologies programmes.

18. NICE considers that 'resources', as referred to in this criterion, includes the availability of funds and that application of the criterion in this way is consistent with its duty to have regard to the broad balance between the benefits and costs of the provision of health services or of social care in England. By doing this, NICE can help to ensure that the necessary resources can be made available for the introduction of new technologies with large, in-year budget impact or with large and enduring budget impacts over time, without causing disruption to other services.

NICE fast track process

19. NICE needs to ensure that the weight and complexity of its appraisals are in proportion to the technical challenges and the risks posed by the evidence that it considers. In line with this, NICE proposes to introduce a 'fast track' appraisal process for the appraisal of health technologies for which a confident judgement about value for money can be made at an early stage. The fast track route would be a variant of the standard technology appraisal process.

20. The aim would be to make available, more quickly, those technologies that NICE can be confident would fall below £10,000 per QALY, and whose budget impact is below the threshold set by NHS England. This cost per QALY level has been selected because technologies with incremental cost-effectiveness ratios at or below £10,000 per QALY can, with a reasonable degree of certainty, be predicted at an early stage in their evaluation as potentially cost effective. Between 2007 and 2014, around 15% of NICE's technology appraisals fell at or below £10,000 per QALY in the final guidance. The introduction of a fast track process would enable them to be routed through a lighter touch appraisal process, speeding up access for patients.

21. The proposed £10,000 cost per QALY level for the fast track process would not change the current standard NICE cost-effectiveness threshold range of £20,000 to £30,000 per QALY. Treatments with incremental cost-effectiveness ratios of between £10,000 and £30,000 per QALY could still be recommended, subject to the application of NICE's published methods.

22. The criteria for application for a technology to be appraised through a fast track process would be:

    - The availability of strong evidence (with a low degree of decision uncertainty) that products would be cost effective at or below £10,000 per QALY.

    - An estimate that the budget impact of the technology would fall under the proposed budget impact threshold for the full patient population relevant to the appraisal.

23. Technologies would be identified through the standard topic selection and referral processes. Companies would be invited to indicate that they would like their product to follow a fast track appraisal. Once referred and when an evidence submission is received, entry into the fast track process would be considered by NICE following an analysis of the company's submission, supported by an external review. If, following this analysis, the selection criteria cannot be satisfied with sufficient confidence, the topic would be re-routed to the standard technology appraisal process.

24. In the case of a newly licensed technology, NICE would undertake a fast track appraisal to enable draft guidance to be issued, in the case of new drugs, immediately after the European Medicines Agency issues the Committee on Human Medicinal Products' opinion. Final guidance, on new drugs, would be published immediately following the publication of the marketing authorisation.

The process for other types of technologies would follow a similar course, taking account of the regulatory processes that apply to individual products.

25. Fast tracked technologies that fall below the proposed £10,000 cost per QALY level and the proposed budget impact threshold would be provided with access to NHS funding within 30 days of the publication of final NICE guidance.

26. The fast track route would involve companies and NICE using less resource. NICE estimates that it would be able to make a 25% saving in process time compared with standard appraisals, with final guidance issued up to 3 months earlier than normal. Companies would need to invest less time in engaging with NICE.

27. The essential elements in the fast track appraisal route are set out below, and presented in the flow diagram in appendix 1:

   - standard topic selection and scoping processes
   - a request from the company to use the fast track route
   - ministerial referral of the topic onto NICE's work programme
   - an evidence submission by the company that holds, or has filed for, the marketing authorisation, or medical technologies equivalent
   - an initial evidence review by NICE, supported by an external review
   - a final decision by NICE that the topic is suitable for the fast track process, following a review of the applicability of the selection criteria
   - the production of a technical briefing by the NICE technical team, supported by an external review
   - consideration by an appraisal committee
   - the publication of a final appraisal determination
   - the opportunity for an appeal
   - a funding requirement when NICE has published guidance.

28. Unlike the standard NICE technology appraisal process, the fast track route would not need the following process elements, which would therefore facilitate a more rapid process:

   - A second appraisal committee meeting (because failure to demonstrate clinical and cost effectiveness at the committee meeting would mean that the technology would be re-routed through the standard appraisal process).

   - Consultation on draft recommendations (because NICE does not normally consult on positive draft recommendations).

   - Attendance of clinical experts, patient experts, commissioning experts, the evidence review group (ERG) and the company (because the basis of the fast track process is built on a clear and convincing case for the clinical and cost effectiveness of the technology).

29. Normally, the elapsed time from the invitation to make an evidence submission in the fast track process to the publication of final guidance would be expected to be 32 weeks. The standard process takes 43 weeks.

30. The NICE technology appraisal process already has a number of variants designed to respond to the particular characteristics of the technologies when, for example, appraising cancer drugs, and those medicines recommended through the early access to medicines scheme.

31. Because a number of arrangements proposed for the fast track appraisal would also apply to an 'abbreviated' technology appraisal process, on which NICE has recently consulted, it is proposed that the abbreviated process should be absorbed into the fast track process. This will mean that topics can be considered for the fast track process irrespective of whether NICE guidance has been published for the key comparator.

32. These proposed process changes are supplemental to NICE's current guide to the processes of technology appraisal.

Linking NICE and NHS England processes for evaluating highly specialised technologies

33. NICE evaluates a small number of (mainly) drugs for very rare conditions each year through its highly specialised technologies programme. NHS England considers many others through its own specialised commissioning prioritisation process. It is therefore important that the 2 processes are properly linked.

34. To help achieve this, it is proposed that the funding requirement for NICE guidance will be applied to technologies it recommends, up to £100,000 per QALY, which is 5 times greater than the lower end of NICE's standard threshold range and would typically allow for a significant additional cost over the standard care comparator. This would provide greater clarity for patients and companies about the point at which highly specialised technologies would receive automatic funding from routine commissioning budgets.

35. Technologies with a QALY value above £100,000 per QALY would not be subject to the funding requirement but would be provided with a further opportunity to be considered for use in the NHS through the NHS England process for prioritising other highly specialised technologies.

36. NICE and NHS England believe that these arrangements would lead to greater equity and consistency in the prioritisation of funding for highly specialised services across the whole range of NHS England's responsibilities for specialised care.

37. NICE would undertake an assessment of the budget impact of the technology as described elsewhere in this consultation. This assessment would be made before the first meeting of the highly specialised technologies committee. The budget impact assessment would not be presented to the committee since it only has a bearing on a consideration of whether a dialogue is needed between NHS England and the company or whether the funding requirement should be deferred. This would be a change to the current interim methods, which require the committee to take account of budget impact in its consideration of the evidence.

38. When the budget impact appears likely to exceed the budget impact threshold, the company would be asked to engage with NHS England, facilitated by NICE through its 'safe harbour' service which provides an opportunity for confidential discussions on matters relating to a current or future evaluation undertaken by NICE. The purpose of this engagement would be to provide an opportunity for the company to propose ways to manage the budget impact of the adoption of the technology, through a commercial agreement with NHS England.

39. Technologies that fall below £100,000 per QALY and the budget impact threshold, with or without a patient access scheme or a commercial agreement, would continue to proceed on the standard highly specialised technologies evaluation timeline.

40. When a product is determined to be below £100,000 per QALY but the NHS England budget threshold is estimated to be exceeded despite the earlier opportunity to reach a commercial agreement, the process would be paused at this point for a maximum of 12 weeks to provide for a second opportunity for a commercial agreement to be reached.

41. In the event that a product is determined to be below £100,000 per QALY, and has exceeded the budget impact threshold, but for which a commercial agreement has not been reached, NICE would nevertheless publish its final draft guidance and NHS England would be able to ask NICE for a variation to the funding requirement.

42. Technologies above £100,000 per QALY would not be funded through the funding requirement but would then be considered by NHS England for funding through its annual specialised commissioning prioritisation process.

43. These proposed process changes are supplemental to NICE's current interim process and methods of the highly specialised technology programme.

Proposed changes to NICE's standard technology appraisals

44. In NICE's standard technology appraisal process, an assessment would be made of the budget impact of the technology as described elsewhere in this consultation. This assessment would be made before the first meeting of the appraisal committee. The budget impact assessment would not be presented to the committee since it only has a bearing on a consideration of whether a dialogue is needed between NHS England and the company or whether the funding requirement should be deferred.

45. When the budget impact appears likely to exceed the budget impact threshold, NICE would ask the company to engage with NHS England, facilitated by NICE through its 'safe harbour' service, which provides an opportunity for confidential discussions on matters relating to a current or future evaluation undertaken by NICE. The purpose of this engagement would be to provide an opportunity for the company to propose ways to manage the budget impact of the adoption of the technology, through a commercial access agreement with NHS England.

46. Products that fall below the standard NICE threshold range and the budget impact threshold, with or without a patient access scheme or a commercial access agreement, would continue to proceed on the standard appraisal timeline.

47. Where a product is determined to be clinically and cost effective at the appraisal committee meeting, but the NHS England budget threshold is estimated to be exceeded despite the earlier opportunity to reach a commercial access agreement, the appraisal process would be paused at this point for a maximum of 12 weeks to provide for a second opportunity for a commercial access agreement to be reached.

48. In the event that a product is determined by the appraisal committee to be clinically and cost effective, but a commercial access agreement has not been reached, NICE would nevertheless publish its final draft guidance and NHS England would be able to apply to NICE for a variation to the funding requirement.

49. These proposed process changes are supplemental to NICE's current guide to the processes of technology appraisal.

Implementation

50. NICE will introduce the fast track process option routinely for technology appraisal topics referred from 1 April 2017.

51. For technology appraisal topics referred before 1 April 2017, and when the company evidence submission deadline is set for later than 1 April 2017, companies can approach NICE to discuss access to the fast track process.

52. The arrangements for the consideration and application of the budget impact threshold will apply from 1 April 2017.

53. The use of the cost per QALY level for the funding requirement for highly specialised technologies evaluations will apply to topics that have their first committee meeting after 1 April 2017.

Consultation questions

NHS England budget impact threshold

1 Do you agree that NHS England should set a budget impact threshold to signal the need to develop special arrangements for the sustainable introduction of cost-effective new technologies?

2 Do you agree that £20 million is an appropriate level? If not, what level do you think the threshold should be set at and why?

3 Do you agree that NHS England should enter into a dialogue with companies to develop commercial agreements to help manage the budget impact of new technologies recommended by NICE?

Varying the timescale for the funding requirement

4 Do you agree that NICE should consider varying the funding requirement for technologies it recommends, for a defined period, in circumstances where NHS England makes a case for doing so, on the grounds that the budget impact of the adoption of a new technology would compromise the allocation of funds across its other statutory responsibilities?

NICE fast track process

5 Do you consider that the criteria for the fast track process are appropriate? If not, what other criteria do you suggest?

6 Do you agree that NICE should 'fast track' new health technologies with a maximum incremental cost-effectiveness ratio of £10,000 per QALY and whose costs are estimated to fall below the budget impact threshold?

7 Do you agree that NHS England should commit to accelerating funding for technologies approved under the fast track process from 90 days to 30 days?

8 Do you agree that NICE should absorb its proposed 'abbreviated' technology appraisal process into the proposed fast track process?

Linking NICE and NHS England processes for evaluating highly specialised technologies

9 Do you agree that NICE and NHS England should use a cost per QALY below which the funding requirement is applied for highly specialised technologies?

10 Do you agree that £100,000 per QALY is the right maximum up to which the funding requirement would be applied? If not, what cost per QALY do you suggest, and why?

11 Do you agree that if the cost per QALY level is exceeded, the technology should be considered through NHS England's specialised commissioning prioritisation process?

12 Do you agree the proposed new arrangements mean that NICE would not need to take budget impact into account in its highly specialised technologies evaluations?

Other

13 Do you consider that any proposals in this consultation would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation?

Appendix 1: Comparison of indicative timelines for a standard appraisal and the fast track process

Weeks	Standard Appraisal	Fast Track Process
0	Invitation to participate	Invitation to participate
8	Evidence submission received	Evidence submission received
10/11	Clarification	*Final decision for FTA process*
18	ERG report received	Technical brief completed
	Committee preparation	Appraisal committee meeting
21	Appraisal Committee meeting	
24	Consultation	FAD for Appeal
29	Appraisal Committee meeting	Final guidance
34	FAD for Appeal	
43	Final Guidance	

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Technology Appraisal and Highly Specialised Technologies programmes

Procedure for varying the funding requirement to take account of net budget impact;

1 Introduction

1.1 This document describes the procedure involved in varying the funding requirement, in cases where NHS England has made an application for NICE to do so, on the grounds that a technology has exceeded the budget impact test.

1.2 This document should be read in conjunction with NICE's Guide to the Processes of Technology Appraisal.

2 Policy context

2.1 The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013, further described as regulations, expect NICE to

- recommend[.] that relevant health bodies provide funding within a specified period to ensure that the health technology be made available for the purposes of treatment of patients' and

- 'specify in a technology appraisal recommendation the period within which the recommendation […] should be complied with', which 'must be a period that begins on the date the recommendation is published by NICE and ends on the date 3 months from that date'.

2.2 The Regulations state that 'if NICE considers it appropriate, NICE must specify a longer period', in the following circumstances:

1. 'the health technology cannot be appropriately administered until—

- - training is,

  - - certain health service infrastructure requirements including goods, materials or other facilities are, or

  - - other appropriate health services resources, including staff, are, in place; or

  2. the health technology is not yet available in England'.

2.3   The regulations require NICE, where it is minded to specify a longer period, to consult with 'such persons with an interest in the appraisal of a health technology … 'about the appropriate period that may be specified in a technology appraisal recommendation', and that this consultation must include 'the Secretary of State and the [Commissioning] Board [now referred to as NHS England]'.

2.4   NHS England has indicated that it may request consideration of a longer time to implement the statutory funding requirements for technologies funded through its specialised commissioning budgets, where the potential net budget impact is expected to exceed £20 million per year in any of the first 3 financial years of its use in the NHS. NHS England has indicated that it will also do this on behalf of clinical commissioning groups, for locally commissioned technologies that have been appraised by NICE.

2.5   NHS England will offer to engage in commercial discussions with companies whose technologies have been appraised by NICE and where the budget impact test has been engaged before requesting a variation to the funding requirement.

2.6   An agreement may not result in a budget impact of less than £20 million per year in each of the first 3 financial years of the product's use in the NHS in England. In such cases, and where NHS England requests a variation to the funding requirement, NICE will take into account any relevant aspects of the agreement in responding to the variation request.

3   Process

Evidence submission

3.1   After receiving the company submission, NICE will make an assessment of the potential budget impact of the technology by estimating the net annual cost to the NHS; using the methods described in this guide.

3.2   NICE will inform the company and NHS England of any topic that it has assessed that is likely to exceed the net budget impact, normally within 12 working days after receiving the company submission.

3.3   Within 5 working days after receiving the net budget impact estimate, NHS England must indicate to NICE that it intends to pursue a commercial engagement with the company. This will allow NICE to plan in advance for potential changes to the timelines of a technology appraisal/HST evaluation.

3.4   The commercial engagement between the company and NHS England will be conducted in parallel with the appraisal/evaluation timescales. NHS England must provide a progress update to NICE at least 5 working days before the first appraisal/evaluation committee meeting. Any commercial agreements confirmed at this point will be to specifically manage the net budget impact of the technology will not be taken into account by the Appraisal/HST Committee in determining the cost effectiveness of the technology.

Figure 1 Steps in budget impact assessment (before the 1ˢᵗ appraisal/evaluation committee)

```
┌─────────────────────────────────────────────────────────┐
│           Company submission is received                 │
└─────────────────────────────────────────────────────────┘
                            ↓
┌─────────────────────────────────────────────────────────┐
│                      Week 2                              │
│           NICE assesses net budget impact                │
└─────────────────────────────────────────────────────────┘
            ↓                              ↓
┌───────────────────────────┐   ┌──────────────────────────┐
│ Budget impact test not    │   │ Budget impact test        │
│ triggered                 │   │ triggered                 │
│ No further action required│   │                           │
└───────────────────────────┘   └──────────────────────────┘
                        ↓                       ↓
        ┌───────────────────────┐   ┌──────────────────────────┐
        │        Week 3         │   │         Week 3            │
        │ NHS England confirm   │   │ NHS England confirm       │
        │ commercial discussion │   │ commercial discussion     │
        │ is not required       │   │ is required               │
        └───────────────────────┘   └──────────────────────────┘
                                              ↓
                                  ┌──────────────────────────┐
                                  │        Week 4-18          │
                                  │ NHS England liaises with  │
                                  │ the company               │
                                  └──────────────────────────┘
                                              ↓
                                  ┌──────────────────────────┐
                                  │         Week 19           │
                                  │ NHS England informs NICE  │
                                  │ of the outcome of the     │
                                  │ commercial discussion     │
                                  └──────────────────────────┘
```

Application to vary the funding requirement

3.5   NHS England can advise NICE that it may need to apply for a variation to the funding requirement directly after receiving the estimate of the net budget impact at the evidence submission stage, as described above, or at later stages in the technology appraisal or highly specialised technology evaluation, as described below.

3.6   When submitting a request for a variation, NHS England should provide the following information:

- The duration of the proposed variation;

- The relevant provisions of any commercial agreement reached with the company;

- In the case of a technology funded from the national specialised commissioning budgets, the amount and phasing of funding that will be made available and how it is intended that this should be applied to eligible patients;

- In the case of technologies funded by clinical commissioning groups, what direction NHS England intends to give about the phasing of funding during the deferred funding period;

- An assessment of the impact on patients, eligible for treatment under the guidance, but whose treatments will be delayed as a result of the funding variation;

- The measures proposed to ensure that the alternative timescale for the funding requirement is not exceeded;

First appraisal/evaluation committee meeting

3.7   When the Appraisal/HST Committee recommends the technology as an option or makes a recommendation that optimises use of the technology, NICE will update its assessment of the budget impact of the technology (see R&I process guide for details).

3.8   NICE will inform the company and NHS England of the (new) estimate for budget impact, at the same time an ACD or FAD is published.

3.9   If NHS England intends to pursue a commercial agreement with the company at this stage of the process, and it anticipates that it will need more time than the next phase of the NICE process provides for, it must formally notify NICE within 5 working days of being informed of the potential impact of the Committee's recommendations on the budget impact.

3.10 As the consideration of net budget impact does not influence the clinical and cost effectiveness of the technology, the next stage of the NICE process will continue as planned.

3.11 If an ACD or ECD has been issued, at the end of that stage, NICE will suspend the appraisal/evaluation process for a maximum of 12 weeks, to allow for a second opportunity for commercial engagement and inform consultees and commentators. NICE will determine the date at which the appraisal/evaluation will re-start. The subsequent appraisal/HST committee meeting will be rescheduled in line with the time required for concluding the commercial engagement.

3.12 If NHS England intends to apply for a variation to the funding requirement at this point, it must submit an application at the earliest opportunity, and no later than the end of the period of suspension of NICE's process.

3.13 Where a FAD or FED will be issued for appeal after the first appraisal committee meeting (straight to FAD/FED), NICE will not offer a formal pause in the process to allow the company and NHS England to re-enter into a commercial engagement period. NHS England and the company will be informed of the net budget impact in advance of release of the FAD/FED and will have an opportunity for commercial engagement in advance of the FAD publication.

Figure 2 Steps in budget impact assessment (after the 1st appraisal/evaluation committee) when a ACD/ECD is released

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┌─────────────────────────────────────────────────────────────────────┐
│              Appraisal/Evaluation committee meeting                   │
└─────────────────────────────────────────────────────────────────────┘
                                  ↓
┌─────────────────────────────────────────────────────────────────────┐
│                    Week 3 (release of ACD/ECD)                        │
│   NICE completes Budget impact assessment of appraisal topic and      │
│           informs NHS England and the company                         │
└─────────────────────────────────────────────────────────────────────┘
          ↓                                            ↓
┌──────────────────────────────┐        ┌──────────────────────────────┐
│ Budget impact test not       │        │ Budget impact test triggered  │
│ triggered                    │        │                               │
│ No further action required   │        │                               │
└──────────────────────────────┘        └──────────────────────────────┘
                              ↓                        ↓
        ┌──────────────────────────────┐  ┌──────────────────────────────┐
        │           Week 4             │  │           Week 4             │
        │ NHS England confirm          │  │ NHS England confirm          │
        │ commercial discussion is     │  │ commercial discussion is     │
        │ not required                 │  │ required                     │
        └──────────────────────────────┘  └──────────────────────────────┘
                                                           │
   ┌──────────────────────────────┐                       │
   │           Week 4             │───────────────────────┘
   │ TA/HST topic pause           │
   │ implemented                  │
   │ (up to 12 weeks)             │
   └──────────────────────────────┘
                                                   ↓
                            ┌──────────────────────────────┐
                            │          Week 4-16           │
                            │ NHS England liaises with the │
                            │ company                      │
                            └──────────────────────────────┘
                                           ↓
                            ┌──────────────────────────────┐
                            │          Week 16             │
                            │ NHS England informs NICE of  │
                            │ the outcome of the commercial│
                            │ discussion                   │
                            │ If a CAA isn't reached,       │
                            │ application for a variation   │
                            │ to the funding requirement is │
                            │ submitted                     │
                            └──────────────────────────────┘
```

Figure 3 Steps in budget impact assessment (after the 1st appraisal/evaluation committee) when FAD/FED is released

```
┌─────────────────────────────────────────────────────────────┐
│          Appraisal/Evaluation committee meeting               │
└─────────────────────────────────────────────────────────────┘
          │                                    │
          ▼                                    ▼
┌──────────────────────────┐      ┌──────────────────────────┐
│ Budget impact test not   │      │  Budget impact test       │
│ triggered                │      │  triggered                │
│ No further action        │      └──────────────────────────┘
│ required                 │            │              │
└──────────────────────────┘            ▼              ▼
```

Week 2	Week 2
NHS England confirm commercial discussion is not required	NHS England confirm commercial discussion is required

Week 3-4
NHS England liaises with the company

Week 4
NHS England informs NICE of the outcome of the commercial discussion
If a CAA isn't reached, application for a variation to the funding requirement is submitted

Week 5
Release of FAD/FED to consultees and commentators

Subsequent Appraisal/HST Committee meeting

3.14 If the Appraisal/HST Committee chooses to alter the draft recommendations, NICE will update its assessment of the budget impact of the technology, where appropriate (see R&I process guide for details). NICE will inform the company and NHS England of the updated budget impact, upon publication of the

FAD/FED. No further pause will be offered for the company and NHS England to re-enter into a commercial engagement period.

3.15 In the event that NHS England intends to apply for a variation to the funding requirement, it must submit an application at the earliest opportunity, and no later than the end of the period for consideration and lodging an appeal.

Guidance Executive

3.16 The NICE appraisal project team will present the application for a variation to the funding requirement to the NICE Guidance Executive (GE) at the earliest opportunity.

3.17 This can be at the stage of developing the ACD, to allow for consultation on GE's decision to take place at the same time as consultation on the recommendations, with the FAD/FED, or during the FAD/FED appeal period.

3.18 At each of these stages, GE will decide whether it is minded to vary the timescale for the funding requirement.

3.19 GE will consider a request from NHS England to vary the timescale for the funding requirement, taking the following into account:

- Has the budget impact test been met;
- Have all reasonable opportunities for commercial discussions been pursued;
- Is the request in proportion with the magnitude of the budget impact;
- Has the request taken account of the severity and acuity of the condition to which the guidance relates;
- Has a commissioning policy been developed for managing appropriate access to the technology during the funding variation period;

3.20 Regardless of the duration of the variation requested, all applications will need to contain proposals for a phased allocation of funding.

3.21 For products where the budget impact test is engaged, NICE Guidance Executive will consider applications to vary the funding requirement, normally

for up to a maximum of 3 years. In exceptional circumstances, a longer period may be considered.

3.22   Applications to vary the funding requirement are specific to each topic. However, when considering technologies with indications for which a technology has already been recommended and for which a funding variation is in place, NICE will take into account the total budget impact for both technologies, when considering an application for a funding variation for the second (and subsequent) technologies.

3.23   Where GE decides to vary the timescale for the funding requirement, this decision will be shared with consultees and commentators, including NHS England and the Secretary of State for Health, for a 3 week consultation period. The provisional decision will be placed on the NICE website 5 working days later; for information.

3.24   Comments received in consultation from consultees and commentators will be presented to the GE to reach a final decision on the timescale for the funding requirement. The decision and comments received will be published on the NICE website at the next appropriate step in the process.

3.25   The final guidance will make reference to the variation to the funding requirement (where appropriate).

3.26   In line with the regulations, consultees, including NHS England, can lodge an appeal against this decision.

3.27   As the decision to vary the timescale for the funding requirement is made by the GE, and not the TA or HST committee, a representative of Guidance Executive will attend the hearing on behalf of NICE.

NICE National Institute for
Health and Care Excellence

Figure 4 Steps in Guidance Executive assessment of application to vary the funding requirement
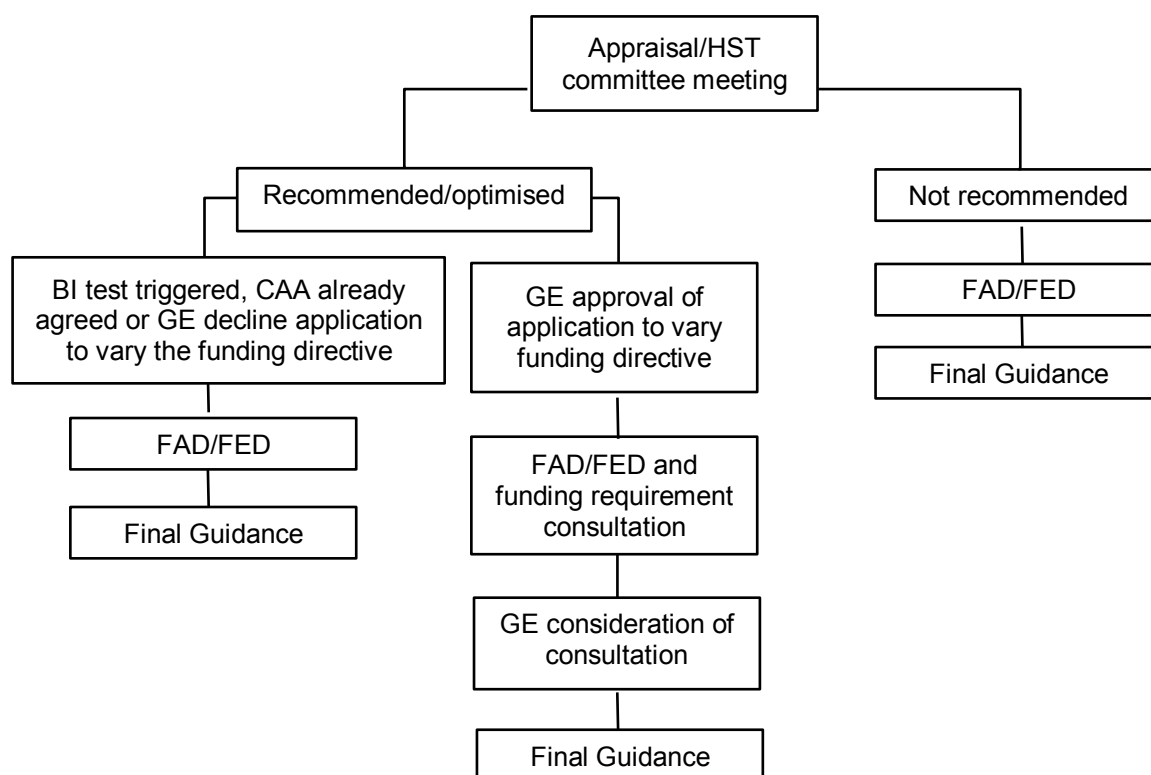
4 Information Handling

4.1   Please see section 3.1.7 – 3.1.29 of the Guide to the processes of technology appraisal for more detail on information handling within an appraisal/HST evaluation.

4.2   If the budget impact analysis for an appraisal/evaluation includes confidential details of a simple patient access scheme for a comparator technology, NICE will not share these details with the company for the new technology being appraised/evaluated. This may limit the level of information that can be shared within the company making the new technology being appraised. All information will be shared with NHS England, under a confidentiality agreement. Under this arrangement, NHS England has access to the confidential details of all patient access schemes.

5 Tools and resources

5.1 The implementation of the budget impact assessment within the appraisal process will not affect the publication of the advice and tools to support the local implementation of NICE guidance. This includes costing tools or statements for most technology appraisals and additional tools, for selected technology appraisals.

6 Methods

6.1 This section provides an overview of the methods for the analysis that supports net budget impact calculations. It builds on the methods outlined in section 5.12 (Impact on the NHS) of NICE's [guide to the methods of technology appraisal, and 'assessing resource impact process manual: technology appraisals and highly specialised technologies'](). This document should be read alongside both these guides.

6.2 The arrangements in this document do not change the consideration by the appraisal committee of the net budget impact of the adoption of a technology on NHS resources (see section 6.2.14 of the guide to the methods of technology appraisal).

6.3 The budget impact assessment will estimate the total net budget impact of providing the technology to the NHS in England as a direct consequence of the guidance. It will therefore be specific to the licensed indication of the technology that is likely to be part of the final guidance; starting with the value proposition by the company, and taking into account, over the course of the appraisal/evaluation, the recommendations being developed by NICE.

6.4 NICE will estimate the potential net budget impact for each appraisal/evaluation in accordance with the 'assessing resource impact process manual'. Key approaches used in this manual are:

- Focus on the cost to the commissioner;

- Sources for estimating future practice include previous uptake of similar technologies, and the NICE medicines and technologies programme;

- Use of a national tariff (price) where possible;

- Cost of the technology appraised and comparator as used in the appraisal (incl. patient access schemes, or commercial access arrangements directed at the value of a technology);

- Estimating costs and savings only as a direct consequence of implementing the guidance;

- Ensuring that costs and savings relate to the same time period (typically 1 year budget cycles);

- Based on accounting principles which may differ from health economic approaches

6.5   Companies are required to provide an estimate of the potential net budget impact, using the NICE evidence submission template for the technology appraisal and for the highly specialised technologies evaluation programme.

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Assessing resource impact process manual: technology appraisals and highly specialised technologies

Contents

1 Introduction

1.1 Overview of NICE

1.1.1 The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care.

1.1.2 NICE was originally set up in 1999 as the National Institute for Clinical Excellence, a special health authority, to reduce variation in the availability and quality of NHS treatments and care.

1.1.3 In 2005, after merging with the Health Development Agency, we began developing public health guidance to help prevent ill health and promote healthier lifestyles. Our name changed to the National Institute for Health and Clinical Excellence.

1.1.4 In April 2013 we were established in primary legislation, becoming a non-departmental public body, which places us on a solid statutory footing as set out in the Health and Social Care Act 2012. We took on responsibility for developing guidance and quality standards in social care, and our name changed to its current form to reflect these new responsibilities.

1.1.5 As a non-departmental public body, we are accountable to our sponsor department, the Department of Health, but operationally we are independent of government. Our guidance is developed by independent committees. The NICE Board sets our strategic priorities and policies, but day-to-day decision-making is the responsibility of our senior management team.

1.1.6 The way in which NICE was established in legislation means our guidance officially applies only to England. However, we have agreements to provide certain NICE products and services to Wales, Scotland and Northern Ireland. Decisions on how our guidance applies in these countries are made by the devolved

administrations, who are often involved and consulted during the development of NICE guidance.

1.2   Centre for Health Technology Evaluation

1.2.1   The Centre for Health Technology Evaluation is made up of 11 teams. It develops guidance on the use of new and existing medicines, including highly specialised technologies, treatments, medical technologies, diagnostics and surgical procedures within the NHS. In addition to its guidance producing activities, the centre is responsible for the Patient Access Scheme Liaison Unit, the science policy and research programme, scientific advice, topic selection and the office for market access.

1.3   NICE technology appraisal guidance

1.3.1   Technology appraisal guidance assesses the clinical and cost effectiveness of health technologies, such as new pharmaceutical and biopharmaceutical products, but also includes procedures, devices and diagnostic agents. This is to ensure that all NHS patients have equitable access to the most clinically- and cost-effective treatments that are viable. The technology appraisals team develops multiple technology appraisals and single technology appraisals. Appraisals provide recommendations on the use of new and existing medicines and treatments within the NHS in England and Wales.

1.4   NICE highly specialised technologies

1.4.1   Highly specialised technologies evaluations are recommendations on the use of new and existing highly specialised medicines and treatments within the NHS in England. The highly specialised technologies programme only considers drugs for very rare conditions.

1.4.2   Recommendations are made by an independent advisory committee. The highly specialised technologies evaluation

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committee considers a range of health and non-health related criteria and, after reviewing the evidence and commentary, reaches a consensus on whether the highly specialised technologies can be recommended for national commissioning.

1.5 Compliance with a NICE-approved medicine or treatment

1.5.1 Commissioners have a statutory responsibility to make funding available for a drug or treatment recommended by a NICE technology appraisal or highly specialised technologies within the timeframe recommended in that guidance. Compliance is therefore achieved if a clinician and their patient think a health technology is the right treatment and it is available on the NHS, as described in the NHS Constitution, which should not be impeded by national or local funding or formulary restrictions, or other health system or process barrier.

1.5.2 When NICE recommends a drug as 'an option', this is an option for the clinician and patient to consider alongside other potential treatments, not an option for commissioners or providers to not make the treatment available.

1.6 The purpose of this process manual

1.6.1 This process manual describes the role of the resource impact team in estimating the resource impact (cost or saving) of technology appraisals and highly specialised technologies and

providing support products to help organisations implement this NICE guidance.

1.6.2   Process manuals are produced to ensure that NICE work programmes are carried out in an open, credible, transparent and timely way, allowing input from internal and external stakeholders.

1.6.3   This process manual is written to:

- help the resource impact team work effectively with the technology appraisal and highly specialised technologies teams
- help other NICE teams and external stakeholders understand the role of the resource impact team.

1.6.4   It does this by:

- defining how the resource impact team works alongside technology appraisal and highly specialised technologies teams that produce the guidance
- describing the processes involved in developing resource impact products
- highlighting when liaison with internal and external stakeholders takes place.

1.6.5   The resource impact team works closely with technology appraisal and highly specialised technologies programmes, and this process manual should be read in conjunction with the following manuals:

- [Guide to the processes of technology appraisal](#)
- [Guide to the methods of technology appraisal](#)
- [Interim process and methods of the highly specialised technologies programme](#).

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1.6.6   This manual covers technology appraisal and highly specialised technologies programmes only. A separate manual has been produced for guidelines.

1.7   Overview of resource impact

1.7.1   The resource impact team estimates the cost or saving of implementing technology appraisal and highly specialised technologies guidance.

1.7.2   The team follows guidance development from an early stage and informs key stakeholders (NHS England, NHS Improvement) in order to help NHS financial planning about guidance that may have significant cost. This is normally at the stage when a draft recommendation is known and an appraisal consultation document is produced.

1.7.3   As well as costs and savings, the team gives advice to committees on wide-ranging issues such as workforce, capacity and demand, training, facilities and educational implications of the recommendations. It may also advise on where responsibility for implementation rests (by identifying the commissioners and providers) and who the costs or savings are for (the commissioner or provider).

1.7.4   The resource impact team also consider where services are delivered, for example primary or secondary care.

1.7.5   The team also gives strategic advice and information about the resource impact of guidance to national partner organisations including the Department of Health, Department for Education, NHS England, NHS Improvement and Public Health England.

1.7.6   The team's overall aim is to:

- help in the development of technology appraisal and highly specialised technologies guidance, by providing an initial

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estimate of the resource impact of implementing the recommendations

- inform healthcare organisations as early as possible about the likely resource impact of implementing the guidance, to support their financial planning

- support future financial planning by profiling the resource impact over the coming 5 financial years if possible

- provide a clear and concise resource impact report and template of the resource impact of implementing technology appraisal and highly specialised technologies guidance.

1.7.7   There is more information about how resource impact is calculated and how the resource impact team works in chapters 4 and 5.

1.8   Key audiences

1.8.1   Resource impact products are of interest and relevance to many external stakeholders:

Organisations

- Department of Health
- Department for Education
- NHS England
- Local authorities
- Public Health England
- NHS Improvement
- Clinical commissioning groups
- Royal Colleges
- Health Education England
- NHS Digital
- Health and social care providers
- Pharmaceutical companies
- Medical and diagnostic technology companies
- Academic Health Science Networks

- Organisations representing people who people who use health and social care services.

Individuals

- Health and social care professionals responsible for putting new technology appraisal guidance into practice
- Clinical directors and clinical managers
- Social care managers
- Business managers and finance managers in provider organisations
- Commissioning staff, including clinical leads and chairs in clinical commissioning groups and clinical and commissioning networks
- Staff with a responsibility for quality improvement
- People who use health and social care services, their families and carers, and the public.

2 Resource impact principles and perspectives

This chapter sets out the principles behind NICE resource impact products. This applies to all work undertaken by the resource impact team.

2.1 Principles

2.1.1 The following key principles underpin development of NICE resource impact products:

- Standard accounting principles are applied. These are set out in the NHS manual for accounts and NHS foundation trust annual reporting manual.
- Only direct consequences of implementing individual guidance recommendations are included.
- Resource impact changes cover only those funded by the NHS (this includes the funding of services provided by the public, private, third and charity sectors).

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- Assessments are consistent with the economic analysis in the guidance.
- The best available datasets are used and supplemented with expert opinion.
- Key stakeholders are consulted.
- National estimates are provided wherever possible.

2.1.2 The resource impact report focuses on the financial impact of guidance but also looks at other areas of resource impact, if relevant, such as:

- workforce
- capacity and demand
- infrastructure
- training and education.

2.2 Perspectives

2.2.1 The resource impact may differ when it is viewed from either the commissioner's or the provider's perspective. There will be a difference in whether activity for care and services is being commissioned or provided. For example, in the NHS acute activity falls mainly under national tariff, so the cost to commission activity informs commissioners of what they might be expected to pay in the future, and helps the provider to estimate expected income.

2.2.2 It is recognised a significant number of technologies appraised by NICE are high cost drugs and devices which are outside of the scope of national tariff.

2.2.3 For highly specialised technologies, which may not be paid by national tariff and for which bespoke arrangements are in place, the resource impact team works with the highly specialised technologies team and the commissioner. This ensures the

resource impact of commissioning such activity is correctly identified.

2.2.4   Generally resource impact reports focus on the cost to the commissioner. The provider is usually better placed than the commissioner to review what the change will mean in practice and to assess the actual cost of providing the activity.

2.2.5   It is difficult to provide full cost details for providers because of structural resource variations between providers. Implications for providers are highlighted if the information is robust.

3   Populations affected, activity levels and unit costs

This chapter describes the process of estimating populations and of identifying activity levels and unit costs of activity.

3.1   Background

3.1.1   To prepare a resource impact product we need to identify the population affected by the guidance, the likely change in activity as a result of the guidance and the unit cost associated with the recommended activity.

3.1.2   Resource impact processes meet information governance standards. This includes requesting, receiving, storing, sharing and destroying data in line with information governance requirements of NICE.

3.1.3   Where NHS Digital provide data (such as Hospital episode statistics) for resource impact assessments, the resource impact

team meet contractual and information governance requirements set out by NHS Digital.

3.2 *Population sources*

3.2.1 There are 2 main measures of population: resident population and registered population. The estimated resident population of an area includes everyone who usually lives there. The registered population is the number of people registered with a GP.

3.2.2 If possible, the resident population is used because the registered population may be overstated. The main reasons for this are people leaving the country or area and not notifying their GP, and the delay between a patient registering with a new GP and being removed from the register of their original GP.

3.3 *Incidence and prevalence data*

3.3.1 Incidence and prevalence measure different aspects of disease or care need in a population, although they are related.

3.3.2 The cumulative incidence of a particular condition is the proportion of a population who develop the condition in a defined time period. The incidence rate is the rate at which new events occur in a population.

3.3.3 The prevalence of a condition is the number of people in a given group or population who are reported to have the condition at a given time. It is important to understand the basis on which data on incidence and prevalence are gathered and presented.

3.3.4 Examples of incidence and prevalence:

- Annual incidence – the number of people who will develop a disease or have a care need over the course of a year; this is the most common way of expressing incidence.
- Point prevalence – the burden of disease or care need in a population at a particular point in time.

- Lifetime prevalence – a measure of how many people may be affected by a disease or have a care need during the course of their lifetime.

3.3.5 Both prevalence and incidence data may need to be considered within a single resource impact tool so that the resource impact of different recommendations can be calculated accurately. For example, to determine the annual treatment cost for a chronic condition lasting many years we need to know the prevalence, whereas the annual cost relating to initial diagnosis is linked to the annual incidence.

3.3.6 For highly specialised technologies, rare disease incidence and prevalence data are limited. Additional information to give clarity may be requested from commissioner and patient groups.

3.4 *Data sources for establishing current activity.*

3.4.1 The data used to establish the current practice vary depending on the topic of the guidance. In some cases multiple sources may be needed. The data used should be accurate and credible and its source referenced.

3.4.2 Commonly used types of data and sources used to establish a baseline may include:

- hospital data – such as Hospital episode statistics
- prescribing data – such as Electronic prescribing analysis and cost tool (ePACT) system
- primary care data – such as GP medical databases, for example THIN (provided by Quintiles IMS, through NHS Digital)
- Hospital pharmacy audit index (provided by Quintiles IMS, through NHS Digital)
- NHS Digital
- Personal Social Services Research Unit
- Pharma (industry/company submission)

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- publications that measure uptake of NICE guidelines.

3.4.3 It should be recognised that for highly specialised technologies disease incidence and prevalence data are limited and may not be available from these sources (see section 3.3).

3.5 Data sources to establish future practice

3.5.1 Predicting future practice following the implementation of a recommendation poses significant challenges. Predictions of future uptake should not rely on a single source.

3.5.2 Assumptions made are documented and fully referenced, and checked with topic experts, who may be involved in the guidance development. This could be an expert in the area the guidance relates to, a commissioner either from specialised commissioning or a clinical commissioning group, committee members involved in guidance development, and technology appraisal and highly specialised technologies team members.

3.5.3 Sources used for estimating future practice include:

- company submission
- previous uptake of similar drugs, technologies or other interventions
- NICE Medicines and Prescribing Associate programme
- information used to inform related economic models.

3.6 Activity and unit costs

3.6.1 The estimated activity for care and services resulting from the recommended guidance is checked to see if there is an identifiable

cost assigned to the activity or whether there are specific unit costs that can be used.

Healthcare

3.6.2 In healthcare there are a number of sources for which activity and cost are linked as follows:

- Secondary care hospital acute activity has a national tariff (price) or reference costs can be used when assessing the resource impact. However recognition is needed where local flexibility is possible in respect of national tariffs.

- National tariff should always be used when available

- If it is not possible to use tariff or reference costs, unit prices may be obtained from NHS organisations currently providing the service. This is useful for very new procedures that have not yet been included in the tariff. It also applies to high cost procedures that are specifically excluded from the scope of the tariff.

- The technology price is that used in the cost effectiveness model. Where this is not subject to a confidential discount. Please note any agreed confidential discount price is always used in the cost effectiveness model.

- The technology price for comparator technologies prices is that used in the cost effectiveness model. Where this is not subject to a confidential discount. Please note any agreed confidential discount price is always used in the cost effectiveness model.

- The medicines evidence and advice team provides advice on the source of the latest price available. If prices are not confidential but have changed since the cost effectiveness model this is noted in the resource impact report.

- In some instances the Department of Health and the company agree that the technology will be available to the NHS with a patient access scheme, which makes the technology available with a discount. The size of the discount may be commercial in confidence. If this is the case, the reduced cost of the technology

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is not included in the published resource impact products. However commissioners and providers will have the option to input confidential discount price into published resource impact template locally.

- Highly specialised technologies services may have bespoke tariff structures and these may need to be requested from NHS England.

4   Role of the resource impact team

This chapter defines resource impact and explains how it is calculated for technology appraisals and highly specialised technologies.

4.1   What is resource impact?

4.1.1   Resource impact is the financial change in the use of resources (cost or saving) as a result of implementing guidance. It can also be called the budget impact.

4.2   Assessing resource impact

4.2.1   The approach for estimating the resource impact is the same for technology appraisals and for highly specialised technologies. The process applies equally to multiple technology appraisals and single technology appraisals.

4.2.2   The resource impact is determined by estimating costs and savings as a direct consequence of implementing the guidance. Direct consequences are the changes in practice that will result from implementation. For example, this could include a change in prescribing practice or a change in the number of patient admissions. The follow-on impact – for example, preventing adverse events and avoiding future admissions – is also considered as a direct consequence.

4.2.3   The resource impact assessment looks only at the population recommended in the guidance where technology is for multiple

indications (e.g. paediatric and adult) within the same TA. This will be clearly identified.

4.2.4   Value added tax (VAT) is included within a resource impact assessment where it is payable by the NHS. The resource impact work includes all costs of implementing guidance this includes VAT.

4.2.5   It is recognised that avoiding future admissions may not save money for the commissioner if the bed is used for other activity, but this is considered outside the impact of guidance and therefore not included in resource impact assessment.

4.2.6   An example of an indirect consequence is a scenario in which a person who has an intervention that prevents them from dying goes on to develop other diseases that are costly to treat. However, because the person could develop any disease totally unrelated to the guidance recommendation for their original condition, this indirect consequence cannot be considered in the resource impact work.

4.2.7   Resource impact is based on accounting principles. These may differ from health economic principles used in the cost effectiveness calculation. For example the health economic analysis may include events avoided as part of considering the lifetime impact, whereas the resource impact tool focuses on the costs or savings for the first 3 to 5 years after the guidance is published.

4.2.8   The health economic analysis may use reference costs, which are the average costs to provide activity, whereas the resource impact tool could use the national tariff, which is the price to commission activity. This may result in differences between the unit costs but the activity classification should be consistent.

4.2.9   The resource impact team ensures that costs and savings relate to the same time period, usually a financial year. Differences may

arise if costs are incurred earlier on that will result in savings in the future. It is not acceptable to combine costs and savings to produce a 'net' cost saving if time periods don't match.

4.2.10　Resource impact tools do not form guidance to the NHS, but aim to support implementation of NICE guidance.

4.3　Process overview

4.3.1　To help the NHS plan for the resource impact of technology appraisal and highly specialised technologies guidance, the resource impact team forecasts the resource impact from initial referral to NICE through to publication of guidance.

4.3.2　If possible (namely if prices are not confidential) the resource impact team informs the NHS through the resource planner when a preliminary positive recommendation is made (in the appraisal consultation document) whether the use of a technology in the NHS is likely to be low, medium or high cost. The following definitions of resource impact are used:

- Below £0 – cost saving.
- Up to £5 million – low cost or not significant.
- £5 million up to £20 million – medium cost.
- £20 million and over – high cost.

4.3.3　The resource impact team uses a 'budget impact test' of £20 million, set by NHS England, to signal the need for a dialogue between NHS England and the companies to agree special arrangements to better manage the introduction of new technologies recommended by NICE. This is anticipated to apply to a small number of technologies that, once determined as cost

effective by NICE, would have a high cost impact on the NHS budget.

4.3.4　　NICE assesses the potential budget impact by estimating the net annual cost to the NHS. The test is regarded as having been met if the budget impact is greater than £20 million in any of the first 3 financial years of a technology's use in the NHS.

4.3.5　　To estimate whether the resource impact of technology appraisal guidance is significant the resource impact team undertakes the following:

- Reviews the company submission, including the section on impact on NHS resources.
- Reviews the topic selection and block scoping.
- Reviews professional, patient and commissioning group submissions.
- Discussion with the company.
- Discussion with clinical experts.
- Discussion with commissioners.
- Reviews the Evidence Review Group report.
- Reviews the appraisal consultation document and the final appraisal document.
- Discusses the guidance with the technical team from the technology appraisal or highly specialised technologies programmes.

4.3.6　　At key milestones the resource impact team notifies the technology appraisal and highly specialised technologies teams of those technologies that will meet the budget impact test of £20 million in

any of the first 3 financial years following implementation of the guidance.

Milestone	Maximum timescale
Company submission	10 working days from notification by technology appraisal or highly specialised technologies team that the company submission is available to review
Evidence Review Group (ERG) report	10 working days from notification by technology appraisal or highly specialised technologies team that the ERG report is available
Appraisal consultation document (ACD)	10 working days from committee meeting
Final appraisal determination (FAD)	10 working days from committee meeting

4.3.7   At each stage where those technologies that will meet the budget impact test of £20 million in any of the first 3 financial years following implementation of the guidance consultation will take place with the company

4.3.8   The resource impact team estimates the national cost for England of implementing positive guidance recommendations alongside the appraisal consultation document. This is reported in the resource planner if prices are not confidential.

4.3.9   For draft guidance with an estimated resource impact above the budget impact of £5 million at a national level when the appraisal consultation document is produced, a draft resource impact report and resource impact template are shared with stakeholders. No information is reported in the resource planner until after this consultation with key stakeholders including the company.

4.3.10   Stakeholders include the Department of Health, NHS England, NHS Improvement, the company, companies for comparator technologies (if they have completed the confidentiality agreement form) as defined in the scope, and commissioners. Only data that is not confidential are published as the Resource Impact

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Assessments reflecting confidential net pricing will need to be shared confidentially with key stakeholders.

4.3.11   The resource impact team produces a resource impact report and template for all final technology appraisal guidance with a resource impact of more than £5 million at a national level and publishes the documents alongside the final guidance.

4.3.12   If costs and savings are not considered to be significant at final guidance (below £5 million at a national level), a statement is issued on the NICE website.

4.3.13   If technologies (technology appraisal or highly specialised technologies) are not recommended in the guidance, no resource impact tools are produced.

4.4   Confidential prices

4.4.1   Technologies being appraised or a comparator technology may have a confidential price, usually a patient access scheme. If so, a procedure is put in place between the technology appraisal or highly specialised technologies team and the resource impact team to protect the confidentiality of the price. This includes allowing

restricted access to the confidential price within the resource impact team.

4.4.2   Under no circumstances is a confidential price shared by a member of the resource impact team either within the team or externally, other than as specified in the procedure.

4.5   Appraisal of Cancer medicines and the Cancer drugs fund

4.5.1   A modified appraisal process for cancer drugs was introduced on 1 April 2016 and now allows NICE to make 1 of 3 recommendations:

- Recommended for routine commissioning – 'yes'.
- Not recommended for routine commissioning – 'no'.
- Recommended for use within the Cancer Drugs Fund (new).

4.5.2   The new recommendation available to NICE – 'recommended for use within the Cancer Drugs Fund' – can be used when NICE considers there to be plausible potential for a drug to satisfy the criteria for routine commissioning, but there is significant remaining clinical uncertainty.

4.5.3   The NICE appraisal process starts much earlier with the aim of publishing draft guidance before a drug receives its marketing authorisation, and then final guidance within 90 days of marketing authorisation whenever possible.

4.5.4   All drugs on the previous Cancer Drugs Fund as of 31 March 2016 will be reconsidered or appraised by NICE over the course of 18 months from April 2016. Until NICE is able to provide a commissioning recommendation, these drugs will continue to

receive funding from the Cancer Drugs Fund budget at current commercial terms.

4.5.5   The approach for estimating the resource impact for appraisals linked to the Cancer Drugs Fund is the same as for technology appraisals and highly specialised technologies but, if applicable, the resource impact report and template need to also identify the following:

- Previous Cancer Drugs Fund activity.
- Impact on routine commissioning compared with current Cancer Drugs Fund activity and resource impact.
- Impact of new approvals for the Cancer Drugs Fund.
- Impact of new approvals for routine commissioning.
- The funding directive attached to the appraisal.

4.6   Timeframe

4.6.1   The resource impact report and template covers the 5 financial years after guidance publication. Both the report and template will identify separately the resource impact for each of the next 5 financial years. The report indicates the timeframe in which full implementation is assumed to be achieved.

4.6.2   The uptake of guidance over the first five years from approval is based on a number of sources, company submission, experts views, commissioner expectation and where applicable uptake of similar drugs.

4.6.3   The budget test of £20 million is regarded as having been met if it is projected to be reached or exceeded in any of the first 3 financial

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years of a technology's use in the NHS. Only technologies which exceed £20 million in first 3 financial years will be notified to NHSE.

4.6.4   Forecasts may be updated following implementation see chapter 7 for further details.

4.7   Sensitivity analyses

4.7.1   Several assumptions are made in estimating resource impact. These are subject to uncertainty, particularly predictions about future practice after the recommendations are implemented.

4.7.2   Reasonable minimum and maximum values of variables are recorded when gathering evidence. These inform sensitivity analysis that highlights which variables the resource impact estimation is most sensitive to.

4.7.3   Results are presented in tables and a short explanation included to describe the variables that have most effect on the total resource impact.

5   Resource impact products

This chapter describes resource impact products. The key outputs of the resource impact team are:

- the resource planner
- resource impact reports and templates
- resource impact statements.

5.1   Resource planner

5.1.1   Each month the resource impact team publishes the NICE resource planner on the NICE website. It is also sent to chief financial officers and other people who request it. The resource planner contains information on guidance published in the previous

financial year and guidance publishing in the current and next financial years.

5.1.2   The aim of the resource planner is to help organisations plan and implement NICE guidance by:

- summarising the resource implications of published guidance
- listing forthcoming guidance with indicative resource impact for England profiled over the next 5 years, based on draft guidance.

5.2   Resource impact report

5.2.1   A resource impact report is a Microsoft Word document that sets out the estimated resource impact of implementing the technology appraisal guidance. The report provides national estimates if possible and explains the assumptions made for estimating the resource impact.

5.2.2   Only published list prices of technologies are discussed in published resource impact reports. Confidential data is never disclosed in published resource impact reports

5.2.3   A shorter version is prepared if the resource impact cannot be estimated or is likely to vary locally. This highlights the areas of costs and savings to be considered at a local level.

5.3   Resource impact template

5.3.1   A resource impact template is an Excel spreadsheet that enables users to estimate the local cost of implementing guidance using NICE assumptions or by inputting their own assumptions.

5.3.2   In some instances the Department of Health and the company agree that the technology will be available to the NHS with a patient access scheme, which makes the technology available with a discount. The size of the discount may be commercial in confidence. If this is the case the resource impact template is designed to allow those who have access to the confidential

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price(usually commissioners and providers) to input the confidential price locally and therefore estimate the resource impact of the technology

5.3.3   The national resource impact template is based on the population of England. However, local commissioners such as clinical commissioning groups can amend the template to their local population to estimate local resource impact. The template can also be amended to estimate the resource impact for the population of Wales and Northern Ireland.

5.3.4   Resource impact templates are produced if it is possible to quantify the resource impact and it is considered to be significant (over £5 million for England). In rare instances for technology appraisals for which costs cannot be quantified but are still considered to be significant, a resource impact template is prepared but with the major cost drivers identified for completion by users in their own local settings.

5.4   Resource impact statement

5.4.1   A resource impact statement is a web-based statement. This is used if costs and savings are not considered to be significant (less than £5 million for England).

6   Quality assurance process and publication

This chapter explains the process of quality assurance and publication of resource impact products. Resource impact products are all subject to a quality assurance process before either consultation or publication.

6.1   Resource planner

6.1.1   The resource planner is published once a month. Before submission for publication senior business analysts review the work of business analysts within their team. Once this process is complete the resource impact assessment manager reviews the

resource planner and submits it to the associate director for resource impact.

6.1.2   The accuracy of the planner is checked for consistency with the NICE website, and the resource impact forecasts are checked to ensure that the conclusions are supported by the evidence.

6.1.3   The associate director for resource impact then approves it for publication on the NICE website.

6.2   Resource impact reports and templates

6.2.1   Senior business analysts provide advice to business analysts on the production of resource impact reports and templates. This is before a formal internal review.

6.2.2   Senior business analysts are responsible for ensuring products are of a robust quality for formal internal review by checking patient pathways, reasonableness of assumptions made, sources of evidence and costing data used.

6.2.3   Before resource impact data are shared with external stakeholders an internal review takes place.

Internal review

6.2.4   The process for an internal review is described below:

- Meetings are planned at least 2 months in advance to allow full attendance.
- Papers are distributed 5 working days before the meeting.
- The following people are invited:
  - associate director for resource impact, or resource impact assessment manager
  - the business analyst and senior business analyst responsible for the guidance
  - the technical team for technology appraisal or highly specialised technologies.

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6.2.5   The internal review is an opportunity for the business analyst to check the assumptions used in the resource impact report and template. This includes receiving comments from colleagues and peers within NICE to make sure that all relevant and significant factors have been included in the products.

Consultation and sign-off

6.2.6   The documents are shared with the consultees for technology appraisals including:

- the company
- companies for comparator technologies who are participating stakeholders
- patient experts and clinical experts from the committee
- NHS England for NHS England commissioned services
- Department of Health
- a minimum of 3 representatives from the NICE adoption and impact reference panel

6.2.7   The external consultation runs for a minimum of 2 weeks.

6.2.8   Once consultation has closed all comments are collated using a standard table and passed to the business analyst for review. The business analyst notes their response in the table alongside the comment in preparation for final sign-off.

6.2.9   If a consultee's comment needs further clarification the business analyst contacts the consultee.

6.2.10   The process for final sign-off is described below:

- Meetings are planned at least 2 months in advance to allow full attendance.
- Papers are distributed 3 working days before the meeting.
- The same people are invited as to the internal review.

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- All points raised at consultation are documented and actions agreed.
- The meeting concludes with the associate director for resource impact or the resource impact assessment manager signing off the products to proceed to Publication Executive.
- The associate director for resource impact or the resource impact assessment manager advises whether any key issues need to be shared with the Medicines and Technologies Programme director before submission to Publication Executive.

6.3 Editing

6.3.1 The resource planner is not edited by NICE editors.

6.3.2 However, the resource impact reports, templates and statements are edited by NICE editors. Ideally this takes place after final sign-off. To ensure the products publish alongside the guidance, editing can place while they are being consulted on.

6.3.3 The editor checks for consistency between the resource impact report and the guidance, and ensures that the products are in the correct format, easy to understand and navigate, and in line with NICE style.

6.4 Approval for publication

6.4.1 The resource planner is approved for publication by the associate director for resource impact.

6.4.2 The resource impact reports, templates and statements are approved for publication by the NICE Publication Executive, which

meets every week. Products are approved for publication once any queries have been answered.

7 Making post-publication amendments

This chapter explains the process for updating resource impact reports and templates after they have been published.

7.1 New technologies for the same condition

7.1.1 The resource impact team updates resource impact reports and templates if needed, to take into account new technologies for the same or similar conditions. For example, if a new technology becomes available for a condition that already has a resource impact report and template, any new publication will ensure consistency and that costs and savings are not double counted.

7.1.2 This may mean that existing resource impact reports and templates need to be updated and this will be part of the Publication Executive submission when the new guidance publishes.

7.2 Annual review of the resource impact reports and templates

7.2.1 Technology appraisals resource impact reports and templates are reviewed every year as set out below, when uptake data from NHS Digital, company data and other relevant sources are available.

7.2.2 An annual review between the resource impact team and the ABPI will review progress and introduce a feed

7.2.3 The outcome of the review is 1 of the following:

- The report and template remain fit for purpose.
- The report and template need updating.
- The report and template are no longer necessary and are retired.

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7.2.4   When the reports and templates are updated or retired, Publication Executive approval is needed before changes are made to the NICE website.

7.3   Other circumstances in which amendments are needed

7.3.1   Resource impact is based on assumptions about current practice and predictions of future practice, at the time the guidance is published. Sometimes resource impact issues emerge after the guidance is published that were not identified before publication. This can happen particularly during the post-publication engagement with stakeholders validating other implementation products.

7.3.2   There are 2 ways of addressing this:

- revise the original products **or**
- issue a supplementary commentary.

7.3.3   Revising the resource impact or issuing a supplementary commentary is considered in the following circumstances:

- A significant flaw is identified in 1 or more assumptions relating to current or predicted practice that is considered to be greater than local variation.
- The basis of the resource impact assessment is inconsistent with current practice or there has been an inaccurate use of costs.
- Feedback indicates that a recommendation will lead to nationally significant costs or savings that were not identified in initial work.

7.3.4   The criteria against which a decision is made about whether to update the resource impact products are given below:

- Revising the assumptions in the template affects the total resource impact by more than 10%.

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- Revising the unit costs in the template affects the net total resource impact by more than 10%.
- Estimated costs or savings arising from a new recommendation is considered to lead to a total resource impact change of £5 million per year or more for England.
- Revising the resource impact assessment template will correct obvious inaccuracies that, if left, will undermine user confidence in the template, even if the impact on the total net cost does not meet the thresholds above.

7.3.5 The template is not updated in the following circumstances:

- There are differences in baseline and predictions arising from natural variation in local circumstances.
- Unit costs that have been used for drugs and activity were correct at the time of publication but have since changed. Templates are not routinely updated for annual updates to activity costs, such as tariff changes.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Fast track appraisal

Addendum to the

Guide to the Processes of Technology Appraisal

1 Introduction

1.1 This document provides an overview of the NICE fast track appraisal (FTA) process. It builds on the processes outlined in NICE's guide to the processes of technology appraisal for the single technology appraisal (STA) and multiple technology appraisal (MTA) processes. This document should be read alongside the guide. The aims of the FTA process are to provide equally robust but less resource-intensive processes for appraising technologies than the STA and MTA processes.

1.2 Technologies appraised through the FTA process are subject to the funding requirements outlined in NICE's guide to the processes of technology appraisal. Clinical commissioning groups, NHS England and local authorities (with respect to their public health functions) must comply with the recommendations in the appraisal within the specified timeframe. NHS England/ commissioners have committed to providing funding for the highly cost-effective technologies recommended in FTA guidance within 30 days of its date of publication.

2 Selection of technologies

2.1 The topic selection process and prioritisation of all technologies for health technology appraisal follows the selection process outlined in NICE's guide to the processes of technology appraisal. The decision about selecting the technology for a particular process is described in section 3.

2.2   All health technologies that are referred to NICE as technology appraisals, such as pharmaceuticals or medical devices, are candidates for the FTA process as long as they fulfil the criteria (see section 3).

3   Selecting products for the FTA process

3.1   A technology will be appraised through the FTA process if:

- The company's base-case incremental cost-effectiveness ratio (ICER) is less than £10,000 per quality-adjusted life year (QALY) gained.

- It is likely that the most plausible ICER is less than £20,000 per QALY gained, and it is highly unlikely that it is greater than £30,000 per QALY gained.

3.2   Topics will be appraised through the FTA process, considering the criteria outlined in section 3.1, if:

- NICE is satisfied that the proposed route is appropriate

- there is sufficient information to make recommendations through a fast track appraisal and

- the uncertainties in the evidence and consequences of decision error are manageable.

3.3   Topics will not be appraised through the FTA process if NICE considers that the uncertainty is too large for an appropriate recommendation to be made. If NICE considers that the topic is unsuitable for FTA, for example, there is a very high degree of uncertainty in the cost-effectiveness estimates, then the topic will be appraised through the STA process.

3.4   Companies which wish their technology to be appraised through the FTA process are encouraged to engage with NICE during the scoping stage and up to the submission.

3.5   The scheduling of any FTA will initially follow the timing of a standard STA until NICE confirms that the technology being appraised is suitable for FTA.

3.6 The final decision about the routing of the technology is the responsibility of NICE, informed by stakeholder input during scoping. It is based on a review of the evidence by NICE supported by an external review group, and is normally taken 3-4 weeks after the company submission is received.

4 Developing the scope

4.1 Technologies that are being considered for the FTA process will follow the scoping process outlined in NICE's [guide to the processes of technology appraisal](#).

4.2 Consultees and commentators are invited to comment on whether the technology is suitable for the FTA process during the scope consultation.

5 The appraisal process

5.1 The FTA process follow the procedural steps of the STA process as described in section 3 of NICE's [guide to the processes of technology appraisal](#) which consists of 3 phases: evidence submission, evidence review and appraisal (see figure 1).

Figure 1 Overview of the STA and FTA processes

Standard cancer STA	Standard non-cancer STA	FTA**
Invitation to participate (wk 0)	Invitation to participate (wk 0)	Invitation to participate (wk 0)
Evidence submission received (wk8)	Evidence submission received (wk 8)	Evidence submission received (wk8)
Clarification (wk 10/11)	Clarification (wk 10/11)	Scrutiny step (wk 8-11)
ERG report received (wk 17)	ERG report received (wk 17)	NICE and ERG produce technical briefing (wk 12-16)
Committee preparation	Committee preparation	Technical brief completed (wk 16/17)
Appraisal committee meeting (wk 21)	Appraisal committee meeting (wk 21)	Appraisal committee meeting (wk 21)
Consultation (wk 24)	Consultation (wk 24)	FAD for Appeal (wk 24)
Appraisal committee meeting (wk 29)	Appraisal committee meeting (wk 29)	Final guidance (wk 32)
FAD for Appeal (wk 34)	FAD for Appeal (wk 34)	
Final Guidance (wk 43)	Final Guidance (wk 43)	

CHMP positive opinion

Marketing Authorisation

Abbreviations key:
FTA – Fast track appraisal
STA – Single (standard) technology appraisal
CHMP – Committee for medicinal products for human use
ERG – Evidence review group
FAD – Final appraisal determination

*Before ITP, companies must request confirmation that cost comparison submission can be considered
**Expected timelines for FTA process. Timelines may change in response to individual appraisal requirements.

Evidence submission from the company

5.2   NICE invites the company to provide an evidence submission. The company will have at least 8 weeks, from the formal invitation to participate, to prepare the evidence submission. For an FTA, the evidence must be submitted in the STA template [add link] except for a case of 'cost-comparison', where the cost-comparison template should be used [add link – DN template currently in development].

External participation in FTA

5.3   Clinical, patient and commissioning organisations are invited to submit their views on the technology and nominate experts. Clinical, patient and commissioning experts are nominated and selected during the appraisal process and are asked to provide a personal statement as described in section 3.6 of NICE's guide to the processes of technology appraisal.

5.4 Selected experts will not be invited to take part in the Appraisal Committee meeting. In exceptional circumstances, the committee chair and NICE may agree to invite clinical, patient and/or commissioning experts to the meeting to help address specific uncertainties that cannot be resolved through written testimony.

Evidence review, confirming the process and developing the technical briefing

5.5 When a company evidence submission for the FTA process is received, NICE, supported by the evidence review group, will confirm if the selection criteria [see section 3 above] are met, and that the appraisal can proceed as a FTA.

5.6 If the selection criteria are not met, the appraisal will proceed according to the STA process. Where a company has made a case for the FTA process based on 'cost-comparison', the company will asked to make a submission using the full STA template and the topic will be rescheduled into the work programme at the earliest opportunity.

5.7 If a topic is not selected for the FTA process, NICE will inform the company, and provide the rationale for this decision. If a company does not agree with the rationale provided, the company must contact NICE within 2 working days of receiving the routing decision stating reasons for its objections. The Centre Director will then review the routing decision rationale and the companies counter argument and make a final decision on the appropriate route for the appraisal

5.8 When NICE confirms that the appraisal can proceed as a FTA, NICE and the evidence review group will produce a joint, technical briefing summarising the evidence. The joint briefing will replace the ERG report and pre-meeting briefing in the standard STA process.

5.9 The joint briefing will include:

- the case made by the company;

- a commentary of the evidence received,

- a commentary on the testimony from experts;

- the technical judgements of the evidence made by NICE and the ERG;

- the application of NICE's structured decision making framework;

- the scope of potential recommendations.

5.10   Companies will be provided with an opportunity to consider the briefing before the appraisal committee meets.

Appraisal

Appraisal committee meeting to develop the recommendations

5.11   NICE aims to hold the appraisal committee meeting around the time when the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) meets. On occasion therefore, it can be that the appraisal committee meeting is held before the technology gains a Marketing Authorisation.

5.12   After the meeting a final appraisal determination will be developed. The committee can come to one of the following recommendations:

- **Recommended for routine commissioning**

- **Not recommended for routine commissioning**

- **Not recommended for routine commissioning, but recommended for inclusion in the CDF or in some other form of managed access arrangement**

5.13   In exceptional circumstances, the committee may find it unable to develop recommendations for the technology without further scrutiny, or further submission of evidence. If this is the case, guidance will still be produced, indicating that the committee is '**unable to make a recommendation**'.

5.14   When a company wishes to resubmit as a consequence of 'unable to make a recommendation' guidance, the topic will be re-scheduled into the committee work programme although it will not always be possible to prioritise the topic for immediate review.

6   Appeals

6.1   The FTA process includes the opportunity for appeal against the final draft recommendations. The principles and processes for appeals are the same as those for STAs and MTAs, as outlined in section 4 of the [guide to the processes of technology appraisal](#).

7   Patient access schemes and flexible pricing

7.1   The principles and requirements for patient access schemes for the FTA process are broadly similar to those for STAs and MTAs, as outlined in section 5 of the [guide to the processes of technology appraisal](#).

7.2   The exception is that a patient access scheme proposals must be included in the company evidence submission. The initiation of the patient access scheme process will not be accepted at later points in the FTA process. Modifications to access schemes presented in the company evidence submission will be considered.

8   Reviews

8.1   The review of guidance produced through the FTA processes follows the same principles and requirements for STAs and MTAs, as outlined in section 6 of the [guide to the processes of technology appraisal](#).

9   Tools and resources

9.1   NICE will assess the potential budget impact of technologies appraised through the FTA. See budget impact addendum.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Cost comparison

Addendum to the Guide to the methods of Technology Appraisal

1   Introduction

1.1   This document provides a statement about the methods to be used where a cost comparison case is made. It builds on the methods outlined in NICE's [guide to the methods of technology appraisal](). This document should be read alongside the guide.

1.2   A cost comparison case can be made if:

- If a health technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication.

2   Clinical and cost-effectiveness analysis

2.1   The methods for the cost comparison case follow the requirements outlined in the existing [methods guide]() (including the reference case) (for the exceptions related to cost effectiveness see sections 3.3 and 3.4):

Clinical effectiveness

2.2   The clinical effectiveness evidence requirements are consistent with those specified in the existing [methods guide]().

Cost effectiveness

2.3   A cost-utility analysis and aspects of the reference case that apply to cost-utility analyses are not needed where a cost-comparison analysis is used:

- Cost-comparison analysis comprises an analysis of the costs and resource use associated with the intervention compared with that of the

comparator(s). The effects of the intervention and comparator(s) on health outcomes are captured in the clinical effectiveness evidence, and are not included in the cost-comparison analysis.

- The cost-comparison analysis should capture the relevant cost differences between the intervention and comparator(s) over a time horizon that is long enough to reflect materially important differences between the technologies being compared:

  − As a minimum, this must include acquisition costs of the technologies. If other relevant differences in costs or resource use are identified, these may also be included (for example, drug administration, monitoring and healthcare appointments).
  − Costs should be based on use in line with the summary of product characteristics for the new technology (if available).
  − Whenever possible and appropriate, cost data and data sources should be consistent with any corresponding data and sources that were considered appropriate in the published NICE guidance for the comparator(s) for the same indication.
  − If there are relevant differences in health outcomes that affect resource use (for example, managing adverse events), these must be included in the cost-comparison analysis. Substantial differences between technologies in costs directly relating to health outcomes (such as adverse events) indicate that the intervention and comparator(s) may not provide similar overall health benefits, so any such cost differences must be clearly justified.

2.4 A systematic review of published, relevant evidence on the cost effectiveness of the technology is not needed.

Exploring similarity

2.5 For the acceptance of a cost comparison case, evidence in support of similarity between the intervention and comparator technologies, in terms

of overall health outcomes, must be presented in the company's evidence submission.

Cost Comparison Sensitivity Analysis

2.6   Appropriate sensitivity analysis will, in general, include clinically relevant scenario analyses and univariate sensitivity analyses to identify parameters that may have a substantial impact on the cost-comparison. A probabilistic sensitivity analysis is not needed.

Impact on the NHS

2.7   Information on the net budget impact of implementing the health technology in the NHS (and personal and social services, when appropriate) is needed, including impacts on cost, resource use and service delivery (see sections 5.12 of NICE's [guide to the methods of technology appraisal](#)

3   Structured decision-making

Appraisal of the evidence

Structured decision-making: clinical effectiveness

3.1   Decision-making follows the [methods guide](#), with the exceptions detailed in sections 4.2 and 4.3.

3.2   The appraisal committee's judgements on clinical similarity in a cost comparison case take account of:

- The nature and quality of the evidence in the company's submission.
- Evidence that the new technology provides similar or greater overall health benefits than the comparator(s), taking into account relevant outcomes (for example, clinical effectiveness outcomes and adverse effects), and specifically:
  - evidence that the clinical effectiveness of the intervention is the same or greater than the comparator(s)

- – if relevant, whether apparent differences in effectiveness are clinically meaningful
- – the degree of clinical or biological plausibility of similarities in health benefits
- Consideration of the evidence submitted for licensing and, if available effectiveness in clinical practice.

Structured decision-making: cost-comparison analyses

3.3   In a cost-comparison the appraisal committee considers the intervention relative to its comparator(s). The committee's judgements on the cost-comparison analysis take account of:

- The robustness and appropriateness of the approach to cost comparison.
- The results from relevant cost-comparison scenario and univariate sensitivity analyses.
- The committee's preferred analysis, taking into account all of the cost-comparison evidence submitted.

Decision-making

3.4   The appraisal committee's main considerations when developing recommendations in a cost-comparison case are:

- On balance, whether the technology is likely to provide similar or greater overall health benefits to patients than technologies recommended by NICE for the same indication, measured by relevant outcomes
- On balance, whether the use of the technology is likely to result in similar or reduced overall costs to the NHS than technologies recommended by NICE for the same indication.

Table 1: Committee recommendations in case of a cost-comparison

Decision	Type of recommendation
Technology provides similar or greater benefits at a similar or lower overall costs than the comparator(s)	Recommended as an option
Technology provides less health benefit at a similar or greater cost *or* Technology provides similar health benefits at a greater cost	Not recommended

NICE and NHS England consultation on changes to the arrangements for evaluating and funding drugs and other health technologies assessed through NICE's technology appraisal and highly specialised technologies programmes

NHS England and NICE recently consulted publicly on proposals to change the arrangements for evaluating and funding drugs and other health technologies assessed through NICE's technology appraisal and highly specialised technologies programme.

In light of this consultation, the Board is invited to consider and comment on the recommendations for making changes to the arrangements.

NHS England's Specialised Services Commissioning Committee considered the response to consultation at its meeting on Wednesday 22 February. The recommendations in this paper are consistent with the position adopted by NHS England at that meeting.

This paper only addresses the proposals relating to the highly specialised technologies programme. The response to the other two proposals put forward in consultation are the subject of a separate paper.

A revised statement of the methods and processes for the evaluation of highly specialised technologies, incorporating the changes set out in this document, will be submitted to the Board at its meeting in April.

Professor Carole Longson
Director of the Centre for Health Technology Evaluation
March 2017

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NICE and NHS England consultation on changes to the arrangements for evaluating and funding drugs and other health technologies assessed through NICE's technology appraisal and highly specialised technologies programmes
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Purpose of this paper

1. For the Board to consider the comments received in consultation on the joint proposals of NICE and NHSE for changes to the HST programme.

2. For the Board to consider and approve amendments made to the original proposals.

3. For the Board to consider and approve plans for implementation and next steps.

Background

The proposals

4. NICE and NHS England held a public consultation on proposals to change the arrangements for evaluating and funding drugs and other health technologies assessed through NICE's technology appraisal and highly specialised technologies programme, that would seek to provide:

   - Rapid access for patients to the most cost-effective new treatments;

   - More flexibility in the adoption of technologies into the NHS which are cost effective but high in budget impact; and

   - Greater clarity for patients and companies about the point at which treatments for very rare conditions appraised by NICE will automatically be routinely commissioned.

The consultation

5. In October 2016, NICE published a joint consultation with NHS England containing proposals to change aspects of the NICE Technology Appraisal and Highly Specialised Technologies evaluation programmes.

6. In summary, the proposals covered:

   - **Introduction of 'budget impact threshold' of £20m**. For those technologies that pass the NICE value assessment (applying NICE's published methods) and where the budget impact is below the threshold set, there would be no need to conduct a commercial negotiation. Should the budget impact exceed the set threshold in any of the first three years, a commercial negotiation would be triggered. Should this negotiation fail to conclude or not fully resolve the budget impact issues, NHS England would be able to apply to NICE to vary the funding requirement in order to

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phase introduction of the product over a longer period to help manage its impact on the NHS.

- **Linking NICE and NHSE processes for evaluating highly specialised technologies**. We consulted on introducing quality adjusted life years (QALY) as a measure of value in the HST programme, and on the application of a 'limit' of £100k per QALY below which the legal funding directive would apply (either immediately if there are no budget impact concerns or phased in over a period of time if the budget impact threshold of £20 million is triggered). For those technologies for which the cost per QALY calculation exceeds £100,000, there would be an opportunity to be considered for funding through NHS England's Clinical Priorities Advisory Group (CPAG) relative prioritisation process. This opportunity for a second consideration recognises the special position of very small groups of patients for whom new treatments are exceptionally expensive.

- **Introduction of a new 'Fast Track Appraisal'**. The consultation set out a proposal that appraisals in which we can be confident that a reliable judgement about value for money can be made at an early stage in the appraisal, would be able to enter a new Fast Track Appraisal, which would have lighter touch methods and a shorter process. In addition, where a positive recommendation is made, a shorter period of deferred funding - 30 days instead of 90 days, would be applied. The consultation proposed to use a cost per QALY level of £10,000 as one of the criteria for routing into fast track, as at that level it could, with a high degree of certainty, be predicted at an early stage in the evaluation that a technology would be cost effective. The budget impact threshold would still apply to products qualifying for the Fast Track Appraisal process.

7. The public consultation, which closed on 13 January 2017, received 150 responses. In addition, four webinars for stakeholders (350 people registered to attend in total) and two face-to-face events in London and Manchester (63 attendees in total) were held, along with a number of individual meetings with key stakeholder groups.

8. The consultation report, which has already made available to the Board, includes details of the number of responses by stakeholder type and responses to each consultation question.

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Highly specialised technologies

Questions asked in consultation

9. The following questions were included in consultation:

   - Question 9: Do you agree that NICE and NHS England should use a cost per QALY below which the funding requirement is applied for Highly Specialised Technologies?

   - Question 10: Do you agree that £100,000 per QALY is the right maximum up to which the funding requirement would be applied? If not, what cost per QALY do you suggest, and why?

   - Question 11: Do you agree that if the cost per QALY level is exceeded, the technology should be considered through NHS England's specialised commissioning prioritisation (CPAG) process?

   - Question 12: Do you agree the proposed new arrangements mean that NICE would not need to take budget impact into account in its highly specialised technologies evaluations?

Summary of comments received

10. Respondents raised concerns about the proposal for a cost per QALY limit for automatic funding (though not necessarily any funding) of NICE guidance, developed through the highly specialised technologies programme, as well as the proposed level of £100,000 per QALY. Consultees also expressed broader concerns about linking the process to NHS England's CPAG process.

11. Many of the respondents appear to have interpreted the level at which automatic funding would be applied as a 'threshold' for value. Indeed, a number of respondents asked whether NICE would still 'recommend' a highly specialised technology when the cost per QALY exceeds the level for automatic funding. Some respondents felt that it was not appropriate to use QALYs to determine whether or not a highly specialised technology should be funded.

12. Some respondents felt strongly that the £100,000/QALY level is too low, with no or very few HSTs likely to be able to reach this level for automatic funding. Even taking account of the possibility of funding through the NHS England CPAG process, respondents considered that the prospects for access to

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treatment would be so remote that patients with very rare conditions would be significantly disadvantaged.

13. Another strong message from consultation was concern about the NHS England relative prioritisation process (CPAG). Respondents argued that the CPAG process is not well understood and that the methodology is such that it will be very hard for HST products to move successfully through it. There was also concern that going through CPAG after HST would add too much time into the process and further delay access for patients.

Response, including amendments to the proposals

14. Despite the opposition to the proposal, NICE and NHS England remain of the view that it is essential to develop an objective, systematic, transparent and repeatable approach, to evaluating HSTs, which explicitly recognises the financial constraints under which NHS England's specialised commissioning budgets are operating.

15. NICE and NHS England take the view that using QALYs as a measure of value for highly specialised technologies has merit. Indeed, we consider that expressing health benefits by modelling quality of life and length of life, over a time horizon that is long enough to capture the benefits of a new technology, is a necessary and an important enhancement to the evaluation of these treatments.

16. It is worth noting that most of the highly specialised technology evaluations we have undertaken reveal QALY gain that is an order of magnitude greater than those seen in standard technology appraisals, where the average QALY gain is less than 1. Exposing this explicitly reveals the magnitude of the incremental therapeutic benefit of these treatments and will form the basis of a new approach to their evaluation, which recognises that the NHS has long regarded patients with very rare conditions, and the treatments designed for them, as requiring special consideration.

17. Few consultees considered that migrating topics that NICE is unable to recommend into the CPAG process has merit. Accordingly, this proposal has been withdrawn.

A modified approach

18. NICE and NHS England have reflected on the consultation responses and consider that a modified approach to the application of the £100,000 QALY limit for automatic application of the funding directive should be put in place This will involve the introduction of a QALY weighting, which will progressively advantage treatments that offer greater QALY gains. The £100,000 per QALY

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maximum for automatic funding (subject to the budget impact test) would be retained, but the HST Evaluation Committee would have discretion to apply the QALY weight in defined circumstances. By using incremental QALY gain, we can illustrate, quantitatively, what actually matters to patients (incremental therapeutic benefit) with a corresponding measure that everyone can understand (additional QALYs). And by making it clear that higher incremental cost effectiveness ratios (£s per QALY) are only acceptable when associated with higher QALY gains, we both provide a more explicit framework for decision-making than we have had so far, and we send a clear signal that what matters most, and what will attract the highest premium, is therapeutic benefit.

19. This revised approach takes account of our current methodology for evaluating HSTs. This describes the special features of treatments for very rare conditions. The methodology also describes a range of factors the HST Evaluation Committee needs to take into account during decision making. It is clear that, in reaching its previous decisions, the factor on which the HST Committee placed most weight is the extent to which technologies demonstrate significant therapeutic improvement. This is described in our current HST methods as 'overall magnitude of health benefits to patients and, when relevant, carers'.

20. For the HST QALY modifier to be applied, there would need to be compelling evidence that the treatment offers significant QALY gains over established NHS practice. The HST Evaluation Committee will consider the size of the QALY gain in relation to the additional weight that would need to be assigned to the QALY benefits for the cost-effectiveness of the technology to fall within HST £100,000 QALY limit. Depending on the number of QALYs gained over the lifetime of patients, when comparing the new technology with its relevant comparator(s), the committee will apply a weight of between 1 and 3, using equal increments, for a range between 10 and 30 QALYs gained.

21. The weighting would be applied in the following way:

Table 1 - Weighting of QALYs in HST

Incremental QALYs gained (per patient, using lifetime horizon)	Weight versus 100k/QALY
Less than or equal to 10	1
11 – 29	Between 1 and 3 (using equal increments)
Greater than or equal to 30	3

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22. The proportion of technologies that will attract a weighting will depend the magnitude of the incremental benefit they offer. It is not possible to predict how many will do so, with any certainty. However, it is likely that 3 of the HST topics so far evaluated would have attracted some weighting under the new arrangements. Having attracted a weighting, the cost to the NHS will be the critical determinant in whether NICE is able to issue a positive recommendation.

23. All positive HST guidance will be issued with a description of the special arrangements required for managed access; defining selected populations, starting and stopping rules, requirements for evidence collection, and patient consent.

24. The changes set out above have been incorporated in the process and methods statement for the Highly Specialised Technologies programme.

25. NICE and NHS England will review the revised arrangements and if necessary, make proposals for amendments, after 3 years.

26. Although we indicated in the consultation proposals that we could implement the proposal for all topics that have their first committee meeting after 1 April 2017, in light of the changes proposed, we now intend to put these arrangements for topics that are initiated after 1 April 2017.

Decision

27. The Board is asked to approve:

- The proposals laid out in the consultation, as amended;

- The introduction of a QALY weight;

- The implementation plan, as amended.

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Directors' progress reports

The next 5 items provide non-executive directors and the public with 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 in January and February 2017, and outline the challenges and risks they face.

Professor Carole Longson, Director, Centre for Health Technology Evaluation (Item 10)

Professor Mark Baker, Director, Centre for Guidelines (Item 11)

Jane Gizbert, Director, Communications Directorate (Item 12)

Alexia Tonnel, Director, Evidence Resources Directorate (Item 13)

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

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Centre for Health Technology Evaluation progress report

1. This report sets out the performance of the Centre for Health Technology Evaluation (CHTE) against our business plan objectives during January - February 2017.

2. The joint public consultation on the proposed changes to the technology appraisals and highly specialised technologies evaluation programmes closed on Friday 13th January 2017 and received a significant response. Members of the TA and HST teams at NICE, along with colleagues from NHS England have been working through the comments in order to refine the proposals. The NHS England Specialised Services Commissioning Committee (SSCC) discussed the proposals in February and the NICE Board are reviewing the final proposals at this meeting.

3. Scientific Advice passed the DH digital services assessment in December to allow the Medtech Early Technical Assessment (META) tool to proceed to a live beta version. We are in the final stages of development and expect to launch the tool in late April/early May. Scientific Advice also held a very successful patient engagement event in January to help patients, patient organisations and industry understand the role of patient experts within NICE, how patients help shape product development programmes and what learning and support activities NICE is offering to patient experts.

4. The NICE Office for Market Access (OMA) successfully delivered another multi-stakeholder safe harbour engagement meeting on 27 January. Along with the company and colleagues from the Medicines and Technologies Programme, attendees included representatives from NHS England and the DH Commercial Medicines Unit.

5. The Medical Technologies Evaluation Programme is planning to publish the 100th Medtech Innovation Briefing in March 2017, supported by enhanced media promotion.

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Performance

Table 1 Performance update for January - February 2017

Objective	Actions	Update
Publish 50 technology appraisals guidance (including up to 15 CDF reconsiderations)	The programme published 5 pieces of final guidance in January 2017 and 2 pieces of final guidance in February 2017.	Technology Appraisals are still on target to publish 50 pieces of guidance within the 2016/17 business year.
Publish 35 interventional procedures guidance	The programme will publish 2 pieces of guidance on 22 Feb 2017.	
Publish 6 diagnostics guidance	The programme published 1 piece of guidance in both January and February 2017.	The diagnostics assessment programme has completed its publications for the 2016/17 business year with 5 pieces of guidance.
Publish 3 highly specialised technologies guidance	The programme published 1 piece of final guidance in February 2017.	Highly specialised technologies are still on target to publish 3 pieces of guidance within the 2016/17 business year.
Publish 7 medical technologies guidance	The programme published 2 pieces of final guidance in February 2017.	The programme plans to publish 5 pieces of guidance in the 2016/17 business year.
Publish 36 Medtech Innovation Briefings (MIBs)	The programme published 7 MIBs during January & February 2017.	Medical technologies are still on target to publish over 36 MIBs within the 2016/17 business year.
Submit advice to ministers on 12 Patient Access Schemes	PASLU expects to issue 4 pieces of advice to the Department of Health during January and February 2017.	The target for PASLU is to issue 12 pieces of advice to the DH for 2016/17. PASLU expects to have issued 30 pieces of advice to the DH by the end of 2016/17.

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Objective	Actions	Update
Deliver up to 14 Commissioning Support Documents (CSDs)	The set up phase for this programme is ongoing following changes to the specification of required work.	Discussions are ongoing with NHS England
Effective management of Scientific Advice income generated activity	4 further completed/live projects 2 further speaking events	Total 41 completed/live projects for 2016/17 Total 5 seminars completed with 1 further seminar scheduled for 2016/17 Total 34 speaking events with 6 further scheduled for 2016/17

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Figure 1 Performance against plan Centre for Health Technology Evaluation from April 2016 - February 2017
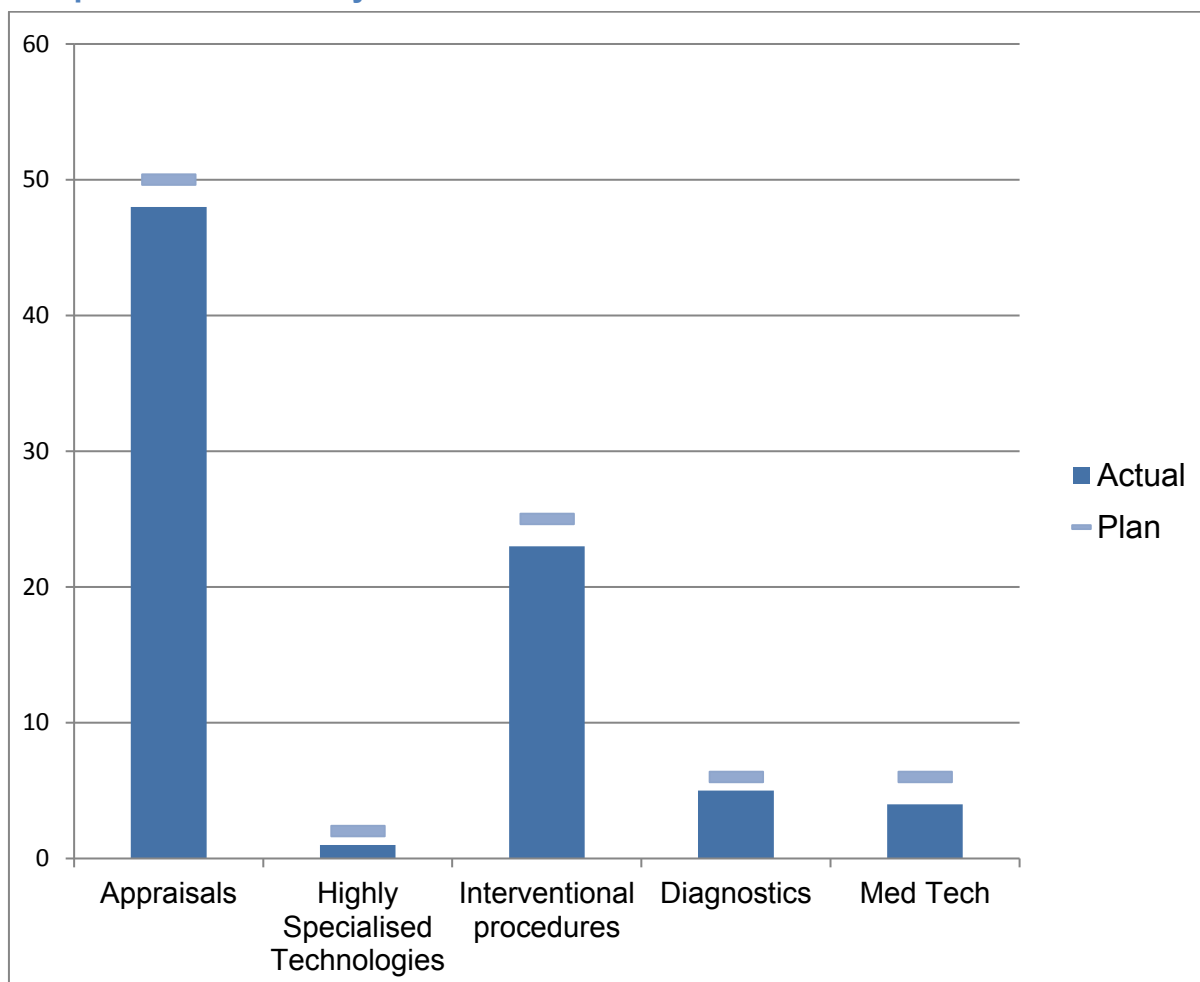
Key developments and issues

6. In October 2016 the Board approved a business case for consultants to undertake the initial work on the CHTE 2020 transformation project. It has not been possible to proceed as planned, mainly because it has not been possible to secure an external consultancy. Instead we have developed an in-house option which is within the budget set for the consultancy project. This option involves existing senior staff taking on additional responsibilities to develop and implement the change project, and backfilling some of their current duties with fixed term or bank staff. Senior staff with time formally allocated to the project include two programme directors (Mirella Marlow and Meindert Boysen) and an associate director (Jenniffer Prescott). We also have a small contingency provision to engage with external consultants if required.

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7. The Interventional Procedures Advisory Committee Terms of Reference and Standing Orders have been updated.

8. The Observational Data Unit (ODU) is renewing its Memorandum of Understanding with NHS England, to continue to provide a portfolio of 6 Commissioning Through Evaluation projects in 2017/18. New pipeline projects are being planned to replace 3 that will end in 2017/18. The ODU is also leading on a section of a EUnetHTA Joint Action 3 Work Package, on developing quality standards for registers. Initial work on this project has entailed conducting a global survey on current use of register quality standards by HTA agencies, and writing a report on the results. Expertise gained in the ODU is being used to advise other teams in NICE on issues relating to collecting and using observational data, including the Cancer Drugs Fund team and the HSC Directorate as it prepares its work on Improving Access to Psychological Therapies.

9. Recent developments in the Medical Technologies Evaluation Programme include:

    -   The [30th piece](#) of medical technologies guidance was published in December 2016. Two guidance topics planned to be published in 2016/7 have been delayed to 2017/18 to coincide with the availability of key evidence (MT250 Endocuff Vision for endoscopic investigation) and because committee meetings had to be cancelled because they were not quorate (MT294 ENDURALIFE-powered CRT-D devices for treating heart failure).

    -   The Programme is surveying industry and health and care system users on their views on medtech innovation briefings (MIBs).

    -   [Medical technology guidance 29](#) (reported in the Daily Mail as 'Burst of green light that could banish night-time trips to the loo') attracted 1 of the largest media responses to our guidance so far.

    -   The programme is currently developing 4 proof-of-concept briefings on health apps.

    -   Discussions with NHS England and other key stakeholders are taking place over proposals for NICE to develop a national, systematic framework for tracking in-development innovative non-drug technologies including devices, diagnostics and digital (MedTechScan), an approach which was recommended by the Accelerated Access Review.

    -   The MTEP Programme research facilitation workstream promotes collaborative research to answer guidance research recommendations. Our proposed clinical studies on 2 guidance topics, MTG20 Parafricta

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Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers and MTG21 The ReCell Spray‑On Skin system for treating skin loss, scarring and depigmentation after burn injury, have recently attracted funding of over £0.5m and are expected to start shortly, subject to research ethics approval.

- The project to retender the External Assessment Centre evidence preparation and assessment services from April 2018 has been initiated. The requirements specification will release efficiency savings.

- A research paper describing the first 5 years of MTEP's experience of non-drug health technology assessment has been accepted for publication by the International Journal for Health Technology Assessment. This will join a significant publication output from the Programme.

10. Following the reform of the Cancer Drugs Fund (CDF) to facilitate managed access, the technology appraisals team has adapted its ways of working and absorbed a significant amount of additional work. Our methods and processes for technology appraisal were updated on 1 April 2016 and between then, and February 2017, we have published 30 pieces of guidance on cancer topics, including 25 recommendations for routine commissioning and 1 recommendation for use in the CDF (allowing access while additional data collection takes place to address clinical uncertainty). The NICE CDF team is currently involved in 15 topics where there is a high possibility of a recommendation for use in the CDF. The team has hosted 5 data collection working group meetings attended by companies, NHS England, Public Health England and committee representatives to develop draft manged access agreements. NICE's CDF team actively monitors all cancer topics, providing NHS England with regular updates to support them with introducing interim CDF funding for positive draft recommendations for eligible cancer treatments.

11. Part of this CDF work includes appraising 'transition topics', which are treatments that had been approved for use in the previous model of the CDF including:

- Licensed drug indications which had previously been appraised by NICE and received final guidance with negative recommendations (group 1; n=11)

- Licensed drug indications which were within the NICE technology appraisal process but had not received final guidance (group 2; n=9)

- Licensed drug indications which had not been referred to NICE for appraisal (group 3; n=11)

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Positive final guidance has been published for 8 of the group 1 topics and 3 of the group 2 topics. All remaining topics have been scheduled into the work programme and final guidance for these is expected to be published by 31 December 2017.

12. CHTE is a partner on three Big Data for Better Outcomes (BD4BO) projects funded by the European Innovative Medicines Initiative (IMI), which are being delivered by a fully funded project team within the CHTE Science Policy and Research programme and collectively will run for between 2 and 5 years. Two of the projects are disease specific (ROADMAP – Alzheimers disease, and HARMONY – blood cancers) which will work to create real world evidence platforms for collection and analysis of evidence to better understand these diseases and how best to treat them, ensuring input from patients and carers is embedded in this. The third project, DO-IT, will coordinate the knowledge generated by other BD4BO projects acting as a programme 'hub', to bring together stakeholder groups and ensure quality and consistency within the individual projects. NICE will be a lead partner in all three projects, coordinating the input of both health technology assessment (HTA) and payers across Europe to ensure their requirements are taken into account and the projects deliver outputs that are useful for regulatory and HTA agencies as well as being of high scientific quality. The IMI office has confirmed that these projects will continue on a "business as usual basis" following the UK EU membership referendum outcome.

Risks

Table 2 Risks identified January – February 2017: key controls and ratings

Risk	Key controls	Risk rating now	Risk rating year end
Resource allocation for Commissioning Support Programme does not cover revised specification from NHS England	Key decision makers from NICE and NHS England attending weekly steering group to agree way forward	Amber	Green

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Appendix 1 Guidance published since April 2016

Guidance title	Publication date	Notes
Technology Appraisals		
TA433; Apremilast for treating active psoriatic arthritis	February 2017	Recommended
TA432; CDF reconsideration - Everolimus for the second-line treatment of metastatic renal cell carcinoma (review of TA219)	February 2017	Recommended
TA431; Mepolizumab for treating severe refractory eosinophilic asthma	January 2017	Optimised
TA430; Sofosbuvir–velpatasvir for treating chronic hepatitis C	January 2017	Recommended
TA429; Ibrutinib for previously treated chronic lymphocytic leukaemia and untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation	January 2017	Recommended
TA428; Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after chemotherapy	January 2017	Recommended
TA427; Pomalidomide for multiple myeloma previously treated with lenalidomide and bortezomib	January 2017	Recommended
TA426; CDF partial reconsideration of TA251 – Dasatinib for untreated chronic myeloid leukaemia	December 2016	Recommended
TA425; CDF partial reconsideration of TA241 – Dasatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia	December 2016	Recommended
TA424; Breast cancer (early, HER2 pos) - pertuzumab (neoadjuvant)	December 2016	Recommended
TA423; Breast cancer (locally advanced or metastic) review TA250 - eribulin	December 2016	Recommended

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Guidance title	Publication date	Notes
TA422; CDF reconsideration - Crizotinib for the treatment of previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene (review of TA296)	December 2016	Recommended
TA421; CDF reconsideration - Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA295)	December 2016	Recommended
TA420; Ticagrelor for preventing atherothrombotic events after myocardial infarction	December 2016	Recommended
TA419; Apremilast for treating moderate to severe plaque psoriasis - Rapid Review	November 2016	Recommended
TA418; Dapagliflozin in triple therapy for treating type 2 diabetes - STA	November 2016	Recommended
TA417; Nivolumab for previously treated advanced renal cell carcinoma - STA	November 2016	Recommended
TA416; Lung cancer (non-small-cell, EGFR and T790M positive, metastatic) - osimertinib (after EGFR-TKI) – STA	October 2016	Recommended within the CDF
TA415; Rheumatoid arthritis - certolizumab pegol (after TNF inhibitor) – STA	October 2016	Optimised
TA414; Melanoma (BRAF V600, unresectable, untreated, metastatic) - cobimetinib (with vemurafenib) – STA	October 2016	Not recommended
TA413; Hepatitis C (chronic) - elbasvir-grazoprevir – STA	October 2016	Recommended
TA412; Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases - STA	September 2016	Optimised
TA411; Necitumumab for untreated advanced or metastatic squamous non-small-cell lung cancer - STA	September 2016	Not recommended

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Guidance title	Publication date	Notes
TA410; Talimogene laherparepvec for treating unresectable metastatic melanoma - STA	September 2016	Optimised
TA409; Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion - STA	September 2016	Recommended
TA408; Pegaspargase for treating acute lymphoblastic leukaemia - STA	September 2016	Optimised
TA407; Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors - STA	September 2016	Recommended
TA406; Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer - STA	September 2016	Recommended
TA405; Trifluridine–tipiracil for previously treated metastatic colorectal cancer - STA	August 2016	Recommended
TA404; Degarelix for treating advanced hormone-dependent prostate cancer - STA	August 2016	Optimised
TA403; Ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer - STA	August 2016	Not recommended
TA402; Pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin – CDF rapid reconsideration	August 2016	Recommended Will now move from the CDF into baseline commissioning
TA401; Bosutinib for previously treated chronic myeloid leukaemia – CDF rapid reconsideration	August 2016	Recommended Will now move from the CDF into baseline commissioning

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Guidance title	Publication date	Notes
TA400; Nivolumab in combination with ipilimumab for treating advanced melanoma - STA	July 2016	Recommended
TA399; Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts - STA	July 2016	Not recommended
TA398; Lumacaftor–ivacaftor for treating cystic fibrosis homozygous for the F508del mutation – STA	July 2016	Not recommended
TA397; Belimumab for treating active autoantibody-positive systemic lupus erythematosus – STA	June 2016	Optimised
TA396; Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma – STA	June 2016	Recommended
TA395; Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer – STA	June 2016	Recommended
TA394; Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia - STA	June 2016	Optimised
TA393; Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia - STA	June 2016	Optimised
TA392; Adalimumab for treating moderate to severe hidradenitis suppurativa - STA	June 2016	Recommended
TA391; Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel - STA	May 2016	Recommended
TA390; Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes - MTA	May 2016	Optimised

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Guidance title	Publication date	Notes
TA389; Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer - MTA	April 2016	Various
TA388; Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction - STA	April 2016	Optimised
TA387; Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated - STA	April 2016	Recommended
Interventional procedures		
IPG575 - Trabecular stent bypass microsurgery for open-angle glaucoma	Feb 2017	Standard
IPG574 - Lateral interbody fusion in the lumbar spine for low back pain	Feb 2017	Standard
IPG573 - Radiation therapy for early Dupuytren's disease	Dec 2016	Special
IPG572 - Irreversible electroporation for treating prostate cancer	Dec 2016	Research
IPG571 - Extracorporeal shockwave therapy for Achilles tendinopathy	Dec 2016	Special
IPG570 - Epiduroscopic lumbar discectomy through the sacral hiatus for sciatica	Dec 2016	Research
IPG569 - Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity	Nov 2016	Standard
IPG568 - Percutaneous insertion of craniocaudal expandable implants for vertebral compression fracture	Nov 2016	Other
IPG567 - Endoscopic transluminal pancreatic necrosectomy	Nov 2016	Standard
IPG566 - Single incision sub-urethral short tape insertion for stress urinary incontinence in women (formerly TVT Secur)	Oct 2016	Standard

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Guidance title	Publication date	Notes
IPG565 - Miniature lens system implantation for advanced age-related macular degeneration	Sept 2016	Standard
IPG564 - Extracorporeal carbon dioxide removal for acute respiratory failure	August 2016	Research
IPG563 - Percutaneous endoscopic laser balloon pulmonary vein isolation for atrial fibrillation	June 2016	Special
IPG562 - Ultrasound-guided percutaneous radiofrequency ablation for benign thyroid nodules	June 2016	Special
IPG561 - Transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting	June 2016	Standard
IPG560 - Microstructural scaffold (patch) insertion without autologous cell implantation for repairing symptomatic chondral knee defects	June 2016	Standard
IPG559 - Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine	May 2016	Standard
IPG558 - Biodegradable subacromial spacer insertion for rotator cuff tears	May 2016	Special
IPG557 - Endovenous mechanochemical ablation for varicose veins	May 2016	Special
IPG556 - Percutaneous transforaminal endoscopic lumbar discectomy for sciatica	April 2016	Special
IPG555 - Percutaneous interlaminar endoscopic lumbar discectomy for sciatica	April 2016	Standard
IPG554 - Balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension	April 2016	Standard
IPG553 - Microwave ablation for treating liver metastases	April 2016	Research

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Guidance title	Publication date	Notes
Diagnostics		
DG23 PIGF-based testing to help diagnose suspected pre-eclampsia (Triage PIGF test, Elecsys immunoassay sFlt-1/PIGF ratio, DELFIA Xpress PIGF 1-2-3 test, and BRAHMS sFlt-1 Kryptor/BRAHMS PIGF plus Kryptor PE ratio)	May 2016	Triage PIGF, Elecsys immunoassay sFlt-1/PIGF ratio recommended to help rule out pre-eclampsia. DELFIA Xpress PIGF 1-2-3 test, BRAHMS sFlt-1 Kryptor/BRAHMS PIGF plus Kryptor PE ratio not recommended
DG24 ImmunoCAP ISAC 112 and Microtest for multiplex allergen testing	May 2016	Research
DG25 High-throughput non-invasive prenatal testing for fetal RHD genotype	November 2016	Recommended
DG26 Integrated multiplex PCR tests for identifying gastrointestinal pathogens in people with suspected gastroenteritis (xTAG Gastrointestinal Pathogen Panel, FilmArray GI Panel and Faecal Pathogens B assay)	January 2017	Research
DG27 Molecular testing strategies for Lynch syndrome in people with colorectal cancer	February 2017	Recommended
Highly Specialised Technologies		
HST4; Fabry disease - migalastat	February 2017	Recommended
HST3; Ataluren for treating Duchenne muscular dystrophy with a nonsense mutation in the dystrophin gene	July 2016	Recommended
Medical technologies		
MTG32 HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography	February 2017	Recommended

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Guidance title	Publication date	Notes
MTG31 HumiGard for preventing inadvertent perioperative hypothermia	February 2017	Promising but further research recommended
MTG30 XprESS multi-sinus dilation system for treating chronic sinusitis	December 2016	Recommended
MTG29 GreenLight XPS for treating benign prostatic hyperplasia	June 2016	Recommended

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Centre for Guidelines progress report

1. This report sets out the performance of the Centre for Guidelines against our business plan objectives for the months of January and February 2017.

Performance

2. Two clinical guidelines were published.

3. Two public health guidelines were published.

4. No social care guidelines were published.

5. Twelve surveillance reviews were published.

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Table 1 Performance update for January and February 2017

	Objective	Actions	Update
1	Publish 25 clinical guidelines including updates	Three publications were planned for January and February 2017.	Two guidelines were published in January and February. A third guideline was due to publish in January 2017, however, in August 2016 we added four additional review questions, thereby extending the development time. This guideline will now publish in 2017/2018.
2	Publish 5 public health guidelines	Two publications were planned for January and February 2017.	Two guidelines were published in January and February 2017.
3	Publish 1 social care guideline	No publications were planned for January or February 2017	
4	Publish 40 clinical surveillance reviews and 5 exceptional reviews	Four surveillance reviews were planned for publication in January and February 2017.	Ten clinical surveillance reviews and 2 exceptional reviews were published in January and February 2017.
5	Develop sustainable processes and methods for reviewing clinical guidelines	Evaluate the new processes/methods and make improvements as appropriate Complete 'live' guidelines pilot topics and plan broader implementation of such approach including tracking system for key trials and develop and test continuous surveillance methods and processes for a diabetes standing committee	The expert adviser panel has recruited 768 former GDG members. Currently 630 experts have completed their registration and are active on the database. Approximately 1600 invites covering 169 guidelines have been sent out to date. We have recruited 32 experts form open adverts to fill identified gaps in expertise.

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	Objective	Actions	Update
		Complete registration for Topic Expert panel so that sufficient Topic Experts are pre-recruited for Surveillance Reviews and Clinical Guideline Update Team to utilise Pre recruiting panel of GC Chairs for all Committee activity (approx. 50)	
6	Operate the Centre within budget and put in place plans to meet the agreed efficiency savings	Centre budget balanced at year-end and demonstrates ability to make agreed efficiency savings. Agree a management of change process that will demonstrate efficiency savings. Deliver management of change exercises.	The SMT approved the CfG Management of Change proposals. Following consultation, interviews and slotting in are currently underway, with completion due on 22 February 2017.
7	Put in place plans to ensure that contractors (including the BNF) and developers embed new processes and methods that will maintain and improve the quality of work and contribute to efficiencies.	Put in place plans to support business continuity to minimise risks to the work programme during the transition period of the new contractors. Demonstrate delivery of quality to time and to budget through performance managing	Quarter 3 review meetings with two external contractors (NGA and NGC) have been undertaken, at the time of reporting both contractors are within budget and reporting no high risks.

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	Objective	Actions	Update
		the contracts through quarterly review meetings. Develop new contract monitoring systems for all contractors and developers. Develop new processes that will improve quality assurance of clinical guidelines.	The NCSSC contract will end in March 2018. An exit plan is being drawn up to minimise the risks in closing the contract and to ensure that the quality of the remaining guidelines are maintained. To date, contract deliverables are still being met. The BNF are developing an app as an alternative way for clinicians to access BNF information. The app is being tested and will be launched in April 2017.
8	Develop new methods and processes of updating clinical guidelines to contribute to agreed efficiencies	Develop new sustainable methods and processes to reduce the time interval between review and publication of updates. Set up a working group to develop new ways of working Pilot new ways of working internally	Methods and processes have been developed for scoping medium sized topics in-house, following extensive planning by the senior team. We have commissioned three guideline updates using the new process
9	Develop the methods of clinical guideline development to maintain enhance the Centre's reputation for methodological quality and efficiency.	Contribute to the management of change process to bring together health economists from across CfG in to a single team to provide for enhanced access to health economics resource across CfG functions;	Plans are complete for bringing together the health economic function from across CfG into a single team. Implementation will commence following completion of the MoC exercise. The third steering group meeting of the UK GRADE Network was held in January 2017.

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	Objective	Actions	Update
		Develop service delivery guidelines to expected quality and time, Contribute to the development of methods and processes for considering resource impact in guideline development; Establish and maintain links and networks with external research initiatives, organisations and projects to address our methodological needs and ensure our methods continue to reflect internationally-recognised best-practice. Continue to develop the methodology supporting the NICE guideline contextualisation service.	We have also hosted the first 'GRADE clinic' (February), bringing together attendees from across the GRADE network including staff from NICE and our Guideline Development Centres, Cochrane and BMJ Evidence to discuss in depth some of the challenges in applying GRADE. In January, the Centre hosted a 1-day workshop for guideline developers on "Diagnostic test accuracy systematic reviews and meta-analysis" facilitated by our Technical Support Unit. And in February, our TSU delivered a presentation to the NICE Technical Forum on "Sensitivity of treatment decisions to bias adjustment in network meta-analysis" resulting from work we commissioned in 2016. In January we signed off for public consultation in New Zealand, a draft contextualised NICE guideline. We continue to develop plans for contextualising the first guideline for Ireland.
10	Support the Implementation of the guidelines manual and the NICE content strategy; oversee the transforming guidance development programme	Consider required revisions and amend processes and templates accordingly. Plan and deliver projects aimed at improving NICE content and the development and delivery of NICE guidance	Work continues on digital development projects to improve the quality standards knowledge base, and the discovery phase of work on reuse of content is now underway. A tool enabling staff to source freely available journal articles has been launched, and will greatly improve the efficiency of this work.

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Objective	Actions	Update
		Development of an administration module for document supply is underway, and these features will be integrated into the EPPI-Reviewer tool once complete. Approval to start work on the first of a number of packages to support guidance development (external consultations) is being sought from Government Digital Services.

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Key issues

6. Following the establishment of the Centre for Guidelines in July 2016, a major redesign of the Centre's functions has been proposed in line with NICE's approach to reducing its cost base whilst maintaining the breadth of its offer. Plans will be fully implemented from March following appointments to the new structures over the next two months.

7. The Management of Change exercise has affected every team with changes in both personnel and ways of working. However, any delays in the production have been kept to a minimum. The future programme remains secure and strengthened as a result of the changes.

8. We have just commenced a new programme of work, sitting jointly with the public health and medicines practice teams, on the management of common infections. This work, commissioned by DH as part of the strategy to overcome antimicrobial resistance, will produce a large number of short treatment guidelines over the course of the next 2-3 years using a shortened timeline and simpler process. The first publication is expected in July 2017.

Risks

Table 2 Risks identified January and February 2017: key controls and ratings

Risk	Key controls	Risk rating now	Risk rating year end
Management of change exercise alongside development of new ways of working – risk of reduction in delivery of outputs due to altered structures to deliver guidance production	Effective plans are being implemented to ensure new structures are in place following the management of change exercise. Internal meetings are being held to develop operational plans for new ways of working. Recruitment is prioritised to maintain adequate workforce to deliver outputs	Medium	Medium
Failure to deliver social care guidance to time and or quality due to altered structures and agreement	Plans are being developed to ensure structures are in place to deliver the work programme.	Medium	Medium

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Risk	Key controls	Risk rating now	Risk rating year end
to not renew contract with current developer.	Plans are being put in place to manage the non-renewal of contract		

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Appendix 1 Guidance published since April 2016

Total number of guidelines and surveillance reviews published in 2016-17 to date.

Guidance title	Publication date	Notes
Clinical guidelines		
Routine preoperative tests for elective surgery (NG45)	April 2016	(update)
Crohn's disease: management (standing committee update) (CG152)	May 2016	
Psychosis and schizophrenia in children and young people: recognition and management (CG155)	May 2016	
Haematological cancers: improving outcomes (NG47)	May 2016	
Neonatal jaundice (CG98)	May 2016	
Non-alcoholic fatty liver disease (NAFLD): assessment and management (NG49)	July 2016	
Cirrhosis in over 16s: assessment and management (NG50)	July 2016	
Sepsis: recognition, diagnosis and early management (NG51)	July 2016	
Non-Hodgkin's lymphoma: diagnosis and management (NG52)	July 2016	
Fertility problems: assessment and treatment (CG156)	August 2016	(standing committee update)
Heavy menstrual bleeding (CG44)	August 2016	(standing committee update)
Multimorbidity: clinical assessment and management (NG56)	September 2016	
Mental health problems in people with learning disabilities: prevention, assessment and management (NG54)	September 2016	
Low back pain and sciatica in over 16s: Assessment and management (NG59)	November 2016	

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Guidance title	Publication date	Notes
Physical health of people in prison (NG57)	November 2016	
Chest pain of recent onset: Assessment and diagnosis (CG95)	November 2016	(standing committee update)
Chest pain of recent onset: Assessment and diagnosis (CG95)	November 2016	(standard update)
Intrapartum care for healthy women and babies (CG190)	November 2016	(standing committee update)
Inadvertent perioperative hypothermia (CG65)	December 2016	(standing committee update)
End of life care for infants, children and young people with life limiting conditions: planning and management (NG61)	December 2016	
Cerebral Palsy in under 25's: Assessment and management (NG62)	January 2017	
Spondyloarthritis (NG65)	February 2017	
Public Health and Social Care		
Oral health for adults in care homes (NG48)	July 2016	
Transition between inpatient mental health settings and community and care home settings (NG53)	August 2016	
Harmful sexual behaviour among children and young people (NG55)	September 2016	Planned to publish in July 2016
Coexisting severe mental illness and substance misuse: Community health and social care services (NG58)	November 2016	
HIV testing: increasing uptake among people who may have undiagnosed HIV (NG60)	December 2016	
Antimicrobial stewardship: changing risk-related behaviours in the general population (NG63)	January 2017	

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Guidance title	Publication date	Notes
Drug misuse prevention: targeted interventions (NG64)	February 2017	
Surveillance reviews		
CG126 Stable angina: management	April 2016	
CG101 Chronic Obstructive Pulmonary Disease	April 2016	
CG100 Alcohol use	April 2016	
CG130 Hyperglycaemia In acute coronary Syndrome	July 2016	
CG54 Urinary tract infection in children	July 2016	
CG51 Drug misuse	July 2016	
CG57 Atopic eczema in children	July 2016	
CG140 Opioids in palliative care	July 2016	
CG142 Autism spectrum disorder in adults; diagnosis and management	July 2016	
CG138 Patient experience in adult NHS services: improving the experience of care for people using adult NHS services	August 2016	
CG141 Acute upper gastrointestinal bleeding in over 16s: management	August 2016	
CG143 Sickle cell disease: managing acute painful episodes in hospital	August 2016	
CG170 Autism spectrum disorder in under 19s; support and management	September 2016	
CG128 Autism spectrum disorder in under 19s; recognition, referral and diagnosis	September 2016	
CG167 STEMI	September 2016	
CG94 Unstable angina and NSTEMI: early management	September 2016	
CG133 Self harm: Longer term management	September 2016	
CG16 Self harm in over 8's: Short term management and prevention of reoccurrence	September 2016	

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Guidance title	Publication date	Notes
CG175 Prostate cancer: diagnosis and management	October 2016	
CG127 Hypertension in adults: diagnosis and management	October 2016	
CG136 Service user experience in adult mental health	November 2016	
CG144 Venous thromboembolic diseases	November 2016	
CG134 Anaphylaxis	November 2016	
CG150 Headaches	November 2016	
CG145 Spasticity in children	November 2016	
CG155 Psychosis and schizophrenia in children & young people	November 2016	
CG120 Coexisting severe mental illness (psychosis) and substance misuse	November 2016	
CG135 Organ donation for transplantation	December 2016	
CG76 Medicines adherence	December 2016	
CG37 Postnatal care up to 8 weeks after birth	January 2017	
CG129 Multiple pregnancy: antenatal care for twin and triplet pregnancies	January 2017	
CG70 Inducing labour	January 2017	
CG132 Caesarean section	January 2017	
CG149 Neonatal infection early onset; antibiotics for prevention and treatment	January 2017	
CG107 Hypertension in pregnancy: diagnosis and management	January 2017	
CG68 Stroke and transient ischaemic attack in over 16s: diagnosis and initial management	January 2017	
CG74 Surgical site infections: prevention and treatment	January 2017	
NG25 Preterm labour and birth	January 2017	
CG62 Antenatal care for uncomplicated pregnancies	January 2017	
CG147 Peripheral arterial disease: diagnosis and management	February 2017	

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Guidance title	Publication date	Notes
CG61 Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care	February 2017	

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Appendix 2 Figure 1-3 Performance against planned publications in January and February 2017

Cumulative Clinical Guideline Publications 2016/17

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Cumulative Surveillance Review Publications 2016/17

Legend:
- Actual
- Planned

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Cumulative Public Health and Social Care Publications 2016/17

Chart: Bar chart showing cumulative publications by month (April to Feb) with "Actual" (dark blue bars) and "Planned" (light blue markers). Values: April 0, May 0, June 0, July 1, Aug 2, Sept 3, Oct 3, Nov 4, Dec 5, Jan 6, Feb 7.

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Communications directorate progress report

1. This report sets out the performance of the Communications directorate against our business plan objectives during January and February 2017. These Communications directorate business objectives are closely aligned to the NICE strategic objectives.

2. 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.

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Table 1 Performance update for January and February 2017

Objective	Actions	Update
1. CONTENT Curate and facilitate high quality content in the outputs from the communication directorate and across NICE (in order to help NICE achieve its high level objective to publish guidance, standards and indicators).	Provide expertise and training to enable teams across NICE to produce quality content.	**Guidance and supporting products** In addition to editorial support for all guidance, in January and February we contributed advice and expertise to ensure both high quality content and to improve efficiency. These activities included working with developers on the structure of the antimicrobial stewardship guideline, and quality assurance of endorsement of resources to support the guideline. Following discussions with the CHTE, we updated templates for several types of document, making them shorter and easier for both developers and readers to use. NICE's plans to better support shared decision making, include stopping producing information for the public for individual guidelines from April 2017. To implement this, we have been re-working the 'Information for the public' tab on the guidance pages of the website. We will use the tab to provide key messages about the guidance and links to news stories and resources. It will also contain links to centralised, generic information about shared decision making and other topics, such as the use of off-label medicines. Editors have also been developing new formats to provide information for the public about appraisals, interventional procedures and other CHTE guidance. The new Information for the public tab is scheduled to launch in April.
1. Content (cont.)		**Training and support for quality**

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Objective	Actions	Update
		We ran a workshop for the National Guideline Centre on writing the new rationale sections for guidelines. We also ran 2 workshops on writing minutes and a Writing for NICE workshop, all of which had positive feedback.
	Provide communications expertise into the digital transformation project.	The content team worked on the update to the guidelines manual, and in particular on the new section on preference sensitive decision points to support shared decision making. The team also gave feedback on the functionality of MagicApp for reviewing and editing content, making suggestions for changes that could improve its use in the development of NICE guidance.
	Create clear brand guidelines which establish the voice and personality of NICE and govern every aspect of communication from NICE	A brand refresh was carried out by external engagement team, working in collaboration with colleagues in Digital Services. A new colour-palette was rolled out on 31st January across nice.org.uk, Pathways, our newsletters, stationary, social media channels and events materials. The brand refresh ensures that all content from NICE look consistent and professional. The new brand guidelines also provide guidance on how images, infographics, language and social media should support the NICE Brand. The guidelines were published online, and a suite of additional resources including new branded PowerPoint templates and logos were made available to staff via NICE Space.

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Objective	Actions	Update
1. Content (cont.)	Ensure website content is up to date and accurate and deliver a rolling programme of improvements.	**Website guidance content** As part of the quality improvement work, new overviews have been drafted for all quality standard topic pages. They will be quality assured before they are uploaded to the website. Similar work is in progress for technology appraisals. In January and February we prepared 88 documents for digital publication, and published 3 new and 1 updated quality standard in the knowledge base. **Website corporate content** We published a number of new content items on the website to increase engagement with NICE. This included a new register an interest in IP form and notify an interventional procedure form. We also streamlined the register as a stakeholder journey for medtech and created an easier way to notify NICE of a new medical technology. Other work included improvements to the join a committee pages and creating a section for the new NICE brand guidelines.
1. Content (cont.)	Maintain 100% of guidance in NICE Pathways and continue the programme of continuous improvement.	We continue to maintain 100% of guidance in NICE Pathways. In January and February we published 3 new pathways and updated 22 to take account of new guidance. As part of our quality improvement project we fully updated 9 pathways, to bring them up to date with current standards of pathway content and presentation. 30 pathways were updated to add links to related pathways or for routine maintenance.

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Objective	Actions	Update
		User research has suggested that people confuse NICE Pathways with care pathways. We made some changes to pathways to explain more clearly what they are: everything NICE says on a topic in an interactive flowchart. We also launched a project to work with colleagues to ensure this message is used in templates, on the website and in other communications that mention pathways.
	Use new online software package such as 'Shorthand' to present our new guidance to media and other stakeholders	The media team produced Shorthand news stories to promote the draft guideline on child abuse and the final guideline on antimicrobial resistance.
2 ENGAGEMENT Create a structured and coordinated approach for working with and listening to stakeholders	Lead a project to develop a customer relationship management (CRM) system that can be used across the organisation	Work on the tender has restarted following the change in the CRM package offered by Microsoft. We are working on a revised tender to reflect the changes in the Microsoft offer, and are working closely with colleagues in the field team and intellectual property and content business team to incorporate their requirements in the specification
	Develop an internal speaking engagement grid to help improve coordination of senior NICE representatives' speaking commitments	NICE staff and committee members spoke at 16 conferences and events in January/February. The external engagement team are working with colleagues in the NHS England events team to maximise NICE's involvement with their flagship NHS Expo conference in Manchester in September. We have submitted bids for 4 pop up university sessions, a plenary panel debate, and are working up plans for a satellite session featuring the Field Team's work to support the implementation of STPs locally.

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Objective	Actions	Update
	Develop a new interactive online newsletter with content tailored for key audiences	We are exploring options for delivering content to audiences including newsletters in a personalised way.
	Develop personalisation functionality on the NICE website (working with the digital services team) that allows visitors to tailor content to their needs	This project is being scoped.
2 Engagement (cont.)	Make greater use of social media including creating a Facebook presence and using Twitter to interact directly with audiences	Engagement on Twitter and Facebook is now an established part of the media team's work. Writing is more consistent and engaging leading to steady increases in audience. The media team used a new social media platform, Snapchat, to promote the antimicrobial resistance guideline which suggested educating children and young people about the importance of simple handwashing. We were the first public health body to use this social media platform. We published a Snapchat story and a NICE nose geofilter to promote engagement.
	Develop an guidance/issues grid that allows senior management and non-executive members to see 'at-a glance' scheduled guidance and the related strategic issues	A media grid is sent weekly to SMT and the Board on the week's issues. Feedback has helped to improve this service. A medium term grid is available.
	Further develop a system to capture audience insights (including Twitter and Website analytics) and provide regular reports to senior management	The media team are exploring new software to consolidate our social media analytics. Our new and existing platforms continue to grow. Page views on Facebook are up 47% and our Twitter followers have increased by 3% to 118,000. We had over 2.1 million impressions (number of people who saw our tweets) in January to February, which was similar to the previous period.

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Objective	Actions	Update
		Mentions increased 29% but largely due to online petitions for two breast cancer drugs. Top tweets came from graphics created by the team for our learning disabilities quality standard and the child abuse draft guideline.
	Provide a policy and parliamentary monitoring and briefing service	The public affairs team has provided briefings for David Haslam's visits to the royal colleges and other professional organisations, as well as ad-hoc briefings as required by SMT on parliamentary or policy issues.
3. ADOPTION and IMPACT Promote NICE's work and help users make the most of our products by providing practical tools and support, using innovative and targeted marketing techniques. Contribute to demonstration of impact though regular evaluation 3. Adoption and Impact (cont.)	Develop protocol for using graphics and images to help explain guidance and related products	This work has been completed within the brand refresh project.
	Develop new online guidance summaries which are short, concise and use infographics and multimedia techniques	This project is being scoped.
	Bring content to life by reusing case studies, shared learning examples and other material.	The changes to the information for the public tab for guidance topic pages will include using links to news items to communicate important information about new guidance topics.
	Use a variety of evaluation techniques to assess the impact of our work and to regularly gauge the views of our stakeholders	Work continues on the Cabinet Office - sponsored pilot project to assess stakeholder views of NICE. The Reputation Institute (commissioned to provide support for the project) has provided additional pro bono consultancy work and the questionnaire has been finalised subject to sign off by the Senior Management Team. The Reputation Institute have given permission for us to use their RepTrak questions in the

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Objective	Actions	Update
		survey and will carry out the analysis using their trademarked methodology. The survey will go live at the end of March.
4. PRODUCTIVITY To be effective and efficient and to work better with less	Develop and begin to roll out efficiencies and cost savings plan that will support the communication needs of the organisation in 2017-2018 and beyond.	The implementation of the Management of Change for the directorate is nearing completion and savings will be delivered from April 2017.
	Identify efficiencies within the Comms team by reusing content and procuring software that reduces time and effort in editing copy	Tender interviews were held in February to provide an integrated solution for press release distribution, media and parliamentary monitoring services and a contract has been awarded.

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Other issues

News coverage

3. Overall coverage between January and February was 75% positive. Positive coverage was driven by the quality standard on preventing falls, the antimicrobial stewardship guideline and the launch of the child abuse guideline consultation. The press conference for child abuse and neglect was attended by BBC, BMJ, Daily Mail, Guardian, Telegraph and the Times, plus some trade publications. It made the Daily Telegraph front page and all major national outlets. The news story on antimicrobial stewardship also got wide coverage with [Professor Gillian Leng, deputy CEO at NICE interviewed by the Times, Daily Telegraph and Sky News.](#)

Enquiry handling

4. During January and February we responded to 1997 enquiries. We responded to 34 MP letters, with the majority focussing on breast cancer topics. We also contributed to 43 Parliamentary Questions with further interest in the proposed changes to technology appraisals and highly specialised technologies, alongside questions about the availability of continuous glucose monitoring systems and new treatments for pancreatic cancer.

5. We responded to 15 requests made under the Freedom of Information Act. Requested information varied widely and covered our expenditure on alcoholic drinks, salary ranges at all levels of the organisation, further enquiries as part of a campaign on our guideline on chronic fatigue syndrome/myalgic encephaomyelitis and information on anti-depressant prescribing practice.

Employee engagement

6. In January we supported the annual Healthy Work Week campaign with a range of communication activities including polls on NICE Space and a popular 'healthy selfie' competition. In a survey following healthy work week, 99% staff said they were aware of the activities and 56% said they participated in the activities. 24% stated they had made a change to their health or lifestyle as a result of the campaign.

7. In February the internal communications team won a prestigious award at The Chartered Institute of Public Relations (CIPR) Inside Story Awards. NICEtimes, took top spot in the 'best use of digital platform - digital magazine or ezine' category. The awards recognise and reward best practice in internal communications

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Risks

Table 2 Risks identified during January and February - key controls and ratings

Risk	Key controls	Risk rating now	Risk rating year end
Failure to seek feedback from stakeholders in how we work and communicate with them	Reputation survey with key sector stakeholders Use of analytics to monitor and evaluate audience use of products and their views on NICE's outputs	Green	Green
Proposals for management of change in the directorate fail to offer efficiency savings or present a viable structure for supporting NICE in the future	Working with colleagues in HR to implement the Management of Change and recruit to posts in the restructured teams.	Amber	Green

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Appendix 1 Website statistics

8. In January and February there were more than 3 million sessions on the NICE website, up 10% on the pervious reporting period. In 82% of these sessions there was a 'meaningful interaction' such as downloading guidance, reading a recommendation, following links to implementation tools etc.

9. NICE Pathways had 617,000 sessions with a meaningful interaction rate of 56%. January was NICE Pathways busiest month to date with over 220,000 users completed over 340,000 sessions.

10. There were 77,485 page views on news stories in January and February. The most read news story in January was 'Everyone with learning disabilities should have their mental health checked annually' with 3,013 views and in February was 'Preventing falls in older people through conversation' with 2,486 views.

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Evidence Resources progress report

1. The Evidence Resources directorate comprises three teams which provide a range of functions to NICE:

   - The Digital Services team delivers NICE's digital transformation programme and maintains all NICE's digital services.

   - The Information Resources team provides access to high quality evidence and information to support guidance development and other NICE programmes. It also supports the provision of evidence content to NICE Evidence Services and it commissions key items of content made available to the NHS via the NICE Evidence Services.

   - The Intellectual Property (IP) and Content Business Management team manages the range of activities involved in granting permissions to use NICE's IP and content and in responding to international delegation enquiries.

2. The directorate manages the NICE Evidence Services, a suite of evidence services including a search portal (Evidence Search), the Clinical Knowledge Summary service (CKS), the BNF microsites (BNF and BNFc), access to journals and bibliographic databases via a federated search (HDAS), and medicine awareness products.

3. This report sets out the performance of the Evidence Resources directorate against our business plan objectives during January and February 2017. It also highlights performance against agreed metrics and provides an update on the risks managed within the directorate.

Performance

4. The directorate is making good progress towards completing its agreed objectives for the year. Progress in January and February 2017 is summarised in the table below.

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Table 1 Performance update for January and February 2017

Objective	Actions	Update
Evidence Information Services		
Deliver and continue to improve the suite of digital evidence services and evidence awareness products that constitute the NICE Evidence Services.	• Maintain and continually improve the components services of NICE Evidence Services.	• Objective completed for HDAS in Q4. A series of improvements were released to HDAS in January. In February the new HDAS was successfully assessed against the Minimum Viable Product. The HDAS Redevelopment Project Board has agreed to switch off the old HDAS service on 3rd March 2017. • Objective completed for Evidence Search: New Types of Information (TOI) for Evidence Search were launched in Q3. Further, the Shared Decision Aids from Right Care were added to the Evidence Search index in Q4. • Objective completed for the contract for the Access and Identity Management System (AIMS): The new contract is being drawn up and the service is due to go live on 1st May. • Near complete: Tenders for a Link Resolver and Knowledge Base service for the NHS have been assessed and bidders invited to interview. Selection of the provider will have completed by the end of Q4. This service is required to complete the user journey from bibliographic search to full text journal article fulfilment.
	• Manage transition to a smaller portfolio of evidence awareness services.	• Completed in Q2.

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Put in place arrangements to collaborate with key stakeholder organisations on the provision of evidence services to their users.	• Continue to develop NICE's partnership with Health Education England, by advancing the role of Evidence Services as a continuing professional development resource. • Continue to explore arrangements for information sharing and interoperability of content with providers of social care and public health information. • Identify opportunities for syndicating suitable NICE Evidence Services across the sector.	• The HEE/NICE liaison group quarterly meeting was held in February. A Memorandum of Understanding between NICE and HEE has been drafted and is expected to be signed in Quarter 4. • HEE have confirmed that NICE should extend the contracts for National Core Content for one year (April 2018 – March 2019) • No further progress this period. • No further progress this period.
Guidance Information Services		
Develop information services capacity and support for new programmes of work	• Develop information services support and identify capacity for new programmes of work. • Determine and implement any change to requirements for information services support as a result of the Accelerated Access Review. • Sponsor and provide expert stakeholder input to the Evidence Management project, with specific focus on the reference management, literature sifting and document supply functions.	• Completed – information services support and capacity is in place for the cancer drugs fund (CDF), rapid evidence summaries and commission support documents. • Ongoing – The review is now published and implications for NICE are being considered. • Completed for the literature sifting functions. Work to develop reference management and document supply functionality is anticipated to be completed by end March.

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Explore new methods and approaches, and where suitable, deliver service improvement in the provision of Information Services to NICE	• Continue to monitor the delivery of savings from using the Royal Society of Medicine's (RSM) document delivery service. • Continue to monitor the delivery of savings from requesting copyright cleared journal articles under the new NHS CLA (Copyright Licensing Agency) Licence Plus.	• Savings as expected. No action needed. • Savings as expected. No action needed.
Digital Services		
Deliver digital service projects in line with the agreed investment priorities for 2016/17 and NICE's business plan objectives.	• Support the establishment and prioritisation of projects using the NICE project lifecycle and deliver agreed projects for the relevant strands of the NICE Digital Strategy.	• Digital Services' collaboration with the Communications team to revise the corporate branding for the NICE website has completed. • The MedTech tool, which will provide a consultancy service to medical technologies companies, is undergoing the final stage of development prior to launch by Scientific Advice team in April. • Work on the Knowledge Base project has delivered a Quality Statements viewer. The next phase of the programme is currently being scoped. • Substantial contribution to the link resolver procurement was provided by the Digital Services team during Q4.
Maintain operational service delivery and implement service improvements based on user	• Maintain the NICE Digital Services to agreed service levels (in terms of service availability and time to defect resolution).	• NICE Digital Services continue to fall within the generic agreed service levels for availability. The Operations Stability project continues to implement improvements and changes to our core infrastructure to increase efficiency and resilience. • Defect resolution SLAs are being adhered to. The new hosting infrastructure is being continuously improved for efficiency gains.

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insights and service performance against key performance indicators.	• Refresh digital services performance indicators in line with business priorities and user insights.	• No further progress this period
	• Continue to translate data and observations about the performance of NICE Digital Services into actionable improvement proposals.	• No further progress this period
	• In response to the above, continuously improve NICE Digital Services in line with agreed investment priorities.	• Between 15 December 2016 and to 28 February 2017, 63 defects were closed with 89 remaining open, and 31 Change Control Requests were completed with 49 in progress.
Continue to build capacity and capability across the Digital Services teams.	• Develop NICE's user experience (UX) testing capability and capacity.	• Digital Services now have a full team in place to support user experience testing and design.
	• Develop semantic capability to support our products and platforms.	• No new development this period although the team is identifying and reviewing potential partnerships with users of guidance and system developers to inform next stages of content development.
	• Develop a 'content' model to represent the relationships between NICE products and their components.	• Work was undertaken to compare the existing NICE guideline content structure with the data model used in MAGICapp as part of a strategic assessment of this guidance development software.
	• Put in place an agile project management tool that enables risks and issues within projects to be managed effectively.	• A procurement exercise is underway to identify a new system for Digital Services staff to improve how software is built and managed which includes functionality to automate managing agile projects and reporting on risks and progress.
	• Improve the resilience of NICE Digital Services and ensure an effective tested disaster recovery capability is in place as part of the new hosting arrangements.	• Complete.

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Continue to improve the productivity and effectiveness of the NICE Digital Services teams.	• Continue to reduce the end to end delivery time of small changes to NICE Digital Services ensuring shorter cycles of improvement and learning.	• Digital Services team have held several workshops to explore new ways of working in terms of planning delivery of work and sharing knowledge. A 'Firebreak' is being held in March for contractor staff to share knowledge and cascade skills to permanent staff to ensure live services can be supported effectively.
	• Ensure resources are effectively deployed on projects. This includes improving scheduling of suitable resource across the project portfolio and monitoring project 'burn charts' against plan.	• The Portfolio Management Office is undertaking a review of the work priorities and available capacity over the next quarter to assess the impact of staffing changes on the project delivery pipeline.
	• Robust process for benefits forecasting and tracking put in place to support new digital services implementation and ensure investment is realised.	• No further progress this period
	• Recruit permanent staff and adjust budget assumptions accordingly.	• No recruits this period.
	• Support retention and development of talents	• No leavers in the period.
	• Implement the new hosting solutions across all NICE Digital Services.	• Complete.
Promote collaboration on digital initiatives and content strategy across ALBs and other external stakeholders	• Support NHS Digital in the development and adoption of common standards, taxonomies and language across ALBs. • Maintain an ongoing relationship with the nhs.uk project and promote joint working on digital initiatives including where appropriate local collaboration in Manchester.	During the period, external collaboration work has focused on the following activities: ➤ We continue to work closely with UCL (EPPI) to develop improvements in the evidence management processes and integrate these into NICE systems and tools. The primary objective is to enhance the sifting and surveillance processes for evidence management.

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	• Promote the further understanding of strategic developments in evidence management and their applications for NICE. • Promote the distribution of NICE content through the most effective channels for users and decision makers including through decision support and other third party systems.	➢ We continue to strengthen external collaborations: a live evaluation of the MagicApp software is underway. We are working through a schedule of meetings with organisations with whom we may partner to help improve the structure of our content.

IP and Content Business Management

Develop a strategic plan to grow the commercial activity over the next 10 years.	• Identify and evaluate the options for increasing income from non-Grant-in-Aid sources, inside the UK and beyond. • Evaluate the options for the most effective vehicle for delivering this activity, by June 2016. • Prepare business cases for each element of the programme by December 2016.	Since these objectives were agreed, the responsibility for completing the agreed action has changed as follows: ➢ The donor-funded International Decision Support Initiative work transferred to Imperial College in September 2016. ➢ The business model options for how to develop Scientific Advice activities are being pursued by the Scientific Affairs team in the Centre for Health Technology Evaluations. ➢ The remaining international engagement and content re-use activities are covered below.

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Actively pursue revenue generation opportunities associated with the use and re-use of NICE content and quality assurance.	• Formalise the establishment of the business development team in Evidence Resources.	• Complete.
	• Act as a coordination desk for enquiries associated with use and reuse of NICE content and quality assurance.	• Complete.
	• Develop a robust framework and the necessary tools to support a range of products and services associated with the use and re-use of NICE content and quality assurance. This will include a pricing model, licenses and marketing material.	• A proposal articulating a range of services to support the re-use of NICE content abroad, including a pricing framework for these services, was discussed at the Senior Management Team meeting in December. The proposed costing and pricing framework continues to be piloted while it is with the DH and Treasury for approval. Licences for the above services have been developed and are now in use. Work to develop marketing collateral was initiated with support the Healthcare UK.
		• A separate paper to agree the international Knowledge Sharing offering of NICE (hosting delegations) will be brought to the Senior Management Team in March 2017.
	• Grow revenue stream associated with the use and re-use of NICE content to at least double the size of the revenue stream compared with 2015/16.	• 2015/16 income was £46,000. The 2016/17 income at the end of January 2017 was £ 65,686
	• Continue to log and, where suitable, re-direct enquiries associated with the other commercial opportunities available to NICE.	• A weekly enquiries review meeting is now in place to process international enquiries and pursue revenue generating opportunities associated with knowledge sharing where appropriate. 43 enquiries have been received and actioned between September 2016 and February 2017.
		• The potential for international consultancy activities is being explored with non-consultancy intermediaries.

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Continue to encourage the use of NICE content through the use of the NICE Syndication service	• Update the NICE's Syndication offering in line with other use and re-use of content services of NICE. • Continue to promote the use of NICE content by other ALBs using the NICE Syndication service.	• The syndication licence is being updated to reflect the NICE UK Open Content Licence and International Licences. • No further progress this period.

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Directorate wide		
Subject to the release of budget for this programme of work, support the implementation of the National Information Board (NIB) 'Framework for Action' and specifically contribute to the development of a framework for the assessment of digital applications.	• Provide joint leadership, alongside Public Health England, to a multi-agency working group also involving NHS England and NHS Digital. • Secure the resources necessary for NICE to be able to make a meaningful contribution to the work. Subject to adequate resourcing, agree a programme of work with key partners for 2016/17 and deliver against the agreed work plan. • Contribute expertise to the development of proposals to assess the effectiveness of digital applications to include an evidence guide and the development of a new evidence evaluation process for digital health technologies.	• In light of changes in the governance and objectives of the Paperless 2020 app assessment programme, NICE has clarified its contribution for the end of March 2017 which focuses on piloting the production of Health App Briefings with 4 apps. • The programme of work of NICE is agreed as part of a series of investment justifications (IJ) through which NICE will receive funds for the pilot work from NHS England. • The Centre for Health Technology Evaluations commenced the piloting of 4 Health App Briefings during Q3 following approval of a draft process and methods statement by SMT. These will be completed in Q1 2017-18. The evidence guide was published in Q4.
Implement the first year of a three year strategy to manage the reduction in the Department of Health's Grant-In-Aid funding and plan for a balanced budget in 2017-18.	• Establish how to deliver the saving target allocated to the Evidence Resources directorate. • Conduct management of change exercises with consultations to complete by the end of the summer in accordance with a schedule agreed and monitored by the SMT. • Review and renegotiate supplier contracts in line with savings target and schedule agreed and monitored by the SMT.	• Completed Q1. • Completed Q2. . • Negotiations with suppliers continue.

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5. A new display to report on the performance of NICE Evidence Services and the NICE apps is being introduced this period. It has been created to present the usage statistics in context of the other NICE Digital Services. The only metric reported is 'sessions' which is the number of visits to a website within a date range. The performance dashboards of individual digital services are currently being revisited. When this review is complete, additional performance metrics will be re-introduced into this bi-monthly Board report.

6. Key developments in the last two months can be observed in Figure 1 below and include:

   - Across the NICE digital services portfolio, January has been a very positive month with a 24% month on month increase in web traffic on the Christmas season. The year on year performance confirms the strong January performance with overall web traffic up 12% compared to January 2016. February 2017 received 4% less traffic than January and only 3% up from 2016.

   - 41% of all sessions on NICE digital services during February 2017 came from NICE Evidence Services. 13% came from the Apps.

   - In the course of the last 12 months (comparing January and February 2016 with January and February 2017), the BNF microsite has become the NICE Evidence Service that brings the most digital sessions with a 58% growth over the period.

   - Over the last 12 months, the performance of the other Evidence Services has been as follows:

     o CKS – 38% increase in digital sessions

     o Evidence Search – 7% decrease

     o BNFc microsite – 39% increase

     o HDAS – 21% decrease

     o Other services (Journals, DUETS, eBooks and Library) – 56% decrease

   - Over the last 12 months, the performance of the NICE Apps has been as follows:

     o BNF app – 3% decrease

     o BNFc app – 6% increase

     o NICE Guidance app – 10% decrease

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Figure 1 Monthly sessions across all NICE Digital Services – last 12 months:

Monthly sessions per service

	Mar-16	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16	Jan-17	Feb-17
■ NICE*	1,647,636	1,458,537	1,583,593	1,335,358	1,183,842	1,172,575	1,283,385	1,503,494	1,535,108	1,233,101	1,563,570	1,493,750
■ Pathways*	259,050	267,902	259,832	209,600	182,966	189,523	223,897	268,546	294,945	257,456	340,914	276,946
Evidence Services												
■ BNF microsite	461,174	468,050	515,425	505,002	449,724	497,894	525,408	530,204	552,288	504,945	612,385	621,089
■ BNFc microsite	68,873	62,709	69,146	65,163	55,062	56,435	62,798	66,589	70,827	68,136	78,477	80,786
■ CKS	344,019	351,902	336,772	305,730	269,055	306,208	354,865	390,606	410,484	338,910	448,513	444,844
■ Evidence Search	456,836	463,308	451,351	375,315	329,384	322,507	348,117	400,431	407,735	325,384	427,029	406,874
■ HDAS	34,102	33,147	31,368	28,455	25,095	24,622	25,930	25,119	27,116	20,852	27,457	26,752
■ Journals	18,371	18,331	17,205	15,547	14,111	13,736	13,703	14,486	15,767	11,518	15,139	13,629
Apps												
■ BNF app	447,867	444,002	464,750	446,375	424,091	545,258	519,016	444,565	420,225	394,478	428,586	403,889
■ BNFc app	99,837	92,402	96,586	93,614	93,584	98,190	106,939	96,217	97,083	91,469	92,083	89,074
■ Guidance app*	44,065	45,376	45,107	41,297	40,810	44,086	45,252	49,339	42,635	37,110	39,298	37,415

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Risks

7. There are 4 risks in the high level risk register associated with the Evidence Resource directorate. There were no changes to the status of these risks over the last two months.

8. A new risk to the digital programme delivery was identified in January 2017. This is related to a change in the IR35 legislation which is coming into force in April 2017. The new legislation will require that a public sector body receiving services from an off payroll intermediary establish whether an employment relationship exists with the intermediary. Some of NICE's digital projects may need to be paused to accommodate a loss of contractors currently providing development services to NICE. A similar challenge is currently being faced by most public sector organisations.

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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 during January and February 2017. It also highlights notable developments that have occurred during the reporting period.

Performance

2. The directorate published a number of products during January and February including: 4 quality standards; 3 evidence summaries on the use of medicines; 6 medicines evidence commentaries; and delivery of an evidence based treatment pathway for mental health to NHS England.

3. Work with key national partners continued to be a priority. This included engagement with the Care Quality Commission (CQC) and other social care partners to inform 'Quality Matters', a new quality framework for adult social care. This work is expected to raise NICE's profile within the social care sector and further develop working relationships with key national organisations in the social care sector.

4. Resources have been secured to explore the environmental impact of NICE guidance recommendations through the development of sustainability impact assessments. This will involve close collaborative working with the Sustainable Development Unit, funded by NHS England and Public Health England.

5. Following a recent round of recruitment for the Fellows and Scholars programme, 9 new Fellows and 9 Scholars from across health and social care have been selected. They will start working with NICE from April 2017.

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Table 1 Performance update for January and February 2017

Objective	Actions	Update
Produce intelligence on the impact and uptake of NICE guidance	Publish the Uptake and Impact report Provide quarterly Innovation Scorecard Estimate reports	The quarter 4 Innovation Scorecard published on time in January
Support public involvement across NICE	Identify and consult on proposals for improving NICE's approach to public involvement in guidance and standards development	The consultation on proposals to improve NICE's approach to public involvement in guidance and standards development closed on 28 February. We are reviewing and considering the comments, and revising our proposals as appropriate
	Facilitate the recruitment and identification of lay experts and lay committee members on an 'as needed' basis, including for new committees to be established	In addition to the standard recruitment, we identified 100 people to give testimony to our committees as expert witnesses, and 17 people to join committees as specialist members
Coordinate and operate a programme of external engagement	Deliver 15 student champion training events	Two NICE Evidence Search student champion events have taken place at Bristol Dental School and Plymouth Medical and Dental Schools. In addition, a 'Learning about NICE' day took place and was attended by student champions from across 10 universities. In total the events were attended by 88 people
Provide an endorsement and quality assurance function to support implementation	Publish 30 endorsement statements Publish 50 shared learning examples	Four endorsement statements published in January and February, which is in line with trajectory to meet the annual target Shared Learning continues to be a popular programme and we have published 66 examples, exceeding the annual target

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Figure 1 Performance against plan for Health and Social Care Directorate key publication outputs in April 2016 to February 2017
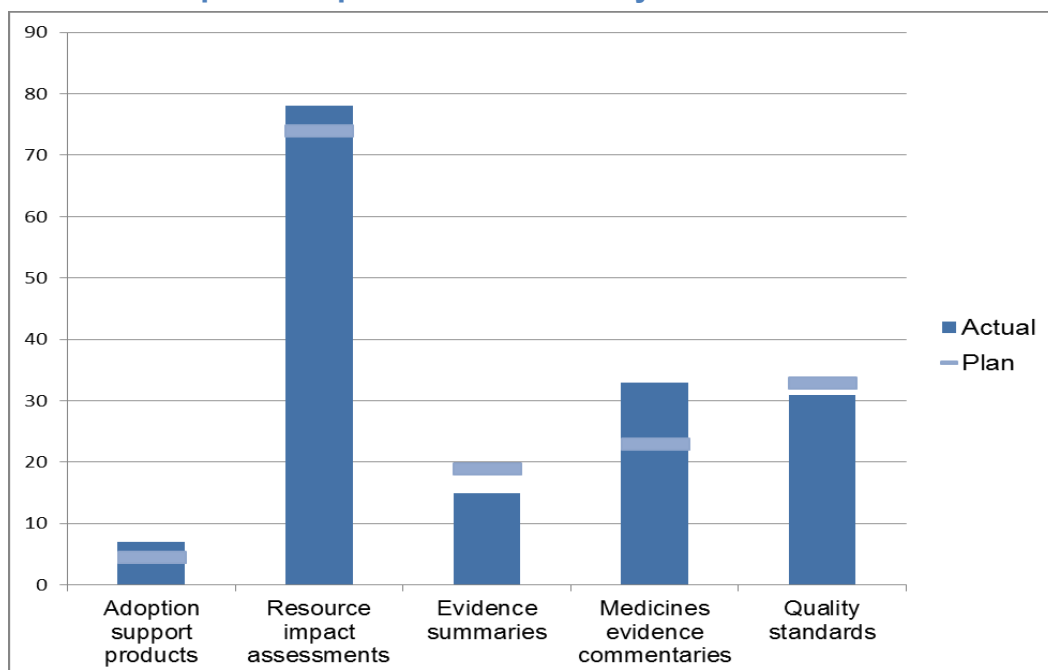
6. Two Quality Standards are due to publish slightly later than originally planned: Community engagement; and Vaccine uptake in under 19s. The publication delay to March (originally scheduled for December and January respectively) was to ensure the most appropriate audience was targeted in the case of Community engagement, and was due to a change in committee meeting scheduling in the case of Vaccine uptake in under 19s. It is expected that the annual target to publish 33 quality standards will be met by year end.

7. A smaller number of evidence summaries have been published than expected, due to a number of factors: a low volume of topics referred by NHS England; time taken to refine the scope; and the unexpected publication of key studies during development. The annual target of 20 remains on track.

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Figure 2 Lay member recruitment performance by the Public Involvement Programme in April 2016 to February 2017
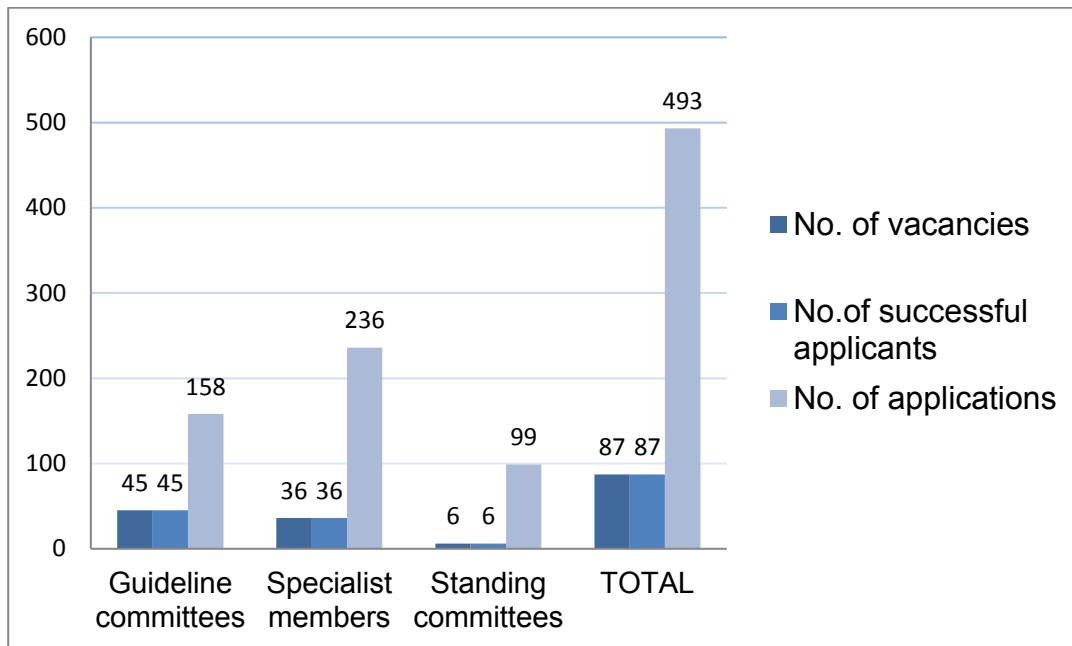
Figure 3 Performance against plan for System Engagement key outputs in April 2016 to February 2017

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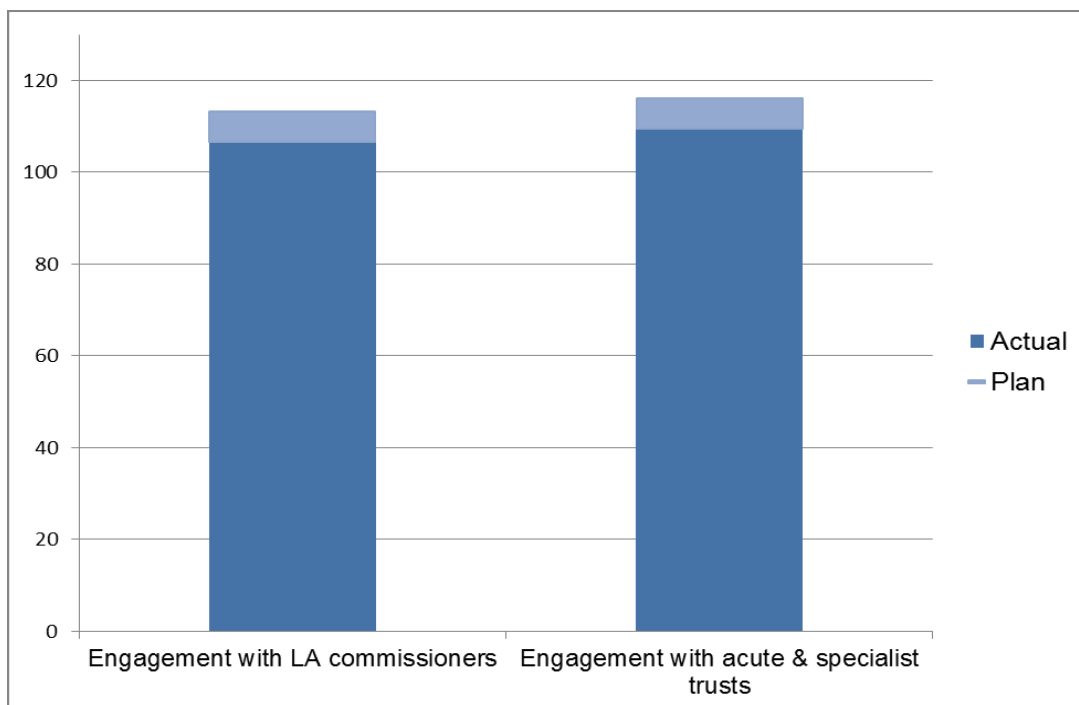
Notable developments

8. This section includes significant developments or issues that occurred during January and February.

Social care and 'Quality Matters'

9. NICE has been closely involved in the development of the new social care quality framework, 'Quality Matters'. The framework sets out shared principles for quality improvement in line with the framework issued by the National Quality Board, and includes practical steps to support providers, commissioners and national bodies in continuously improving the quality of person-centred adult social care. The aim is to launch the framework in March 2017. NICE is referenced in relation to:

   - Measuring, collecting and using data more effectively

   - Better support for improvement

   - Shared focus areas for improvement.

CQC consultation response

10. In February, NICE submitted a response to the Care Quality Commission's consultation 'Our next phase of regulation – A more targeted, responsive and collaborative approach'. The consultation set out further detail on the implementation of CQC's 2016-21 strategy and included a joint consultation with NHS Improvement on a proposed approach to leadership and use of resources in NHS trusts. Opportunities were highlighted in our response where NICE could potentially support CQC and NHS Improvement in developing intelligence, metrics and indicators to inform quality improvement and regulatory frameworks. Support was given for the 9 principles for regulation, with a tenth principle proposed around working with national partners to support quality improvement among providers. It was noted that the proposal for 2 assessment frameworks, on health and adult social care, should cover key issues such as integration and transition and be developed using evidence based resources such as NICE guidance. A second consultation is due in spring 2017, which will focus on the regulation of adult social care and primary medical services.

Revalidation peer review

11. In January, NICE completed the second phase of the revalidation peer review process with NHS Professionals (NHSP) to provide an independent assessment of revalidation processes in both organisations. Work is progressing to implement suggestions from the review of NICE undertaken by NHSP in April 2016.

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12. The NICE process for reviewing NHSP involved an initial scrutiny of the relevant documentation, including their policies and board reports. The NICE Responsible Officer (RO), deputy RO and revalidation manager visited the NHSP offices in Watford to discuss their processes in more detail. We are now finalising a report with some suggestions for consideration, using the standard framework provided by NHS England.

Fellows and Scholars programme

13. Nine Fellows and 9 Scholars from both health and social care backgrounds were appointed in January, to start in April 2017. The number of applications was lower than in previous years, so we will begin a review of the programme in Spring 2017 with a view to identifying options for taking the programme. In the meantime, we will build increasing links between the Fellows and the NICE Field Team.

Supporting the IAPT programme

14. NICE is being funded by NHS England from April 2017 to facilitate the use of therapist-assisted digital treatments within the Improving Access to Psychological Therapies (IAPT) programme. Randomised controlled trials have shown that therapist-supported digital therapies with content in line with that of NICE recommended face-to-face therapies can be effective when compared with no treatment, and in some cases can achieve results comparable to a full course of face-to-face therapy, while requiring much less therapist time per patient.

15. The aim of the new work is to evaluate selected, digitally assisted therapies for depression and anxiety using ongoing data collection to determine whether there are improvements in service efficiency, with patient outcomes that are at least as good as those achieved with NICE recommended non-digital therapy.

16. There are two novel components to this evaluation: 1) the provisional NICE approval of a digital technology; and 2) an evaluation using ongoing data collection. The evaluation will be informed by an NICE Expert Panel, which will have its first meeting in March 2017.

Sustainability

17. NICE has secured resources to test the feasibility of a process to assess the potential environmental impact of guidance recommendations (sustainability impact assessment). This is a unique opportunity for NICE and The Sustainable Development Unit, funded by NHS England and Public Health England, to work collaboratively to provide guidelines for addressing environmental impact of health care. This work feeds into the national cross system group for

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sustainable development of the health and care system and NICE has been used as an exemplar in the Sustainable Development Unit's 'Health Check 2017', which focussed on the contribution of arm's length bodies to environmental sustainability. The NICE sustainability steering group will use the results of this feasibility study to influence future work and consider whether NICE appraisals should be sensitised to take account of environmental impact as well as cost impact.

Shared Decision Making

18. Shared decision making (SDM) is increasingly seen as an important aspect of good clinical practice and a facilitator for people to take greater ownership of their treatment and care - a key element of the Five Year Forward View. For some time now NICE has been providing leadership for the wider system in relation to SDM. NICE has brought together leading thinkers in the SDM world in three collaborative meetings since 2015. This collaborative working has led to the development of a consensus statement and action plan which will be reviewed at the fourth meeting in the summer of 2017. The action plan covers a wide range of activities from education and training, culture change, research and measuring success in SDM.

19. NICE has developed a number of tools to support SDM in a range of conditions and is explicitly embedding SDM concepts into the Guidelines Manual. We have contributed to the Choosing Wisely campaign and formally endorsed patient decision aids that support NICE guidance. We are working with academic colleagues to collaborate on a shared research agenda, which comprises assessment of SDM among pharmacists.

20. On request, NICE has submitted a proposal to NHS England for work to support shared decision making in four areas: a process to update and maintain a suite of patient decision aids; a decision aid quality assurance certification scheme; training and support for decision aid developers; and a repository for decision support tools. We are awaiting further information about taking this forward, and further developments will be reported to the Board as they occur.

Risks

21. As a result of actions taken to control and mitigate risks within the directorate we have not identified any risks that are sufficiently significant to require inclusion within this progress update. Risks continue to be reviewed within the directorate, including planning ahead for the management of risks in 2017/18.

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Appendix 1 Guidance and advice published since April 2016

The table below provides a list of guidance and advice produced between April 2016 and February 2017. For the Health and Social Care Directorate this includes quality standards, evidence based treatment pathways (EBTP), evidence summaries and medicines evidence commentaries (MEC).

Guidance title	Publication date	Notes
Chronic obstructive pulmonary disease: tiotropium/olodaterol (Spiolto Respimat)	May 2016	Evidence summary
Reversal of the anticoagulant effect of dabigatran: idarucizumab	May 2016	Evidence summary
Complicated urinary tract infections: ceftolozane/tazobactam	June 2016	Evidence summary
Complicated intra-abdominal infections: ceftolozane/tazobactam	June 2016	Evidence summary
Visual impairment due to myopic choroidal neovascularisation: aflibercept	June 2016	Evidence summary
Moderate to severe acute post-operative pain: fentanyl transdermal system	June 2016	Evidence summary
Levofloxacin (Quinsair) nebuliser solution for the management of chronic pulmonary infections due to Pseudomonas aeruginosa in adults with cystic fibrosis	Delivered to NHS England - September 2016	Evidence summary
Triethylenetetramine for hepatic, neurological and neuropsychiatry sequelae of Wilson's Disease	Delivered to NHS England - September 2016	Evidence summary
Pre-exposure prophylaxis of HIV in adults at high risk: Truvada (emtricitabine/tenofovir disoproxil)	October 2016	Evidence summary
Minimal change disease and focal segmental glomerulosclerosis in adults: rituximab (November)	November 2016	Evidence Summary
Pulmonary sarcoidosis: infliximab	December 2016	Evidence Summary
Oestrogen deficiency symptoms in postmenopausal women: conjugated oestrogens and bazedoxifene acetate	December 2016	Evidence Summary

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Guidance title	Publication date	Notes
Refractory extrapulmonary sarcoidosis: infliximab	January 2017	Evidence Summary
Glycopyrronium for the treatment of hypersalivation	February 2017	Evidence Summary
Safinamide (Xadago) for the treatment of adult patients with idiopathic Parkinson's disease	February 2017	Evidence Summary
Adverse events associated with off-label medicine use in adults	April 2016	Medicines Evidence Commentary (MEC)
Meniere's disease: betahistine not shown to be superior to placebo	April 2016	Medicines Evidence Commentary (MEC)
Chronic disease in people with severe mental illness: reducing excess mortality	May 2016	Medicines Evidence Commentary (MEC)
Urinary tract infection: antibiotic resistance in children in primary care	May 2016	Medicines Evidence Commentary (MEC)
Supporting adherence to medicines in people with long-term conditions: New Medicines Service community pharmacy scheme	May 2016	Medicines Evidence Commentary (MEC)
Text messaging to help medicines adherence	May 2016	Medicines Evidence Commentary (MEC)
New MHRA drug safety advice: March to May 2016	May 2016	Medicines Evidence Commentary (MEC)
Antibiotic stewardship interventions in hospitals: effect on clinical outcomes	June 2016	Medicines Evidence Commentary (MEC)
Chronic kidney disease: increased risk with proton pump inhibitors	June 2016	Medicines Evidence Commentary (MEC)
Statins: modelling study	June 2016	Medicines Evidence Commentary (MEC)
Antibiotics for infected eczema: the CREAM study	June 2016	Medicines Evidence Commentary (MEC)
Type 2 diabetes: meta-analysis finds no increased risk of mortality, MI or stroke with sulfonylureas	July 2016	Medicines Evidence Commentary (MEC)
Medicines optimisation: effect of a combined education, informatics and financial incentive intervention on high-risk prescribing in general practice	July 2016	Medicines Evidence Commentary (MEC)

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Guidance title	Publication date	Notes
Type 2 diabetes: increased risk of hypoglycaemia with combined use of dipeptidyl peptidase-4 (DPP-4) inhibitors and sulfonylureas	July 2016	Medicines Evidence Commentary (MEC)
Type 2 diabetes: liraglutide reduces cardiovascular risk in people at high risk of having a cardiovascular event	August 2016	Medicines Evidence Commentary (MEC)
Osteoarthritis: network meta-analysis	August 2016	Medicines Evidence Commentary (MEC)
Inhaler use: has technique improved over time?	August 2016	Medicines Evidence Commentary (MEC)
New MHRA drug safety advice: June to August 2016	September 2016	Medicines Evidence Commentary (MEC)
Medicines optimisation: adverse outcomes from potentially inappropriate prescribing in older people living in the community	September 2016	Medicines Evidence Commentary (MEC)
Fracture risk associated with melatonin and other hypnotics	October 2016	Medicines Evidence Commentary (MEC)
Medicines optimisation: impact of inappropriate prescribing on mortality and hospitalisation in older people	October 2016	Medicines Evidence Commentary (MEC)
Chronic obstructive pulmonary disease: indacaterol/glycopyrronium compared with salmeterol/fluticasone for reducing exacerbations (the FLAME study)	October 2016	Medicines Evidence Commentary (MEC)
The risk of myocardial infarction with antipsychotics	November 2016	Medicines Evidence Commentary (MEC)
Antipsychotic prescribing in care homes before and after launch of a national dementia strategy	November 2016	Medicines Evidence Commentary (MEC)
Rotator cuff tendinosis: meta-analysis	November 2016	Medicines Evidence Commentary (MEC)
New MHRA drug safety advice: September to November 2016	December 2016	Medicines Evidence Commentary (MEC)
Comparative Effectiveness of Phosphate Binders in Patients with Chronic Kidney Disease	December 2016	Medicines Evidence Commentary (MEC)
Nursery sickness policies and their influence on prescribing for conjunctivitis	December 2016	Medicines Evidence Commentary (MEC)

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Guidance title	Publication date	Notes
Asthma: vitamin D has a beneficial effect on the risk of exacerbations	January 2017	Medicines Evidence Commentary (MEC)
Risk of hospital admissions for heart failure with non-steroidal anti-inflammatory drugs	January 2017	Medicines Evidence Commentary (MEC)
Myocardial infarction: duration of beta-blocker treatment in people without heart failure	January 2017	Medicines Evidence Commentary (MEC)
Asthma or recurrent wheeze: preventing exacerbations in pre-school children using inhaled corticosteroids	January 2017	Medicines Evidence Commentary (MEC)
The relative risk of poisoning by methadone or buprenorphine within the wider population of England and Wales	February 2017	Medicines Evidence Commentary (MEC)
Bioequivalence of biosimilar tumor necrosis factor-a inhibitors compared with their reference biologics: a systematic review	February 2017	Medicines Evidence Commentary (MEC)
Antimicrobial stewardship	April 2016	Quality standard
Suspected cancer	June 2016	Quality standard
Home care for older people	June 2016	Quality standard
Bronchiolitis in children	June 2016	Quality standard
Motor neurone disease	July 2016	Quality standard
Diabetes in adults (update)*	August 2016	Quality standard
Early years: promoting health and wellbeing in under 5's	August 2016	Quality standard
Obesity: clinical assessment and management*	August 2016	Quality standard
Social care for older people with multiple long-term conditions	September 2016	Quality standard
Intravenous fluid therapy in children and young people in hospital	September 2016	Quality standard
Skin cancer*	September 2016	Quality standard
Contraception	September 2016	Quality standard
Children's attachment	October 2016	Quality standard
Coeliac disease	October 2016	Quality standard
Preterm labour and birth	October 2016	Quality standard
Hip fracture in adults (update)	November 2016	Quality standard

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Guidance title	Publication date	Notes
Blood transfusion	December 2016	Quality standard
Oral health promotion in the community	December 2016	Quality standard
Mental wellbeing and independence for older people	December 2016	Quality standard
Transition between inpatient hospital settings and community or care home settings for adults with social care needs	December 2016	Quality standard
Transition from children's to adults' services	December 2016	Quality standard
Early intervention in psychosis	April 2016**	EBTP
Urgent and emergency psychiatric liaison mental health services	June 2016**	EBTP
Urgent and emergency mental health: blue light services	July 2016**	EBTP
Perinatal mental health services	August 2016**	EBTP
Dementia	September 2016**	EBTP
Urgent and emergency: children and young people's mental health services	September 2016**	EBTP
Eating disorders in children and young people: inpatient and intensive day care	February 2016**	EBTP

*NB: these quality standards combine 2 or more referred topics. Therefore the numbers in this list will not correlate with data in the graphs, which report on publication of referred topics.
** These publications are provided to NHS England.

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NICE National Institute for
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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

AUDIT and RISK COMMITTEE

Unconfirmed minutes of the meeting held on 25 January 2017 in London

Present

Rima Makarem, Non Executive Director (Chair)
Elaine Inglesby-Burke, Non Executive Director
Sheena Asthana, Non Executive Director
Tim Irish, Non Executive Director

In attendance

Andrew Dillon, Chief Executive
Ben Bennett, Business Planning and Resources Director
Martin Davison, Head of Management Accounting, Finance
Natalie Sargent, Head of Financial Accounting, Finance
Barney Wilkinson, Associate Director Procurement & IT
Catherine Wilkinson, Associate Director Finance & Estates
Julian Lewis, Governance Manager
Catherine Hepburn, NAO
Mark Wilson, NAO
Jeremy Nolan, GIAA
Wajid Shafiq, GIAA

APOLOGIES FOR ABSENCE

Andrew Jackson, NAO

DECLARATIONS OF INTEREST

1. There were no declarations of interest.

MINUTES OF THE LAST MEETING

2. The minutes were agreed as a correct record with the exception of changing the employer of our internal audit colleagues from DH to Government Internal Audit Agency (GIAA). In addition, the final paragraph relating to the private discussion between the auditors and the committee was deleted.

3. Action log: Point 170 to be amended to reflect responsible person as Barney Wilkinson and Completion date as March 2017 rather than March 2018.

4. The progress detailed in the action log was noted.

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INTERNAL AUDIT

Progress report

5. Jeremy Nolan presented the report. It is anticipated that the reports on Payroll and Technology Appraisal Appeals will follow at the April meeting, together with the draft Audit Plan for 17/18.

6. It was further noted that no Follow Up work has taken place as the recommendations were made fairly recently.

Contract Management

7. Jeremy Nolan presented the report. The committee briefly discussed the report. Barney Wilkinson confirmed that there is only one supplier that is not delivering, but that it is being managed.

Strategic Financial Management

8. Jeremy Nolan presented the report. The committee discussed the report and concluded that the response from Management as well as some aspects of the recommendations could have been clearer. It was agreed that the trigger point for plan B will be mid-summer, and the committee requested that the corporate risk register be updated.

Action: BB

Risk Management and Assurance Framework

9. Ben Bennett and Andrew Dillon explained the process by which the risk registers are populated. Much thought and discussion goes into drawing up the registers, but this is not visible in the documentation seen by the auditors.

10. Andrew further added that over time NICE has over-complicated the registers and created an industry in creating and maintaining the registers.

11. Jeremy Nolan added that in contrast to a risk register, Assurance Mapping relates to where assurances will come from and whether they would be sufficient and could be relied upon.

12. The committee discussed various approaches for risk registers and concluded that:

   - The Strategic Risk register is in fact a subset of the high level risk register. Work could be halved if only one register is maintained, with the Board considering strategic/high risks only, while lower rated risks are managed by the directorates

   - Risks around Brexit need to be included. These might include funding, procurement, access to experts, workforce issues.

   - Where there is an assurance gap, a corrective action and due date should be included to identify and deal with potential bottlenecks.

Action: JL

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RISK MANAGEMENT

Risk Appetite

13. Ben Bennett presented the paper and Andrew Dillon added that NICE is a cautious organisation. Where judgements on risks are to be taken, it is carried out by Directors/SMT, and it would be useful to share the Risk Appetite within the organisation.

14. The Chair suggested that the current ratings of risk appetite ('low', 'moderate' and 'high') needed to be defined to help the end user. She offered to share the risk appetite definitions from another organisation by way of guidance. She also suggested that financial risks be mentioned more specifically. The committee agreed for this paper to go to the February Board meeting following review by the SMT.

Action: RM

Strategic Risk Register

15. Andrew Dillon explained that the register has evolved over the years and now includes the principal risks, to which Brexit can be added (following point 12 of these minutes).

16. The committee requested that the wording on the risks relating to Life Sciences be reconsidered, and that consideration be given to the alignment of the last two mitigation points of the final strategic objective.

Action: AD

Risk Register

17. The Committee discussed the risk register and alternative approaches to highlight the status of risks. It was agreed:

- That a one page Executive Summary will be produced with a narrative that explains changes in the risks.

- Risk ratings should be given as a number (the product of impact x likelihood) for both pre- and post-mitigation. It was agreed that the colour coding should remain as is.

- Mitigation actions and assurances are not always specific enough, and where they rest on a conversation the risk should not be rated green.

- Some updating is necessary to check that all risks are still live, particularly those where 'no further action' is noted. Closed items to be moved to the bottom of the register, for the Board to focus on ongoing risks only.

- Improvements to the format would reduce the number of columns and make the risk registers easier to read.

Action: AD

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NATIONAL AUDIT OFFICE

Planning Report

18. Mark Wilson presented the paper.

19. Andrew Dillon advised that NICE now have 3 and not 4 objectives. He further requested that the wording on page 7 relating to 'misappropriation of assets' be revised and clarified.

20. The committee noted that reservations were expressed by members on the high level of NAO fees.

Self Assessment

21. The committee noted that it would not be possible to complete the self-assessment this year as the committee is newly formed. The checklist will help though in determining if the committee has the appropriate experience.

CONTRACT WAIVERS

Cochrane Waiver

22. Barney Wilkinson presented the waiver. The committee approved the waiver.

Waivers report

23. Barney Wilkinson presented the report, which was noted.

USE OF SEAL

24. The committee noted that the seal was used on one occasion.

AUDIT RECOMMENDATIONS LOG

25. The committee discussed the report briefly and suggested that the format be changed to 'exception reporting'.

Action: JL

ANY OTHER BUSINESS

26. The committee requested that going forward:

- An annual ARC workplan be produced.

- Ben Bennett and the Chair discuss the agenda before papers are circulated.

- One of the Directors attend each ARC meeting.

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Future meeting dates

26 April 2017 2pm

21 June 2017 2pm

25 October 2017 2pm

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