NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

PUBLIC BOARD MEETING

17 January 2018 at 1.30pm in the Frank Lee Centre, Addenbrookes Hospital, Hills Road, Cambridge CB2 0SN.

AGENDA

18/001	**Apologies for absence** To receive apologies for absence	(Oral)
18/002	**Declarations of interests** To record any conflicts of interest	(Oral)
18/003	**Minutes of the Board meeting** To approve the minutes of the meeting held on 15 November 2017	(Item 1)
18/004	**Matters arising** To consider matters arising from the minutes of the last meeting	(Oral)
18/005	**Chief Executive's report** To receive the Chief Executive's report *Andrew Dillon, Chief Executive*	(Item 2)
18/006	**Finance and workforce report** To receive a report on NICE's financial position to the end of November 2017 and an update on the workforce strategy *Ben Bennett, Director, Business Planning and Resources*	(Item 3)
18/007	**NICE impact: cancer** To review the report *Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate*	(Item 4)
18/008	**Policy on declaring and managing interests for NICE advisory committees** To approve the policy *Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate*	(Item 5)
18/009	**Facilitating adoption of off-patent, repurposed medicines into NHS clinical practice** To note the report *Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate*	(Item 6)

18/010	**NICE social care programme update** To receive an update and review the proposed priorities *Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate*	(Item 7)
18/011	**Directors' report for consideration** Centre for Guidelines *Professor Mark Baker, Centre for Clinical Practice Director*	(Item 8)
	Directors' reports for information	
18/012	Centre for Health Technology Evaluation	(Item 9)
18/013	Communications Directorate	(Item 10)
18/014	Evidence Resources Directorate	(Item 11)
18/015	Health and Social Care Directorate	(Item 12)
18/016	**Any other business** To consider any other business of an urgent nature	(Oral)

Date of the next meeting
To note the next Public Board meeting will be held on 21 March 2018 at Westlands, Yeovil, BA20 2DD.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Public Board Meeting held on 15 November 2017 in the Corn Exchange, 1 George Street, Exeter, EX1 1BU

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
Professor Tim Irish	Non-Executive Director
Dr Rima Makarem	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
Professor Carole Longson	Centre for Health Technology Evaluation 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)

17/091 APOLOGIES FOR ABSENCE

1. Apologies were received from Elaine Inglesby-Burke.

17/092 CONFLICTS OF INTEREST

2. There were no conflicts of interest declared.

3. David Haslam noted that he is unpaid adviser to Vopulus Ltd a healthcare education organisation, and will shortly hold shares in the organisation.[1] Tim Irish declared that he recently joined the Board of Life Sciences Hub Wales Ltd. The register of interests has been updated accordingly.

17/093 MINUTES OF THE LAST MEETING

4. The minutes of the Public Board Meeting held on 20 September 2017, and the Board meeting held in private on 16 August 2017 were agreed as correct records.

17/094 MATTERS ARISING

5. The Board reviewed the actions arising from the Board meeting held on 20 September 2017, noting:

   - The first part of the two stage consultation on changes to the technology appraisal (TA) programme closes shortly. If the consultation feedback indicates the need for material revisions to the proposals, these will be brought to the Board, otherwise the second stage of the consultation on the detailed amendments to the process guide will proceed as agreed at the last Board meeting.
   - Recruitment to the expert patient panel has commenced.
   - The actions relating to antimicrobials and the annual equality report are in hand.

17/095 CHIEF EXECUTIVE'S REPORT

6. Andrew Dillon presented his report, describing the main programme activities to the end of October 2017 and summarising the financial position at the end of September 2017. The report also includes performance against the measures in the balanced scorecard. Halfway through the year, performance is largely on track, with narrative provided for the small number of measures below target performance.

7. The Board received the report.

[1] ***Post meeting note:*** *Subsequent to the declaration the transaction was not completed. David Haslam does not therefore hold any shares in companies with interests in the NHS or social care.*

17/096 FINANCE AND WORKFORCE REPORT

8. Ben Bennett presented the report which outlined the financial position at 30 September 2017 and provided an update on the workforce strategy. There is a total underspend of £1.7m, largely driven by the £1.2m underspend on pay budgets. The full year forecast position estimates the current rate of underspend will reduce and the forecast outturn for the year is a £2m underspend.

9. Board members noted the pay underspend and asked about the impact of the vacancy rate on staff and NICE's performance. Ben Bennett stated that whilst the headline vacancy rate is 10%, a number of posts are intentionally held open to prepare for the further reductions in NICE's grant in aid funding in April 2018. The actual vacancy rate, taking account of this action, is closer to 5%. The turnover rate, 10%, is similar to other organisations and as shown in the Chief Executive's report, NICE's performance has remained on track. The Senior Management Team briefly commented on recruitment challenges in their centre/directorate, and the mitigating actions, which have included utilising external capacity in the Centre for Guidelines and the Evidence Resources Directorate. Asked whether the underspend was too high, Ben stated that a prudent approach has been taken in order to prepare for the further funding reductions in April. The Senior Management Team will continue to consider any suitable proposals to utilise this underspend, providing it does not incur financial commitments beyond the current financial year.

10. The Board received the report.

17/097 NICE IAPT ASSESSMENT BRIEFINGS

11. Gill Leng presented the update on progress with the development of the NICE IAPT assessment briefings (IABs), which form part of a programme commissioned by NHS England. Gill thanked Paul Chrisp, Programme Director for Medicines and Technologies for leading this work.

12. Board members welcomed these new activities. Given the likely external scrutiny of this innovative programme, the importance of a transparent assessment and clear rationale for the evidence evaluation methodology was highlighted. The need to take account of equality considerations in terms of the access to the digital IAPT services was also raised.

13. In response to questions from the Board, Gill Leng and Paul Chrisp clarified the remit of the programme. Whilst the briefings will be published on the NICE website, NICE has been commissioned to evaluate technologies for use in the IAPT programme rather than provide advice and guidance to those seeking to utilise the digital services outside of the IAPT programme. Likewise, NICE will not issue advice to the health and care system on a technology that is not selected for assessment.

14. The Board received the report and requested regular updates on progress through the Health and Social Care Directorate reports.

ACTION: Gill Leng

17/098 NICE CHARTER

15. Jane Gizbert presented the proposed amendments to the NICE Charter following its annual review. The material changes are to add a statement on NICE's work on sustainability and reallocate the text in the 'managing resources' section to distinguish between NICE's support to the health and care system and internal actions to manage NICE's own resources.

16. The Board discussed the level of information in the Charter, including whether there is sufficient reference to NICE's methods and use of social value judgements. Andrew Dillon highlighted that it is not the purpose of the Charter to explain NICE's methods and processes, which are set out in separate documents. He outlined the work underway to review NICE's social value judgements document, which will be brought to the Board following review by the Senior Management Team. In response to a comment from the Board about the length of the Charter, Jane Gizbert noted that a "NICE narrative", which summarises NICE's role, is in development.

17. The Board approved the amended Charter for publication on the NICE website, subject to the addition of a high level reference to the quality adjusted life year (QALY) in the context of how NICE undertakes its work.

ACTION: Jane Gizbert

18. A member of the audience queried the implications of the recently introduced budget impact test on patients' rights under the NHS Constitution to access drugs that have been recommended by NICE for use in the NHS. Andrew Dillon highlighted the information on the NICE website that sets out how the budget impact test will operate and the actions by NICE and NHS England when the test is triggered.

17/099 ACCELERATED ACCESS REVIEW

19. Carole Longson presented the Government's formal response to the Accelerated Access Review (AAR), which largely accepts the review's recommendations. Carole outlined the key implications for NICE of the AAR and the Government's response, noting that the new facility to identify and support the introduction of transformative technologies in a way that is financially sustainable is consistent with the approach taken by NICE in recent changes to its programmes.

20. It was noted that NICE will act as the secretariat for the Accelerated Access Collaborative, and has received funding for this new role. The changes under the AAR envisage a new commercial liaison unit at NICE, and reinvigorating the innovation scorecard as part of enhanced support for the adoption and implementation of new technologies.

21. The Board welcomed the positive development of NICE's role following the AAR, but noted the potential challenges in realising the Accelerated Access Collaborative's envisaged benefits within the anticipated timeframe. The importance of clear roles and responsibilities was noted, with NICE holding a dual role – both as a member of the collaborative and as its secretariat. It was suggested that the collaborative develops metrics to evaluate its impact, with each partner committing to their role in delivering these. Separate measures should be established to evaluate NICE's performance as the secretariat. The collaborative will also need to agree a number of important matters at the outset, including the framework for selecting technologies for the accelerated access pathway, whilst ensuring that the cost of any product placed on the pathway is offset by a product that delivers cost savings. A number of methodological challenges in realising this latter point were noted.

22. The Board noted the report and requested that an update on progress is brought to the January Board meeting.

ACTION: Carole Longson

23. A member of the audience asked whether the clinical and cost effectiveness assessment in the accelerated access pathway will be undertaken as part NICE's technology appraisal programme. Carole Longson stated that the detail of how the pathway will operate is to be developed, but the pathway is likely to utilise the partners' existing processes. As such, NICE would wish to be involved in the assessment of cost and clinical effectiveness.

17/100 AUDIT AND RISK COMMITTEE TERMS OF REFERENCE

24. Ben Bennett presented the revised Audit and Risk Committee terms of reference and standing orders for the Board's approval. Under the revisions, the Committee will review the annual and accounts, together with external audit's opinion on these, and then recommend their approval to the Board.

25. The Board approved the terms of reference and standing orders.

17/101 DIRECTOR'S REPORT FOR CONSIDERATION

26. Gill Leng presented the update from the Health and Social Care Directorate, and highlighted particular areas of note within the report including the wide-ranging guidance and advice publications across health, social care, and public health topics. The report includes performance against the strategic engagement

metrics at the halfway point in the year, which cover activities at the national, regional and local level. These will be reviewed as part of the business planning process, and any suggested changes from Board members for 2018-19 are welcome. Gill also highlighted the online national user research survey which will provide feedback to inform future improvements to NICE products and services. The results will be brought to the Board.

27. The positive response to the social care "quick guides" was noted, which led to a question as to whether similar guides could be produced for other guidance topics. Gill responded that whilst the feedback has been positive, a material consideration is the available capacity at NICE. The Senior Management Team are considering how to prioritise the resources within the publishing team to best effect.

28. The Board noted the report and thanked Gill for the work of the Directorate.

17/102 – 17/105 DIRECTORS' REPORTS FOR INFORMATION

29. The Board received the Directors' Reports.

17/106 AUDIT AND RISK COMMITTEE MINUTES

30. The Board received the unconfirmed minutes of the Audit and Risk Committee held on 25 October 2017.

31. Rima Makarem, chair of the Committee, highlighted the discussions on cyber security, and noted that the Committee will further discuss this issue in April informed by an upcoming internal audit review on cyber security.

17/107 ANY OTHER BUSINESS

32. None.

NEXT MEETING

33. The next public meeting of the Board will be held at 1.30pm on 17 January 2018 in the Frank Lee Centre, Addenbrookes Hospital, Cambridge, CB2 0SN.

National Institute for Health and Care Excellence

Chief Executive's report

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

The Board is asked to note the report.

Andrew Dillon
Chief Executive
January 2018

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Chief Executive's report

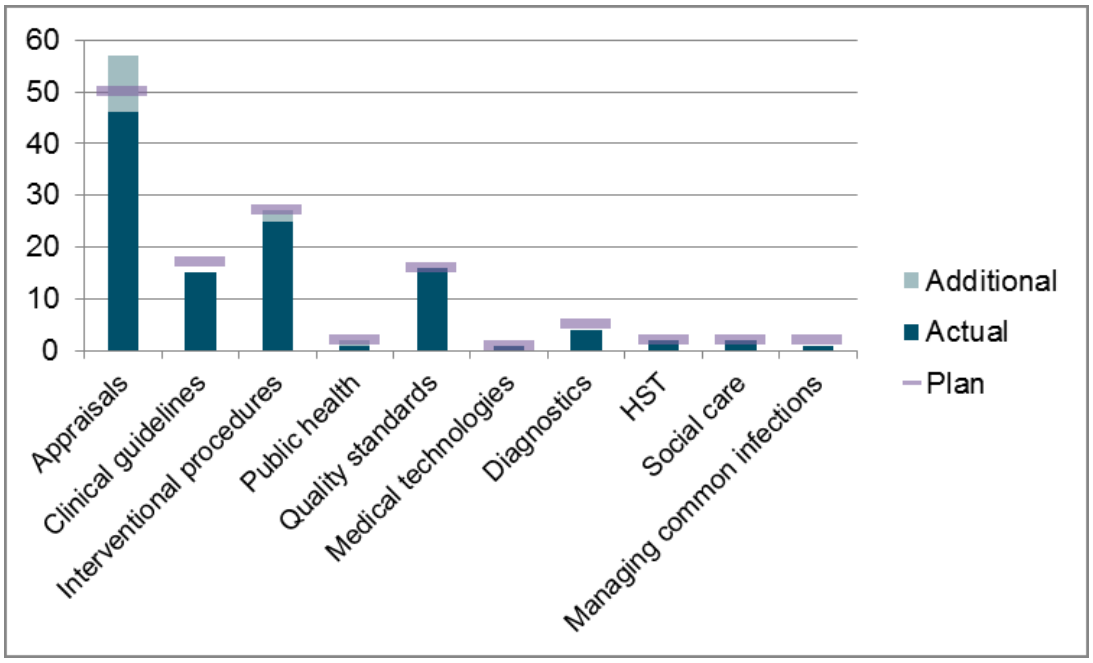
1. This report sets out the performance of the Institute against its guidance, standards and information programmes, for the 9 months ending 31 December 2017, and for the financial position to the end of November. The performance of the Institute against its business plan objectives for the same period is also reported, together with the guidance published since the last public Board meeting in November.

Performance

2. The current position against a consolidated list of objectives in our 2017-18 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 and December 2017 is set out in Charts 1 and 2, below.

Chart 1: Main programme outputs: April to December 2017



Notes to Chart 1:

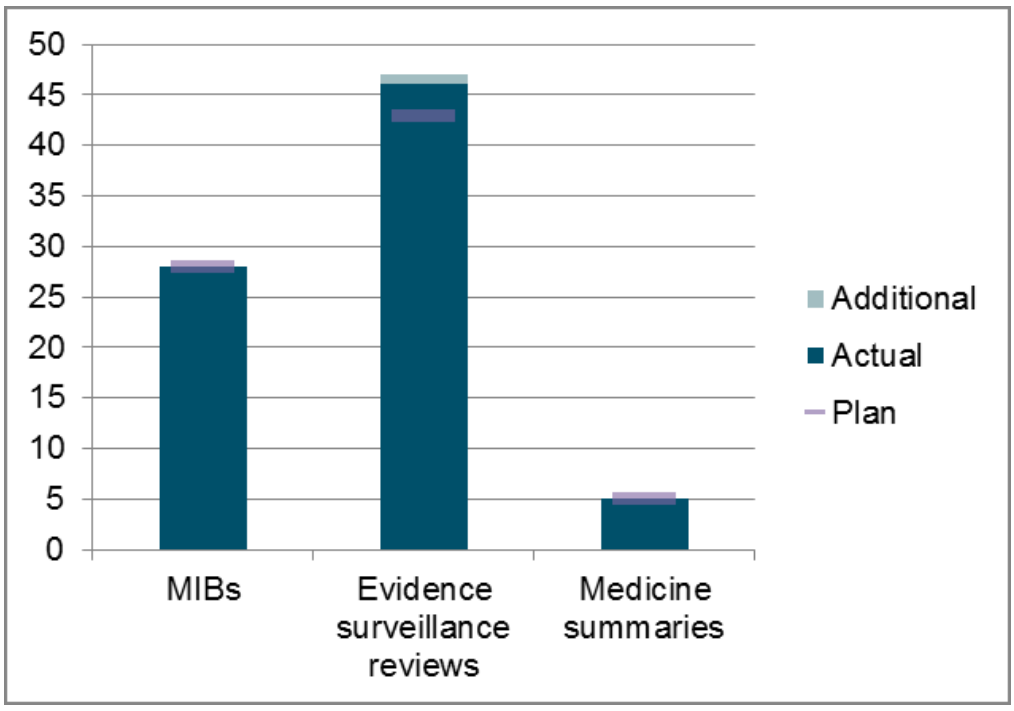
a) HST refers to the highly specialised technologies programme (drugs for very rare conditions)

b) The variance is the difference between the target output for the reporting period, as set out in the business plan and the actual performance
c) 'Additional' topics are either those which should have published in the previous financial year, or that have been added since the publication of the business plan

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 November 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 to December 2017



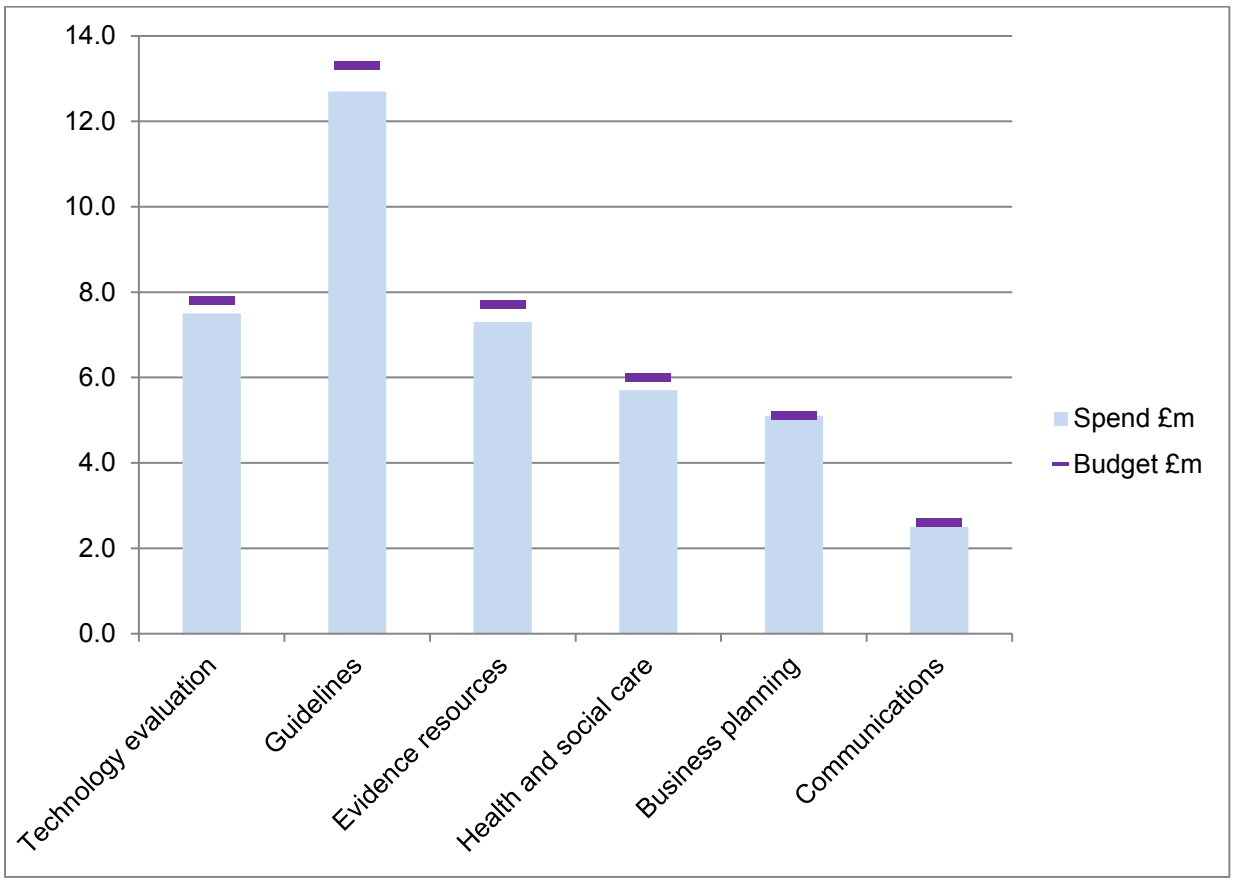
Notes to Chart 2:

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

Financial position (Month 8)

6. The financial position for the 8 months from April to the end of November 2017 is an under spend of £2.2m (6%) (£1.7m - 7% - at the end of September), against expenditure (taking into account projected income) of £44.4m. Non pay is under spent by £0.4m against budget (£0.5m at the end of September). Pay is £1.5m under spent against budget (£1.2m at the end of September). The year-end position is anticipated as an underspend of £2.9m. The position of the main budget 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 to November 2017 (£m)



Appendix 1: Business objectives for 2017-18

In managing its business, NICE needs to take account of the objectives set out in its business plan, and the organisational and policy priorities for NICE set out by the Department of Health. The table below consolidates and tracks progress with the main elements of these influences on our work in 2017-18.

Objective	Actions	Update
Guidance, standards, indicators and evidence		
Publish guidance, standards and indicators, and provide evidence services against the targets set out in the Business Plan and in accordance with the metrics in the balanced scorecard	• 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	• Details of the main programmes' performance against plan, including explanations for any variances are set out elsewhere in this report.
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	• Targeted discussion and engagement on methods aspects has commenced. • Implementation of enhancements to appraisal committee operations already identified is ongoing. CHTE 2020 project has been initiated aiming to review and, where necessary, optimise all CHTE guidance and advice processes. • Implementation of changes to the Technology Appraisal programme and Highly Specialised Technologies evaluation programme commenced on 1 April 2017.

Objective	Actions	Update
		• Initiation of CHTE work related to 'real world data' activity is planned for Q3/4 2017-18.
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. • Establish pre-development recruitment of guideline committee chair and expert members to support scoping	• The new structure is in place and three guidelines have been commissioned using the new process. • The new scoping process has been initiated for the three new commissions. • New methods for updating will be developed as part of the revision of the Manual.
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	• A formal process has been instituted for the revision of the Manual of Methods and processes. • The revised arrangements for health economics have been implemented. • Recruitment has commenced for the GP reference panel and the first commissions agreed. • An implementation plan has been developed to take forward changes to patient and public engagement, following discussion with the Board at its July meeting. Further

Objective	Actions	Update
	• 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	detail has been prepared for the Board on the operation of the Expert Panel.
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 (Clinical Knowledge Summaries (CKS), Cochrane), including those on behalf of HEE (National Core Content), to plan	• The new Link Resolver service was fully launched during October 2017 with no significant implementation challenge to date. • Visits to the NICE BNF microsite are recovering following a significant drop in referrals from search engines after the launch of the new service in June 2017. • The process of withdrawal of the NICE BNF and BNFC apps is underway. Users were notified in October that the NICE apps are no longer updated and are encouraged to download the new open access BNF publisher apps. • The procurement of Clinical Knowledge Summaries concluded with the re-appointment of the incumbent supplier.
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 (AAR) and the Government's life sciences strategy, for NICE guidance programmes • Develop an implementation plan and report to the Board on progress	• Internal teams continue to focus on the requirements of the AAR, and will take forward the recommendations following publication of the Government response to the AAR. The internal NICE AAR Implementation Group continues to meet regularly to plan for this.

Objective	Actions	Update
		• Work has started to establish the Accelerated Access Partnership Programme Office at NICE. • Changes to NICE's appraisal process, to increase capacity were approved by the Board in September 2017 for public consultation.
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	• Work is underway to progress work against new metrics, and a 6 monthly update is provided in the Health and Social Care Directorate progress report.
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 (ISG) to stimulate evaluation of implementation and improvement science	• The 6 monthly reports have been replaced by shorter, topic-focussed reports, which will be brought to the Board for each public meeting. • The ISG met in June 2017 and considered how to encourage more research into implementation, and how to get the best out of the NICE Field Team.
Promote NICE's work and help users make the most of our products by providing practical tools and support, using innovative and	• 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	• A number of staff in the Communications Directorate and elsewhere across NICE are developing skills in image/graphics design. Recruitment for a part time designer has

Objective	Actions	Update
targeted marketing techniques. Contribute to demonstration of impact though regular evaluation	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 (SDM) 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	been unsuccessful. We are exploring options which will likely result in using design agencies for the short and medium term until we reassess the design needs of the organisation. • Work is underway to develop 'quick guide' summaries and other secondary products for public health. • The online savings and productivity resource has been refocussed on key products. This is accompanied by wider work with key partners, including NHS Right Care, to support the use of our work on disinvestment. • Progress is being made in relation to NICE's commitments linked to the Shared Decision Making (SDM) work, including the referral of a guideline on SDM. • The work of the resource impact team has been developed to support budget impact assessments. Monthly assessments of future impact are sent to CCGs and to NHS England.
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)	• NICE attended its first Professional Record Standard Board (PRSB) Advisory Board in October 2017. The PRSB's mission is to support the development of standards in clinical records. This is an opportunity for NICE to understand if and how information

Objective	Actions	Update
	• Fully capitalise on existing relationships with specialists in the evidence management field and extend to other potential partners • 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 • Support NHS England to deliver the digital IAPT pilot programme (Improving Outcomes in Psychological Therapies)	standards such as SNOMED can play a role in adding structure and meta-data to NICE content. • Partnership working continues with the EPPI-Centre in UCL on the development of evidence management and surveillance solutions. • Good progress is being made with the digital IAPT pilot, and two topics have been developed into IAPT Briefings. The Expert Panel did not think these technologies were appropriate for the pilot programme. • In collaboration with Health Innovation Manchester, work has started to explore the potential of establishing a Manchester based "Data Laboratory" as a vehicle for progressing opportunities from digital technologies in evidence generation and guidance production.
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	• The tender process for a new customer relationship management system is on schedule. The tender was advertised in August and we are reviewing the responses. • Newsletters continue to evolve and are being promoted more heavily after analysis showed that people who read news stories via links on newsletters engaged more actively (spent longer on the page, looked at more pages and were more likely to engage

Objective	Actions	Update
	• 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	with the guidance) than readers from other sources. • Whilst longer term options for personalised content on the website are being explored, work is underway to refresh the communities' pages on the website. The new pages will be promoted from the homepage and will be more visually engaging with relevant content tailored to the specific audience. • The social media guide for staff has been published and promoted. The social media strategy is well embedded in practice in the Communications directorate. Interactions with social media channels continue to increase. Regular updates of audience insights and analytics are made in reports to the Board. We are liaising with teams across NICE to offer them training and awareness building around NICE use of social media.
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	A number of projects completed over the last 2 months: • A project to refresh UK Pharmascan reporting completed during October 2017. • Work to build automated testing capabilities for our developers completed at the end of September 2017.

Objective	Actions	Update
	• Translate data and observations about the performance of NICE Digital Services into actionable improvement proposals and implement in line with business priorities	A number of projects are under way: • Work to upgrade our evidence management tools in partnership with UCL is being further extended to the end of December 2017. It is expected that a new web-based version of the EPPI Reviewer software will be available for use in NICE in early 2018. • A four week discovery period was undertaken in October 2017 to prepare for the development of Antimicrobial Prescribing Guidelines content in the MAGICapp software, subject to license agreement. • Work to bring efficiencies to the external consultation process is continuing. The Alpha phase of the work successfully passed the assessment of the Department of Health digital team. Work to scope the Beta phase of the work and seek Government Digital Services approval is underway. • A business analysis and costing project to identify the key areas of potential efficiency along the guidance development process, with a view to guide further investment decisions is progressing well. • Digital Services and the Communications team are putting in place new processes for delivering strategic improvements to the NICE website.

Objective	Actions	Update
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	• Balanced budget set for 2017/18 with adequate contingency to minimise risk of exceeding resource or cash limits. We are on target to operate within our resource and cash limits. Further information is available in the finance and workforce report.
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	• Plans in place for delivery of the year 2 savings programme. • Key management of change projects completed according to schedule and expected to deliver savings as planned. Further minor changes in progress according to plan. • A small scale management of change exercise is starting in the Evidence Resource directorate regarding the Intellectual Property and Content Business 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	• 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	• We are continuing our discussions with the Department of Health on the timing of the implementation of charging. • A Contingency plan is in place should approval be withdrawn permanently and recurring GIA funding not reinstated. More detailed work will commence if cost recovery does not go ahead.

Objective	Actions	Update
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	• The Senior Management Team of NICE has approved a programme of work to refresh and standardise the copyright statement attached to NICE material. Over time, this will help promote the terms under which NICE's content can be re-used in the UK and overseas. • The NICE service offer associated with content re-use and the provision of an international delegation services was published on the NICE website during October 2017. • The NICE Scientific Advice team are delivering a small advisory project for the Vietnam Social Security, funded by the Foreign Commonwealth Office (FCO).
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	• Workforce strategy in place with associated operational plan for HR. • Health and Wellbeing group well established and includes implementation of NICE workplace guidance on its agenda. • In the annual staff survey 2017 79% of staff rated NICE as a good or excellent place to work (78% in 2016). • Resources in place for further management of change

Objective	Actions	Update
Promote a culture of continuous improvement within the organisation and uphold the ambition to remain a world-renowned organisation, benchmarking where possible its systems.	• 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	• In progress. • A review of publications has been completed and a report is being prepared.

Appendix 2: Extracts from the Directors' reports

Director	Featured section	Section/ reference
Health and social care	The quality standards programme was set up in 2009, and formally established in legislation in the Health and Social Care Act 2012. Over this period, a wide range of quality standards have been referred to NICE and there is now a library of 242 topics. NICE has published, or started to develop, 180 of these quality standards (74% of the library). These quality standards set out priority areas for quality improvement for the health and care system, identifying areas where there is variation in care and providing information on how to measure progress. At a national level they inform significant audits (stroke, chronic obstructive pulmonary disorder and heart failure) and support CQUINS (staff health and well-being). At a local level, quality standards are regularly used to inform service specifications and quality improvement projects.	Section/para 12
Guidelines	NIHR's Systematic Review Programme has agreed to commit up to £160,000 over 3 years to fund new or updated Cochrane reviews identified as being important to the NICE guidelines programme. This was in response to a joint proposal from Phil Alderson of the Centre for Guidelines at NICE and Professor Martin Burton of Cochrane UK. From April 2018, the surveillance team in the Centre for Guidelines at NICE will identify a number of Cochrane reviews that will either inform decisions on updating guidelines or be relevant for updates of guidelines, and Cochrane will work to ensure that the Cochrane reviews are delivered when required by NICE with NIHR contracting to support the work.	Section/para: Table 1
Health technology evaluation	At the September 2017 Board meeting, the Board approved a two-phase consultation on proposals to increase capacity within the Technology Appraisal programme. The 1st consultation started on 5 October 2017 and ran until 16 November 2017 and sought to elicit views from stakeholders on the principles of the proposed changes. The programme has reviewed all comments received from stakeholders from the 1st consultation. The 2nd consultation will be focussed on updating the content of Technology Appraisal process guide outlining how the principles will be operationalised. The process guide was released to stakeholders earlier this month, to seek their views. It is anticipated that the Board will review the outcome of both consultations together with the updated process guide for approval in March 2018.	Section/para 13

Evidence resources	NICE continues to monitor NHS England's and NHS Digital's strategy for assessing digital apps. NICE is a member of a new 'Digital Clinical Council' whose role in the process of digital assessment has yet to be fully defined. NICE has offered to undertake further app briefings for the system, subject to funding and commissioning.	Section/Table 1
Communications	The audience insight team delivered a joint project with the system engagement team to explore how guidance is put into practice and what would make it easier to implement. Nearly 900 responses were received to an online survey and 15 in-depth interviews were conducted. A summary of the main findings is included in the Health and Social Care Directorate report. During November and December 18 interviews were carried out with committee members to gain insights and feedback on their experiences of developing guidance. Analysis is underway and a report will be available in January. The Audience Insight team have also provided advice and practical support to a number of teams on audience feedback projects. These included 2 surveys about our internal and external processes relating to risk and audit for the corporate office team, recruitment of external users for alpha phase of new approach to capturing comments on consultations and a survey of committee members to understand the impact the proposed new declaration of interests policy would have on existing committees.	Section/Table 1
Finance and workforce	The General Data Protection Regulation (GDPR) comes into force in May 2018 across the European Union and will replace the Data Protection Act 1998 (DPA) in the UK. Post Brexit it is expected that the requirements of the GDPR will apply in the UK. The GDPR contains many similar requirements to those under the DPA but there are a number of changes. In part these seek to respond to the technological changes and developments in the way personal information is used and shared since the DPA was passed. The GDPR strengthens individuals' rights to privacy and puts greater accountability and compliance obligations on those who process personal data. The new principle of accountability means we need to ensure good record keeping to demonstrate compliance. As large fines can be levied even when no harm has occurred we need to keep clear and accurate records of all processing activities and security protocols, training programmes, audits, policies and procedures. Preparations for the GDPR are well underway and there is a high level of engagement from staff across NICE.	Section/appendix 3

Appendix 3: Guidance development: variation against plan April 2017 – December 2017

Programme	Delayed Topic	Reason for variation
Clinical Guidelines	2 topics delayed	Heavy menstrual bleeding (update): An initial 3 week delay was due to a late submission by the developer. The anticipated publication date is now to be confirmed.
		Type 2 diabetes management (update): Initial scoping work identified the need for a larger, broader update than originally intended. Guideline development was therefore suspended, with a larger update now planned.
Interventional procedures	2 topics delayed	Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma: This procedure is currently out for public consultation following submission of additional data. The anticipated publication date is now April 2018 (Q1 2018-19).
		Ab interno insertion of a micro stent into the supra-ciliary space for open angle glaucoma: Publication was delayed due to the absence of a specialist advisor to discuss this procedure at the July IPAC1 meeting. The anticipated publication date is now February 2018 (Q4 2017-18).
	2 additional topics published in 2017-18, that were not planned for this financial year	Sacrocolpopexy using mesh to repair vaginal vault prolapse: Delayed due to a resolution request. Published June 2017 (Q1 2017-18).
		Hysteroscopic sterilisation by insertion of intrafallopian implants: This guidance published in July 2017. (Note that the guidance was subsequently suspended until the appropriate regulatory authorisation for Essure is in place).
Medical technologies	No variation against plan 2017-18	
Public Health	1 topic delayed	Smoking cessation interventions and services: Publication date delayed as additional work, including the consideration of new evidence was required pre-consultation. The new anticipated publication date is 21 March 2018 (Q4 2017-18).

Programme	Delayed Topic	Reason for variation
	1 additional topic published in 2017-18, that was not planned for this financial year	Sexually transmitted infections - Condom distribution schemes: Publication date moved in order to secure Public Health England cobranding. Published April 2017 (Q1 2017-18).
Quality Standards	No variation against plan 2017-18	
Diagnostics	1 topic delayed	Adjunctive colposcopy technologies for assessing suspected cervical abnormalities (update of DG4): A second consultation on the draft recommendations was required. The third meeting for this topic will now take place on 10 January 2018. The earliest anticipated publication date is April 2018 (Q1 2018-19).
Technology Appraisals	4 topics delayed	Pirfenidone for treating idiopathic pulmonary fibrosis (review of TA282) [ID837]: Delayed following receipt of an appeal. The appeal hearing was held on 1 December 2017. Publication date of final guidance to be confirmed.
		Leukaemia (acute lymphoblastic, relapsed, adults) - inotuzumab ozogamicin [ID893]: Following the appeal hearing held on 3 November 2017, the appeal was upheld and the appraisal is to be remitted to the appraisal committee. Final guidance publication to be confirmed.
		Lung cancer (non-small-cell) - atezolizumab (after platinum chemotherapy) [ID970]: A second ACD has been released with final guidance anticipated in Q1 2018-19.
		Urothelial cancer - pembrolizumab (after platinum chemotherapy) [ID1019]: Following a request from the company to submit additional evidence, the committee discussion was rescheduled to 26 October 2017. Final guidance publication is to be confirmed (Q4 2017-18).
	11 additional topics published in 2017-18, that were not planned for this financial year	Afatinib for treating advanced squamous non-small-cell lung cancer after platinum-based chemotherapy: Published as a terminated appraisal in May 2017 (Q1 2017-18).
		Daratumumab with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma: Published as a terminated appraisal in July 2017 (Q2 2017-18).

Programme	Delayed Topic	Reason for variation
		Bortezomib for treating multiple myeloma after second or subsequent relapse: Published as a terminated appraisal in July 2017 (Q2 2017-18).
		Ibrutinib for untreated chronic lymphocytic leukaemia without a 17p deletion or TP53 mutation: Published as a terminated appraisal in July 2017 (Q2 2017-18).
		Methylnaltrexone bromide for treating opioid-induced constipation: Published as a terminated appraisal in August 2017 (Q2 2017-18).
		Idelalisib with ofatumumab for treating chronic lymphocytic leukaemia: Published as a terminated appraisal in August 2017 (Q2 2017-18).
		Ofatumumab with chemotherapy for treating chronic lymphocytic leukaemia: Published as a terminated appraisal in August 2017 (Q2 2017-18).
		Reslizumab for treating severe eosinophilic asthma: Topic not included in planning for 2017/18 – delayed from 2016/17. Published in October 2017 (Q3 2017-18).
		Ibrutinib for treating Waldenstrom's macroglobulinaemia: Topic not included in planning for 2017/18 – delayed from 2016/17. Published in November 2017 (Q3 2017-18).
		Nivolumab for previously treated non-squamous non-small-cell lung cancer: Topic not included in planning for 2017/18 – delayed from 2016/17. Published in November 2017 (Q3 2017-18).
		Nivolumab for previously treated squamous non-small-cell lung cancer: Topic not included in planning for 2017/18 – delayed from 2016/17. Published in November 2017 (Q3 2017-18).
Highly Specialised Technologies (HST)	No variation against plan 2017-18	
Social Care	No variation against plan 2017-18	
Managing Common Infections	1 topic delayed	Acute sore throat: Following a review of processes the development time was extended slightly. Publication now due in January 2018 (Q4 2017-18).

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

Programme	Topic	Recommendation
Clinical Guidelines	Asthma: diagnosis, monitoring and chronic asthma management	General guidance
	Glaucoma: diagnosis and management	General guidance
	Familial hypercholesterolaemia: identification and management (standing committee update)	General guidance
Interventional procedures	Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea	Special arrangements
	Processed nerve allografts to repair peripheral nerve discontinuities	Standard arrangements
	Extracranial to intracranial bypass for intracranial atherosclerosis	Do not use
	Total distal radioulnar joint replacement for symptomatic joint instability or arthritis	Special arrangements
	Transvaginal mesh repair of anterior or posterior vaginal wall prolapse	Only in research
	Endobronchial valve insertion to reduce lung volume in emphysema	Standard arrangements
	Transcutaneous microwave ablation for severe primary axillary hyperhidrosis	Special arrangements
	Artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure	Special arrangements
	Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death	Standard arrangements
Medical technologies	No publications	
Diagnostics	Tests in secondary care to identify people at high risk of ovarian cancer	Not recommended
Public Health	No publications	
Managing Common Infections	No publications	
Social care	No publications	
Quality Standards	No publications	
Technology Appraisals	Ibrutinib for treating Waldenstrom's macroglobulinaemia	Recommended for use in CDF
	Nivolumab for treating squamous cell carcinoma of the head and neck after platinum-based chemotherapy	Optimised for use in CDF
	Vismodegib for treating basal cell carcinoma	Not recommended

Programme	Topic	Recommendation
	Regorafenib for previously treated unresectable or metastatic gastrointestinal stromal tumours	Optimised
	Venetoclax for treating chronic lymphocytic leukaemia	Optimised for use in CDF
	Aflibercept for treating choroidal neovascularisation	Recommended
	Sarilumab for moderate to severe rheumatoid arthritis	Optimised
	Nivolumab for previously treated non-squamous non-small-cell lung cancer	Optimised for use in CDF
	Nivolumab for previously treated squamous non-small-cell lung cancer	Optimised for use in CDF
	Cladribine tablets for treating relapsing–remitting multiple sclerosis	Optimised
	Atezolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable	Recommended for use in CDF
	Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer	Recommended
	Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer	Recommended
	Naltrexone–bupropion for managing overweight and obesity	Not recommended
Highly Specialised Technologies (HST)	No publications	
Evidence summaries	Antimicrobial prescribing: Ceftazidime/avibactam	Summary of best available evidence
Medtech Innovation Briefings (MIB)	Point-of-care and home faecal calprotectin tests for monitoring treatment response in inflammatory bowel disease	Summary of best available evidence
	HTG EdgeSeq ALKPlus Assay EU for ALK status testing in non-small-cell lung cancer	Summary of best available evidence
Evidence Surveillance Reviews	Behaviour change: general approaches	Surveillance review decision
	Behaviour change: individual approaches	Surveillance review decision
	Hepatitis B and C testing: people at risk of infection	Surveillance review decision
	Psychosis and schizophrenia in adults: prevention and management	Surveillance review decision

Programme	Topic	Recommendation
	Home care: delivering personal care and practical support to older people living in their own homes	Surveillance review decision
	Bipolar disorder: assessment and management	Surveillance review decision
	Looked-after children and young people	Surveillance review decision
	Acute heart failure: diagnosis and management	Surveillance review decision
	Managing medicines in care homes	Surveillance review decision
	Ovarian cancer: recognition and initial management *Please note this is an exception review	Surveillance review decision
	Maternal and child nutrition	Surveillance review decision
	Social and emotional wellbeing in primary education	Surveillance review decision
	Social and emotional wellbeing in secondary education	Surveillance review decision
	Social and emotional wellbeing: early years	Surveillance review decision

Key to recommendation types

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

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

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

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

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

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

Technology appraisals and highly specialised technologies:
This guidance can 'recommend' the use of a new drug or other treatment, 'optimised use', in which the recommendation is positive for some but not all uses, or 'not recommend' routine use in the NHS. Research only use is also sometimes recommended.

Evidence summaries and medtech innovation briefings:
Both publications provide information (but not guidance) about a particular topic.

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

National Institute for Health and Care Excellence

Finance and workforce report

This report gives details of the financial position as at 30 November 2017. The report also includes details and information about the workforce strategy.

The Board is asked to review the report.

Ben Bennett

Director, Business Planning and Resources

January 2018

Performance Summary

1. Table 1 summarises the financial position as at 30 November 2017. There is a full analysis in Appendix 1.

Table 1: Financial position at 30 November 2017

	Year to date (30 November 2017)				Estimated Outturn (31 March 2018)			
	Budget £m	Expenditure £m	Income £m	Variance £m	Budget £m	Expenditure £m	Income £m	Variance £m
Guidance & Advice	34.9	34.5	(1.3)	(1.7)	53.9	53.5	(1.9)	(2.3)
Corporate	8.4	8.9	(0.6)	(0.1)	12.8	13.4	(0.8)	(0.1)
Scientific Advice	(0.1)	1.0	(1.1)	0.1	(0.2)	1.4	(1.6)	(0.0)
Other Income	(7.9)	0.0	(7.9)	0.0	(12.3)	0.0	(12.3)	0.0
Reserves	0.5	0.1	0.0	(0.4)	1.4	1.0	0.0	(0.4)
Grand Total	**35.8**	**44.4**	**(10.8)**	**(2.2)**	**55.5**	**69.2**	**(16.6)**	**(2.9)**

2. Table 1 above shows a total under spend of £2.2m (6%) to the end of November. This is primarily attributable to vacant posts throughout the year with an under spend on pay of £1.5m. There are also under spends on non-pay of £0.3m and an over recovery of income of £0.4m.

3. The full-year forecast position estimates that the full-year outturn will be £2.9m under spent.

4. There is a capital allocation of £0.5m for 2017/18. To date, £0.24m has been spent on upgrading the office facilities in Manchester and new furniture and fittings. There has been spend on IT hardware of £0.02m.

5. A summary of the financial position by directorate is detailed in appendix 1.

6. The proposals for cost recovery of technology appraisals and highly specialised technologies are currently paused. This has an impact on the NICE 2020 strategic savings programme. An update on the impact of this is provided in this report.

7. Progress on the implementation of the workforce strategy is detailed in appendix 2. This includes information and updates relating to transformational change, resourcing, maximising potential, pay and reward and the culture of the organisation.

8. The General Data Protection Regulation (GDPR) come into force in May 2018 across the European Union and will replace the Data Protection Act 1998 (DPA) in the UK. There is an update on our preparations for this at Appendix 3. Our progress is good and the Audit and Risk Committee will receive an internal audit report on NICE's preparedness.

Financial Position as at 30 November 2017

9. The total expenditure during April to November 2017 was £44.4m and income recognised was £10.8m. The net expenditure was therefore £33.5m, which was £2.2m (6%) lower than the budget of £35.8m. The total under spend includes the following key items:

    - Under spend of £1.5m on pay budgets
    - Under spend of £0.4m on non-pay budgets
    - Over achievement on income totalling £0.4m.

10. Appendix 1 shows in detail the financial position and forecast outturn by centre and directorate. Directors receive detailed monthly reports on the budget performance of their directorates and SMT review the summary position.

Pay

11. Total pay expenditure to 30 November 2017 was £21.8m, which was a £1.5m (7%) under spend against budget.

12. The staffing budget for November (as set at the beginning of the year) was 655wte with 605wte actually on payroll. The difference of 50wte equates to a vacancy rate of 8%. The under spend (£1.5m in 8 months) arising from vacancies throughout the year primarily as a consequence of restructures earlier in the year. Further, some vacancies are not being actively recruited to and may be deleted as part of NICE2020 savings plans. In November there were 9wte on agency contracts.

Non-Pay expenditure

13. Total non-pay expenditure to 30 November 2017 was £22.5m, which was a £0.4m (2%) under spend against budget.

14. As noted in the previous finance and workforce report, £50,000 of the under spend has arisen from the indicator development contract within the Quality and Leadership team due to the transition to a new provider. The digital services development budget for external contractors is £160,000 under spent against a total year to date budget of £632,000, this monthly under spend is not expected to continue as new projects are due to commence in the coming weeks. Overall, contracts with external bodies are £325,000 under spent.

15. Budgets relating to committees are under spent by £104,000 against a year to date budget of £675,000. This under spend includes payments to attendees (for

example committee fees and honorariums) and is due to holding fewer committees than expected, notably the Guidelines Updates and Technology Appraisals committees earlier in the year. The 3 standing committees in the updates team have been stood down and will be replaced by normal committees.

16. The Guidance Information Services budget for inter-library loans, journals and subscriptions is £35,000 under spent against a year to date budget of £96,000. This budget will likely be reduced as part of NICE 2020 savings.

17. The HR budget within Business Planning and Resources is under spent as a result of lower than expected expenditure on course fees and training expenses resulting in a £107,000 under spend against a year to date budget of £350,000. This under spend is driven by team restructures and vacancies resulting in lower demand.

18. Other miscellaneous under spends total £451,000 including £210,000 reserves, £136,000 travel and subsistence driven by vacant posts and £105,000 on other miscellaneous items.

19. The budget under spends are partially offset by over spends in the following areas:

    - Purchase of computer hardware, maintenance and software items generating an over spend of £89,000 against the IT non-pay budget.

    - Printing costs are over spending by £228,000 as a result of an over spend on the BNF however this is partially offset by income from devolved administrations giving a net over spend of £116,000. An over spend had been expected due to increases in the paper unit costs and movements in the pound to euro exchange rate, but the over spend was mitigated by reducing the number of copies ordered.

    - There is a cost pressure year to date of £115,000 covering redundancy costs and payments in lieu of notice relating to restructures earlier in the year.

    - There is an over spend year to date of £42,000 on legal / professional fees against a year to date budget of £67,000.

    - Cumulative immaterial over spends across team budgets totalling £117,000.

Income

20. Total income recognised as at 30 November 2017 was £10.8m. Of this, £8.4m was income relating to agreements we have in place with the devolved administrations (£1.4m), NHS England (£4.3m) and Health Education England (£2.7) to use NICE services and products or fund programmes within the organisation. Overall income exceeded the projection by £0.36m. This surplus was spread over a number of different areas.

21. The other income received relates to the Scientific Advice programme (£1.1m), subletting office space (£0.5m), receipts from research grants (£0.4m), and income from the Office for Market Access, intellectual property & content and secondment reimbursements (£0.2m).

22. Scientific Advice generated a £44,000 surplus after staff costs and other expenditure and after making a contribution to overheads. This surplus is projected to reduce slightly to £24,000 by the end of the financial year due to recruitment of new staff, with additional revenues expected to be generated following the launch of the Medtech Early Technical Assessment (META) tool in July 2017.

Forecast outturn

23. The forecast outturn for the year is a net spend of £52.6m against a £55.5m budget, resulting in a projected £2.9m (5%) under spend. This position assumes the under spend on pay due to vacancies and non-pay costs such as contracts and committee costs will continue at but at a lower rate. However, the forecast also includes an assumption that there will be some cost pressures before the end of the financial year relating to increasing the capacity of the Technology Appraisal programme and any potential transition costs arising from delivering the NICE 2020 savings programme.

24. NICE has been asked by the Department of Health to give assurance of the year end forecast and achieve the under spend agreed.

Capital and payments performance

Capital Expenditure

25. The confirmed capital allocation for 2017/18 is £0.5m. To date £244,000 has been spent on refurbishing works in the Manchester office during the summer. There has been spend on IT hardware of £18,000 for hardware and storage.

26. Table 2 details expenditure to date. An adjustment for the prior year has increased the capital allocation by £19,000. Some investment in IT email storage capacity is planned and the estimated cost is £127,000. This would result in a remaining capital balance of £148,000.

Table 2: Current capital expenditure commitments 2017/18

Value (£'000)	Item
518	Capital allocation
19	Prior year adjustment (IT hardware not received)
(244)	Spend to date (Manchester refurbishment and furniture)
(18)	IT hardware, blades and storage (London and Manchester)
275	**Balance**
(127)	Forecast - IT hardware email storage capacity
148	**Forecast - balance**

Payments performance

27. NICE is required to adhere to the Better Payments Practice Code (BPPC). This code requires all public bodies to pay suppliers/other NHS bodies within 30 days of receipt of a valid invoice. Currently the target set by the Department of Health is 95%.

28. 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. NICE's performance against this code is shown in table 3.

29. Table 3 shows that cumulatively year to date at month 8 the BPPC target has been met at 95%. A total amount of £25.6m has been paid to suppliers with £24.6m being paid within the 30 day target.

Table 3: Summary year to date BPPC statistics

Month	Total Invoices Paid (Count)	Paid within 30 days (Count)	Paid within 30 days (%)	Total invoices paid (£000's)	Paid within 30 days (£000's)	Paid within 30 days (%)
April to November 2017	2,044	1,940	95%	25,623	24,639	96%

Aged debt performance

30. Table 4 below shows a summary of the amounts owing to NICE and the age of those debts. The total owing was £0.9m as at the 30 November 2017. Of this

£0.5m (60%) is classified as current which means the debts are still within the required payment terms.

31. Excluded from the aged debt analysis is funding received from NHS England via invoices. At the end of November £2.2m debt was outstanding.

32. NICE debt management is outsourced to Shared Business Service who continue to chase outstanding debt on a regular basis. Outstanding debt is also regularly reviewed internally within NICE, written off when required and included on the losses and compensation register. It is rare for an invoice to be written off and no invoices have been written off during 2017/18.

Table 4: Debt by days overdue as at 30 November 2017

Days overdue	Amount unpaid	
	£000's	%
Current (within payment terms)	533	60%
1-30 days	173	20%
31-60 days	121	14%
61-90 days	20	2%
>90 days	36	4%
Total	**883**	**100%**

NICE 2020 update

33. Following the 2015 spending review the Department of Health confirmed that our strategic savings challenge would be a reduction of 30% in real terms of our Grant-in-Aid (GIA) funding by 1 April 2019. This is applied to the administration element of our funding which was £53.1m in 2015/16. The programme element of our budget would also reduce from £8.9m to £8m. This reduction would also be spread over the spending review period. The overall impact of these reductions equated to a recurring £14m reduction to NICE's GIA budget by 1 April 2019, with plans to achieve this collectively known as the NICE 2020 project.

34. Whilst many of the assumptions have been revisited and recast the £14m projected deficit has remained broadly consistent and we entered 2017/18 on a balanced budget having taken £5m out of the budget up to that date. This left us with £9m still to find. We have plans to save a further £4.1m by 2019/20 leaving a gap of £4.9m. It was intended that income from recovering the cost of technology appraisals from industry would address this remaining savings gap from April 2018.

35. Cost recovery has now been paused and is not likely to start until 2019. This leaves us with a projected resource shortfall of £1.3m in 2018/19 and of £4.9m in 2019/20. Once the programme is established we will return to financial balance. The Department of Health has been briefed on the requirement for transitional funding.

Appendix 1 Summary of financial position - to update for November

The table below is a summary of the financial position per centre and directorate as at 30 November 2017.

Centre / Directorate		Year to Date				Estimated Outturn			
		Budget £000s	Expenditure £000s	Variance £000s	Variance %	Budget £000s	Expenditure £000s	Variance £000s	Variance %
Centre for Guidelines	Pay	4,426	3,923	(503)	(11%)	6,640	6,063	(576)	(9%)
	Non pay	9,318	9,380	62	1%	13,658	13,697	39	0%
	Income	(454)	(599)	(145)	(32%)	(645)	(839)	(194)	(30%)
	Total	**13,291**	**12,704**	**(586)**	**(4%)**	**19,653**	**18,921**	**(731)**	**(4%)**
Centre for Health Technology Evaluation	Pay	5,844	5,521	(322)	(6%)	8,937	8,529	(408)	(5%)
	Non pay	2,533	2,538	5	0%	5,464	5,469	5	0%
	Income	(526)	(591)	(64)	(12%)	(789)	(902)	(113)	(14%)
	Total	**7,850**	**7,468**	**(382)**	**(5%)**	**13,612**	**13,096**	**(516)**	**(4%)**
Health and Social Care	Pay	4,744	4,566	(178)	(4%)	7,149	6,945	(204)	(3%)
	Non pay	1,292	1,175	(117)	(9%)	1,938	1,806	(132)	(7%)
	Income	0	(15)	(15)	--	0	(15)	(15)	--
	Total	**6,036**	**5,726**	**(310)**	**(5%)**	**9,087**	**8,736**	**(351)**	**(4%)**
Evidence Resources	Pay	3,304	3,072	(232)	(7%)	5,032	4,755	(277)	(6%)
	Non pay	4,461	4,291	(170)	(4%)	6,661	6,437	(224)	(3%)
	Income	(59)	(64)	(4)	(7%)	(99)	(104)	(6)	(6%)
	Total	**7,706**	**7,299**	**(407)**	**(5%)**	**11,594**	**11,086.969**	**(507)**	**(4%)**
Subtotal Guidance and Advice		**34,882.4**	**33,197.2**	**(1,685.2)**	**(5%)**	**53,945.7**	**51,841.4**	**(2,104.3)**	**(4%)**

Communications	**Pay**	2,333	2,298	(35)	(1%)	3,543	3,501	(42)	(1%)
	Non pay	321	246	(75)	23%	442	357	(84)	(19%)
	Income	0	(1)	(1)	--	0	0	0	--
	Total	**2,653**	**2,542**	**(111)**	**(4%)**	**3,984**	**3,858**	**(126)**	**(3%)**
Business Planning and Resources	**Pay**	1,751	1,760	9	1%	2,638	2,681	42	2%
	Non pay	3,914	3,927	13	0%	5,971	5,939	(33)	(1%)
	Income	(529)	(557)	(29)	(5%)	(793)	(821)	(28)	(4%)
	Total	**5,136**	**5,130**	**(6)**	**(0%)**	**7,817**	**7,798**	**(19)**	**(0%)**
Depreciation / Capital Adjustments	**Non pay**	651	648	(2)	(0%)	950	950	0	0%
	Total	**651**	**648**	**(2)**	**(0%)**	**950**	**950**	**0**	**0%**
Subtotal Corporate		**8,440.2**	**8,320.7**	**(119.5)**	**(1%)**	**12,751.2**	**12,606.9**	**(144.4)**	**(1%)**
Scientific Advice	**Pay**	620	693	73	12%	930	1,020	90	10%
	Non pay	193	186	(7)	(4%)	290	332	42	14%
	Income	(950)	(1,059)	(109)	(11%)	(1,425)	(1,581)	(156)	(11%)
	Total	**(137)**	**(180)**	**(44)**	**n/a**	**(205)**	**(229)**	**(24)**	**n/a**
Other Income	**Income**	(7,925)	(7,917)	8	0%	(12,334)	(12,334)	0	0%
	Total	**(7,925)**	**(7,917)**	**8**	**(0%)**	**(12,334)**	**(12,334)**	**0**	**0%**
Reserves	**Pay**	298	0	(297)	(100%)	208	0	(208)	(100%)
	Non pay	233	85	(147)	(63%)	1,157	746	(411)	(36%)
	Total	**530**	**85**	**(445)**	**(84%)**	**1,365**	**746**	**(619)**	**(45%)**
NICE Grand Total	**Pay**	**23,318.2**	**21,833.2**	**(1,485.0)**	**(6%)**	**35,077.0**	**33,494.5**	**(1,582.5)**	**(5%)**
	Non pay	**22,915.8**	**22,476.0**	**(439.7)**	**(1.9%)**	**36,530.9**	**35,732.9**	**(798.1)**	**(2%)**
	Income	**(10,443.0)**	**(10,803.3)**	**(360.3)**	**(3%)**	**(16,084.9)**	**(16,596.5)**	**(511.6)**	**(3%)**
	Total	**35,790.9**	**33,505.9**	**(2,285.0)**	**(6%)**	**55,523.0**	**52,630.9**	**(2,892.1)**	**(5%)**

Appendix 2 Workforce Strategy Update

The workforce strategy was approved at the July 2015 Board meeting. Work is continuing to progress activities in all five areas of the Workforce Strategy 2015-18. The table below provides a summary of activity that is currently underway. .

HR Systems	
• Maximising use of technology	The HR team is leading on the roll-out of self-service access to our HR and payroll platform, ESR. This is currently being piloted within the Business, Planning and Resources directorate. The system enables staff to directly access and update their personal data and request leave. Line managers will be able to input information such as sickness absence. Using ESR in this way is expected to result in more accurate data and improved reporting.

Transformational change	
• Enabling change • Business and workforce planning	As a result of the recent review of the management of change process, the HR team is now redrafting our policies and processes on change, with the aim of resulting in a smoother process for all involved, which meets our legal obligations and builds employee support into every stage. In the last month there has been a small management of change exercise which will result in one redundancy. The affected individual is being supported by her line manager and the HR team, including outplacement support. The team is engaging with several teams in anticipation of their change programmes, including working with CHTE on their 2020 transformation programme where members of the HR team have facilitated sessions at an associate directors' strategy session and a technology appraisals/highly specialised technologies away day.

Resourcing	
• Recruitment • Retention • Innovation	Apprentices We have appointed 7 new apprentices in this financial year, with an additional 4 vacancies to be recruited in the next 2 months and 4 apprenticeships to be created for existing staff members. This means we are making good progress against our apprenticeship recruitment target for 2017-18 (which is 2.3% of workforce, or 15 apprentices in this financial year). Recruitment The strategic review of recruitment is now complete, and a proposed strategy presented to the SMT in December 2017. The proposal aims to improve NICE's recruitment performance across the board, including time to hire, difficult to fill roles and quality of applicants. The external communications team has developed a strategy to increase our recruitment-related social media activity, with the aim of increasing awareness of NICE roles and attracting a more diverse range of applicants. We will also be interviewing a staff member on their experience of being a BAME candidate during the recruitment process at NICE. The interview will feature in a blog on NICE Space, and feedback will be incorporated into shaping our recruitment practices.

Maximising potential	
• Leadership and management • Managing performance	Line manager training In November, a survey was to all line managers to ask for input into future topics for training, including recruitment, maximising performance, promoting good attendance, dignity at work and wellbeing. The feedback is now being

Maximising potential	
• Succession planning and talent management	used to develop a range of training and development, which will be a blend of full day sessions, bitesize sessions and e-learning.

Pay and reward	
• Total reward • Pay review	NICE has now completed its gender pay gap reporting, and published its gender pay gap early, in December 2017 in line with DH and other ALBs. Further analysis of the data will now be undertaken. As we drill down further, the picture of gender pay differences in the organisation will become clearer which will inform our action plan.

Culture	
• Engaged workforce • Inclusive workforce • Wellbeing at work	Staff survey NICE is currently tendering for a new staff survey provider, who will provide survey and reporting services for the next 3 years. Interviews are expected to be held on 14 February. Health and wellbeing The health and wellbeing strategy group is making good progress in embedding the NICE quality standards regarding healthy workplaces. The group has highlighted that additional support is required for line managers. To address this, the HR team is coordinating the launch of Mental Health First Aid training in Q4, as well as developing in-house training for all line managers on promoting mental wellbeing, which will showcase the range of resources available to line managers. The Health

Culture	
	and Wellbeing pages on NICE Space will also be refreshed, to make information easier to access. Healthy Work Week Planning is underway for Healthy Work Week 2018 (22-26January), which will build on the success of previous years and take into consideration our staff survey feedback on NICE quality standards. The week will focus on the "Five ways to wellbeing", and will activities have been designed with Manchester, London and homeworking staff in mind. Bullying and harassment A blog was launched in November for Anti-bullying week to reinforce NICE's zero-tolerance approach to bullying, and remind staff of the support available if they have experienced or witnessed bullying. The blog had a personal approach, and was well received by staff, receiving many comments and 5-star ratings.

Appendix 3 - General Data Protection Regulation Update

1. The General Data Protection Regulation (GDPR) comes into force in May 2018 across the European Union and will replace the Data Protection Act 1998 (DPA) in the UK. Post Brexit it is expected that the requirements of the GDPR will apply in the UK.

2. The GDPR contains many similar requirements to those under the DPA but there are a number of changes. In part these seek to respond to the technological changes and developments in the way personal information is used and shared since the DPA was passed. The GDPR strengthens individuals' rights to privacy and puts greater accountability and compliance obligations on those who process personal data.

3. The new principle of accountability means we need to ensure good record keeping to demonstrate compliance. As large fines can be levied even when no harm has occurred we need to keep clear and accurate records of all processing activities and security protocols, training programmes, audits, policies and procedures.

4. Preparations for the GDPR are well underway and there is a high level of engagement from staff across NICE.

5. The work is overseen by the Information Governance Steering group (IGSG), which is chaired by the Business Planning and Resources Director and attended by NICE's Information Asset Owners (IAO's), Associate Director - Corporate Office and the Governance Manager: information.

6. The IGSG review key activities from the GDPR action plan - this 'live' document is refreshed regularly by the Governance Manager: information is based on guidance provided by the Information Commissioner's Office. Some of the main activities undertaken to date include:

    - Raising awareness: decision makers and key people/teams at NICE (e.g. HR, enquiries handling, those involved in committee recruitment) have been made aware that the law is changing and the impact this is likely to have has been explained.
    - Identify what we hold and identify legal basis for processing personal data: a thorough mapping exercise of what personal data is held at NICE has been conducted, it has involved all teams at NICE. The focus of the exercise has been to map where personal data we process comes from, who it is shared with, identify the type of data processing we are carrying out and why.

- Auditing whether current systems at NICE support and comply with GDPR requirements: the focus of this activity has so far been the Electronic Staff Record and the contacts database (including planning tools) – these are the main systems in which personal data is stored at NICE. Amendments have been made to the permissions of staff granted access to these systems to ensure they can only see the minimum amount of personal data necessary for them to do their jobs. The contacts database group has been meeting monthly to identify the development work required to make the system as GDPR compliant as possible.
- Updating policies, procedures and training: all information governance (IG) policies and procedures which will be impacted by the GDPR have been identified, and are in the process of being amended. Guidance about the GDPR is available to staff on the Information Governance intranet page. A new training package which includes an overview of the GDPR has recently been released - this training is mandatory and all staff must complete it by the end of March 2018.

7. NICE's preparation for the GDPR are currently the focus of an audit being carried out by the Government Internal Audit Agency. The audit is being conducted across all ALB's – the aim is to provide independent and objective assurance that there are robust and effective planning and governance arrangements in place to implement changes required to deliver GDPR compliance by May 2018. The results of the audit are expected in January.

National Institute for Health and Care Excellence

NICE impact: cancer

This first NICE impact report in a new format gives the Board information on how NICE guidance is used in the national priority area of cancer care.

The Board is asked to review the report.

Professor Gillian Leng

Deputy Chief Executive and Director, Health and Social Care Directorate

January 2018

NICE National Institute for Health and Care Excellence

NICEimpact cancer

NICEimpact *cancer*

One in 2 people will be diagnosed with cancer in their lifetime, and the disease is responsible for more than a quarter of all deaths in the UK. This report considers how NICE's evidence-based guidance might contribute to improvements in the diagnosis and treatment of cancer.

Cancer referrals p4

The annual number of people being urgently referred to a specialist has increased since the publication of the NICE guideline on suspected cancer: there were over 300,000 more urgent referrals in 2016/17 than in 2014/15. However, there is still wide variation across England in the percentage of people whose cancer is detected early, at stage 1 or 2.

Cancer medicines p6

Prescribing data for medicines used for treating melanoma and prostate cancer show the same pattern: new medicines which are more effective, more convenient to take or with fewer side effects than existing medicines show increased prescribing following a NICE recommendation.

Access to new medicines p12

The reformed Cancer Drugs Fund (CDF) gives fast access to cancer treatments, and makes promising new medicines available while more evidence is gathered. By November 2017, NICE had recommended 11 promising treatments for use within the CDF. We have also rapidly reconsidered 11 treatments in the previous fund and recommended them for routine use in the NHS.

Commentary p17

Professor Chris Harrison reviews recent achievements and considers NICE's role in contributing to the further transformation of cancer care.

Why focus on cancer?

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

NICE provides evidence-based guidance and advice to improve health and social care services. The uptake of NICE guidance is influenced by close relationships with our partners in the system. The NHS Five Year Forward View identified that improving outcomes for people with cancer is one of the top priorities for the NHS and so, in this report, we have focused on what we know about the uptake and impact of our recommendations in this area.

The Forward View highlights that cancer survival in England remains below the European average and suggests that late diagnosis and variation in access to some treatments may be important issues to address. It sets out objectives to deliver better prevention, faster diagnosis and better treatment and care. This report considers how NICE guidance can contribute to the delivery of these objectives.

204
Technology appraisals

19
Guidelines

13
Quality standards

One of NICE's first technology appraisals was of taxanes for treating ovarian cancer. Published in May 2000, it represented a hugely significant move towards providing equitable access to new and innovative treatments across the NHS. Since then, NICE has produced over 230 evidence-based guidelines, quality standards and technology appraisals aimed at improving outcomes for the almost 300,000 people diagnosed with cancer each year.

We routinely look for data which give us information about the uptake of our guidance. In this report, we have focused on data which tell us about the uptake of the NICE guideline on suspected cancer and guidance published by our technology appraisal programme. These data help us understand how our recommendations might be making a difference to the care and treatment people with cancer receive. They also highlight areas where there remains room for improvement.

Cancer referrals

The annual number of people being urgently referred to a specialist has increased since the publication of NICE's guideline on suspected cancer: there were over 300,000 more urgent referrals in 2016/17 than in 2014/15.

More people with cancer reported being referred to a specialist without having to visit their GP 3 or more times.

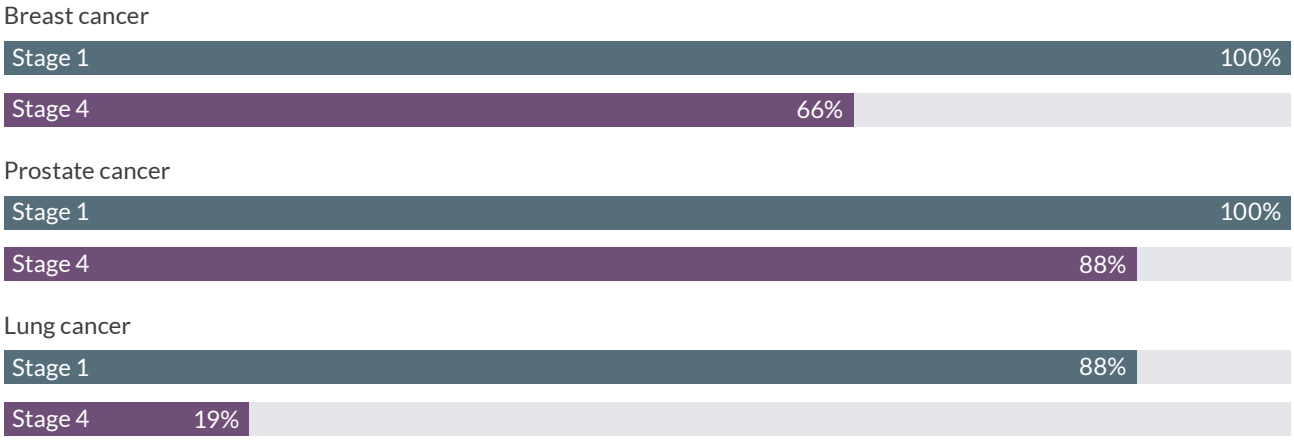
There is wide variation across England in the percentage of people whose cancer is detected at stage 1 or 2.

Early referrals to a specialist are important because the sooner a diagnosis is made, the greater the chances of survival for a longer period of time. The number of urgent referrals has increased over the past 3 years, one of several important factors in the early diagnosis of people with cancer.

In June 2015, NICE published an updated guideline on **suspected cancer: recognition and referral**. This guideline focuses on the symptoms that a patient might experience and go to their GP with. Data from the Office for National Statistics on **cancer survival by stage at diagnosis** for the 3 most common cancers in England show the importance of identifying cancer early. People who have their cancer diagnosed at stage 1 are much more likely to survive for a year than those diagnosed at stage 4. The identification of people with suspected cancer usually happens in primary care, and the NICE guideline clearly identifies those symptoms which should trigger an urgent referral.

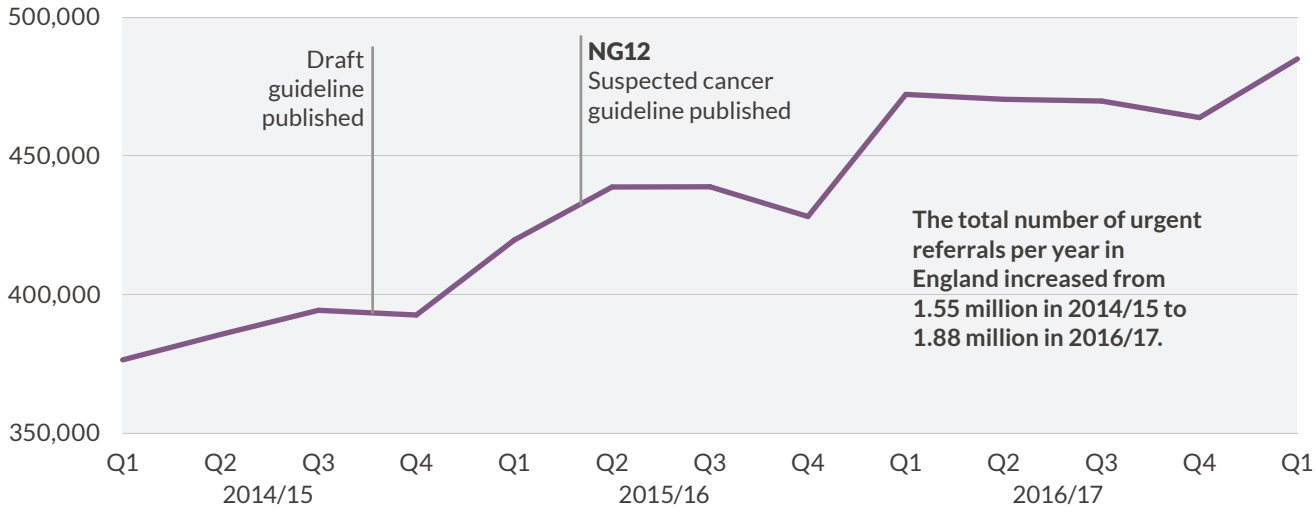
People who have their cancer diagnosed at stage 1 are much more likely to survive for a year than those diagnosed at stage 4.

One-year survival by stage at diagnosis in England, 2015

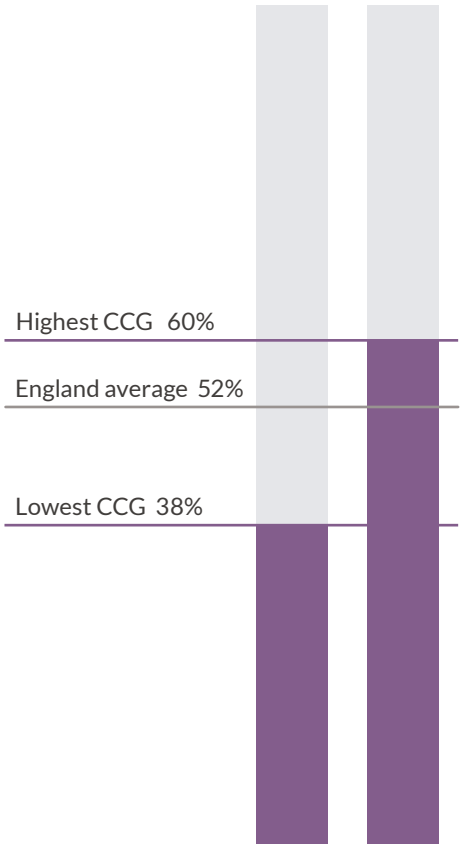


The current target in England is that people should be seen by a specialist within 14 days following an urgent GP referral. Data about these referrals are routinely published by NHS England as part of the cancer waiting times statistics.

Urgent (2 week wait) referrals for suspected cancer in England



Percentage of people whose cancer is detected at stage 1 or 2 in England, 2015



The National Cancer Patient Experience Survey records the number of people who say that they saw their GP only once or twice about the health problem caused by their cancer before they needed to go to hospital. Between 2014 and 2016 this increased slightly, from 75% to 77%. This suggests that fewer people with a cancer diagnosis visited their GP 3 or more times with symptoms which warrant a referral.

GP referrals are just one of the elements contributing to early diagnosis of people with cancer. The Independent Cancer Taskforce report Achieving World-Class Cancer Outcomes highlights other important elements, including access to screening and public awareness of symptoms. The report argues that late diagnosis is one of the major factors explaining England's poorer outcomes when compared to countries with similar wealth and universal health coverage such as Sweden, Australia and Canada.

Rates of early diagnosis are monitored in the NHS Outcomes Framework. This records the percentage of people whose cancer is detected at stage 1 or 2, giving them the best chance of successful treatment. The national percentage has slightly increased overall, from 51% in 2014 to 52% in 2015. However, there is wide variation across the country. This suggests that there is room for improvement in early diagnosis in many parts of England.

Cancer medicines

NICE has a vital role to play in ensuring that all patients have access to the most clinically- and cost-effective treatments. Patterns of prescribing for cancer medicines used for treating prostate cancer and melanoma show that access to new medicines increases after a NICE recommendation.

NICE recommendations are based on both clinical and economic evidence:

Clinical evidence *shows how well the medicine works.*

Economic evidence *shows whether it represents value for money to the NHS.*

Medicines considered for this report

Cancer medicines appraised by NICE
92

Recommended since January 2012
62

Prescribing data available from the Innovation Scorecard
48

Marketing authorisation for a single indication
19

Enough prescribing data to analyse trends; at least 9 months
15

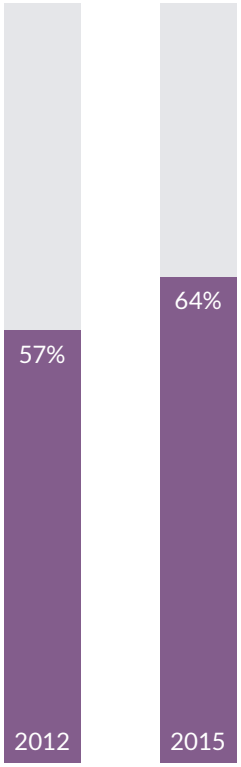
The NICE technology appraisal programme assesses the clinical- and cost-effectiveness of new medicines, significant licence extensions and other health technologies. This is to ensure that all NHS patients have equitable access to the most clinically- and cost-effective treatments that are available. The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisals. Since April 2016, it has been agreed that all new cancer medicines and significant new licenced indications will be appraised by NICE.

In 2009, growing concern about access to new cancer medicines led NICE, with the agreement of the Government, to introduce additional flexibility when appraising medicines that extend survival in patients with short life expectancy. This extended the cost-effectiveness threshold for 'end of life' treatments which was, and remains, controversial. As well as questioning whether a medicine can be regarded as cost-effective in the NHS at the increased threshold, critics argue that other life-limiting diseases and conditions, with which people live for long periods with very poor quality of life, deserve similar consideration.

In this report, we have looked at the prescribing of medicines using data published in the Innovation Scorecard. This reports on the use of medicines and medical technologies which have been recommended by NICE. We have considered appraisals published from 2012 onwards, because the Innovation Scorecard contains prescribing data from April 2012.

The Innovation Scorecard shows total prescribing for each medicine, and many cancer medicines have multiple marketing

Percentage of people with advanced non-small-cell lung cancer receiving systemic anticancer treatment



authorisations. When medicines have been appraised more than once, or are licensed for indications which have not been appraised by NICE, it can be difficult to see if NICE recommendations have had an effect on prescribing. In this report we have focused on medicines which have marketing authorisation for a single indication, to make it easier to identify prescribing patterns.

NICE recommends medicines as an option for treatment. Looking at prescribing of an individual medicine can be misleading without considering the prescribing of other options for the same indication. We have therefore reviewed the 15 medicines which meet the above criteria and identified 3 groups of medicines for 2 conditions, melanoma and prostate cancer. This enables us to look at patterns of prescribing for a condition.

Many medicines NICE appraises are recommended because they are more effective or have fewer side effects than a current medicine, and sometimes both. The availability of newer, better tolerated medicines can sometimes mean that more people are able to receive treatment. For example, the National Lung Cancer Audit reports an increase in the percentage of people with advanced non-small-cell lung cancer who received treatment as new medicines with less toxicity became available. NICE has recommended 8 new medicines for this indication since 2012.

The availability of newer, better tolerated medicines can sometimes mean that more people are able to receive treatment.

The medicines we have looked at in this report, used for treating melanoma and prostate cancer, show similar prescribing patterns in each group. Newer medicines which are more effective or have fewer or less severe side effects show an increase in prescribing when they are recommended.

Prescribing of cancer medicines: prostate cancer

Prostate cancer is the second most common cancer in England, accounting for around a quarter of all male cancers. Cancer registration statistics show that there were over 40,000 new cases in 2015, and over 10,000 deaths.

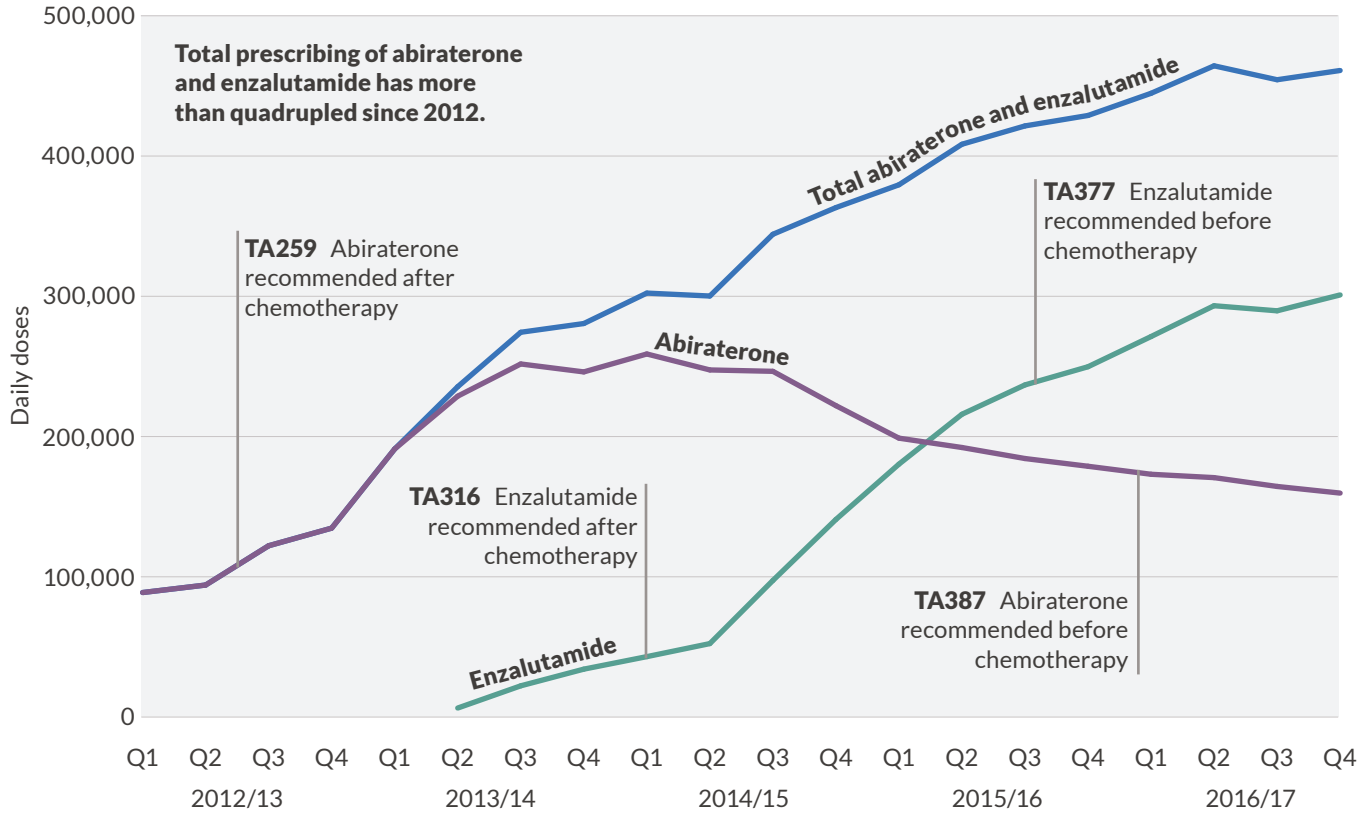
Abiraterone provided a treatment option for people whose cancer had progressed after chemotherapy when it was first recommended by NICE. Enzalutamide, which may be more convenient to take and is less likely to cause liver toxicity, has become more commonly prescribed than abiraterone since being recommended.

Most prostate cancers are either localised or locally advanced at diagnosis. A number of treatments are available, including active surveillance and surgery. Hormone therapy is the usual primary treatment for metastatic prostate cancer. However, if the cancer continues to progress despite standard hormone therapy, treatment options are more limited.

In 2006, NICE recommended **docetaxel**, a chemotherapy medicine, which became the standard treatment option for hormone-relapsed metastatic prostate cancer. In 2012, NICE recommended a new type of hormone therapy, **abiraterone**, to be used when the disease had progressed after treatment with docetaxel. Prescribing of abiraterone increased until a new option became available.

Enzalutamide is similar to abiraterone, but it is less likely to cause liver toxicity and may be more convenient to take for some people. In July 2014, NICE recommended enzalutamide for use after chemotherapy and prescribing of this new option overtook that of abiraterone by early 2015. NICE has since recommended both medicines for use before chemotherapy and total prescribing has more than quadrupled since 2012.

Prescribing of medicines for treating metastatic hormone-relapsed prostate cancer



Prescribing of cancer medicines: melanoma

In 2015, cancer registration statistics show that there were over 13,000 new cases of malignant melanoma in England, and over 2,000 deaths. Most cases of melanoma are identified early and treated with surgery, and the overall survival rates are among the highest of all cancers. However, for people with advanced or unresectable melanoma, treatment options are limited.

There were over 13,000 new cases of malignant melanoma in England in 2015, and over 2,000 deaths

Until 2012, the standard therapy for people with advanced melanoma was dacarbazine, a chemotherapy medicine. However, in the last few years, progress has been made in the development of new and innovative medicines. In December 2012, NICE recommended 2 new medicines for this population, ipilimumab and vemurafenib.

Ipilimumab and vemurafenib were step-changes in the treatment of advanced melanoma when they were launched. Newer alternatives, which are more effective or with fewer side effects, showed rapid uptake when NICE recommended them as options for treatment.

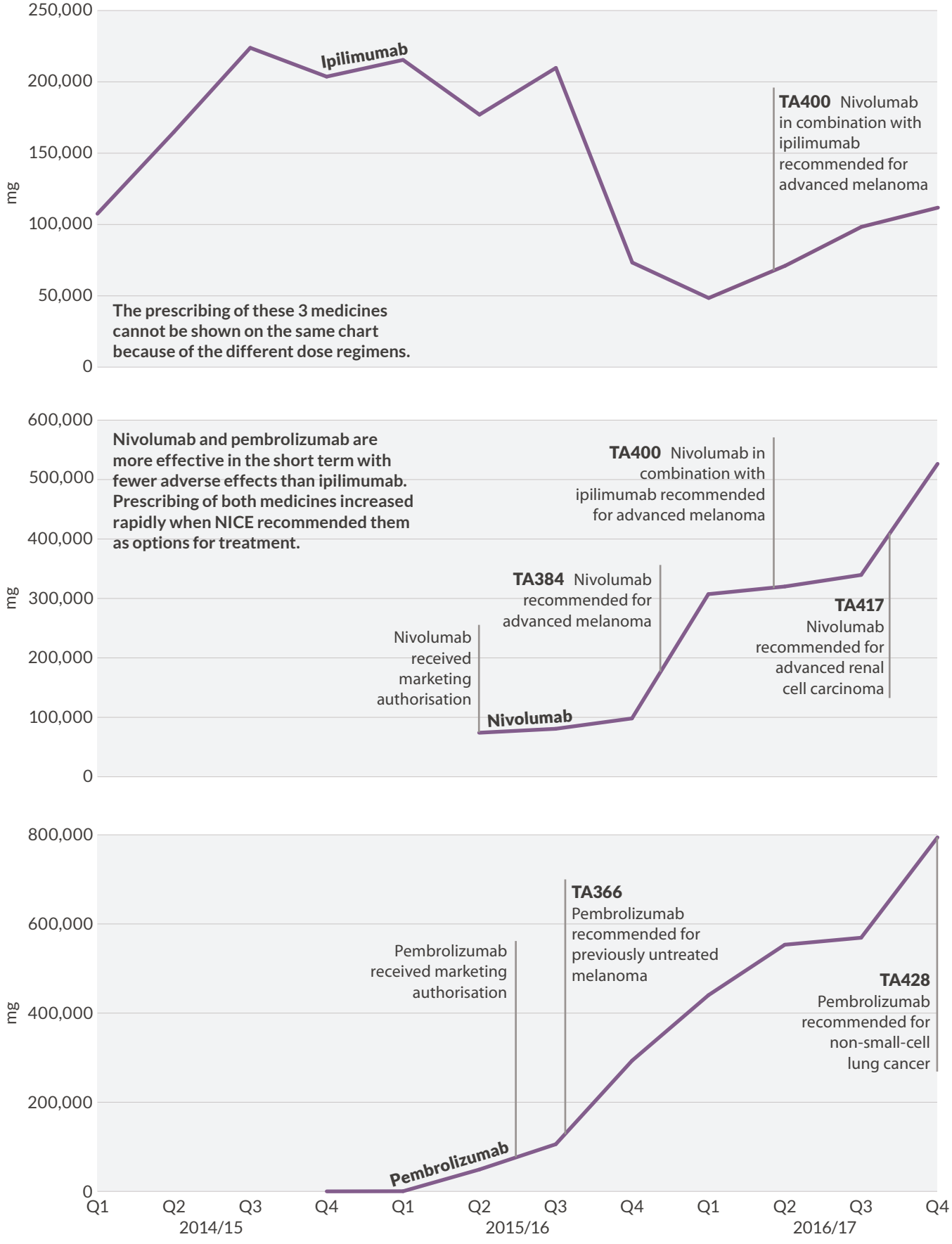
Immunotherapy

Ipilimumab triggers the immune system to fight cancer cells. It was recommended by NICE in 2012 for people with advanced, unresectable melanoma after chemotherapy. When the medicine's marketing authorisation was widened, NICE recommended it for use in people who had previously untreated advanced melanoma. Prescribing increased rapidly, from around 87,000 mg a quarter before the NICE recommendation to a peak of more than 215,000 mg between April and June 2015.

In 2015/16, NICE recommended 2 alternative immunotherapy medicines, nivolumab and pembrolizumab. These medicines are more effective in the short term than ipilimumab, with fewer adverse effects. As can be seen in the prescribing charts, both of the newer medicines saw rapid increases in prescribing as ipilimumab began to decrease. However it should be noted that both were also recommended for other indications towards the end of the time period shown in these charts.

In July 2016, NICE recommended nivolumab in combination with ipilimumab. This option is more effective in the short term than ipilimumab alone for people who can tolerate the combination. Following this recommendation, the prescribing of ipilimumab has once again increased.

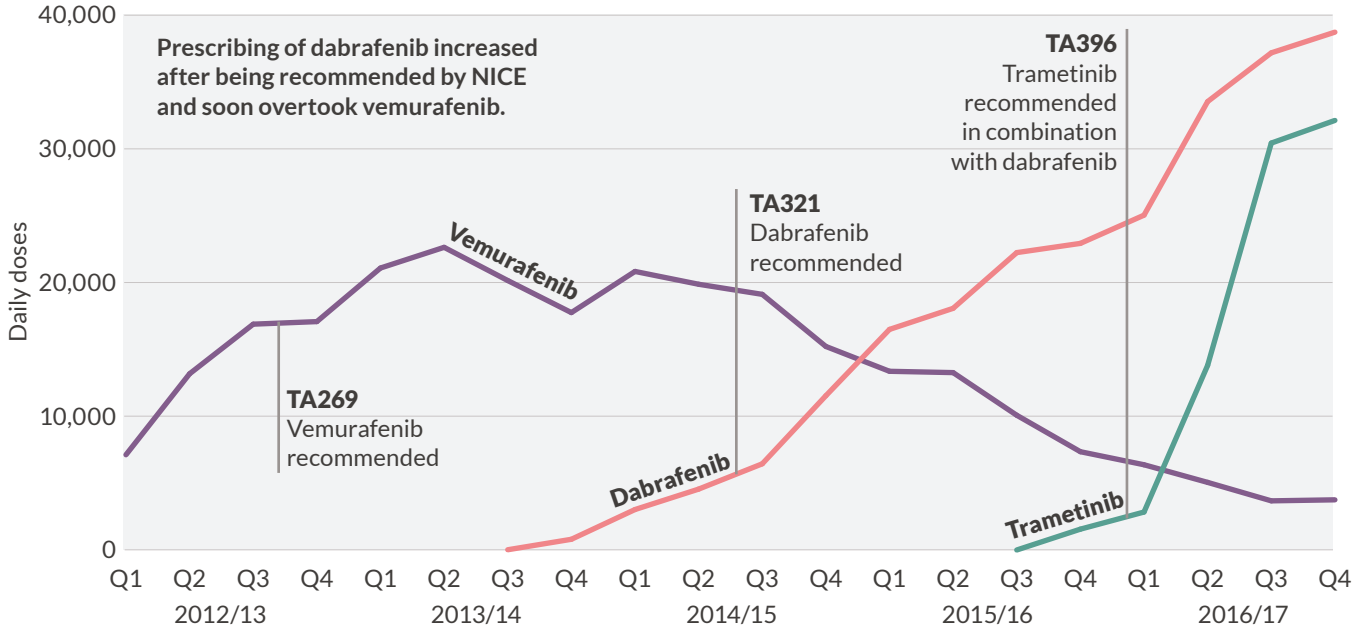
Prescribing of medicines for treating advanced melanoma



BRAF V600 targeted therapy

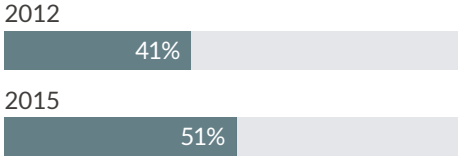
Vemurafenib was recommended by NICE in December 2012 for treating people with locally advanced or metastatic melanoma with a BRAF V600 mutation. In October 2014, another BRAF V600 inhibitor, dabrafenib, was recommended by NICE. These medicines do not differ in clinical effectiveness, but dabrafenib has a lower incidence of photosensitivity, which may be a major problem for some patients.

Prescribing of medicines for treating advanced BRAF V600 mutation-positive melanoma



Data from the Office for National Statistics on cancer survival by stage at diagnosis suggest that the survival of people with advanced melanoma has improved since 2012 when immunotherapy and BRAF V600 targeted medicines were first recommended by NICE.

Percentage of people diagnosed with melanoma at stage 4 who survive for 1 year after diagnosis



Following the NICE recommendation, prescribing of dabrafenib increased rapidly, and by January 2015 had overtaken vemurafenib. The combined prescribing of these medicines has steadily increased.

Most people with advanced melanoma are now initially treated with immunotherapy, regardless of their BRAF V600 mutation status. However, for patients with rapidly progressing disease, a short life expectancy or poor prognostic features, a BRAF V600 inhibitor may still be the most appropriate medicine. New treatments continue to be developed.

In June 2016, NICE recommended trametinib in combination with dabrafenib. This combination therapy is more effective than therapy with a single medicine, without any increase in adverse effects. Prescribing of trametinib has since increased rapidly. In October 2016, NICE was asked to appraise this combination for treating people with non-small-cell lung cancer with a BRAF V600 mutation.

Access to new medicines

Through working in partnership with NHS England Specialised Services, NICE is ensuring that new medicines can be accessed more quickly. The Cancer Drugs Fund (CDF) gives fast access to cancer treatments, and makes promising new medicines available while more evidence is gathered.

By November 2017, NICE had recommended 11 promising treatments for use within the CDF while more evidence is gathered.

NICE has rapidly reconsidered 11 treatments in the previous fund and recommended them for routine use in the NHS.

Interim funding for cancer medicines which have been granted a marketing authorisation is now available based on a draft recommendation from NICE, before final guidance is published.

The data in this report show an increase in prescribing of new medicines following a NICE recommendation. However, data from the Office for Life Sciences (OLS) **Life Science Competitiveness Indicators** suggest that the overall uptake of new medicines may be slower in the UK than in comparator countries. The OLS compared uptake of a selection of medicines first granted marketing authorisation between 2011 and 2015. The data show that, in the first year of launch, the median relative uptake in the UK compared to the selected other countries was 18%, rising to 79% in year 3.

There are many reasons why uptake of new medicines may vary, and OLS urge extreme caution when performing any analysis of their data because of this. NICE can contribute to faster uptake by more closely aligning the timing of our decisions with the marketing authorisation and launch of new medicines. Over recent years, NICE has made significant improvements in the speed of production of draft and final guidance following a marketing authorisation. In April 2017, a new **fast-track appraisal process** was introduced to give faster access to the most cost effective new treatments. For cancer medicines, early access has been made possible by reforms to the **Cancer Drugs Fund**.

The Cancer Drugs Fund

In 2011, the UK government set up the CDF, intended to help patients gain access to cancer medicines not routinely available on the NHS. However, the fund came under unsustainable financial pressure and political scrutiny. NICE and NHS England worked in partnership to develop a new model and the reformed CDF was launched in July 2016.

NICE now has the option of recommending medicines for use within the CDF. Previously, if a medicine looked promising but there was not strong enough clinical evidence to show it was cost-effective, NICE had to say no. Now the medicine can be made available through the CDF, with a managed access agreement between the company and NHS England, while more evidence is gathered to help resolve the key areas of clinical uncertainty.

Promising new cancer medicines can now be recommended for use within the CDF while more evidence is gathered.

By November 2017, NICE had recommended 11 treatments for use within the CDF. Some of these medicines had previously been recommended for treating different indications, but NICE would not have been able to recommend them for use in the NHS for these new indications without the option of the CDF. However, these recommendations are too recent to allow us to look at any patterns in prescribing.

For most medicines, when NICE recommends a treatment 'as an option', the NHS must make sure it is available within 3 months (unless otherwise specified) of the final guidance publication. As part of the changes to the CDF, interim funding for medicines which have been granted a marketing authorisation is now available based on a draft recommendation, which means faster access to cancer medicines.

Interim funding for cancer drugs is now available based on a draft recommendation, which means faster access to new treatments.

NICE now aims to publish draft guidance for cancer medicines prior to marketing authorisation so that interim funding is available as soon as marketing authorisation is granted. For medicines which received a marketing authorisation in 2017, data to November 2017 show that the average time taken to release draft guidance after marketing authorisation for all new medicines was less than 2 months, and less than 1 month for cancer medicines.

Cancer Drugs Fund: olaratumab

Olaratumab is a new medicine which NICE has recommended for use within the CDF. It is used for treating sarcoma, a rare type of cancer that affects tissues that connect, support and surround other body structures and organs. People with advanced soft tissue sarcoma having the current standard treatment, doxorubicin, alone are expected to live for 12 to 16 months after starting treatment. Evidence reviewed during the appraisal of olaratumab suggests that having olaratumab plus doxorubicin increases the length of time people live by a median of 11.8 months. This is potentially a step-change in treatment.

Evidence suggests that having olaratumab plus doxorubicin increases the length of time people live by a median of 11.8 months. This is potentially a step-change in treatment.

However, there are not enough long-term data to know the overall length of time people having olaratumab plus doxorubicin live compared with doxorubicin alone. An ongoing trial is expected to address the uncertainty in the data. NICE therefore recommended olaratumab for use within the CDF while further data are collected and around 450 people per year with advanced sarcoma will be eligible for this new medicine. The company that markets olaratumab has agreed to make it available under special arrangements with NHS England, which will see the medicine funded at a discounted price while data collection continues.

'I'm excited about being able to try olaratumab. You hear so much about new treatments for other cancers like immunotherapies coming through, and until recently we've had little in the way of new drugs come through for treating sarcoma. Doxorubicin has been used for over 30 years with sarcoma, so having olaratumab fills me with hope. The fact that it can be given for a lengthier period of time makes me hopeful it can keep my tumour under control for longer. My plan is to visit my grandchildren in Australia next spring, and I'm hoping olaratumab will play a part in maintaining a good quality of life and allow me to do this.' Gill, sarcoma patient

Medicines from the previous Cancer Drugs Fund

As part of the reforms to the CDF, NICE was asked to carry out 11 rapid reconsiderations of medicines in the previous fund. In many cases, companies were able to supply discounts or additional evidence, allowing NICE to reconsider an original decision that a medicine should not be recommended. All 11 treatments are now recommended for routine use in the NHS.

NICE has recommended 11 treatments for routine use in the NHS after a rapid reconsideration process.

The first CDF reconsiderations were of **bosutinib** for chronic myeloid leukaemia and **pemetrexed** for non-small-cell lung cancer. Pemetrexed is also recommended for many other indications, so we have looked at the prescribing of bosutinib in this report. Since these first reconsiderations, NICE has been able to reconsider and recommend medicines such as **everolimus** and **trastuzumab emtansine** for treating breast cancer, **crizotinib** for treating non-small-cell lung cancer and **cetuximab** for treating cancer of the head and neck. These medicines are now in routine use in the NHS, but the recommendations are too recent for prescribing data to be available for this report.

Cancer Drugs Fund reconsideration: bosutinib

Bosutinib provides a treatment option for people with chronic myeloid leukaemia (CML) when other medicines no longer work or cause severe side effects. The CDF reconsideration process has allowed NICE to recommend this medicine for routine use in the NHS at an agreed discount. Prescribing has increased rapidly since the NICE recommendation.

Bosutinib provides a treatment option for people with chronic myeloid leukaemia when other medicines no longer work or cause severe side effects. The CDF reconsideration process has allowed NICE to recommend this medicine for routine use in the NHS at an agreed discount. Prescribing has increased rapidly since the NICE recommendation.

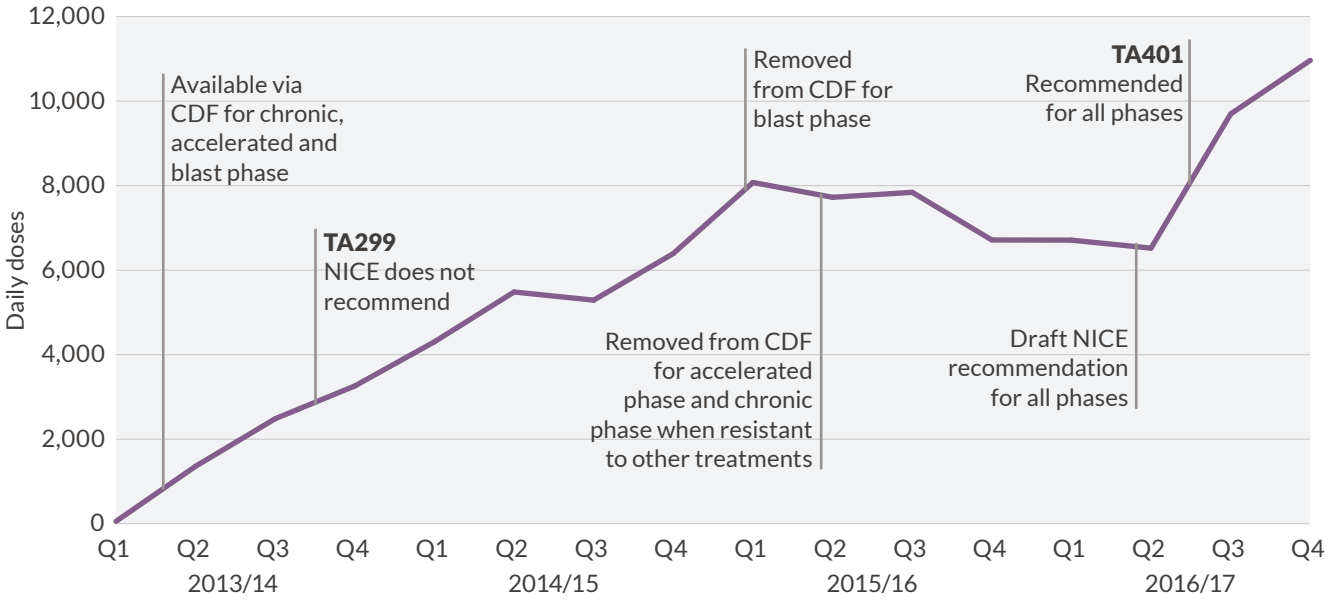
Bosutinib was first appraised by NICE in 2013, when it was found to be not cost-effective and was not recommended. It was made available via the CDF until January 2015, when the fund decided not to retain bosutinib for treating blast phase CML. In September 2015 the CDF panel made a decision not to retain bosutinib for treating accelerated phase CML, or for chronic phase CML patients who were resistant to other treatments. However, when NICE reconsidered this medicine in 2016, a discount was agreed with the company which was

'Being given access to bosutinib, now through NHS funding, has meant that I am now able to live completely normally and, quite often, even forget I have leukaemia. Having had issues with four other medicines this was my last option but, four years on, my counts are stable and side effects minimal and the fact that I can pop those small pills every day means I can continue working and leading a full life.' Karen, CML patient

included in the new cost analysis. This allowed NICE to recommend the medicine for routine NHS use in all 3 phases of CML.

Since the NICE recommendation, prescribing of this medicine has increased rapidly. Recommending this medicine for routine use appears to have made it available to many more people.

Prescribing of bosutinib for treating chronic myeloid leukaemia



Commentary

Professor Chris Harrison, December 2017

Professor Chris Harrison is National Clinical Director for Cancer, and Medical Director (Strategy), The Christie NHS Foundation Trust.

The last 3 decades have seen remarkable improvements in cancer care across the UK. In 2016 and 2017 more people survived cancer than ever before. More focus has been put on prevention and many treatments have become less toxic and more personalised.

And yet, as the national cancer strategy for England based on the 96 recommendations from the national cancer task force sets out, there is a lot more to do. We have already been making improvements. Less than 2 years into the 5 year implementation programme we have, amongst other things, made good progress by setting up cancer alliances, replacing and upgrading radiotherapy equipment and designing new models for diagnostic services.

Against this background 2 questions come up a lot: how do we best address the persistently identified differences in cancer survival between UK jurisdictions and comparable countries, and how do we best tackle the persistent inequalities in outcomes and experience of cancer care within our own populations?

The people leading cancer alliances will need clear, evidence-based information to help make decisions and tackle difficult choices.

NICE has an important role in helping us to confront these issues and the current report is a significant contribution to this effort. In England, cancer alliances are designed to coordinate and lead service provision and commissioning in a way which ensures seamless care across the multitude of boundaries between organisations within the NHS and beyond into social care, commercial organisations and the third sector. The people leading alliances will need clear, evidence-based information to help make decisions and tackle difficult choices between the potential benefits of interventions for individuals against wider population considerations.

NICE guidelines have contributed to improvements in the identification, diagnosis, management and treatment of cancer. This report shows how guidance from NICE has helped to support GPs to identify those people with symptoms of

cancer and refer sooner than in the past. Fewer patients now have multiple GP visits before referral and more are referred for urgent assessment. Variations still exist and cancer alliances are building on innovations in the cancer vanguard to further support GPs and to develop models for multi-disciplinary diagnostic clinics which provide more rapid assessment for the many patients with less specific symptoms, often those with rarer and harder to diagnose cancers.

The time taken between licensing of new drugs and NICE draft recommendations being available has in the past created the possibility of variation in access where commissioners have had to make their own decisions whilst awaiting recommendations. Through cancer alliances we now have a mechanism for collective decisions to be taken by CCGs and other commissioners but speeding up the process as has been started through the new arrangements for the Cancer Drugs Fund and greater leverage of the purchasing power of the NHS is an important way of reducing inequalities.

At a time of financial constraints on the NHS, the clarity and timeliness of NICE recommendations become all the more important.

There is no doubt that NICE guidance is persuasive and this is seen by the increase in uptake of cancer medications following recommendations. At a time when the financial constraints on the NHS are widely acknowledged and choices have to be made, the clarity and timeliness of these recommendations become all the more important. At the coal face, commissioning decisions often need to be taken on the basis of imperfect or developing information. The examples in this report show how NICE can support this process.

The national cancer programme spans the interests and responsibilities of all the Department of Health's arm's length bodies including NICE. All sit round the national Cancer Transformation Board table as it oversees and coordinates implementation of the national strategy. The 19 cancer alliances are the key mechanism for real change to be made on the ground. They will continue to need timely evidence-based guidance on the relative cost-effectiveness of cancer treatments and service organisation if they are to succeed in the job of improving outcomes and reducing inequalities.

Published January 2018

Any enquiries regarding this publication or any other enquiries about NICE and its work should be made to:

National Institute for Health and Care Excellence
10 Spring Gardens
London SW1A 2BU
Telephone: +44 (0)300 323 0140
Fax: +44 (0)300 323 0148

National Institute for Health and Care Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester M1 4BT
Telephone: +44 (0)300 323 0140
Fax: +44 (0)300 323 0149

Email: **uptake@nice.org.uk**
Website **www.nice.org.uk**

www.nice.org.uk

National Institute for Health and Care Excellence

Policy on declaring and managing interests for NICE advisory committees

In July 2017 the Board approved a public consultation on a draft new policy on declaring and managing interests for NICE advisory committees. The policy has been revised in response to both the consultation feedback, and the subsequent discussion at the December Board Strategy meeting. It is now presented for the Board's approval for implementation.

The changes from the consultation draft seek to simplify the policy, and address concerns that the approach to managing interests could undermine NICE's ability to recruit suitably qualified and experienced committee chairs and members.

One of the main themes in the consultation feedback was the treatment of interests arising from private practice. In response, a more flexible approach is now proposed in the policy. Likewise, following the Board's discussion in December the policy also now provides greater discretion to involve a committee member in a topic on which they have previously expressed a view. The circumstances in which an interest becomes 'specific', and therefore requires potential exclusion from the committee's discussion has also been revised.

The Board is asked to:

- Approve the policy
- Support the approach for implementing the policy (as outlined in paragraphs 26 to 28)
- Confirm that appellants against NICE's technology appraisal and highly specialised technologies guidance are not required to make a declaration of interests.

Professor Gillian Leng

Deputy Chief Executive and Director, Health and Social Care Directorate

January 2018

Background

1. In July 2017 the Board approved a public consultation on a draft new policy on declaring and managing interests for NICE advisory committees. The policy was developed by a cross Institute working group, chaired by the Deputy Chief Executive, and sought to maintain consistency with the NHS England guidance on managing conflicts of interest in the NHS, published in February 2017, with necessary amendments to reflect NICE's circumstances. The working group felt this consistency would assist NICE's committee members who also make declarations in other NHS roles.

Consultation feedback

2. The consultation ran from 24 July to 18 September 2017 and received 52 responses. The main issues that were raised in the consultation are summarised below:

    - Greater clarification in some areas of the policy: Some respondents asked for greater detail and clarity about what the policy did and did not include. Some stated that a greater number of examples in certain cases would be helpful.
    - Definition and application of private practice: The issue around private practice was raised in different parts of the consultation. Again clarity was sought on this issue. It was noted that the definition of 'private practice' in reality was not as clear cut as had been presented. Furthermore, there were concerns that the proposed approach could lead to the exclusion of a number of skilled and qualified professionals, which in turn may cause difficulties in committee recruitment.
    - Impact on recruitment of committee members and chairs: Linked to the above point on private practice, there was a concern that the proposals in general were too restrictive. A number of the respondents highlighted that some elements of the policy may make it difficult to attract and recruit experienced and appropriately qualified chairs and committee members.
    - Timescale for declaration of interests: A number of respondents felt that 12 months was not a long enough time period for declarations of interest. Suggestions ranged from 2 years to adopting a more flexible case-by-case approach.

Response to consultation

3. The working group that developed the consultation draft reviewed this feedback and the policy was revised and simplified. The ordering within the policy has

been amended, and sections merged to avoid duplication and repetition. NICE's editing team reviewed the policy prior to consultation and have reviewed the amended version following the consultation.

4. The updated policy was shared with colleagues from guidance programmes, and a selection of internal stakeholders with a particular focus on the changes regarding private practice and GPs, and then reviewed by the Senior Management Team (SMT) and the Board at the December Strategy meeting.

5. The material changes from the consultation draft are outlined below.

Simplifications and clarifications

6. The scope of interests to be declared has been narrowed to anything relevant to the work of the NICE committee in question (the consultation version required declarations to cover anything relevant to NICE overall).

7. The fact that a declared interest may not be a conflict of interest has been clarified and emphasised.

8. The matters to be declared have been reviewed and simplified.

9. The examples in the appendices have been amended to provide further guidance on the approach for handling conflicts of interest. New examples have been added to clarify that in most instances GPs are not precluded from involvement in a NICE committee on the grounds of a conflict of interest.

10. Amendments clarify the respective provisions for standing committees and topic-specific guideline committees.

Private practice

11. The provisions around private practice have been amended, both in terms of the activities that need to be declared and how such work affects involvement in a NICE committee. The revised policy provides greater flexibility for a clinician with relevant private practice to participate in the NICE committee than is permitted under the wording of the current policy.

12. The revised policy states that where the interest relates to private practice and income in the commercial sector, a committee member may be able to participate if their clinical experience is considered vital to the discussion. In such circumstances, the level of involvement (full involvement or partial exclusion) will depend on the scope for potential benefit (and risk of conflict of interest). This approach is explained further in expanded examples in the appendices.

13. Two consultation respondents suggested declarations should be expanded to include a wider range of income sources, including NHS income. NICE considered this proposal and agreed this would not be proportionate to the level of risk of a conflict of interest, and could undermine our ability to engage health and social care professionals and lay members in our advisory bodies.

Impact on committee recruitment

14. A number of respondents queried whether the policy represents a shift in approach of moving to chairs who are not necessarily experts in that particular topic field. In response and to clarify the rationale for the restrictions on chairs' interests, further information on the role of the chair, as currently stated in the guidelines manual, has been added to clarify that chairs are not appointed for their topic expertise.

15. To further address concerns about whether the approach is too restrictive and would impact on committee recruitment and guidance production, the policy now states that an individual will not usually be excluded from involvement if a financial interest occurred in the last 12 months and is no longer held. For example, if an individual has ceased to hold shares or undertake relevant private practice. This is because the potential to benefit has ceased.

16. In response to the Board discussion in December, the action to be taken when a committee member has previously expressed a view on the matter being considered by the committee has been revised. The policy now states that the response to this non-financial interest should take account of the nature of the view expressed and the risk to the person's perceived objectivity. In determining the level of involvement the chair should consider the balance between this risk and the benefit of the individual's input to the committee.

17. In response to internal feedback on the policy, the circumstances in which an interest is specific have also been revised. Income received from consultancy or other advisory services will be treated as a specific interest when it relates to the product under consideration, or the comparator to that product. Advisory services on matters unrelated to these products is not a specific interest. This maintains the approach currently in operation in the Centre for Health Technology Evaluation and enables an individual who has received funding from the manufacturer of the product under review, or the comparator, to participate in the committee's discussion if this income is for work unrelated to the product under review.

Timescale for declarations

18. Consistent with NICE's existing policy, the draft policy proposed that declarations should cover the preceding 12 month period. Eleven consultation respondents

felt a longer time period would be more appropriate, particularly where an individual has expressed strong views on a matter due before the NICE committee. Different suggestions for a more appropriate length of time included 2 years, 3 years, 10 years and one said there should be no limit.

19. NICE considered this proposal and agreed that a set timescale is important in ensuring there is clarity over the matters to be declared. On balance it was agreed to retain the 12 month timeframe. Extending this could complicate the process, increase the likelihood of items inadvertently not being declared, and would not be a proportionate approach. Where an individual has stated a view on an issue outside of this 12 month period, the impact can be considered during committee recruitment as part of the assessment of an individual's ability to objectively consider the evidence.

Other changes in response to feedback

20. Several consultation respondents commented that the policy did not go far enough in requiring people with a current or planned active role in a research project or trial to declare this (declarations were only required at the conclusion of such work). Ongoing and upcoming research has therefore been added as a non-financial interest. Similarly, to address concerns about the impact of interests that may arise during the committee's work, the policy now states that when making their initial declaration individuals should consider any new interests that are not currently held but will arise during involvement with the committee (for example a new research project).

21. Drawing on the NHS conflicts of interest policy and following a suggestion from the consultation, a new reference has been added to state that in some circumstances, it may be appropriate to withhold the meeting papers from a committee member who is excluded from the discussion on the grounds of a conflict of interest.

22. The policy also now states witnesses attending on behalf of an organisation should consider whether any funding to that organisation from the commercial sector could represent an indirect interest that should be declared.

Technology appraisal and highly specialised technologies appeals

23. As with NICE's existing conflicts of interest policy, the new policy will apply to the panels convened to hear appeals against NICE's final draft technology appraisal and highly specialised technologies guidance. This is an important part of the safeguards to ensure objectivity in NICE's guidance development process.

24. NICE's existing conflicts of interest policy does not apply to the individuals representing the appellants at these appeal hearings. The appellants will have a clear interest in the technology that is subject of the appeal, often as the manufacturer, or bodies advocating the technology. As such they could be deemed as having a conflict of interest when the terms of the policy are applied. Also, the appeal process is focused on potential breaches of NICE's process and arguably the background of the appellants is not relevant to the appeal panel's consideration of these points. Stakeholders commenting on draft guidance are not required to declare any interests.

25. Given the above, the Board is asked to confirm that the appellants' representatives are not required to make a declaration of interests at appeal hearings. The rationale for this will be clearly stated at the start of the appeal hearings after the declarations from the appeal panel and NICE representatives.

Implementation

26. Once approved by the Board it is proposed that the new policy applies to committee recruitment with immediate effect. It will then apply at committee meetings from April 2018. This will provide time to assess existing chairs' and members' interests under the new policy and take appropriate action, and establish the new processes for declaring and publishing interests. Training on the new policy will be available to the guidance teams (NICE and external development centres) and advisory committee members.

27. It is proposed to exempt from the new policy the 9 guidelines due to be submitted to NICE for consultation before the end of August 2018, in addition to the 11 guidelines submitted before the end of March 2018. This is because these 9 committees will have largely completed their discussions by April 2018; applying the policy at this stage could delay the guidelines' publication if additional meetings are required to discuss recommendations that have been developed with members for whom a new declaration under the revised policy identifies a potential conflict of interest. These 9 guidelines are due for final publication by the end of April 2019. It would not be a proportionate use of expenditure to rerun meetings and potentially discard guideline recommendations developed under existing robust processes. The affected guidelines are outlined in appendix 1. The approach outlined in paragraph 26 will apply to all other guideline committees.

28. The key milestones for implementing the policy are summarised below.

Table 1: implementation timetable

Action	Date
Policy approved by the Board	17 January 2018
Policy circulated to guidance teams	w/c 22 January 2018
Policy used in all new committee recruitment	w/c 22 January 2018
Policy published on NICE website	w/c 22 January 2018
Training available to guidance teams and committees	w/c 5 February 2018
Existing committee chairs and members submit declaration of interests under the new policy	During February 2018
Approach for handling any newly identified conflicts of interest agreed by the programme team	Completed by 30 March 2018
Committees operating in line with new policy (e.g. declarations prior to meetings, and response to such interests)	From 3 April 2018 (with exception of Centre for Guidelines – see above note)
Publication of registers of interests on NICE website	April 2018
Review impact of new policy and consider any required amendments	April 2019

29. A revised policy on declaring and managing interests for staff will be developed and brought to SMT, which will reflect the committee policy where appropriate.

Conclusion

30. The Board is asked to:

- Approve the policy
- Support the approach for implementing the policy (as outlined in paragraphs 26 to 28)
- Confirm that appellants against NICE's technology appraisal and highly specialised technologies guidance are not required to make a declaration of interests.

National Institute for Health and Care Excellence

January 2018

Appendix 1: Guidelines to which the new policy will not apply

Guideline	(Proposed) submission date to NICE	Proposed date of final publication
Lyme disease	15 August 2017	4 April 2018
Hearing loss in adults	12 October 2017	23 May 2018
Dementia	13 November 2017	20 June 2018
Brain tumours (primary) and brain metastases in adults	23 November 2017	11 July 2018
End of life care for adults in the last year of life	27 November 2017	18 July 2018
Rheumatoid arthritis	30 November 2017	11 July 2018
Early and locally advanced breast cancer	4 December 2017	18 July 2018
Pancreatitis	25 January 2018	5 September 2018
Chronic heart failure	26 January 2018	29 August 2018
Renal replacement therapy	22 February 2018	3 October 2018
Abdominal aortic aneurysm	29 March 2018	7 November 2018
Post-traumatic stress disorder	26 April 2018	5 December 2018
Lung cancer	1 May 2018	28 November 2018
Cerebral palsy in adults	31 May 2018	15 January 2019
Chronic obstructive pulmonary disorder	27 June 2018	21 January 2019
Urinary incontinence in women and pelvic organ prolapse in women	28 June 2018	8 February 2019
Renal stones	12 Jul 2018	20 February 2019
Intrapartum care for high risk women	24 July 2018	6 March 2019
Stroke	2 August 2018	6 March 2019
Specialist neonatal respiratory care for babies born preterm	16 August 2018	3 April 2019

NICE National Institute for Health and Care Excellence

Policy on declaring and managing interests for NICE advisory committees

Also includes witnesses, expert commentators and other contributors

Responsible officer	
Author	
Date effective from	
Date last amended	
Review date	

Contents

Introduction

1. NICE aims to achieve and maintain high standards of probity in the way we conduct our business. These standards include impartiality, objectivity, integrity, and the effective stewardship of public funds. Managing potential conflicts of interest is an important part of this process.

2. Effectively managing interests – and identifying potential conflicts – is essential if health and care professionals, and the public, are to maintain confidence in our work. It is central to how we develop guidance, and appoint members to our advisory committees[1].

3. This policy supports a culture in which we are open and transparent about the interests of those who are members of, or work with, our advisory committees, so that the effect of interests is known, understood and managed.

4. The policy provides guidance on:

   - what interests need to be declared and when
   - how declared interests should be recorded
   - when a declared interest could represent a conflict of interest and the action that should be taken to manage this.

Scope

5. This policy applies to everyone involved in our advisory committee discussions, including the following groups:

   - advisory committee chairs
   - advisory committee members, including co-opted and topic-specific members or experts
   - those invited to give evidence or advice to advisory committee meetings, including expert witnesses
   - technology appraisal and highly specialised technologies appeal panel chairs and members.

6. The principles in this policy also apply to other NICE contributors to products that do not use a formal committee process, for example, peer reviewers who provide a published commentary.

[1] See also the NICE recruitment and selection to advisory bodies policy.

7. A separate policy applies to:

   - Board members and employees of NICE
   - agency workers and contractors on temporary contracts
   - secondees (people seconded to NICE from other organisations)
   - employees of the external guidance centres and the 'evidence contractors' working directly or indirectly to supply evidence that is used by the advisory committees.

Defining and categorising interests

8. Committee members and advisers bring a range of experiences and perspectives to NICE's work. It is likely they will have a variety of interests, arising from different contexts and activities done in a professional or personal capacity. This can include employment and other sources of income, speaking engagements, shareholdings, publications and research, and membership of professional or voluntary organisations.

9. Having advisory committee members with varied interests is a positive attribute, but it is vital that interests are openly declared so they can be appropriately managed. Declaring an interest does not mean there is a conflict of interest.

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

10. Interests that are not, or could not be perceived to be, relevant to the NICE committee's work need not be declared. This could include, for example, membership of sports and recreation societies, positions in local community groups, and shareholdings in companies unrelated to NICE's work.

11. For the avoidance of doubt, a person living with a disease or condition relevant to the matter under discussion, or who has a family member in that position, is not seen as an interest and this does not need to be declared.

12. It is important to exercise judgement, and if there is any doubt as to whether an interest is relevant to the committee's work, it should be declared. This includes indirect interests, such as those relating to family and friends, when they are known. In the case of particular uncertainty,

further advice is available from the NICE team or external developer. When there are no interests to declare, a 'nil return' should be made.

13. The following categories describe the types of interests relevant to the work of NICE. In each case, a benefit may be a gain or avoidance of a loss.

Direct interests

14. A direct interest is when there is, or could be perceived to be, an opportunity for a person involved with NICE's work to benefit. This benefit could be financial (a financial interest) or non-financial (a non-financial personal or professional interest). These are explained further below.

15. ***Financial interests:*** When a person gets direct financial benefit. This means anything of monetary value, including: payments for services; equity interests, including stocks, stock options or other ownership interests; and intellectual property rights, including patents and copyrights and royalties arising from such interests.
Examples of financial interests are:

    - Work in the commercial sector[2], including a directorship, employment, or consultancy, that attracts regular or occasional payments or benefits in kind such as hospitality. This includes clinicians undertaking private practice.
    - Ownership or part ownership of a healthcare provider, including a GP who is a partner in a practice or a community pharmacist who owns their business.
    - Direct payment from the commercial sector to attend a meeting, conference or event, over and above funding to support reasonable travel, accommodation and attendance costs.[3]
    - Shareholdings in the commercial sector.
    - Funds that include investments in the commercial sector that are held in a portfolio where the person has the ability to instruct the fund manager as to the composition of the fund.
    - Personal payment to undertake sponsored research.

[2] The term 'commercial sector' refers to businesses and trade associations. Those particularly relevant to NICE include private health and social care providers, companies involved in products that might affect the public's health such as food, alcohol and tobacco industries, and companies with an interest in products, technologies and services that apply to the health and care sector.
[3] In the case of any doubt over 'reasonable' see the NICE travel and subsistence policy.

16. ***Non-financial professional and personal interests:*** When a person has a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation. This can include situations where the person:

    - Is an advocate for a particular group or is a member of a lobbying or pressure group with an interest in health or social care.
    - Holds office or a position of authority in a professional organisation such as a royal college, a university, charity, or advocacy group.
    - Is actively involved in an ongoing or scheduled trial or research project aimed at determining the effectiveness of a matter under review.
    - Has published a clear opinion about the matter under consideration.
    - Has authored or co-authored a document submitted as an evidence publication to the relevant NICE advisory committee.

Indirect interests

17. An indirect interest is when there is, or could be perceived to be, an opportunity for a third party closely associated with the person in question to benefit. This could be through a close association with another person or organisation that has a financial or non-financial interest (as defined above), and could benefit from a decision the person is involved in making through their work on an advisory committee.

18. Indirect interests can arise from people (such as close relatives, close friends and associates and business partners), and also employers (for example with research grants or other funding to the unit in which they work).

Declaring interests

19. Committee chairs and members make their first declaration when applying for a specific advisory committee role. Witnesses and other contributors make their first declaration when invited to contribute to a committee meeting. The **initial declaration** covers the preceding 12-month period. Consideration should also be given to any new interests that are not currently held but will arise during involvement with the committee (for example a new research project).

20. People will be prompted to **update** their declaration:

    - before each meeting, by email
    - at the start of each meeting, orally
    - each year (standing committees), by email.

21. Any new information provided before or during meetings, or at the annual update, is added to the original declaration, to give a full picture of the 12 months before beginning work with NICE.

22. It is the person's responsibility to identify and declare interests at the earliest opportunity, and to ensure this declaration remains up-to-date.

23. The declaration of interests form is available in appendix A. A summary of the process for declaring interests is set out in appendix B.

Identifying and responding to potential conflicts of interest

24. The response to declared interests depends on a person's role within the advisory committee (for example, chair, member, adviser, witness) and what is being considered by the committee.

25. Each case is different and the circumstances must be clarified with the people involved to assess the perceived risk of a conflict of interest. When the interest is specific to the topic under discussion, there is greater likelihood of a conflict of interest (see below). Good judgement is needed to ensure proportionate management of risk.

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

Responses to declared interests

26. There are 3 potential responses following a declaration of interest:

    - **No action other than the process of open declaration** – the person can engage in all aspects of the committee's work. This is usually because nothing is considered to represent a perceived conflict of interest, but may in some circumstances be because an open declaration is considered sufficient to mitigate any risk of conflict. Open declaration will usually be sufficient if a financial interest occurred in the last 12 months and is no longer held. For example, if a person has ceased to hold shares or undertake relevant private practice. This is because the potential to benefit has ceased.

- **Partial exclusion** – the person can engage in committee discussion or provide advice to the meeting (for example, because of their expert knowledge), but is excluded from developing recommendations and decision-making on the matter relating to the interest. Involvement may be limited to answering direct questions from the committee.

- **Complete exclusion** – the person can have no input to a specific topic, either from the start (non-appointment) or for part of the committee's work relating to that topic. When an interest leads to exclusion for a specific topic, it may be appropriate to withhold any confidential meeting papers for that item especially when the person could benefit from the information.

Interests at appointment

27. Assessment of an applicant's declared interests and curriculum vitae is done by a senior member of the NICE guidance programme (or external contractor), who agrees a final declaration with each applicant. The appointment panel considers whether any interests mean that they cannot be appointed. In the case of doubt, the relevant director considers the declared interests and, in very unusual circumstances, the decision is referred to the 'conflict of interest reference panel' (see appendix C for terms of reference).

28. Examples of how interests are handled during the appointment process are given in appendix D.

Chairs

29. The chairs of advisory committees are in a special position in relation to the work of their committee and have greater scope to influence the outcome of discussions. The chair helps the committee to work collaboratively, ensures a balanced contribution from all committee members and takes decisions about the potential conflicts of interest of their committee members. Chairs are appointed for their expertise and skill in chairing groups, and although they may have some knowledge of the topic, this is not their primary role in the group. Specialist knowledge is provided by other committee members.

30. The interests of potential chairs need to be considered in relation to the type of committee. Topic-specific guideline committees cover a defined area, therefore it is possible (and necessary) to identify and exclude possible conflicts of interest before appointment. This means chairs of topic-specific committees cannot have any direct interests. Standing committees cover a broad range of topics, therefore potential conflicts

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

Appointing chairs

Topic-specific guideline committees:

Chairs cannot have any direct interests (financial, non-financial professional or personal) that relate to the services, interventions, products, or delivery of care to be considered within the scope of the guideline.[4]

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

Standing committees:

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

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

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

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

Appointing members to all committees

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

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

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

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

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

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

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

Before the meeting

32. In advance of each committee meeting, the NICE guidance team (or external contractor) identifies the issues being considered at the meeting. The NICE guidance team (or external contractor) reviews the list of declared interests from the chair, members and co-optees to determine whether there are any potential conflicts of interest relating to these specific areas.

33. The NICE guidance team (or external contractor), in consultation with the chair, considers the actions needed and notifies the affected person. In the event of an unresolvable disagreement or uncertainty between the chair and a member of the advisory body, the view of the relevant NICE

programme director or authorised deputy must be sought. When uncertainty or disagreement remains, the programme director may decide to escalate the issue to the director. Following discussion with the programme director, the director will either resolve the matter or refer this to the 'conflicts of interest reference panel' for consideration (see appendix C for terms of reference).

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

Specific interests at committee meetings	Approach to handling at meetings
Direct financial interests	Any **member or standing committee chair** with a specific financial interest leaves the meeting for the duration of the relevant item. In exceptional circumstances, when a **member** has particular expertise that would otherwise not be available to the committee, they may attend to answer specific questions, but would not usually take part in the decision-making. When the interest relates to private practice and income in the commercial sector, a **member** may be able to participate if their clinical experience is considered vital to the discussion.[5] In such circumstances, the level of involvement (full involvement or partial exclusion) will depend on the scope for potential benefit (and risk of conflict of interest).
Direct, non-financial interests (personal and professional)	Any **member or standing committee chair** with a specific non-financial interest may need to leave the meeting for the relevant item. Particular care is needed around any reputational interest related to positions held in other organisations, and publications authored or public statements made, which could reasonably be interpreted as potentially prejudicial to an objective interpretation of the evidence. A decision on participation should balance this risk with the benefit of the committee's access to the person's expertise. Involvement in guidelines developed in accordance with international criteria does not usually lead to exclusion from the meeting.
Indirect interests	Any **member or chair** with specific indirect interests usually needs to do no more than declare this interest. However exclusion may be needed when a close family member could potentially gain from the committee's work.

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

Witnesses and other contributors (non-committee members)

35. Others contributing to the committee are likely to be either providing expert advice or giving a particular perspective, but will not be contributing to the final decision-making. Every effort will be made to select experts who do not have a conflict of interest that would require a member of the committee to withdraw from the discussion. However, there is discretion to invite an expert with such a conflict when the work of the committee would be seriously compromised without their testimony. For example, in an area where the number of experts is very small and there has been close collaboration between a clinical specialty and the life sciences industry in developing new technologies.

36. Those attending on behalf of an organisation should consider whether any funding to the organisation from the commercial sector represents an indirect interest that should be declared.

At the meeting

37. At each meeting, a copy of all declared interests, including those of the chair, any co-optees and additional invited experts, is made available to the committee.

38. The chair asks whether there are any new interests to be added or any potential conflicts of interest specific to the issues being considered at the meeting. This is to confirm, and to potentially add to, the interests that have already been identified before the meeting.

39. If a person is aware that a product or service under consideration is, or may become, a competitor of a product or service developed, manufactured, sold or supplied by a company in which they have a current financial (either direct or indirect) interest, this should be declared.[6]

40. The chair informs the meeting attendees of the actions agreed in relation to any specific interests.

Records and publication

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

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

committee. This is available on the NICE website and at the start of each committee meeting, and updated as needed.

42. For members and the committee chair, the register will include the interests from the date of appointment plus the preceding 12 months. If there is a reappointment to a standing committee, the register will include the interests from the date of reappointment plus the preceding 12 months.

43. For standing committees, the register will include the interests of those who attended the committee to give evidence or advice in the previous year. For topic-specific guideline committees, it will include the interests of those who attended the committee to give evidence or advice during guideline development.

44. A written audit trail is maintained of the information considered and any actions taken. The committee minutes record the interests declared and action taken in response. Interests are also published as part of the guidance publications.

Exceptions

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

Wider transparency initiatives

46. In keeping with the purpose of this policy, NICE fully supports wider transparency initiatives in healthcare. For example, we strongly encourage people to give their consent for payments they receive from the pharmaceutical industry to be disclosed as part of the Association of British Pharmaceutical Industry (ABPI) Disclosure UK initiative. These ‘transfers of value’ include payments relating to:

    - speaking at and chairing meetings
    - training services
    - advisory board meetings
    - fees and expenses paid to healthcare professionals

- sponsorship of attendance at meetings, which includes registration fees and the costs of accommodation and travel, both inside and outside the UK
- donations, grants and benefits in kind provided to healthcare organisations.

47. Further information about the scheme can be found on the ABPI website.

Dealing with breaches

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

Identifying and reporting breaches

49. To ensure that interests are effectively managed, staff, those participating in our committees and stakeholders are encouraged to speak up about actual or suspected breaches.

50. Anyone who is aware of actual breaches of this policy, or who is concerned that there has been, or may be, a breach, should report these concerns to the chair of the committee and a senior member of the NICE (or guideline developer) team.

51. NICE investigates each reported breach according to its specific facts and merits, and gives relevant parties the opportunity to explain and clarify the circumstances.

52. Following investigation NICE:

    - decides if there has been, or is potential for, an actual breach and if so, the materiality of the breach
    - assesses whether further action is required
    - considers who should be made aware of the breach
    - takes action and clarifies the policy, if necessary.

Learning and transparency

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

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

Review

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

Relevant legislation, guidance and NICE policies

- The Bribery Act 2010, which includes the offences of offering or receiving a bribe
- Freedom of Information Act 2000
- ABPI: The Code of Practice for the Pharmaceutical Industry (2016)
- ABHI Code of Business Practice
- NHS Code of Conduct and Accountability (July 2004)
- NICE Standards of Business Code of Conduct
- Recruitment and selection to advisory bodies' policy and procedure
- NICE gifts and hospitality policy
- NICE non-staff travel, subsistence and general expenses policy

Appendix A: declarations of interest form

Declarations of interest form				
Name: **Advisory committee:** **Role:**				
Type of interest	**Description of interest**	**Relevant dates**		**Comments (for NICE / external contractor to complete)**
		Interest arose	**Interest ceased**	

** Please see over the page for information on how to populate the above boxes*

The information submitted will be held by NICE to comply with the organisation's policies. This information may be held in both manual and electronic form in accordance with the Data Protection Act 1998. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and will be published in registers that NICE holds.

I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then I may be asked to stand down from the advisory committee.

I **do / do not** [delete as applicable] give my consent for this information to be published on registers that NICE holds. If consent is NOT given, please state reasons: (please note this will be agreed in exceptional cases only).

Signed:	Dated:

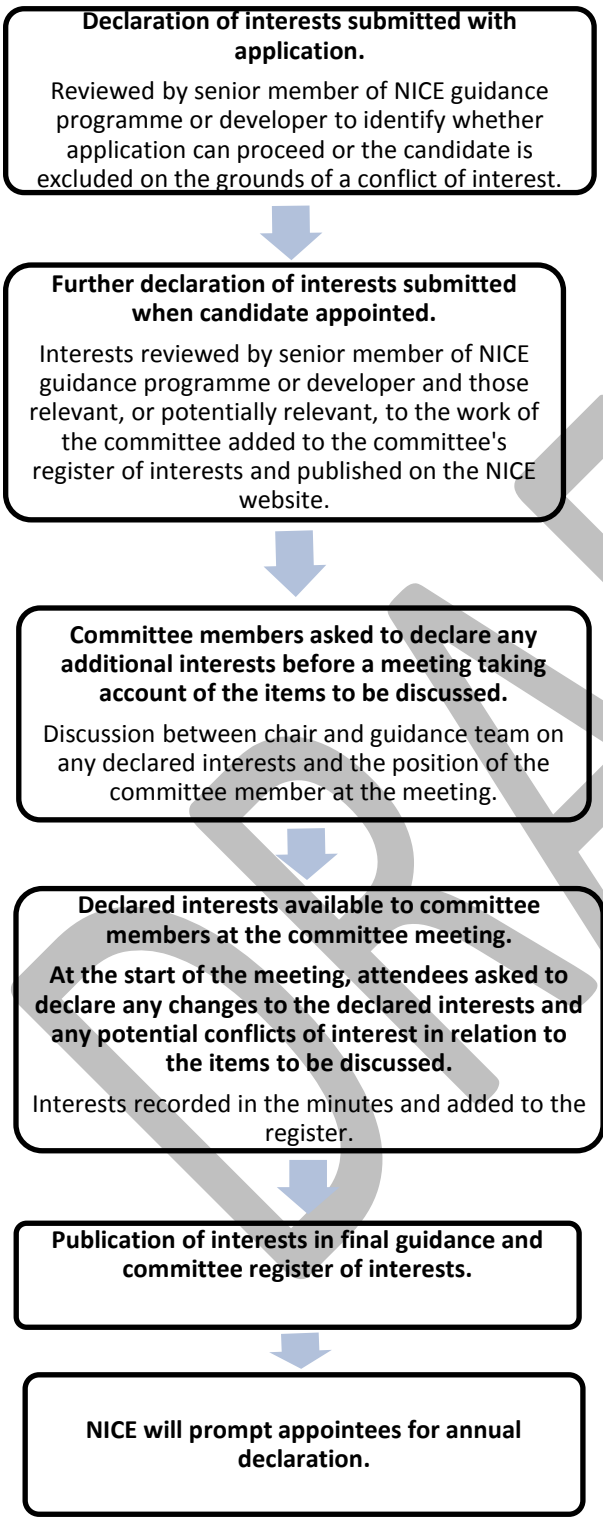
Please return this form to [insert contact details of individual/team]

* Guidance notes for completion of the Declarations of interest form

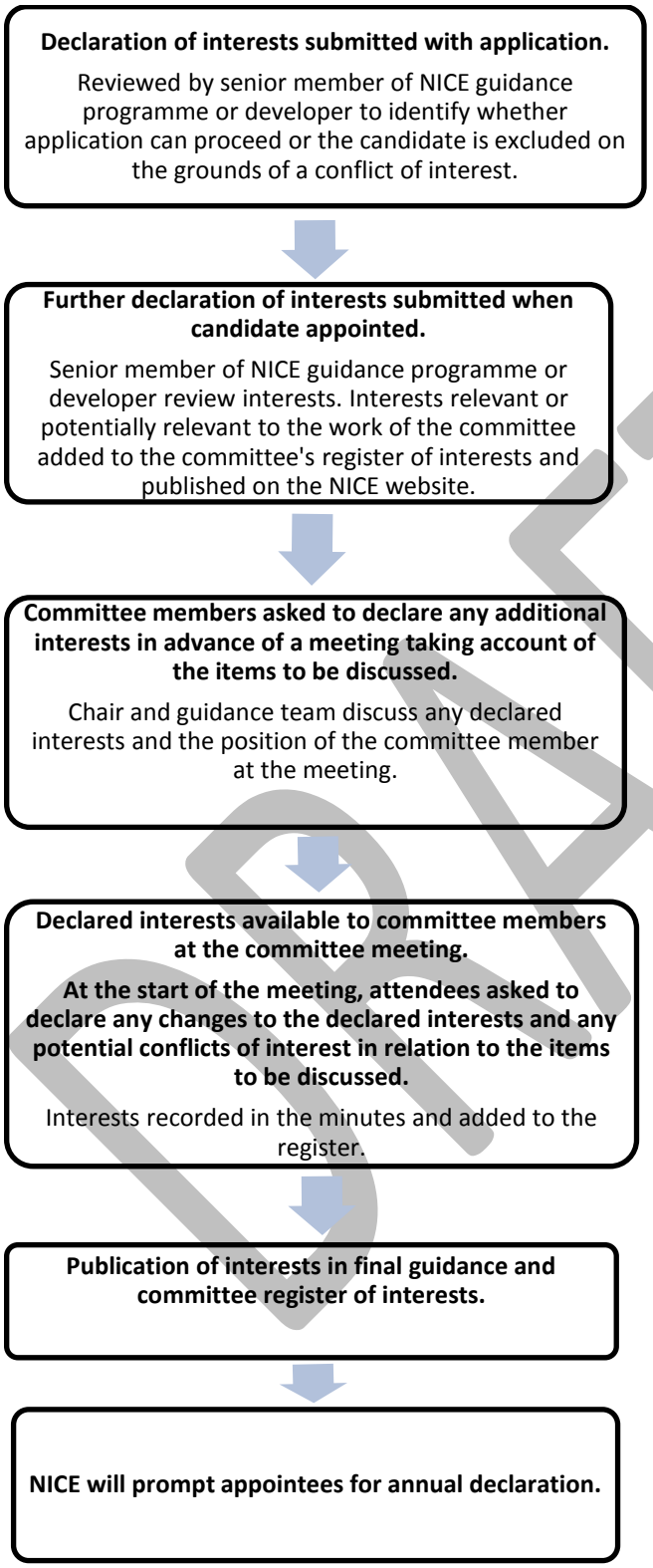
Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest. Types of interest: **Direct interests** **Financial interests** - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. *For examples of financial interests please refer to the policy on declaring and managing interests.* **Non-financial professional and personal interests -** Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. *For examples of non-financial interests please refer to the policy on declaring and managing interests.* **Indirect interests -** Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit. A benefit may arise from both a gain or avoidance of a loss.
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Appendix B: process for declaring interests

Committee chairs and members



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



Appendix C: conflict of interest reference panel terms of reference

Objectives

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

Membership

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

Ways of working

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

Appendix D: examples of handling interests at appointment

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

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

Topic-specific guideline committees: examples of appointable chairs

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

Standing committees: examples of non-appointable chairs

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

All committees: examples of non-appointable members

Committee	Member not appointable	Rationale
Technology appraisal and highly specialised technologies	Member with a broad portfolio of shares in the pharmaceutical industry.	This represents a direct financial interest and the broad portfolio covering a number of companies would probably mean exclusion from more than 50% of the committee's discussions.
Guideline on high blood pressure	Cardiologist with a broad portfolio of research funded primarily by the pharmaceutical industry.	This represents a direct financial interest and the extent of research portfolio funded by a number of companies would probably mean exclusion from more than 50% of the meetings.

Appendix E: examples of handling specific interests at meetings

Example of interests	Action and rationale
Consultancy fee received by a committee member from the company producing the product under consideration, or the comparator.	The action depends on the nature of the consultancy undertaken. • Complete exclusion – if this relates to the product under consideration, or the comparator, as the interest is a specific direct financial interest. • Declare and remain – if the consultancy is unrelated to the product under consideration or the comparator, as the interest is not specific. If the consultancy income from the manufacturer of the product under review, or the comparator, accounts for a majority of the person's income then it may be appropriate to exclude the person from the discussion (in the way an employee of the manufacturer would be – see below example).
Technology appraisal committee member employed by a company that manufactures a competitor to the product under review.	Complete exclusion –this represents a direct financial interest. It may be appropriate to withhold from the member confidential information in the meeting papers for the topic if these contain commercially sensitive information.
Private practice income from the procedure, intervention or delivery of care under consideration.	**Chairs** - complete exclusion. **Members** – complete exclusion unless their clinical experience is considered vital to the discussion.[7] In such circumstances, the level of involvement (full involvement or partial exclusion) will depend on the scope for potential gain (and risk of conflict of interest). For example, full participation may be appropriate if general medical services are provided on a salaried basis and mirror NHS activity. Whereas there is greater scope for a perceived conflict of interest when non-NHS income is directly contingent on the volume of a specific procedure.
Publications in which a member expresses a clear opinion about the intervention being considered.	Potential exclusion – this is non-financial professional interest and the response will depend on the nature of the view expressed and the risk to perceived objectivity. In determining the level of involvement the chair should consider the balance between this risk and the benefit of the member's input to the committee. It may be decided to allow a member to remain in the room to answer questions but not take part in decision-making.

Grant income received by the member's employer from the company that manufactures the product.	Declare and remain – this is an indirect interest, because the income goes to the employer.
Spouse doing research in the area under discussion.	Declare and remain – this is an indirect interest with no direct financial gain.
Employee of a charity with an interest in the condition.	Declare and remain – this is a direct interest, but with no clear financial benefit to the person. However, a person may need to be excluded if they hold a senior position of authority in an organisation that has expressed a clear opinion on the issue, if this could reasonably be interpreted as affecting the objective interpretation of the evidence.
Research publications covering epidemiology of the condition.	Declare and remain –this is not an intervention that might be recommended in the guidance.
Previous member of a guideline on the same topic produced by a professional body.	Declare and remain – the guideline was produced collaboratively by consensus and was not the person's own work. The benefit of their expertise in this topic outweighs a risk of perceived bias.
Indicator Advisory Committee member who is a GP.	Declare and remain – while the GP's income could ultimately be affected, the benefit of their expertise in this topic outweighs a risk of bias.

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

National Institute for Health and Care Excellence

Facilitating adoption of off-patent, repurposed medicines into NHS clinical practice

This report summarises the background to, and recommendations of, a report 'Facilitating adoption of off-patent, repurposed medicines into NHS clinical practice', published on 4 December 2017. NICE actively participated as a stakeholder and made a significant contribution to the development of the report.

The Board is asked to note the recommendations and next steps identified in the report.

Professor Gillian Leng

Deputy Chief Executive and Director, Health and Social Care Directorate

January 2018

Introduction

1. A report 'Facilitating adoption of off-patent, repurposed medicines into NHS clinical practice' was published on 4 December 2017. The report was prepared in response to a request from the office of the Minister for Life Sciences in 2015 to explore the potential for using off-patent, repurposed medicines.

2. The report was produced by a working group convened and chaired by the Association of Medical Research Charities (AMRC). The group consisted of a range of stakeholders including NICE, the Department of Health, NHS England, the Medicines and Healthcare products Regulatory Agency (MHRA), the General Medical Council (GMC), industry and medical research charities.

3. The report was shared with Lord O'Shaughnessy, Parliamentary Under Secretary of State for Health, on 4 December and published on the AMRC website.

Background

4. The report is the response to the Off-Patent Drugs Bill, which was first introduced to Parliament in 2014, and again in 2015. The Bill would have required the Government to seek licences for off-patent drugs when there was evidence that they could be clinically effective for a new purpose and when no pharmaceutical company had sought a licence. The Bill also intended to require these drugs to be referred to NICE for a technology appraisal which, if positive, would give the NHS a legal obligation to fund them.

5. The licensing recommendation in the Bill would not have addressed the issue of access to off-label medicines. There are a number of other factors at work around this complex issue, including commissioning, prescribers' responsibilities, shared decision making and how evidence gets into clinical practice.

6. The Department of Health worked collaboratively with a range of stakeholders, including NICE, the MHRA, the GMC, industry and medical research charities to identify mechanisms to support prescribers and ensure patients receive the care they need, while not undermining the regulatory framework for assuring the safety, effectiveness and quality of new medicines introduced into clinical practice in England.

7. A working group was established in November 2015 after the then Minister for Life Sciences requested the AMRC to explore non-legislative ways to ensure that strong evidence about new uses for off-patent drugs could be identified and brought into patient care routinely where clinically appropriate.

8. The working group identified that more advice and support is needed for organisations and individuals who may want to use a licensed, off-patent, medicine in an indication outside its licence where research has shown value for treatment of identified conditions. Some well-established off-patent medicines are identified through new research and evidence to have potential therapeutic use outside their licensed indications, a process described in the report as “drug repurposing”.

9. The report provides insights about the repurposing of off-patent medicines, including how the drug regulation system and national bodies can support it and how to navigate the different routes that support uptake and access to repurposed drugs for NHS patients.

10. The report also acknowledges that repurposed medicines are included in the potential technologies to be considered for the Accelerated Access Pathway (AAP), as set out in the Government’s response to the Accelerated Access Review.

11. NICE's place in facilitating access to off-patent, repurposed medicines is in providing scientific advice, making recommendations in guidelines, raising awareness through evidence summaries and medicines and prescribing networks, supporting shared decision making, and informing the BNF's processes for systematically including information on off-label and unlicensed use of medicines.

12. Two examples in the report, bisphosphonates for preventing secondary breast cancer and docetaxel (in addition to standard hormone therapy) in metastatic prostate cancer, demonstrate the cost-effective and life-extending benefits to patients. In the case of bisphosphonates, a study showed that giving a bisphosphonate to post-menopausal women with primary breast cancer could reduce the risk of breast cancer spreading to the bone within 10 years by nearly a third; reduce the risk of breast cancer spreading to any site, including the bone, within 10 years by around a fifth; and reduce the risk of death from breast cancer within 10 years by a sixth. The study was the subject of a NICE medicines evidence commentary in November 2015 to coincide with publication of the study to raise awareness. For docetaxel, NICE published a rapid evidence review within 5 days of trial data being published, which was used as a basis for routine commissioning by NHS England in January 2016.

13. The report makes a number of recommendations:

    - MHRA licensing should be the preferred route for making repurposed generic medicines available for use in the NHS.

- A financial incentive for generic medicines manufacturers to participate in medicines re-purposing should be established, by extending the scope of HMRC Research & Development Tax Credits to include repurposing of generic medicines.
- A UK Catalyst Fund should be explored to establish the UK as a leader in medicines repurposing.
- One or more repurposed drugs should be used to test the framework outlined in the report. The outcome and any recommendations for changes to the framework or any of its elements should be shared with the Drug Repurposing Group by end of 2018.
- The time it takes for a drug to progress through the framework should be monitored with a view to setting expectations for how quickly the system will respond to robust evidence in the future. The uptake should be included within the evaluation with a view to making recommendations on how to ensure clinical confidence in prescribing repurposed drugs.
- Healthcare professionals should be supported to understand the availability of resources that can support prescribing decisions for repurposed medicines. This includes education about the responsibilities in relation to the off-label prescribing of medicines, the need for shared decision making and obtaining informed consent and where to access high quality information, e.g. the BNF.
- The BNF should continue to review its policy on inclusion of off-label uses of medicines in the Formulary. This should ensure that it routinely considers off-label uses where there is robust evidence that the benefits outweigh any risks.
- The MHRA should proactively communicate that clinical trial protocol advice, scientific advice and the Innovation Office are available to medical research charities, academic research groups and other stakeholders.
- Medical research charities, academic groups and other stakeholders should use MHRA scientific advice in order to ensure that evidence generated (through their clinical research programmes) is robust, and to determine the process by which a repurposed drug can be licensed.
- The Accelerated Access Collaborative should horizon scan to ensure that repurposed medicines are included in the Accelerated Access Pathway.
- The newly formed Regional Medicines Optimisation Committees should provide a route via which advice on the use of repurposed medicines from CCGs can be considered and utilised.

14. The report also identifies a series of next steps:

- To identify a list of repurposed drugs with practice-changing clinical research data, available now and over the next three years.
- To evaluate three repurposed drugs for licensing or progress through the drug repurposing framework, with progress to be evaluated at the end of 2020.
- To engage with HMRC and others on expanding the scope of R&D Tax Credits to include repurposing of generic medicines, or other incentive mechanisms.
- To engage with the relevant agencies regarding the establishment of a UK Catalyst Fund for repurposed medicines.
- To communicate the recommendations of the report through one or more workshops for medical research charities, researchers and others involved in medicines repurposing
- The Drug Repurposing Group to meet at the beginning of 2019 to evaluate progress made on next steps and agree any further actions

15. The NICE communications team is aware of the report and has activity planned for January outlining NICE's place in facilitating access to repurposed medicines.

Conclusion

16. The Board is asked to note the recommendations and next steps identified in the report.

National Institute for Health and Care Excellence

January 2018

National Institute for Health and Care Excellence

NICE social care programme update

This report gives details of the social care programme at NICE, covering our engagement, implementation and guidance activities over the last 12 months.

The Board is asked to review the proposed priorities for 2018/19.

Professor Gillian Leng

Deputy Chief Executive and Director, Health and Social Care Directorate

January 2018

Introduction

1. This report gives details of the social care programme at NICE, covering our engagement, implementation and guidance activities over the last 12 months.

Background

2. The Health and Social Care Act 2012 gave NICE a formal role to develop quality statements and associated guidance for social care from April 2013. Since then, NICE has published 10 social care guidelines, 12 quality standards, 7 quick guides and 10 implementation resources, and developed positive relationships with a wide range of social care stakeholders. This report provides an update on NICE's work in social care in the last 12 months.

3. The social care programme at NICE is overseen by the NICE Social Care Forum. This is chaired by the Deputy Chief Executive and is attended by senior representatives from relevant parts of the organisation, including Health and Social Care Directorate, Centre for Guidelines and the Communications Directorate. The forum meets on a monthly basis and ensures delivery of NICE's strategic objectives and operational oversight of NICE's work in social care. The forum also considers the need for additional work to ensure acceptability of NICE guidance in the sector.

4. There are also issues specific to the sector and ways of working in social care which have required some modification in our approaches. These issues include:

    - Differences in culture and language between social care and health
    - Well-established focus on personalisation and self-directed support
    - Importance of involving people with care and support needs and taking a coproduction approach
    - Much greater extent of legislation and statutory guidance
    - Diversity and size of the sector, for example 24,000 providers in England
    - Difference in funding arrangements for adult social care compared with health
    - Evidence more likely to be qualitative
    - Levels of research funding in social care have historically been at a much lower level then in health
    - Culture of using evidence-based resources less well developed

- High levels of innovation and change
- Difference in evaluative culture with greater focus on case studies.

Engagement with national, regional and local social care stakeholders

5. NICE developed a strategic engagement plan for 2017/18 which included engagement priorities for each of the three sectors - health, public health and social care. Key driver and enabler organisations and individuals are identified in the plan. Strategic engagements leads were also appointed for each of the sectors, who report on a regular basis to the Strategic Engagement Oversight Group (SEOG), chaired by the NICE Deputy Chief Executive.

6. A programme of regular engagement with key national social care stakeholders is reported and monitored by the group to identify further opportunities to develop NICE's position in both adult and children's social care. Meetings with the chairs of national organisations have also been added to the NICE's chair's annual engagement meetings.

7. At regional and local level, NICE has developed links with key sector organisations. In the last 12 months there has been a particular focus on developing links with Skills for Care regional networks.

8. Strategic engagement metrics have also been identified for the social care sector as part of the SEOG work, which capture outputs resulting from regular engagement at national and regional/local level. For social care these are currently reported to the Social Care Forum, SEOG and the NICE Board. The metrics for 2018/19 are being developed, building on the metrics for 2017/18 which were reported to the November Board meeting.

Quality Matters

9. NICE is a member of the steering group that developed Quality Matters - a shared commitment to improving quality in adult social care. We have signed up to support four of the six priorities included in the plan for 2017/19, including leading one of the priorities jointly with Skills for Care.

    - Priority 2 - measuring, collecting and using data more effectively
    - Priority 3 - commissioning for outcomes
    - Priority 4 - better support for improvement
    - Priority 5 - shared focus areas for improvement (NICE/Skills for Care lead)

10. The NICE quality improvement resource for adult social care was included as one of the actions under priority 3, and launched under the Quality Matters banner. Quality Matters is supported by the Department of Health, and a new governance board has been established to monitor delivery, of which the NICE Deputy Chief Executive is a member.

Resources to support uptake of NICE guidance in the social care sector

NICE social care quick guides

11. Following feedback from the sector that NICE guidelines are too long for use by practitioners in social care, a view endorsed by the NICE triennial review in 2015, NICE commissioned the Social Care Institute for Excellence (SCIE), to develop a series of quick guides, of which 5 have been published in the last 12 months (see appendix 1 for example):

    - Discussing and planning medicines support
    - Understanding intermediate care, including reablement
    - Moving between hospital and home, including care homes
    - Recognising and preventing delirium
    - Building independence through planning for transition

12. SCIE will be developing a further 10 quick guides per year for the next 2 years, after being awarded a further contract by NICE. This will provide an opportunity to further extend NICE's reach into different areas of the sector, and to new audiences.

Care Improvement Works website

13. The Care Improvement Works website was developed by Skills for Care and SCIE to provide a guide to improvement resources for adult social care providers. In 2017 the website was redeveloped to map all resources on it to the new CQC adult social care inspection framework, and all relevant NICE quality standards, quick guides and guidelines added.

NICE quality improvement resource for adult social care

14. Feedback from engagement with local authority commissioners of adult social care highlighted a need for a resource which would provide them with easier access to relevant NICE guidance, categorised in a way which would help with navigation. A resource based on all relevant NICE quality statements and managing medicines guidelines recommendations has been developed, mapped

to the CQC adult social care inspection framework (NICE Quality improvement resource for adult social care). The resource was developed with a coproduction group involving local authority commissioners, social care providers, CQC and Skills for Care. It is intended that the resource will increase direct use of NICE quality statements and recommendations within adult social care contracts, quality monitoring systems and individual packages of support to providers assessed as requiring improvement in particular areas.

15. The resource was launched in October 2017 with a supportive quote from the President of the Association of Directors of Adult Social Services. Further development of the resource will be considered in 2018, following evaluation. Initial data shows that in the first month after the resource was published, the resource was downloaded 1,990 times.

Case studies

16. A number of social care practice case studies have been added to the NICE shared learning examples database. These include the 2017 winner of the NICE Shared Learning Award, the Mansfield and Ashfield ASSIST early hospital discharge scheme, and the Sutton red bag scheme, both of which were developed using NICE guideline NG27 Transition between inpatient hospital settings and community or care home settings for adults with social care needs. The NICE quality improvement resource also includes a number of examples of how local authority commissioners and providers are using NICE quality standards to improve the quality of care and support. Case studies are important for demonstrating the value of NICE guidance to the social care sector, and further work is planned to develop more case studies.

Other engagement, communications and dissemination work

17. The NICE in Social Care bulletin was revamped this year and now features blogs and articles by committee chairs and others. We are continuing to promote the bulletin, and have increased subscriptions by 40% in 6 months. The information in the bulletin is regularly included in the newsletters of social care organisations, such as the National Care Forum and Association of Directors of Children's Services.

18. The recruitment of NICE fellows has in recent years had a particular focus on suitable candidates with social care experience, and there are now 6 NICE fellows who work in the sector, who are supporting NICE's work in a number of ways.

NICE social care guidance

Social care guidelines

19. Three guidelines referred as social care topics were published in the last 12 months (see appendix 2 for full list of social care topics):

    - Managing medicines for adults receiving care in the community (NG67)
    - Intermediate care including reablement (NG74)
    - Child abuse and neglect (NG76)

20. Most of the guideline topics referred to NICE as social care topics have been developed by NICE collaborating centre for social care. The contract for the centre ends in March 2018, and the centre will close. In future social care topics will be developed by the National Guidelines Alliance and National Guidelines Centre. Additional support and advice, including workshops and technical advice, is being provided by NICE in recognition of the different types of evidence more commonly used in social care guidelines.

Quality standards

21. 2 quality standards referred as social care topics were published in the last 12 months:

    - Transition from children's to adults services for young people using health or social care services (QS140)
    - Transition between inpatient mental health settings and community and care home settings (QS159)

22. Another quality standard of particular relevance to social care was also published:

    - Oral health for adults in care homes (QS151)

Work to support research and evidence in social care

23. NICE has developed a social care research strategy to support the prioritisation of social care research using NICE research recommendations. Work with social care research funders such as the NIHR School of social care research and the Department for Education has been positive, and included a workshop with all research funders in early 2017. This is being followed up with a workshop to support better evidence in personalisation, being held jointly with the Think Local Act Personal partnership (TLAP) in March 2018.

24. The University of York's Centre for Health Economics has recently published a research paper aimed to inform NICE on the methods available for use in undertaking economic evaluation of social care interventions, the methods in development, the methods challenges faced and the methods gaps. A systematic review of the published literature and a survey of experts were undertaken for the study. Results of the research suggest that there needs to be a better developed evidence base in order to undertake economic evaluation of social care interventions, including undertaking primary studies were evidence is not sufficient. The researchers also state that investment in applied economic evaluations of social care interventions will support more informed recommendations and also develop research capacity in social care.

Uptake and impact of social care work

25. A recent survey of mainly local authority social care practitioners carried out by the NCCSC found more than half of the respondents were aware of NICE's social care guidelines, and the majority of these thought they were useful for practice. The main channels for finding out about NICR resources were through training and emails. Feedback from the NICE field team and social care practitioners attending national conferences also suggests that awareness and use of NICE guidelines, quality standards and resources is steadily increasing in the last year.

26. The quick guides are proving popular and since the first ones were published on the NICE website in October 2016 they have been viewed over 16,000 times. In March 2017, the Audience insight team conducted a review of into the first 2 social care quick guides; 'Better home care for older people', and 'Improving oral health in care homes'. The feedback on the content of the quick guides was extremely positive with 85% of survey respondents (n=60) rating the guides as 'good' or 'very good' on a range of areas including the layout, usefulness of the information and use of infographics.

27. Respondents to the quick guide feedback survey suggested that they will disseminate the guides among their organisation: 50% said they would direct a user of services to the quick guides, and 70% said they would direct a colleague to the resource, which highlights the longer-term benefits of increasing awareness through promotion. People are coming to the quick guides most often from direct links rather than a google search or a search on the NICE website. This supports the need for ongoing promotion both directly with the relevant audiences and through partner organisations.

28. The Quality improvement resource for adult social care is also proving popular with over 3,900 views so far (to 20 November 2017). As with the quick guides, 70% of views came from a direct link. The blog which was published to promote

the resource has been read over 1,000 times. After viewing the Quality improvement resource 48 people went on to subscribe to the NICE in social care bulletin which indicates that we are successfully reaching new audiences.

29. The recent NICE implementation survey will provide further insight into the impact and uptake of NICE guidance for social care, and will be reported to the NICE Board in March 2018.

Priorities for the next business year 2018/19

- Developing NICE's work to support Quality Matters, including using our influence to support better joint working across health and social care, and working with partners to provide better support for improvement in adult social care
- Continuing development of our work with Skills for Care at regional level
- Supporting better awareness of NICE guidance through CQC inspection activity
- Delivery of focused joint work with Ofsted to strengthen links between their research programme and NICE guidance
- Continuing to increase out reach into the sector through
  - Speaker sessions and stalls at social care conferences
  - Increase the number of subscribers to the NICE in social care bulletin
  - Articles and blogs in high profile newsletters
- Developing better links with social care training providers and educators
- Supporting better evidence in social care

Conclusion

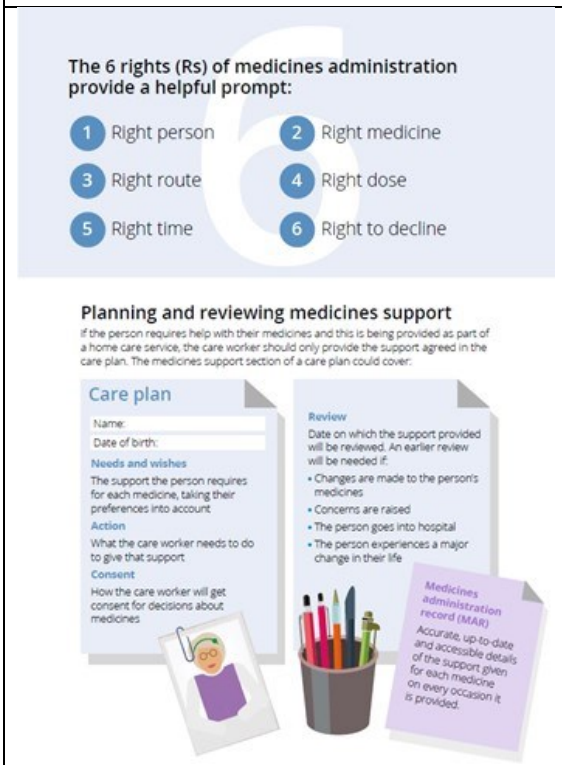
30. The Board is asked to:

- Consider the proposed priorities for the next business year 2018/19

National Institute for Health and Care Excellence

December 2017

Appendix 1: NICE quick guide



Appendix 2: NICE social care work programme - guidelines, quality standards and implementation resources (referred as social care topics)

Topic	Guideline publication	QS publication	Implementation resources
Adult social care: improving people's experience	Feb 18	17/18	Tbc
Autism in children and adults	CG128 (update 18) CG170 CG142	QS51	Published
Care and support of older people with learning disabilities	Apr 18	Tbc	Tbc
Carers: provision of support for adult carers	July 19	Tbc	Tbc
Child abuse and neglect	NG76	Sept 18	Feb 18 Quick guide
Children's attachment	NG26	QS133	Tbc
Decision making and mental capacity	May 18	Tbc	Tbc
Delirium	CG103	QS63	Quick guide
Dementia	CG42 (update Jun 18)	QS1 QS30	Published
Home care	NG21	QS123	Quick guide
Intermediate care including reablement	NG74	Aug 18	Quick guide
Learning disabilities and behaviour that challenges: service design and delivery	Mar 18	Tbc	Tbc
Looked-after children and young people	PH28	QS31	Published
Managing medicines for adults receiving care in the community	NG67	Jun 18	Quick guide
Managing medicines in care homes	SC1	QS85	Published
Mental wellbeing for older people in care homes	PH16	QS50	Published

Topic	Guideline publication	QS publication	Implementation resources
Older people with social care needs and multiple long-term conditions	NG22	QS132	Published
Oral health for adults in care homes	NG48	QS151	Quick guide
Transition between inpatient hospital settings and community or care home settings for adults with social care needs	NG27	QS136	Quick guide
Transition between inpatient mental health settings and community and care home settings	NG53	QS159	Apr 17 Tailored resource
Transition from children's to adults' services for young people using health or social care services	NG43	QS140	Quick guide

Future social care topics referred to NICE

- Adults with complex needs (including learning disabilities) and mental health needs: social work interventions
- Adults with lifelong or very severe hearing or visual impairment: health and social care support
- Advocacy for adults with health and social needs
- Children and young people with severe complex needs: social care support
- Independent living: supporting and preventing isolation in adults of working age with social care needs
- Safeguarding adults in care homes

National Institute for Health and Care Excellence

Directors' progress reports

The next 5 items provide reports on the progress of the individual centres and directorates listed below. These reports give an overview of the performance of each centre or directorate and outline the challenges and risks they face.

Professor Mark Baker, Director, Centre for Guidelines (Item 8)

Professor Carole Longson, Director, Centre for Health Technology Evaluation (Item 9)

Jane Gizbert, Director, Communications (Item 10)

Alexia Tonnel, Director, Evidence Resources Directorate (Item 11)

Professor Gillian Leng, Director, Health and Social Care Directorate (Item 12)

January 2018

National Institute for Health and Care Excellence

Centre for Guidelines progress report

1. This report sets out the performance of the Centre for Guidelines against our business plan objectives during November and December 2017.

Performance

2. 3 clinical guidelines and 14 surveillance reviews were published. Variation from the Business Plan targets are explained in Table 1.

Table 1 Performance update for November and December 2017

Objective	Actions	Update
To publish 34 guidelines, which includes, 25 clinical, 3 public health, 3 managing common infections, and 3 social care guidelines.	3 clinical guidelines were published. in November and December 2017	The standing committee Type 2 diabetes (update) guideline was suspended during development and work discontinued. This guideline will not be published as planned. The Depression in adults (update) was delayed as an additional committee meeting was needed before the consultation with stakeholders and a large number of stakeholder comments have been received. The Heavy menstrual bleeding update was delayed due to the Chair declaring a conflict of interest. The Technical Support Unit has reviewed the guideline in detail as a result. The Smoking cessation public health guideline was delayed as new evidence was identified, which required additional work before stakeholder consultation. In addition, the Acute medical emergency guideline, was delayed as we agree a publication date with NHSE.
To publish 56 surveillance reviews, which includes, 45 clinical, 10 public health and 1 social care.	14 surveillance reviews were published in November and December 2017.	

Objective	Actions	Update
To refine and implement new methods and processes to accelerate the development of updated guidelines.	Establish 6 internal capacity slots updating guidelines using new accelerated methods and processes by year end. Implement new staffing structure and functions. 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. Establish pre-development recruitment of guideline committee Chair / expert members to support scoping.	The methods and processes for the scoping phase are complete and continue to be reviewed. The methods and processes for the post consultation/validation phase are complete. 6 updates are currently following this new accelerated process.
To manage contracts to time, quality and budget and further develop systems that will maintain and improve the quality of work and contribute to efficiencies, and manage the change from the existing to the new commissioning arrangements for social care guidance.	Maintain delivery of quality of outputs, to time and budget through performance management through quarterly review meetings. Ensure appropriate risk management strategies are identified and managed.	Quarter 2 review meetings with both internal and external guidance developers and contractors were completed in November. All contractors remain within budget and are on target to deliver all objectives.

Objective	Actions	Update
	Efficient and sympathetic management of the non-renewal of contract with the Social Care National Collaborating Centre (NCCSC), by 31 March 2018. Manage the transition to the new commissioning arrangements for social care guidance. Work with BNF to deliver agreed KPIs to time.	All contractors' risks were reviewed and appropriate mitigation is in place. All contractors are currently developing Business Plans for 2018/19 which will be finalised in January 2018. We continue to work closely with SCIE to plan the transition of social care topics and maintain quality of outputs during the final phase of the contract. Discussions are underway with current and future contractors. The new, freely available BNF app, which publicly launched on the 12 July, continues to grow in popularity. The number of users and sessions each week now significantly exceeds the levels that the old NICE BNF app was achieving before the new app launched. As agreed by SMT, the NICE BNF app was retired in early December. There has been no negative feedback following the NICE BNF app's withdrawal. The campaign to distribute the print copies of BNF 74 and BNFC 2017 commenced in September and was completed by the end of November as planned. The number of print copies is being reduced this year by 9% for some users. A communication strategy

Objective	Actions	Update
		continues to encourage prescribers to share copies and to use the BNF app or BNF on-line where possible. There is a delay to the printing of the Nurse Prescribers Formulary (NPF) 2017 as the content has yet to be agreed within the Department of Health. A meeting with key stakeholders is planned for early 2018 to take this forward.
To harmonise and integrate methods and processes for guideline development and quality assurance across clinical, public health and social care.	Establish harmonised methods and processes for stakeholder management across centre. Establish harmonised methods and processes for quality assurance across clinical, public health and social care guidelines.	Harmonised methods and processes for quality assurance across public health, social care and clinical are complete. The process for stakeholder management and engagement across public health, social care and clinical guidelines has been harmonised and a unified process is now in place. All clinical, public health and social care guidelines are now hosted on a single planning system.
To embed the merger of clinical, public health and social care surveillance functions, processes and methods, and develop sustainable methods and processes for reviewing guidelines.	Implement changed processes for surveying clinical guideline topics including continuous searching (diabetes pilot) and event tracking surveillance.	A pilot process on selected surveillance topics is underway. The Expert Advisers Panel currently has 950 confirmed members who contribute to various guideline related activities. Having

Objective	Actions	Update
	Implement new staffing structure and functions. Review different process designs across functions and harmonise. Plan the evaluation of the new processes/methods and collect necessary data to ensure they are fit for purpose.	completed the recruitment for clinical guidelines, we are now recruiting for public health specialties. The Expert Advisers database is now being used consistently across the Centre for Guidelines, including external developers. The Expert Advisers Panel is the main source of expert engagement for all surveillance reviews. NIHR's Systematic Review Programme has agreed to commit up to £160,000 over 3 years to fund new or updated Cochrane reviews identified as being important to the NICE guidelines programme. This was in response to a joint proposal from Phil Alderson of the Centre for Guidelines at NICE and Professor Martin Burton of Cochrane UK. From April 2018, the surveillance team in the Centre for Guidelines at NICE will identify a number of Cochrane reviews that will either inform decisions on updating guidelines or be relevant for updates of guidelines, and Cochrane will work to ensure that the Cochrane reviews are delivered when required by NICE with NIHR contracting to support the work.

Objective	Actions	Update
Develop sustainable methods for developing and maintaining guidelines and enhance the Centre's reputation for methodological quality and rigour.	To continue to develop the methods and processes of guideline development to maintain enhance the Centre'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. Develop a NICE GP Reference Panel to advise on the scoping of guidelines.	In November, 2 members of staff attended a meeting of the CERQUAL group in Geneva and a link with the group has been established. Implementation of the new structure bringing together the health economic function from across CfG into a single team has been completed. We continue to struggle to recruit health economic analysts to the team and we are considering alternative long term strategies for next year. The Health Economic Team continue to input into Public Health England's health economic and return on investment work (ROI) through various health economic engagement and steering groups, including the public health prioritisation framework, health inequalities, CVD and air pollution ROI tools. The Health Economic Team also continue to be closely involved in the MRC Extending the QALY project, through the project team, steering group and advisory group, particularly participation in a workshop on developing tool domains. In November, the Centre hosted the 6th meeting of the UK GRADE Network steering group (comprising members from NICE,

Objective	Actions	Update
		UCL, Cochrane and the BMJ Knowledge Centre). In December, we delivered an advanced training workshop on GRADE for Diagnostic Test Accuracy Studies that was attended by staff from NICE, our external development centres, Cochrane and the BMJ Knowledge Centre. Holger Schunemann (McMasters University) and Miranda Langendam (Dutch GRADE Network) were invited speakers at this workshop. The GP Reference Panel continues to provide helpful feedback on guideline scopes. During November and December they provided comments for the update of Diagnosis and Management of VTE Diseases.
Undertake a programme of transformation activities related to guideline content, process, and methods and oversee the corporate transforming guidance development programme, ensuring the needs of all NICE teams are met.	Embed the NICE content strategy principles and develop new presentations of guidelines to facilitate easy access for professional users and to support shared decision making. Plan and deliver projects to support the development of structured content, management of evidence and development of guidance.	Digital development work has focused on the redevelopment of the EPPI-Reviewer systematic reviewing tool in partnership with EPPI-Centre. It is anticipated that the new tool will be available for use internally at the end of Q4 2017/18; roll-out is anticipated to bring benefits internally through improvements to the user experience, adoption of priority screening functionality, and enabling reuse of information.

Objective	Actions	Update
		The comment collection project is moving through external approvals for the development phase of a tool to support external consultations at NICE. Work is expected to commence in Q4 2017/18, and will deliver a system that reduces the manual effort associated with consultations, and improves the user experience for stakeholders. The final strand of transformation relates to the development and presentation of NICE guidance as structured content. We are currently evaluating the MAGICapp tool; alongside prototyping and technical work to enable layered presentation of NICE guidance on our website, we are using the tool live to develop antimicrobial prescribing guidance.
To undertake a scheduled update of 'Developing Guidelines the Manual'.	Plan a scheduled update of 'Developing Guidelines the Manual' for consultation. Develop a plan for internal and external engagement taking into account areas for development. Deliver an updated 'Developing Guidelines the Manual' for implementation in 2018.	Developing NICE guidelines: the manual has been reviewed and updated with input from teams across Centre for Guidelines, publishing and PIP. External input has been sought from a newly established virtual reference group, and from external guideline developers via the guidelines methodology group.

Objective	Actions	Update
		The full draft updated manual will undergo final internal review and editing in early 2018 prior to submission to the March 2018 Board for approval to consult publicly on the changes. Following a 3 month consultation period and further Board review it is anticipated that the updated manual will be published in October 2018 and implemented from January 2019.

Figure 2 Performance against plan for guidelines between April 2017 and December 2017

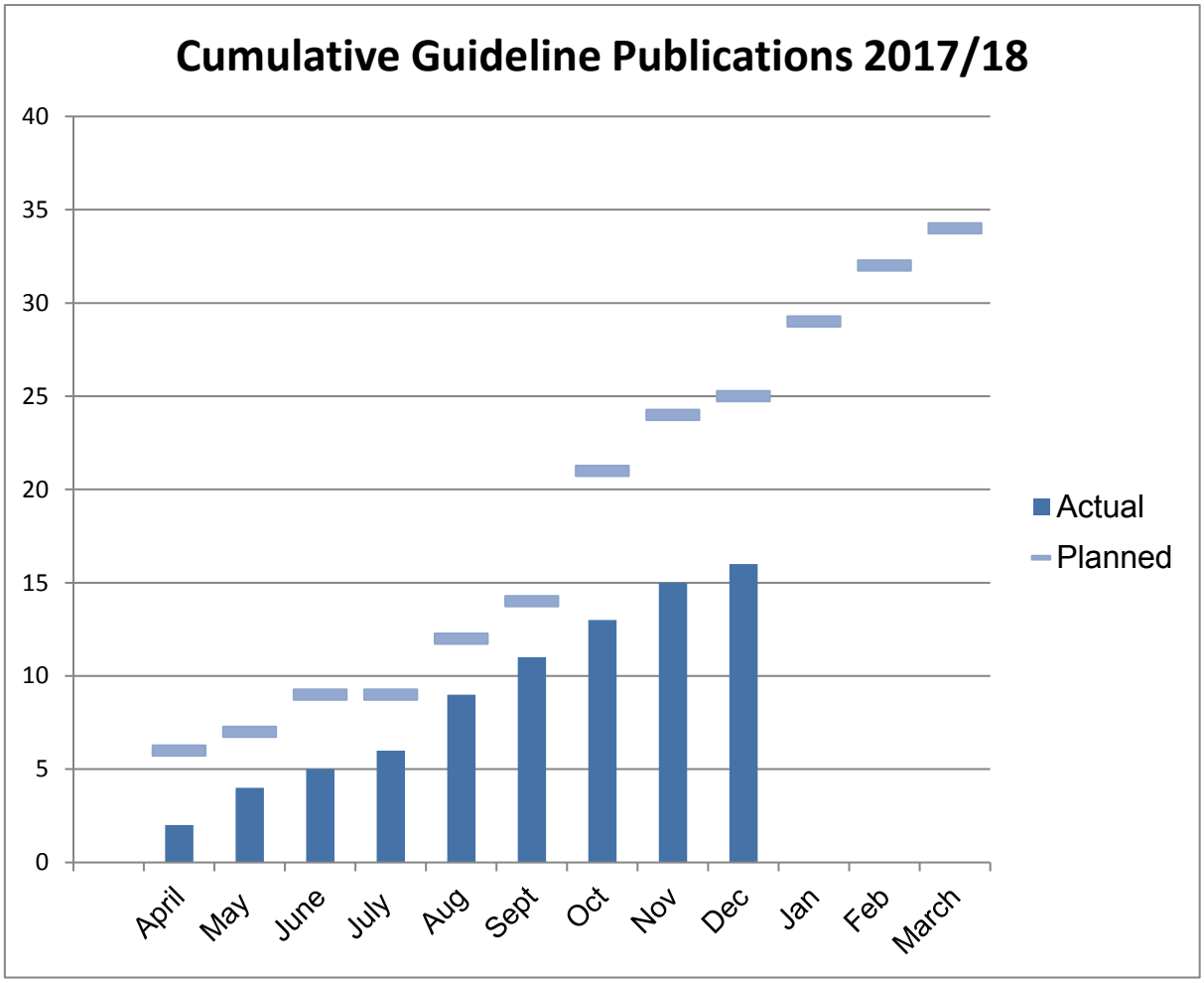


Figure 3 Performance against plan for management of common infections between April 2017 and December 2017

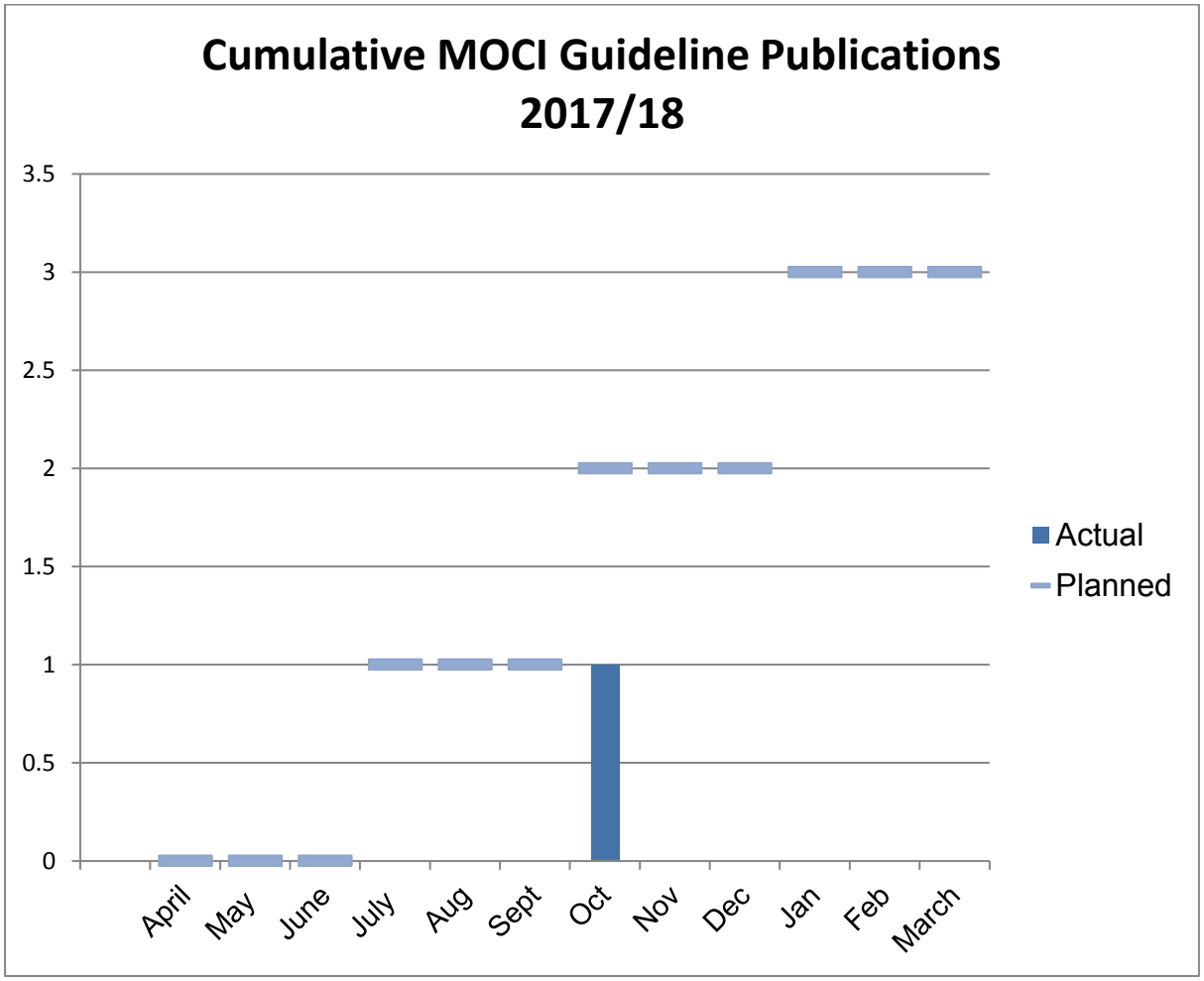


Figure 4 Performance against plan for surveillance reviews between April 2017 and December 2017

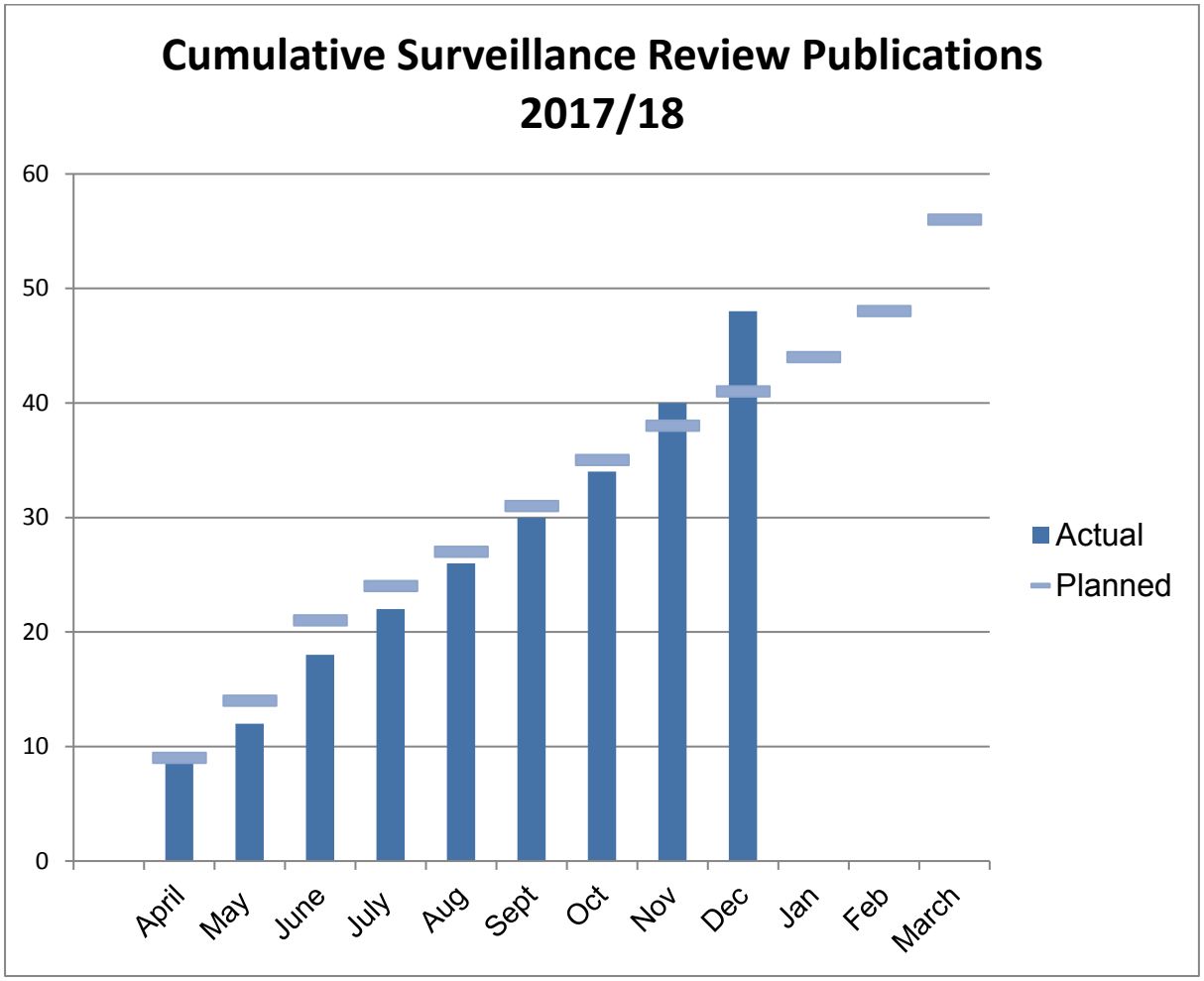


Table 2 Risks identified November and December 2017: key controls and ratings

Risk	Key controls	Risk rating now	Risk rating year end
Risk: Reputational risk to NICE arising from criticisms about contentious or contested clinical, social care or public health guidelines relating to their content or their fiscal or workforce impact. This is a particular risk in the guidelines programme because it does not have a formal appeal or resolution process.	Quality assurance processes are in place throughout the development cycle of guidelines. Application of the Declarations of Interest policy is monitored closely at committee appointment stage and at each meeting of the committees. External validation is used for potentially contentious recommendations. For potential contentious guidelines - in conjunction with national partners, develop a process for agreeing a joint narrative on the financial and workforce impact of our guidance.	Medium	Medium

Appendix 1 Guidance published since April 2017

Guidance title	Publication date	Notes
Sexually transmitted infections: Condom distribution schemes (NG68)	April 2017	Public health guideline
Alcohol use disorders (CG100)	April 2017	Clinical guideline - Standing committee update
Hip fracture (CG124)	May 2017	Clinical guideline - Standing committee update
Eating disorders (NG69)	May 2017	Clinical guideline
Air pollution: outdoor air quality and health (PH92)	June 2017	Public health guideline
Parkinson's Disease (NG71)	July 2017	Clinical guideline
Advanced breast cancer (CG81)	August 2017	Clinical guideline - Standing committee update
Developmental follow up of children and young people born preterm (NG72)	August 2017	Clinical guideline
Urinary tract infections in under 16s (CG54)	September 2017	Clinical guideline
Intermediate care including reablement (NG74)	September 2017	Social care guideline
Endometriosis: diagnosis and management (NG73)	October 2017	Clinical guideline
Cystic fibrosis: diagnosis and management (NG78)	October 2017	Clinical guideline
Cataracts in adults: management (NG77)	October 2017	Clinical guideline
Child abuse and neglect (NG76)	October 2017	Social care guideline
Type 2 diabetes: prevention in people at high risk (PH38)	October 2017	Public health
Glaucoma: diagnosis and management (NG81)	November 2017	Clinical guideline
Asthma: diagnosis, monitoring and chronic	November 2017	Clinical guideline

Guidance title	Publication date	Notes
asthma management (NG80)		
Autism spectrum disorder in under 19s: recognition, referral and diagnosis (CG170)	December 2017	Clinical guideline - Standing committee update
Sinusitis (acute): antimicrobial prescribing	October 2017	MOCI
Metastatic malignant disease of unknown primary origin in adults: diagnosis and management (CG104)	April 2017	Surveillance review
Fever in under 5s: assessment and initial management (CG160)	April 2017	Surveillance review
Acute kidney injury: prevention, detection and management (CG169)	April 2017	Surveillance review
Chronic kidney disease (stage 4 or 5): management of hyperphosphataemia (CG157)	April 2017	Surveillance review
Chronic kidney disease in adults: assessment and management (CG182)	April 2017	Surveillance review
Chronic kidney disease: managing anaemia (NG8)	April 2017	Surveillance review
Intravenous fluid therapy in adults in hospital (CG174)	April 2017	Surveillance review
Antisocial behaviour and conduct disorders in children and young people: recognition and management (CG158)	April 2017	Surveillance review
Patient group directions (MPG2)	April 2017	Surveillance review
Idiopathic pulmonary fibrosis in adults: diagnosis and management (CG163)	May 2017	Surveillance review

Guidance title	Publication date	Notes
Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease (CG172)	May 2017	Surveillance review
Head injury: assessment and early management (CG176)	May 2017	Surveillance review
Psoriasis: assessment and management (CG153)	June 2017	Surveillance review
Crohn's disease: management (CG152)	June 2017	Surveillance review
Ulcerative colitis: management (CG166)	June 2017	Surveillance review
Social anxiety disorder: recognition, assessment and treatment (CG159)	June 2017	Surveillance review
Antenatal and postnatal mental health: clinical management and service guidance (CG192)	June 2017	Surveillance review
Constipation in children and young people: diagnosis and management (CG99)	June 2017	Surveillance review
Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition (CG32)	July 2017	Surveillance review
Cancer of the upper aerodigestive tract: assessment and management in people aged 16 and over (NG36)	July 2017	This was an exceptional review
Transition between inpatient mental health settings and community or care home settings (NG53)	July 2017	This was an exceptional review
Vitamin D: increasing supplement use in at-risk groups (PH56)	July 2017	Surveillance review

Guidance title	Publication date	Notes
Workplace health theme: 1. Workplace health: long term sickness absence and incapacity to work (PH19) 2. Workplace health: management practices (NG13)	August 2017	Surveillance review
Immunisations: reducing differences in uptake in under 19s (PH21)	August 2017	Surveillance review
Osteoarthritis: care and management (CG177)	August 2017	Surveillance review
Neuropathic pain in adults: pharmacological management in non-specialist settings (CG173)	September 2017	Surveillance review
Chronic Fatigue Syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management (CG53)	September 2017	Surveillance review
Atrial fibrillation: management (CG180)	September 2017	Surveillance review
Hepatitis B (chronic): diagnosis and management (CG165)	October 2017	Surveillance review
Bipolar disorder: assessment and management (CG185)	October 2017	Surveillance review
Long-acting reversible contraception (CG30)	October 2017	Surveillance review
Contraceptive services for under 25s (PH51)	October 2017	Surveillance review
Psychosis and schizophrenia in adults: prevention and management (CG178)	November 2017	Surveillance review

Guidance title	Publication date	Notes
Hepatitis B and C testing: people at risk of infection (PH43)	November 2017	Surveillance review
Acute kidney injury: prevention, detection and management (CG169)	November 2017	Surveillance review
Behaviour change: general approaches (PH6)	November 2017	Surveillance review
Behaviour change: individual approaches (PH49)	November 2017	Surveillance review
Ovarian cancer: recognition and initial management (CG122)	November 2017	Surveillance review
Looked-after children and young people (PH28)	December 2017	Surveillance review
Acute heart failure: diagnosis and management (CG187)	December 2017	Surveillance review
Managing medicines in care homes (SC1)	December 2017	Surveillance review
Maternal and child nutrition (PH11)	December 2017	Surveillance review
Home care: delivering personal care and practical support to older people living in their own homes (NG21)	December 2017	Surveillance review
Social and emotional wellbeing in primary education (PH12)	December 2017	Surveillance review
Social and emotional wellbeing in secondary education (PH20)	December 2017	Surveillance review
Social and emotional wellbeing: early years (PH40)	December 2017	Surveillance review

National Institute for Health and Care Excellence

Centre for Health Technology Evaluation progress report

1. This report sets out the performance of the Centre for Health Technology Evaluation against our business plan objectives during November to December.

Performance

Table 1 Performance update for November - December 2017

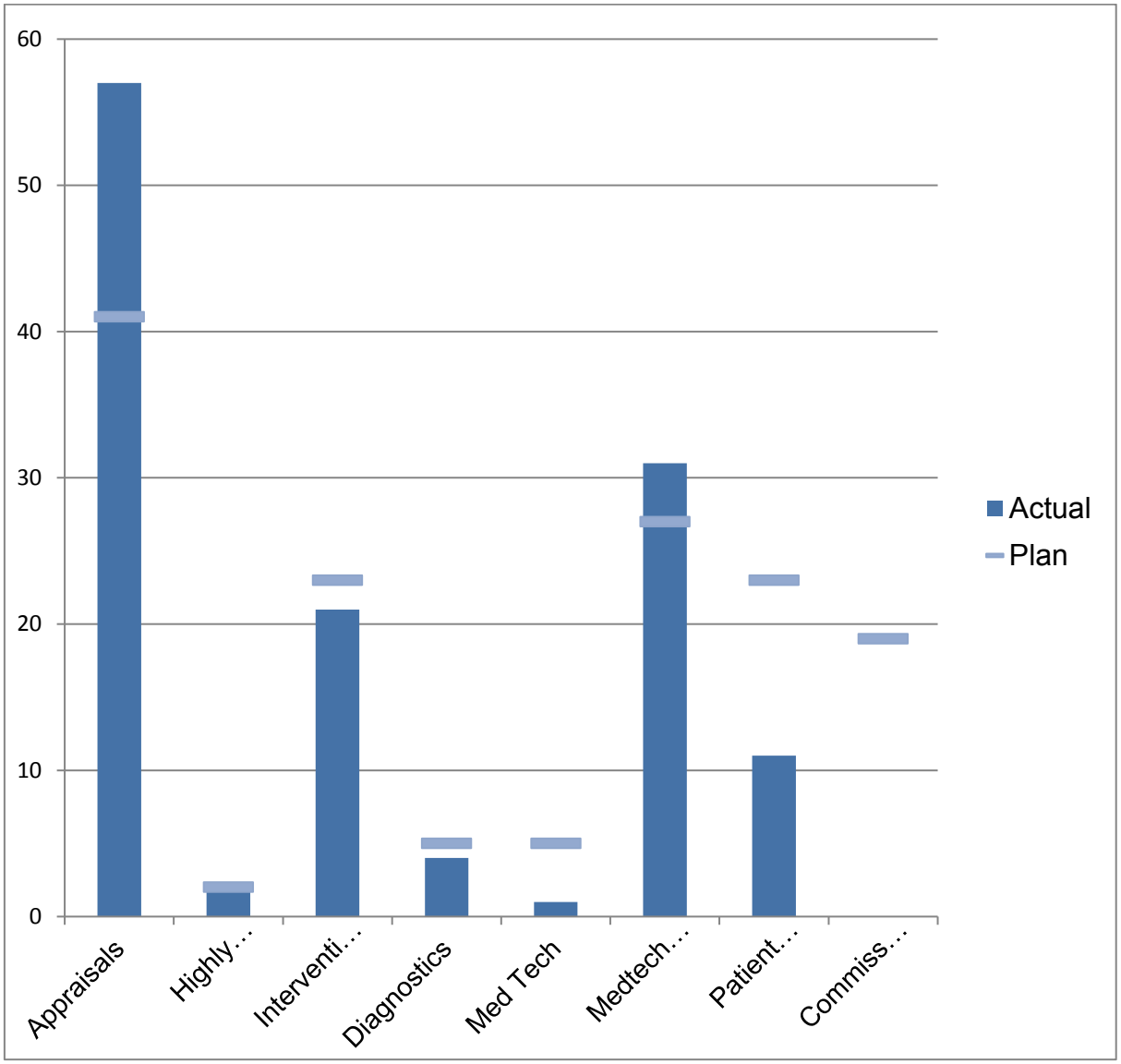
Objective	Actions	Update
Publish 55 technology appraisals guidance (including up to 15 CDF reconsiderations)	15 pieces of guidance published	Have now published more than the target of 55 pieces of guidance in 2017/18 (currently anticipated to be 67 by the end of the business year)
Publish 30 interventional procedures guidance	4 pieces of guidance published	On target to publish 30 pieces of interventional procedures guidance in 2017/18
Publish 6 diagnostics guidance	1 piece of guidance published	On target to publish 4 pieces of guidance in 2017/18
Publish 3 highly specialised technologies guidance	No HST guidance published in November or December 2017 (none planned)	On target to publish 3 pieces of guidance in 2017/18
Publish 7 medical technologies guidance	No guidance published	Expect to publish 5 medical technologies guidance in 2017/18
Publish 36 Medtech Innovation Briefings (MIBs)	2 Briefings published	On target to publish 36 MIBs in 2017/18
Submit advice to ministers on 30 Patient Access Schemes	4 pieces of advice have been issued to the Minister	On target to issue 30 pieces of advice in 2017/18

Objective	Actions	Update
Deliver up to 25 Commissioning Support Documents	Submitted 5 topics to NHS England December clinical panel	On target to handover agreed topics to NHS England in January 2018
Effective management of Scientific Advice income generated activity	Completed 5 standard, 15 EUNetHTA, 2 Express, 1 Light, 1 MHRA and 1 PRIMA project with 10 Standard, 7 EUNetHTA, 1 FDA-NICE, 1 Light and 1 MHRA project on-going. For the META Tool, there are 3 completed projects, 1 on-going project and 1 confirmed licensee.	On target to recover all costs and fully contribute to NICE overheads

2. For medical technologies guidance, 1 topic planned to publish in 2017-18 is delayed awaiting availability of key clinical trial data (MT250 Endocuff) and 1 topic is delayed because a committee meeting had to be cancelled because it would have been inquorate (MT318 Neuropad).

3. For diagnostics guidance, 1 topic planned to publish in 2017/18 is delayed as a third committee meeting will be required. This topic will now publish early in 2018/19. A second topic was delayed to allow more work to be carried out by the External Assessment Group (EAG.) This topic will also publish in 2017/18.

Figure 1 Performance against plan Centre for Health Technology Evaluation in April to December 2017



Key developments and issues

Office for Market Access

4. In November 2017, the Office for Market Access (OMA) launched their new web pages on the NICE website, www.nice.org.uk/OMA. The web pages provide a helpful, comprehensive overview of the services OMA offer. Pre-launch user feedback from the life sciences industry helped tailor the web pages accordingly.

5. There are a number of company engagement meetings scheduled until April 2018, covering many different aspects of market access strategy. Interest in OMA services continues to increase with many engagements to be scheduled for 2018-2019.

Scientific Advice

6. Following board approval, Scientific Advice initiated work with Grant Thornton on the design and implementation of the new Scientific Advice business unit. The project is broken down into 5 different workstreams covering Structure, Governance, Communications, HR and Project Accounting. The individual workstreams will receive input from a number of teams at NICE, including HR, Corporate Office, Communications, Digital Services, Procurement and Finance. Grant Thornton's work started in November and will conclude in January where the proposals from the 5 workstreams will be reviewed by SMT.

7. Scientific Advice completed the first pilot for PRIMA, a new service aimed at quality assuring economic models by providing expert advice on the model structure, data entry and transformations, computations, coding, usability and transparency. The team received a very positive feedback from the pilot and have now officially launched the PRIMA service.

8. AdviSeME is a new competition run by Scientific Advice, aimed at SMEs developing transformative products that have the potential to change patients' lives and/or save the NHS money. Review of the 20 applications is complete. The AdviSeME expert panel - comprised of Prof Carole Longson (Director, Centre for Health Technology Evaluation, NICE) Prof Sue Hill OBE (Chief Science Officer, NHS England), Prof Sir Michael Rawlins (Chairman, MHRA) and Ian Campbell (Director for Health and Life Sciences, Innovate UK) - has been appointed to review the 8 shortlisted applications and select the winner, who will be notified in January. The winner will then have the opportunity to seek scientific advice at, no cost to them, within the following 12 months.

Medical Technologies Evaluation Programme

9. The final health app briefing on GDm-Health for people with gestational diabetes was published in mid-November 2017 as MIB131. The three topics reviewed provided useful proof-of-concept experience in exploring how to collate relevant evidence and provide a useful commentary on these type of health technologies. In addition to the briefings themselves, an output of the work, capturing methods for evidence assessment, is available to app developers and other stakeholders via the Medical Technologies Evaluation External Assessment Centre website and as a guide to evidence generation.

10. The tender process to re-procure external assessment centre services for the Medical Technologies Evaluation Programme is expected to be complete by March 2018.

Interventional Procedures

11. There has been a significant interest in the treatment of urinary incontinence (SUI) and pelvic organ prolapse (POP) with “mesh” devices. By 15 December the IP team will have updated and published all 8 pieces of guidance where mesh is used to treat SUI and POP. This work was undertaken in response to a specific recommendation in the NHS England “mesh working group” report.

Science Policy and Research

12. The Improved Methods and Actionable Tools for enhancing Health Technology Assessment (IMPACT HTA) is a 5 year Horizon 2020 funded project starting January 2018. The NICE SP&R team is co-leading a work package commencing summer 2019 with the London School of Economics, on the analysis and interpretation of non-randomised studies to inform health economic evaluation for methodological guidance. NICE will collaborate on a number of other work packages that aim to develop a new, publicly accessible tool for undertaking decision-theoretic modelling through Discretely Integrated Condition Event (DICE) simulation and develop materials to support HTA decision-making for orphan medicinal products. The guidelines and HST teams at NICE will input, respectively, into these deliverables. NICE will also play an advisory role in developing a costing methodology and a core dataset of costs for facilitating cross border comparisons in economic evaluation and producing guidance on extrapolation of randomised clinical trial results using real world data.

Technology Appraisals and Highly Specialised Technologies

13. At the September 2017 Board meeting, the Board approved a two-phase consultation on proposals to increase capacity within the Technology Appraisal

programme. The 1st consultation started on 5 October 2017 and ran until 16 November 2017 and sought to elicit views from stakeholders on the principles of the proposed changes. The programme has reviewed all comments received from stakeholders from the 1st consultation. The 2nd consultation will be focussed on updating the content of Technology Appraisal process guide outlining how the principles will be operationalised. The process guide was released to stakeholders earlier this month, to seek their views. It is anticipated that the Board will review the outcome of both consultations together with the updated process guide for approval in March 2018.

14. As reported in the previous Board report, we have implemented the arrangements for the budget impact test in both the technology appraisal (TA) and highly specialised technologies (HST) programmes. The test is used to trigger discussions about developing potential 'commercial agreements' between NHS England and companies in order to manage the budget impact of introducing high cost treatments. Thirty-nine appraisal and HST topics have been assessed for the budget impact test so far and three topics have been identified that may meet the budget impact test criteria.

Risks

Table 2 Risks identified November - December: key controls and ratings

Risk	Key controls	Risk rating now	Risk rating year end
Capacity issues within the Technology Appraisal programme for the 2017/18 business year. Demand will outstrip supply.	1. Develop and submit a business case for NHS England to request additional resource to increase capacity 2. Use Diagnostics Assessment Programme technical and project team resource within CHTE to reduce the capacity pressure in the Technology Appraisal Programme. This will delay initiation of assessment of some diagnostics topics.	Red	Amber
Increased running cost associated with the establishment of NICE	Full affordability model to be undertaken as part of the business unit implementation work	Amber	Green

Risk	Key controls	Risk rating now	Risk rating year end
Scientific Advice business unit	Plans to revise the fee structure across all services		
Inability to fill team vacancies with high calibre candidates	Working with colleagues in HR to develop more agile recruitment plans to react quickly and reach a broader audience when advertising new posts	Amber	Green
Failure to get new External Assessment Centres via the retender process of the new framework contract arrangements, because of potential instability for suppliers	Working with colleagues in procurement and finance to ensure sufficient initial call-off orders are in place in new External Assessment Centres to underwrite required capacity for normal medtech activities and outputs from summer 2018	Amber	Amber

Appendix 1 Guidance & Advice published since April 2017

Guidance title	Publication date	Notes
Technology Appraisals		
TA496; Ribociclib for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer	December 2017	
TA495; Palbociclib for breast cancer (metastatic, hormone-receptor positive, HER2-negative, untreated)	December 2017	
TA494; Naltrexone–bupropion for managing overweight and obesity	December 2017	
TA493; Cladribine tablets for treating relapsing–remitting multiple sclerosis	December 2017	
TA492; Atezolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable	December 2017	
TA491; Ibrutinib for treating Waldenstrom's macroglobulinaemia	November 2017	
TA490; Nivolumab for treating squamous cell carcinoma of the head and neck after platinum-based chemotherapy	November 2017	
TA489; Vismodegib for treating basal cell carcinoma	November 2017	
TA488; Regorafenib for previously treated unresectable or metastatic	November 2017	

Guidance title	Publication date	Notes
gastrointestinal stromal tumours		
TA487; Venetoclax for treating chronic lymphocytic leukaemia	November 2017	
TA486; Aflibercept for treating choroidal neovascularisation	November 2017	The first Fast Track Appraisal (FTA) to publish following implementation of the new process in April 2017.
TA485; Sarilumab for moderate to severe rheumatoid arthritis	November 2017	
TA484; Nivolumab for previously treated non-squamous non-small-cell lung cancer	November 2017	
TA483; Nivolumab for previously treated squamous non-small-cell lung cancer	November 2017	
TA482: Immunosuppressive therapy for kidney transplant in children and young people	October 2017	
TA481: Immunosuppressive therapy for kidney transplant in adults	October 2017	
TA480: Tofacitinib for moderate to severe rheumatoid arthritis	October 2017	
TA479: Reslizumab for treating severe eosinophilic asthma	October 2017	
TA478: Brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma	October 2017	
TA477: Autologous chondrocyte implantation for treating symptomatic	October 2017	

Guidance title	Publication date	Notes
articular cartilage defects of the knee		
TA476: Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer	September 2017	
TA475: Dimethyl fumarate for treating moderate to severe plaque psoriasis	September 2017	
TA474: Sorafenib for treating advanced hepatocellular carcinoma	September 2017	
TA473: Cetuximab for the treatment of metastatic and/or recurrent squamous cell carcinoma of the head and neck (review of TA172)	August 2017	
TA472: Lymphoma, non Hodgkin's NHL indolent, rituximab & refract) - obinutuzumab	August 2017	
TA471: Irritable bowel syndrome (diarrhoea) - eluxadoline	August 2017	
TA470: Leukaemia (chronic lymphocytic, relapsed) - ofatumumab (with chemotherapy)	August 2017	terminated
TA469: Leukaemia (chronic lymphocytic) - idelalisib (with ofatumumab)	August 2017	terminated
TA468: Constipation (opioid induced) - methylnaltrexone bromide	August 2017	terminated
TA467: Holoclar for treating limbal stem cell deficiency after eye burns	August 2017	

Guidance title	Publication date	Notes
TA466: Baricitinib for moderate to severe rheumatoid arthritis	August 2017	
TA465: Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma	August 2017	
TA464: Bisphosphonates for treating osteoporosis	August 2017	
TA463: Cabozantinib for previously treated advanced renal cell carcinoma	August 2017	
TA462: Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma	July 2017	
TA461: Roflumilast for treating chronic obstructive pulmonary disease	July 2017	
TA460: Adalimumab and dexamethasone for treating non-infectious uveitis	July 2017	
TA459: Collagenase clostridium histolyticum for treating Dupuytren's contracture	July 2017	
TA458: Trastuzumab emtansine for treating HER2-positive advanced breast cancer after trastuzumab and a taxane	July 2017	
TA457: Carfilzomib for previously treated multiple myeloma	July 2017	
TA456: Ustekinumab for moderately to severely active Crohn’s disease after previous treatment	July 2017	
TA455: Adalimumab, etanercept and ustekinumab	July 2017	

Guidance title	Publication date	Notes
for treating plaque psoriasis in children and young people		
TA454: Daratumumab with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal)	July 2017	
TA453: Bortezomib for treating multiple myeloma after second or subsequent relapse (terminated appraisal)	July 2017	
TA452: Ibrutinib for untreated chronic lymphocytic leukaemia without a 17p deletion or TP53 mutation (terminated appraisal)	July 2017	
TA451: Leukaemia (chronic myeloid, acute lymphoblastic) - ponatinib [ID671]	June 2017	
TA450: Leukaemia (acute lymphoblastic, B-precursor, relapsed, refractory) - blinatumomab [ID804]	June 2017	
TA449: Neuroendocrine tumours (metastatic, unresectable,progressive) - everolimus and sunitinib [ID858]	June 2017	
TA448: Etelcalcetide for treating secondary hyperparathyroidism [ID908]	June 2017	
TA447: Lung cancer (non-small-cell, metastatic, untreated, PDL1) - pembrolizumab [ID990]	June 2017	

Guidance title	Publication date	Notes
TA446; Brentuximab vedotin for treating CD30-positive Hodgkin's lymphoma	June 2017	
TA445: Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs	May 2017	
TA444: Afatinib for treating advanced squamous non-small-cell lung cancer after platinum-based chemotherapy (terminated appraisal)	May 2017	
TA443: Obeticholic acid for treating primary biliary cholangitis	April 2017	
TA442: Ixekizumab for treating moderate to severe plaque psoriasis	April 2017	
TA441: Daclizumab for treating relapsing–remitting multiple sclerosis	April 2017	
TA440: Pegylated liposomal irinotecan for treating pancreatic cancer after gemcitabine	April 2017	
Highly Specialised Technologies		
HST6: Asfotase alfa for treating paediatric-onset hypophosphatasia	August 2017	Recommended with a Managed Access Agreement and commercial terms with NHS England.
HST5: Eliglustat for treating type 1 Gaucher disease	June 2017	
Interventional Procedures		
IPG598 Hypoglossal nerve stimulation for moderate to	November 2017	Special

Guidance title	Publication date	Notes
severe obstructive sleep apnoea		
IPG597 Processed nerve allograft to repair peripheral nerve discontinuities	November 2017	Special
IPG596 Extracranial to intracranial bypass for intracranial atherosclerosis	November 2017	Do not use
IPG595 Total distal radio-ulnar joint replacement for symptomatic joint instability or arthritis	November 2017	Special
IPG594 Intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by high spinal cord injuries	September 2017	Research only
IPG593 Intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by motor neurone disease	September 2017	Do not use
IPG592 High intensity focused ultrasound for symptomatic breast fibroadenoma	September 2017	Special arrangements
IPG591 Ab externo canaloplasty for primary open-angle glaucoma	September 2017	Standard arrangements
IPG590 Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer	August 2017	Standard arrangements
IPG589 Radiofrequency treatment for haemorrhoids	August 2017	Special arrangements
IPG588 Liposuction for chronic lymphoedema	August 2017	Standard arrangements

Guidance title	Publication date	Notes
IPG587 Hysteroscopic sterilisation by insertion of intrafallopian implants	July 2017	Standard arrangements
IPG586 Transcatheter aortic valve implantation for aortic stenosis	July 2017	Standard arrangements
IPG585 Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease	July 2017	Special arrangements
IPG584 Uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse	June 2017	Standard arrangements
IPG583 Sacrocolpopexy using mesh to repair vaginal vault prolapse	June 2017	Standard arrangements
IPG582 Infracoccygeal sacropexy using mesh to repair uterine prolapse	June 2017	Special arrangements
IPG581 Infracoccygeal sacropexy using mesh to repair vaginal vault prolapse	June 2017	Special arrangements
IPG580 Endoscopic full thickness removal of non-lifting colonic polyps	May 2017	Special arrangements
IPG579 Irreversible electroporation for treating pancreatic cancer	May 2017	Research only
IPG578 Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain	April 2017	Standard arrangements
Diagnostics		
DG31 Tests in secondary care to identify people at high risk of ovarian cancer	November 2017	
DG30 Quantitative faecal immunochemical tests to	July 2017	

Guidance title	Publication date	Notes
guide referral for colorectal cancer in primary care		
DG29 Multiple frequency bioimpedance devices to guide fluid management in people with chronic kidney disease having dialysis	June 2017	
DG28 Virtual chromoendoscopy to assess colorectal polyps during colonoscopy	May 2017	
Medical Technologies		
MTG34 SecurAcath for securing percutaneous catheters	June 2017	

Advice title	Publication date	Notes
Medtech Innovation Briefings		
MIB132 Point-of-care and home faecal calprotectin tests for monitoring treatment response in inflammatory bowel disease	December 2017	
MIB131 Health app: GDm-Health for people with gestational diabetes	November 2017	3rd Health App Briefing. Not counted in against MIB target.
MIB130 Health app: ChatHealth communication platform in school nursing services	November 2017	2nd Health App Briefing. Not counted in against MIB target.
MIB129 Health app: Sleepio for adults with poor sleep	November 2017	1st Health App briefing published. Not counted in against MIB target.
MIB128 HTG EdgeSeq ALKPlus Assay EU for ALK status testing in non-small-cell lung cancer	November 2017	

Advice title	Publication date	Notes
MIB127 Radiation dose monitoring software for medical imaging with ionising radiation	October 2017	
MIB126 Promonitor for monitoring response to biologics in rheumatoid arthritis	October 2017	
MIB125 PleuraFlow Active Clearance Technology for maintaining chest tube patency	October 2017	
MIB124 Mepilex Border dressings for preventing pressure ulcers	October 2017	
MIB123 Memokath-028, 044 and 045 stents for urethral obstruction	October 2017	.
MIB122 Thora-3Di for assessing asthma in children	October 2017	
MIB121 Farco-fill Protect for indwelling urinary catheterisation	September 2017	
MIB120 Caris Molecular Intelligence for guiding cancer treatment	September 2017	
MIB119 Aptiva for painful diabetic neuropathy	September 2017	
MIB118 Fungitell for antifungal treatment stratification	August 2017	
MIB117 Biopatch for venous or arterial catheter sites	August 2017	
MIB116 Urethrotech UCD for difficult or failed catheterisation	August 2017	
MIB115 The VEST external stent for coronary artery bypass grafts	August 2017	

Advice title	Publication date	Notes
MIB114 Febridx to differentiate bacterial and viral respiratory tract infections	July 2017	
MIB113 Nasal Alar SpO2 sensor for monitoring oxygen saturation by pulse oximetry	July 2017	
MIB112 The Arctic Sun system for therapeutic hypothermia after cardiac arrest	July 2017	
MIB111 L-DEX U400 for lymphedema in breast cancer	July 2017	
MIB110 FreeStyle Libre for glucose monitoring	July 2017	
MIB109 Ridascreen tests for monitoring infliximab in inflammatory bowel disease	June 2017	
MIB108 Neo pedicle Screw System for spinal fusion surgery	June 2017	
MIB107 SecurAcath for securing cerebrospinal fluid catheters	June 2017	
MIB106 Bindex for people with suspected osteoporosis	May 2017	
MIB105 Permacol for treating anal fistulae	May 2017	
MIB104 NaviCam for diagnosing gastrointestinal tract conditions	May 2017	
MIB103 Hemosep for cell salvage	May 2017	
MIB102 VAAFT for treating anal fistulae	April 2017	

National Institute for Health and Care Excellence

Communications Directorate progress report

1. This report sets out the performance of the Communications Directorate against our business plan objectives during November and December 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.

Table 1 Performance update for September and October 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.	We worked with the commissioning support team on their submission template and standard operating procedure document. Our first proofreading workshop was run for colleagues at the start of 2017. Since then, we have run more - both general and tailored for teams. In November, we added a proofreading training module on the Learning Zone on NICE Space. We have had very positive feedback on the proofreading sessions and on the minute-writing - more than 50 people have attended one since the end of 2016. The Health Quality and Improvement Partnership asked us to follow up on the training we did for them in October by running a charged-for session at a seminar for their developers. We prepared an interactive sessions for 80 people, which included working together on refining and editing recommendations in line with the principles of plain English. We were also able to explain NICE's new rationale and impact sections.
	Provide communications expertise into the digital transformation project.	We contributed to the work that successfully demonstrated that the content of a guideline could be exported from the structured content system into NICE Publications and be presented in a way that replicates the current format. We are continuing to contribute to work on version control.

Objective	Actions	Update
	Implement brand refresh and create clear brand guidelines which establish the voice and personality of NICE	Done/ongoing monitoring
	Ensure website content is up to date and accurate and deliver a rolling programme of improvements.	Work is continuing to publish more engaging content on the website. A new style communities page for Social Care was published in November and has received a lot of positive feedback. We have also created an online version of the latest quick guide for home care managers on medicines support. We are working closely with digital services to create new topic pages to provide a more engaging overview of guidance and associated resources.
	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 November the sign off on pathways was transferred to the NICE publication executive. We gave a presentation to the group to help them with their new responsibility.
	Expand on use of new online interactive and multimedia software packages such as 'Shorthand' to present our new guidance to media and other stakeholders	Ongoing - we continue to explore new software packages and their compatibility with NICE systems
	Provide communications expertise for NICE's support in shared decision making	Ongoing - we have developed text for the shared decision making section of the update to the guideline manual, and supporting information for developers. We are also contributing to developing a process guide for decision support tools from NICE.

Objective	Actions	Update
2 ENGAGEMENT 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	The business process workshops took place as planned in November and an initial requirements specification has been delivered by SeeLogic. Some additional scoping work is underway on a small number of complex requirements in order to finalise the tender for the build phase. The tender is planned to go out in January.
	Develop a new interactive online newsletter with content tailored for key audiences	A survey has been designed to capture feedback from all our newsletter subscribers and will be distributed in January. The results will inform a development plan for our suite of newsletters.
	Develop personalisation functionality on the NICE website (working with the digital services team) that allows visitors to tailor content to their needs	Work has begun to create a life sciences landing page to provide a clear route in to services such as OMA, Scientific Advice and Medtech guidance programmes.
	Deliver a programme of events and speaking engagements to enable NICE to engage directly with key audiences on priority topics	A new programme is being developed for 2018 and has had input from senior staff at NICE
	Implement social media strategy to increase engagement and drive traffic to corporate content	During World Antibiotic Awareness Week in November 2017, the media team streamed its first Facebook Live with NICE Chair David Haslam, using a TV interview format to talk about the work NICE is doing in this area. It received more than 800 views in less than 48 hours. The awareness week was also used to launch our Instagram account to target younger social media audiences (25 – 34 years old) with an innovative animated character, NICE Nadia,

Objective	Actions	Update
		to introduce how NICE guidance can combat the global threat of antimicrobial resistance and what individuals can do to help. A full round-up of the content can be viewed here.
	Further develop a system to capture audience insights (including Twitter and Website analytics) and provide regular reports to senior management	The audience insight team delivered a joint project with the system engagement team to explore how guidance is put into practice and what would make it easier to implement. Nearly 900 responses were received to an online survey and 15 in-depth interviews were conducted. A summary of the main findings is included in the Health and Social Care Directorate report. During November and December 18 interviews were carried out with committee members to gain insights and feedback on their experiences of developing guidance. Analysis is underway and a report will be available in January. The Audience Insight team have also provided advice and practical support to a number of teams on audience feedback projects. These included 2 surveys about our internal and external processes relating to risk and audit for the corporate office team, recruitment of external users for alpha phase of new approach to capturing comments on consultations and a survey of committee members to understand the impact the proposed new declaration of interests policy would have on existing committees.
3. ADOPTION and IMPACT	Use graphics and images to help explain guidance and related products	We developed and published a 2-page visual presentation to support local decision-making on the use of the new intravenous antimicrobial, ceftazidime/avibactam (Zavicefta). It

Objective	Actions	Update
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		included data on effectiveness, safety, patient factors, resource impact and resistance. This product was published alongside the first of the antimicrobial prescribing evidence summaries.
	Build 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	We are exploring options for embedding specialist software in the website to create interactive graphs and infographics. We hope to procure software, and pilot interactive content from January.
	Using external comms and marketing to explain NICE internal methods and processes, and work programme to interested stakeholders	We supported the Chair with briefings for visits to the Royal College of Ophthalmologists and Local Government Association. We placed articles in a number of stakeholder newsletters - including the ADPH and Skills for Care. The Care Quality Commission's internal bulletins featured our Quality Improvement Resource. The team organised a piece by Andrew Dillon in the New Statesman on NICE's role at the nexus of health, social care, industry and government.
	Bring content to life by reusing case studies, shared learning examples and other material	We have submitted a feature article for Councillor Magazine on our Shared Learning Award winner in 2017 (Mansfield District Council – ASSIST programme). Another piece for the Government Magazine on NICE's guidance on people's experience in adult social care services is awaiting publication in the New Year.
	Use a variety of evaluation techniques to assess the impact of our work and to regularly gauge the views of our stakeholders	After the sinusitis guideline was published we set up monitoring to find out how people were interacting with the pages on the website. We discussed the results with the project team for the

Objective	Actions	Update
		guideline, and made some changes to the format of presentation of future topics.
4. PRODUCTIVITY To be effective and efficient and to work better with less	Regularly assess directorate structure and future needs to ensure that resources are in place to enable delivery of directorate and wider corporate objectives.	We met the directors of guidance producing centres in November to discuss their future editorial requirements. No major changes in the team structure were requested, but it was agreed that we should explore with the centres how we can further improve efficiency in how we work together.
	Continue to roll out efficiencies and cost savings plan that will support the communication needs of the organisation in 2017-2018 and beyond	The publishing team will meet the target for the savings by April 2018 by disestablishing vacant posts and making some cuts in the non-pay budget.
	Continue 2017-2018 work to develop a directorate that is content-focused, able to work in social and multi-media and makes most productive use of communications resources.	Ongoing

Other issues

News coverage

3. Publication of the final updated guidance on familial hypercholesterolemia (FH) in November generated a great deal of positive media coverage, including in the Telegraph (front page), Times, Sun and Daily Mail. Most of the coverage led with the recommendation that children with FH should be offered statin therapy.

4. Positive draft guidance for breast cancer drugs palbociclib and ribociclib following price cuts was positively reported in the Telegraph, Times, Guardian, Daily Mail, Sun, Mirror and BBC Online, as well as in the local/regional press. Most of this focused on NICE's part in getting companies to reduce their prices.

5. In addition the press team produced a considerable amount of content to support World Antibiotic Awareness Week in November. The results can be seen here.

6. The guideline on hearing loss received blanket coverage, mostly focusing on recommendations not to remove earwax with cotton buds. It was covered by Telegraph, Times and Daily Mail.

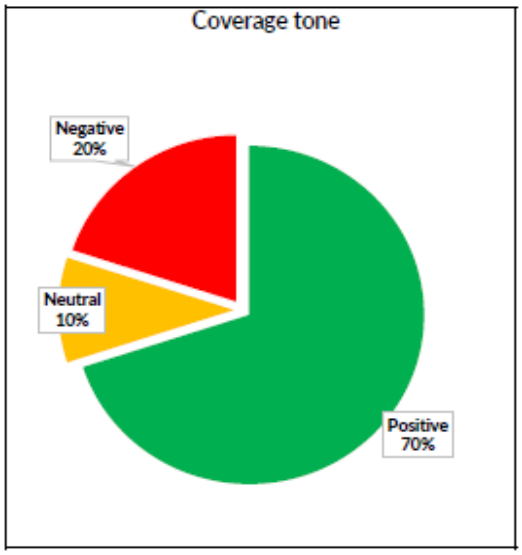
7. The BBC Victoria Derbyshire show obtained a leaked copy of the last interventional procedures guidance to be updated on vaginal mesh. This produced a large amount of coverage across the BBC, Guardian, Independent, ITV, and Sky. Many reported that NICE would recommend use of mesh be ‘banned’ in this indication. The media team worked hard to correct this and later coverage after publication on 15 December more accurately reflected the ‘research only’ recommendation.

Social media

NICE National Institute for Health and Care Excellence

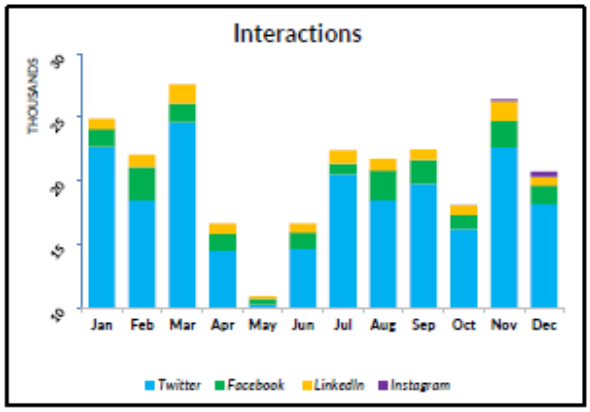
Digital metrics report
Nov-Dec

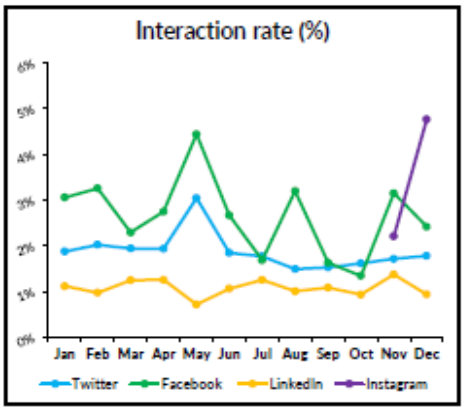
Most viewed website news stories	
Topic	Views
Remove earwax if causing hearing loss	7,147
Two breast cancer drugs available routinely	3,254
New ways to diagnose and manage asthma	2,448
FH should be identified and treated early	1,832
Use antibiotics effectively	1,356
Help people with LD plan	1,242
MS patients to have beta interferon	1,010
Specialist CBT helps eating disorders	965
NICE launches PRIMA	930
People at low risk of glaucoma can avoid referral	889



Newsletter subscribers		
Main	23,637	↑
Primary care	12,449	↑

Followers	138,424 ↑	2,825 ↑	7,623 ↑	380 ↑
Impressions	2,341,612 ↑	127,359 ↓	186,165 ↑	15,083 ↑





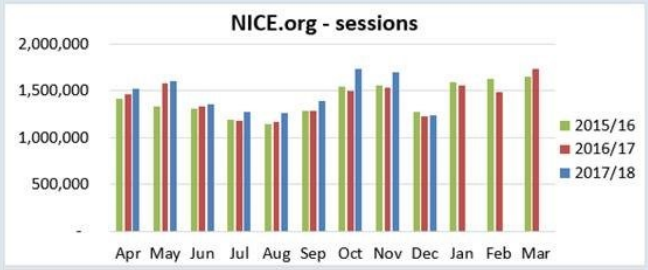
YouTube	
Views	4,860
Watch time (mins)	8,719

Events

8. We attended two conferences in November/ December: the Royal College of Midwives Annual Conference in Manchester and the Acute and General Medicine Conference, London. We have begun advertising the NICE Annual Conference 2018 which this year will be a 1-day event on 26 June.

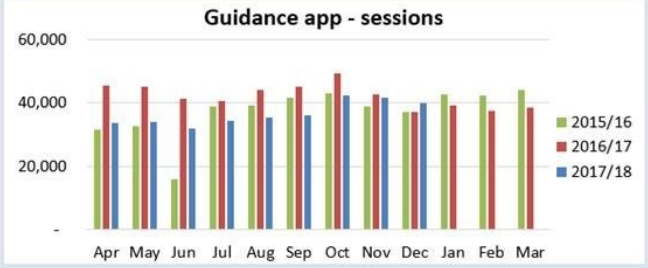
Website and Pathways statistics

Performance of services which provide access to NICE guidance



In December 2017	1,243,912	Var. last year	1%
		Var. last month	-27%
In year ending December 2017	17,879,432	Var. last year	4%

In December 2017	213,422	Var. last year	-17%
		Var. last month	-27%
In year ending December 2017	3,139,282	Var. last year	7%



In December 2017	40,096	Var. last year	8%
		Var. last month	-4%
In year ending December 2017	444,768	Var. last year	-15%

9. In November and December we prepared 218 documents for digital publication. For NICE Pathways we:

    - Published 10 fully updated pathways
    - Updated 26 pathways to include new quality standards, CHTE guidance, NICE advice or clinical knowledge summaries
    - Updated a further 25 pathways to add related pathway links or as maintenance updates.

10. There are currently 239 live pathways.

Enquiry handling

11. During November and December we responded to 1615 enquiries which included 18 MP letters, 19 freedom of information (FOI) requests and 33 parliamentary questions.

12. Our technology appraisal guidance on bisphosphonates for treating osteoporosis has prompted several queries from commissioners. They have requested clarity on how to interpret probability of osteoporotic fragility fracture risk, treatment thresholds, the role of DXA scans in light of the technology appraisal and how to put our technology guidance into practice alongside the relevant recommendations within the clinical guideline on osteoporosis. In light of the volume and nature of enquiries, the enquiry team has produced a clarification statement with input from colleagues in the medicines educations team. This statement will be published on the website following sign off by the senior management team.

13. Other popular topics for the general public have included interest in our draft and final recommendations for transvaginal mesh repair of anterior or posterior vaginal wall prolapse following extensive media coverage, queries about sequencing of treatments for choroidal neovascularisation and misdirected queries following NHS England's response to their consultation on items which should not be routinely be prescribed in primary care. In addition, we have also fielded enquiries following the removal of the do not do recommendations database - explaining why the database has been removed and redirecting people to our other resource planning tools.

National Institute for Health and Care Excellence

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), a document supply ordering service and medicine awareness products.

3. This report sets out the performance of the Evidence Resources directorate against our business plan objectives for 2017/18. It also highlights performance against agreed metrics and provides an update on the risks managed within the directorate.

Performance

4. The directorate's progress achieved in November and December 2017, against the objectives set for the year 2017/18 is summarised in the table below.

Table 1 Overview of performance in November/December 2017 against FY 2017/18 objectives

Objective	Actions	Update
Information Resources		
Deliver the suite of digital 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	• **On track** - with traffic across all sub-services performing well during the period. Specifically, traffic from the BNF microsites is continuing to recover from the drop experienced in June 2017 when the new sites were launched. This drop was due to a decrease in referrals from search engines. Since that time usage levels are coming back strongly. The total number of BNF sessions for November 2017 is now 17% greater than in November 2016. The BNFc sessions have not recovered as well and are 21% lower for November 2017, compared with November 2016. • **Completed** - The process of withdrawal of the NICE BNF and BNFc apps has completed. After warning users in October and November that the NICE apps was no longer updated, the apps were retired in December. Users continue to be encouraged to download the new open access BNF publisher apps.
	• Procure and maintain the underpinning Link Resolver and Identity Management services	• **Completed** – The new Link Resolver service was fully launched during October 2017 and the risk associated with this implementation was removed from our risk register in December.
	• Manage content procurement contracts (CKS, Cochrane), including those on behalf of HEE (National Core Content)	• **On track** - Planning work for the re-procurement of the National Core Content in 2018/19 has started. • **Completed** - Cochrane and CKS re-procurements.
	• Manage the NICE Framework Agreement which supports local purchasing of information resources.	• **On track** - Annual contract review meetings were held with all suppliers on the Framework during this period.

Deliver efficient and high quality information services to NICE centres and directorates	• Develop Information Services capacity and support for new or growing programmes of work in line with 2017/18 activity plans. • Explore new methods and approaches, and where suitable, deliver service improvement in the provision of Information Services across NICE. This will involve close engagement with the Evidence Management project.	• **On track** – new or additional support in place for medtech innovation briefings, commissioning support documents, IAPT assessment briefings and technology appraisals. • **On track** – the full document supply tool went live in Q1; sponsor and expert user input ongoing in to the development of EPPI-R5.

Digital Services		
Deliver digital service projects in line with the agreed investment priorities for 2017/18 and NICE's business plan objectives.	• Guidance Production Services: key priorities are the Evidence Management programme, the continued development of a structured content authoring platform and improving the processes of external consultations.	• **On track** - a number of digital projects have either completed or are under way across the portfolio. This includes: **Guidance production services:** • Work has started on the initial phase of the MAGICapp evaluation which involves a 10-week alpha phase, where we plan to develop mechanisms to publish content stored in MAGICapp on the NICE website and to develop and quality assure content directly in MAGICapp. This work is in progress and scheduled to complete in mid-February 2018. • Work to upgrade our evidence management tools in partnership with UCL is being further extended to the end of February 2018. It is expected that a new web-based version of the EPPI Reviewer software will be available for use in NICE in early 2018/19. An important aspect to this work is the alignment and strategic fit in terms of evidence management process for NICE and NCCs and also act as a key enabler for the surveillance of evidence objectives outlined for the Transforming Guidance Development project. • Work to bring efficiencies to the external consultation process is continuing. The 'Alpha' phase of the work successfully passed the 'service standard assessment' of the Department of Health digital team and the business case for the 'Beta' phase was submitted in December. A response is expected in early January 2018 after which work will resume.

Deliver digital service projects in line with the agreed investment priorities for 2017/18 and NICE's business plan objectives. (continued)	• NICE Website: continue to improve user experience across our sites. Other priorities to be confirmed through Q4 2016/17.	**NICE website:** • Work to upgrade the search technology across the NICE website services (including the Pathways search) completed in July 2017. A follow up project to optimise the use of the new technology will complete in January 2018. • Digital Services and the Communications team are now implementing their new 'user journey' approach to delivering continuous strategic improvements to the NICE website, initially focusing on two key journeys: accessing guidance and stakeholder registration.
	• NICE Evidence Services: continue to enhance operations stability and performance. • Other projects arising during the year:	**NICE Evidence Services:** • Search technology replacement was extended to all Evidence Services and this concluded at the end of August 2017. A follow up project to optimise the use of the new technology will complete in January 2018. • **Completed** - Link resolver was implemented as planned during October 2017. • **Completed** - A project to refresh UK Pharmascan reporting went live in November 2017. In addition, Evidence Resources are supporting the Centre for Health Technology Evaluation with managing an external digital agency to undertake the design and build of the new MedTechScan database. The discovery phase completed in December 2017 with the development of a prototype, a summary of findings from stakeholder engagement and a technical proposal for the build. A decision to proceed with the Beta phase of the project (main build) will be subject to a decision by NICE's SMT and the MedTechScan Project Board chaired by NHS England, the project commissioner, in January 2018.

Maintain operational service delivery and implement service improvements based on user insights and service performance against key performance indicators.	• Maintain the NICE Digital Services to agreed service levels (in terms of service availability and time to defect resolution). • Maintain digital services performance indicators in line with business priorities and user insights. • Continue to translate data and observations about the performance of NICE Digital Services into actionable improvement proposals. • In response to the above, continuously improve NICE Digital Services in line with agreed investment priorities.	• **On track** - NICE Digital Services operated within the generic agreed service levels for availability. Defect resolution SLAs were adhered to in 57% of cases. In November and December 136 defects were closed. • **On track** - Service Groups' usual reports and insights have been distributed and additional analysis has been done for the Structuring Guidance Authoring project and the Topic page work. • **On track -** a 'journey map process' to support iterative changes to the NICE website has been agreed with the Communications team. • **On track** – maintenance and continuous improvement priorities for 2017/18 are being agreed with service groups and shared with SMT. In November and December, 23 Change Control Requests were completed. • **Completed** - Work to build automated testing capabilities for our developers ended in September 2017.

Maintain and where possible improve the productivity of the digital services function	• Progressively introduce new working practices that will lead to increased knowledge sharing amongst the multi-disciplinary teams and increase throughput.	• **On-going** – in early June 2017, three new multidisciplinary 'Service Delivery Teams', Evidence, Content and Channels, were launched. Work continues to ensure the roles and responsibilities of different team members within the multidisciplinary teams remain clear.
	• Continue to reduce the end to end delivery time of small changes to services ensuring shorter cycles of improvement and learning.	• **Completed** – JIRA, our new platform for managing software projects, was rolled-out across the digital services team between August and October 2017 with all activity now managed through this platform.
	• Continue to develop semantic capability to support our products and platforms, including a revised classification vocabulary and a metadata repository.	• Software used to manage NICE ontology was decommissioned during the autumn. Software options for managing NICE's classification vocabulary and a metadata repository will be explored alongside broader data management and governance considerations during spring 2018.
	• Continue to optimise the hosting infrastructure.	• **On-going** – Shortlisting for re-procuring the service took place during December 2017.
	• Ensure the business benefits expected from projects run under the Digital Strategy are clearly defined in project documentation and that processes are in place with teams across NICE to ensure the realisation of benefits is monitored and reported.	• **On track-** The first phase of a business analysis and costing project to assess the savings expected from the External Consultation project concluded in November 2017. The work continues to identify the key areas of potential efficiency along the guidance development process. This will support the prioritisation of our digital transformation investments during 2018/19.
	• Recruit permanent staff in line with budget assumptions. Monitor success of recruitment and adjust budget assumptions accordingly.	• **On-track** – a service delivery manager is joining the team in January 2018. The recruitment of the Associate Director for Service Delivery and Programme Management is under way. Four other positions (a tester, a senior developer, a web engineer and a portfolio performance analyst) are still open.
	• Support retention and development of talents.	• No leavers this period.

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	• **On-going –** NICE attended its first Professional Record Standard Board (PRSB) Advisory Board in October 2017. The PRSB's mission is to support the development of standards in clinical records. NICE is discussing with the PRSB how it can sustainably inform the development of new record standards. • In December, NICE also met with the NHS Digital's Standards Transformation team (overseeing the implementation of SNOMED across the NHS systems) to discuss if / how SNOMED could be applied to NICE guidance and to identify potential use-cases.
	• Maintain an ongoing relationship with the nhs.uk project (re-development of NHS Choices).	• **No further progress this period**. NICE is kept abreast of changes to nhs.uk, especially its topic pages and new medicine pages.
	• 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.	• **No further progress this period.**
	• Fully capitalise on existing relationships with specialists in the evidence management field and extend to other potential partners.	• **On track** - currently enabled through our partnership with the EPPI-Centre at UCL and their link with NaCTeM at Manchester University. Other connections are being made with King's College London to support the management of 'provenance' information in the guideline production process. Our team has also gained a better understanding of the work of the National Institute for Health Research Innovation Observatory (NIHRIO) and how it may support the process of automated surveillance for NICE.

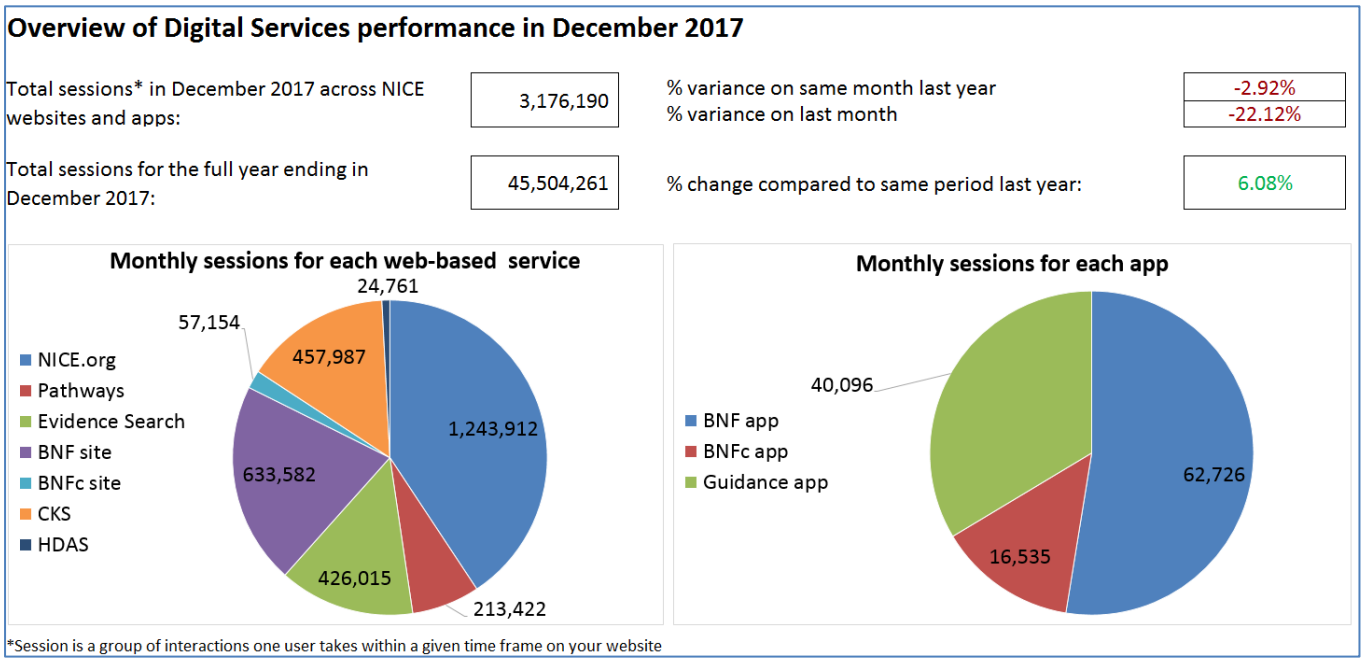
IP and Content Business Management		
Actively pursue revenue generation opportunities associated with international interest in the expertise of NICE and the re-use of NICE content and quality assurance.	• Articulate and promote NICE's value propositions associated with the re-use of NICE content outside of the UK – this will include 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 – this will include supporting international delegations and enabling targeted advisory services.	**On-track:** • **Completed** - infrastructure and standard operating procedures for generating revenue associated with international sales are in place. The NICE website includes a specific page for international NICE services. This includes details of how international organisations can request NICE to host a delegation or deliver targeted advisory services overseas.

Directorate wide		
Subject to available resources, work with partner agencies to continue to engage and support the wider app evaluation programme.	• Liaise with PHE, NHS England, NHS Digital, the Office for Life Sciences (OLS), MHRA and CQC to ensure that NICE Health App Briefings are promoted and are part of wider app evaluation discussions.	• **No further progress this period.** NICE continues to monitor NHS England's and NHS Digital's strategy for assessing digital apps. NICE is a member of a new 'Digital Clinical Council' whose role in the process of digital assessment has yet to be fully defined. NICE has offered to undertake further app briefings for the system, subject to funding and commissioning.
Implement the second year of a three year strategy to manage the reduction in the Department of Health's Grant-In-Aid funding.	• Maintain focus on identifying new cost saving opportunities arising across the directorate portfolio of activities. • Review and renegotiate supplier contracts in line with savings target and schedule agreed and monitored by the SMT.	**On-track** • All savings targets including renegotiated new contracts are in line with agreed savings plans for 2017/18. • A management of change exercise completed in the small Intellectual Property and Content Business Management team. The change will contribute to the directorate's savings plans in 2018/19.

Performance of the live services supported by NICE digital services

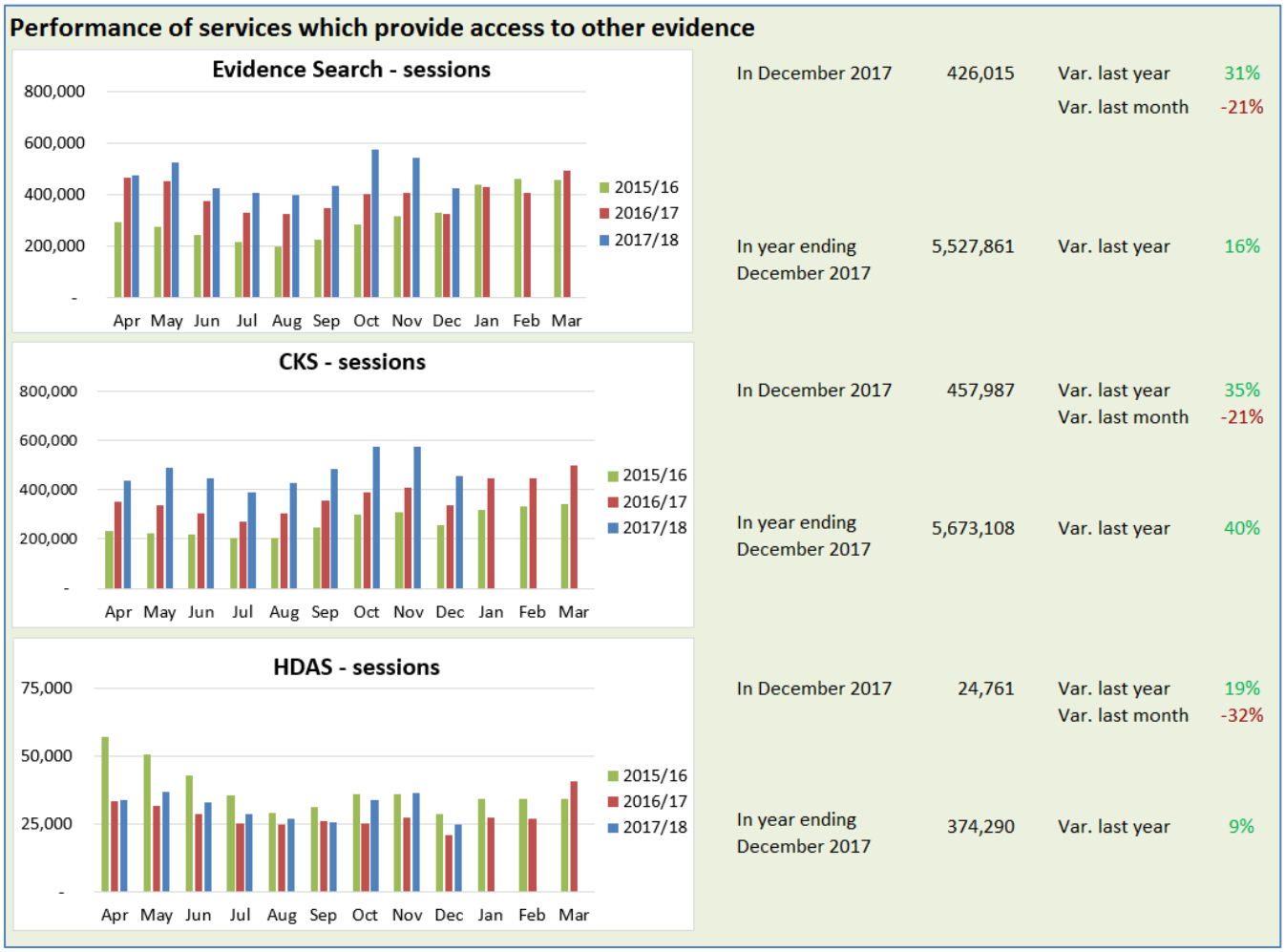
5. Figure 1 below summarises the position of all NICE's digital services at the end of December 2017, exposing the relative size of the different externally facing services of NICE, measured in number of 'sessions' (the number of visits to a website within a date range). There were over 45 million sessions across all digital services in the last twelve months which translates to a 6% increase in comparison with the same period in 2016/17. NICE services were stable between October and November 2017 with a seasonal decline of 22% between November and December 2017.

Figure 1: Overview of NICE's digital services performance as of December 2017



6. Figure 2 below details the performance of the 3 services which provide access to evidence beyond that produced by NICE: Evidence Search, Clinical Knowledge Summaries (CKS) and HDAS. October was a strong month for all services and this was replicated in November when the results were particularly strong for CKS and HDAS. December saw the usual seasonal drop in sessions but performance against 2016/17 remained strong.

Figure 2: Performance of services providing access to 'other evidence' as of December 2017



7. Figure 3 summarises the performance of our BNF services, the microsites and the apps.

8. The new BNF and BNFc microsites are recovering gradually from the decline in sessions experienced in July and August. BNF sessions for November 2017 are 17% greater than in November 2016, and BNFc sessions are 21% lower for November 2017 compared with the previous year.

9. Sessions on the BNF and BNFc apps continue to decline - the BNF app has received 84% fewer sessions than December last year whereas BNFc app 82% fewer, reflecting the withdrawal of the NICE apps in December in favour of the open access BNF apps produced by the BNF publisher.

Figure 3: Performance of services providing access to BNF content as of December 2017

Risks

10. There were 5 Amber risks reported by the Evidence Resources directorate to the Senior Management Team in the previous period. One of these risks, "the transition to the new national Link Resolver provider service is not successful, resulting in a reduction in the ability of users to access the journal content they have purchased", was removed in December 2017 following its successful mitigation and completion of the migration to the new Link Resolver provider.

National Institute for Health and Care Excellence

Health and Social Care Directorate progress report

1. This report sets out the performance of the Health and Social Care Directorate against our business plan objectives for the period November - December 2017. It also highlights notable developments that have occurred during the reporting period.

Performance

2. The directorate successfully delivered a number of key products during November - December 2017 including: 1 adoption support product; 2 evidence summaries on the use of medicines; 1 IAPT assessment briefing; 4 medicines evidence commentaries and 1 social care quick guide. Details of these publications are given in Appendix 1.

3. In September and October 2017, an online survey was widely distributed through multiple channels to determine how and why people use NICE guidance and quality standards. A total of 860 responses were received and, of these, 566 respondents provided details of the sector in which they work: 74% worked in healthcare; 10% in public health; 9% in social care; and 6% in education.

4. A few highlights from the survey responses include:

    - NICE guidance and quality standards were ranked as the most important resources to inform decisions about improving local practice, compared to other external information sources. The majority of users stated that NICE guidance had improved their local services at various levels, and their overall experience was positive.
    - 55% of respondents considered that short summaries or factsheets containing key recommendations would make it easier to use NICE guidance.
    - 44% of respondents asked for more practical advice about local implementation and support. However, there was variation in the reasons, experience, and expectation of putting different types of guidance into practice, depending on the audience.
    - 43% asked whether NICE could broaden the scope of evidence, for example by incorporating people's real life experiences of their condition, treatment or a service.

5. The full report with an outline action plan will be presented at NICE's public board meeting in March 2018.

Table 1 Performance update for November - December 2017

Objective	Actions	Update
Publish guidance, standards and indicators, and provide evidence services against the targets set out in the Business Plan	Deliver standards, indicators and other products in accordance with the schedule set out in the Business Plan	Products delivered as planned (see Figure 1, Figure 2 and Appendix 1 for details of key outputs). Adoption Support Products: At the end of December, the delivery of Adoption Support Products will be ahead of schedule. However, by the end of March 2018, it is expected that 4 out of the 5 planned adoption support products will be completed. This is within the 80% tolerance as indicated in the NICE Business Plan Balanced Scorecard. This is because one of the resources (Senza spinal cord stimulation) will now publish in 2018/19 as the related guidance publication date has been delayed as a result of a larger than anticipated volume of consultation comments.
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	Develop an Accelerated Access Review implementation plan and report to the Board on progress	Interactions between NICE and the national and regional Academic Health Science Networks (AHSNs) have been mapped to ensure alignment, and to support the development of objectives in the 2018/19 business plan. NICE has been invited to be a member of the AHSN strategic development board, which has been established to set the future direction of the AHSNs. The NICE Implementation Collaborative (NIC) Board will meet in February to consider a list of potential adoption projects. The future alignment of the Innovation Scorecard to clinical networks is being taken forward with partner organisations.

Objective	Actions	Update
Deliver a programme of strategic and local engagement	Support the use of NICE guidance and standards through the work of other national organisations and by working with local health and care systems	NHS England (NHSE) NICE is working with NHS England to develop a process for considering resource impact of guidelines in advance of publication, with the view to providing advice to the wider system.
		NHS Improvement (NHSI) NICE has produced a further statement of its pledges to the delivery of the system-wide Developing People Improving Strategy one year on to ensure it is incorporated in the business planning process. The partnership agreement has been developed and is awaiting sign off from NHSI.
		Public Health England (PHE) There are regular on-going strategic meetings between NICE, PHE and the Department of Health. These meetings are to ensure that the principles for ways of working agreed between PHE and NICE of complementarity, singularity and inclusivity are implemented. In addition, at the beginning of December, there was an annual meeting between the two chief executives to review these partnership arrangements. PHE is a formal supporting organisation for the 3 public health quality standards published this year: oral health in care homes; physical health of people in prisons and HIV testing: encouraging uptake. PHE in the regions: North: • NICE, PHE and NHSE have designed and delivered 2 workshops on 'behaviour change and service improvement' for Sustainability and Transformation Partnerships (STPs).

Objective	Actions	Update
		Midlands and East: • NICE has worked with PHE's Midlands and East Regional Office Cardiovascular Disease (CVD) Prevention task group to co-ordinate system wide support to STPs. London: • NICE is a member of the London CVD prevention group and attended the first strategy meeting in October. The meeting was led by PHE's London Regional Office and supported by NHS RightCare. South: • NICE is a member of the PHE South CVD Prevention Board, a sub-committee of the regional STP Board. Working with other Arm's Length Bodies and STPs the Board has developed a draft set of ambitions focusing particularly on hypertension and atrial fibrillation. • Tailored support has been offered to one STP on NICE resources to help them identify opportunities for returns on investment in public health.
		Care Quality Commission (CQC) The first workshop on learning disabilities was held with CQC. NICE guidance and quality standards were used to inform training for CQC social care inspectors. Two further workshops in January and March have been agreed. A further meeting was held with the CQC Academy in December to progress the development of a webinar for inspectors (social care, hospital and primary medical services) to support them to use NICE guidance and standards. However this may not happen before the end of March as personnel at CQC have changed and so actions have been delayed by CQC.

Objective	Actions	Update
		Sustainability and Transformation Partnerships (STP) A cross institute task and finish group has been established to oversee the development of the NICE support offer for STPs.
		Social Care The 7 regional events for social care have now been delivered in conjunction with Skills for Care. The presentations/workshops for regional managers networks tended to focus on medicines management at their request. NICE, NHSE, the Registered Nursing Home Association, Social Care Institute for Excellence (SCIE) and the Local Government Association (LGA) held a meeting to progress Quality Matters priority 5. November saw the largest increase in subscribers to the NICE in Social Care monthly e-bulletin, not related to people signing up at a particular event. The annual target of 243 additional subscribers has already been doubled, and November saw an additional 77 people choosing to receive regular updates about our work in social care.
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	The first of the new topic-based reports focusing on specific clinical areas has been developed. The report centres on cancer referral and uptake of new medicines and is due for review by NICE's Board in January 2018.
	Consult with the research community through the Implementation Strategy Group	The implementation strategy group met on 29 November 2017. The group heard from the Horizons Transformation team about the effectiveness of using social media and how this could be utilised by the field team to support engagement with the field. The group also heard the findings from the implementation online survey and a consideration of NICE's position in relation to improvement versus implementation science. In this context they confirmed that the current NICE implementation strategy is valid.
Promote NICE's work and help users	Deliver 50 shared learning examples	Thirty-one shared learning examples have been published since April to end December, in line with planned performance.

Objective	Actions	Update
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	Deliver 30 endorsement products	Twenty-two endorsement statements have been published since April to end December, 1 more than planned.
	Support shared decision making within NICE through delivery of commitments in the action plan of the Shared Decision Making Collaborative	We are continuing to take forward the NICE actions from the Shared Decision Making Collaborative meeting earlier in the year. This includes close working with NHS England, particularly in relation to musculoskeletal disorders, as reflected in a recent BMJ publication: Leng GC, Ingham Clark C, Brian K, Partridge G. Collaborating to improve shared decision making. http://bmj.com/cgi/content/full/bmj.j4746.
	Develop the resource impact team to enable it to deliver the budget impact assessments as part of the TA and HST programmes	Resource impact support statements were produced for the 43 company submissions received during the period April - December.
Promote collaboration on digital initiatives and content strategy across ALBs and with academic establishments and other external stakeholders	Support NHS England to deliver the digital IAPT pilot programme (Improving Outcomes in Psychological Therapies)	Three IAPT assessment briefings (IABs) have been developed. Two technologies have been assessed as provisionally suitable for IAPT. A third is eligible for development funding administered by NHS England. Two IABs expected to publish in December have been delayed until January due to the refinement of processes and a delay caused by non-quoracy at the November 2017 Expert Panel meeting. The programme is on track to deliver 6 by end of March 2018, in line with planned performance.

Figure 1 Performance against plan for Health and Social Care Directorate key publication outputs for period April to December 2017

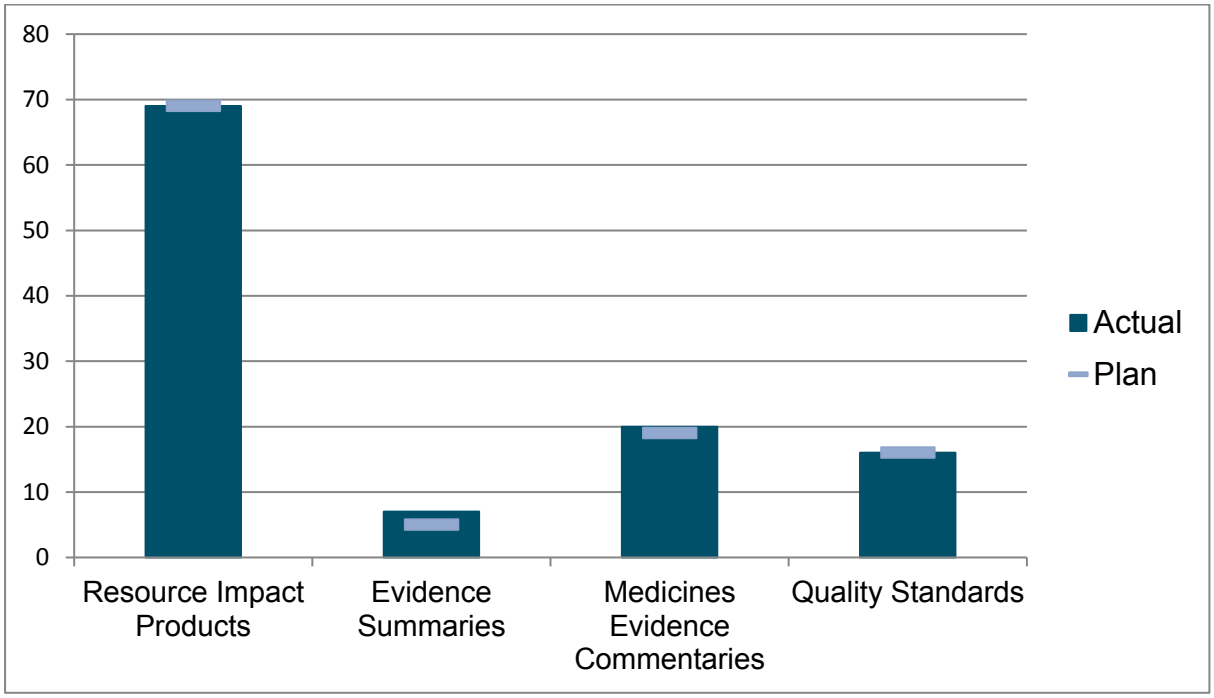
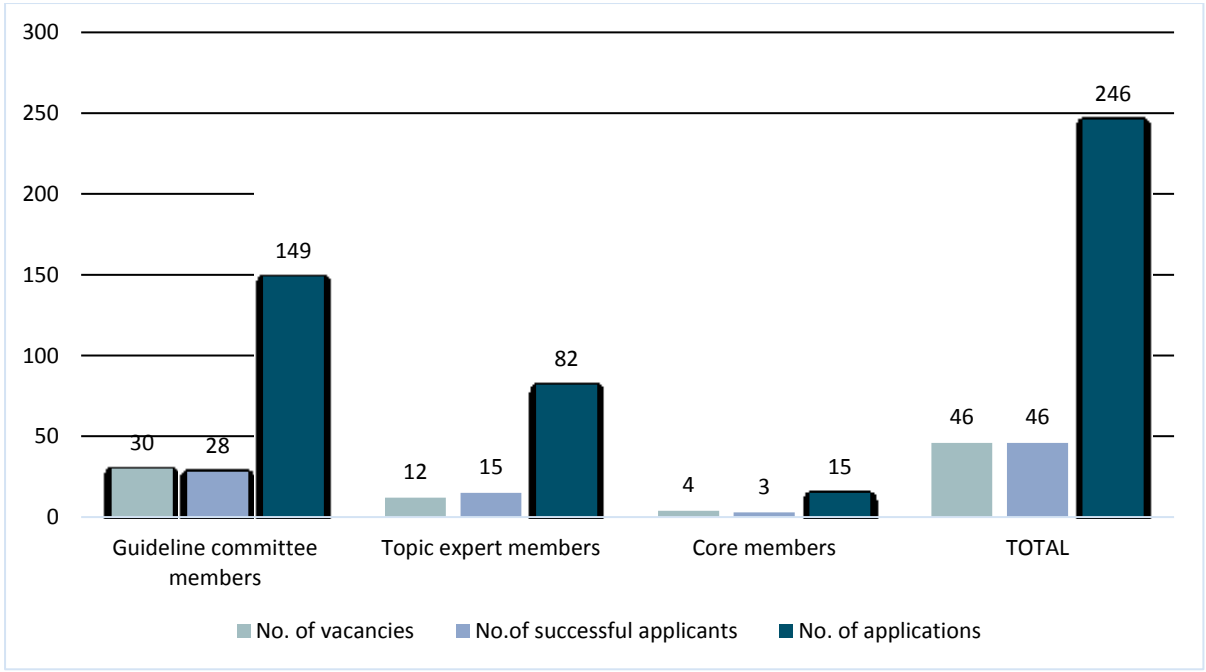


Figure 2 Patient & public committee member recruitment for the period April to December 2017



6. Overall, the ratio of applications to vacancies was 5.3:1; the target being 2:1 or greater. In addition 61 people gave testimony to NICE's committees and 11 people were invited to join committees as specialist members.

Notable Developments

7. This section includes significant developments or issues that occurred during November - December 2017.

Strategic Engagement

Health

8. NICE is preparing a response, due for submission in January, to the joint consultation published by the Care Quality Commission (CQC) and NHS Improvement. The consultation proposes a new approach in which non-specialist trusts will receive a rating for their use of resources alongside CQC's rating of quality. NICE's response will highlight where our guidance might support the use of resources at NHS trust level and recommends that the new approach retains a balance between quality, performance, cost and any potential environmental and social impact.

Social care

9. NICE was invited to be a member of the CQC's system reviews expert advisory group and attended the first meeting in December. These reviews of the NHS and local government provide an opportunity to improve the quality of care for people across the health and social care sectors which includes the use of NICE guidance and standards.

Public health

10. Under the umbrella of the Points of Engagement meeting between DH, PHE and NICE, we are reviewing how our interactions work across a range of themed sub-groups. This is to ensure that time and expertise are used as efficiently as possible, taking into account which guidance topics are in development. A particular focus over the next year will be on managing common infections, an area where the communications teams of PHE and NICE will work together to ensure aligned messages go out to stakeholders and the public.

Public involvement and social media

11. From August 2017, the Public Involvement Programme began piloting its new social media strategy on Twitter. The approach is part of the public involvement strategic review, and aims to encourage people to communicate directly with NICE and enhance NICE's existing approaches to social media. The results to date have been positive, including an increase in daily impressions, likes and retweets as well as overall follower numbers. A larger than expected number of applications was received for lay members to join the advisory committee for the quality standard on promoting health and preventing mortality in black, Asian and other minority ethnic groups.

Quality standards library update

12. The quality standards programme was set up in 2009, and formally established in legislation in the Health and Social Care Act 2012. Over this period, a wide range of quality standards have been referred to NICE and there is now a library of 242 topics.

13. NICE has published, or started to develop, 180 of these quality standards (74% of the library). These quality standards set out priority areas for quality improvement for the health and care system, identifying areas where there is variation in care and providing information on how to measure progress.

14. Quality standard topics cover the three sectors: healthcare, such as sepsis, breast cancer and psychosis and schizophrenia; public health, such as healthy workplaces, oral health promotion and preventing harmful alcohol use; and social care including managing medicines in care homes. There are also a number of topics that support integration and support quality improvement across sectors including skin cancer, autism and transition between inpatient hospital settings and community or care home settings.

15. Quality standards are used at many levels across the system. At a national level they inform significant audits (stroke, chronic obstructive pulmonary disorder and heart failure) and support CQUINS (staff health and well-being). At a local level, quality standards are regularly used to inform service specifications and quality improvement projects

Risks

16. Two new risks have been identified in this reporting period which are detailed in the paragraphs and table below.

17. A review of the Quality and Outcomes Framework (QOF) was outlined in NHS England's General Practice Forward View (NHS England, 2016). A review of the QOF may result in indicators that are based on NICE guidance being removed from the framework. In addition the QOF provides valuable data on the care provided in general practice, these data support work on the uptake and impact of NICE guidance.

18. Additional administrative capacity will be required during 2018/19 to support the replacement of NICE's electronic customer relationship management (CRM) system, which is also used by the Field team to record their activities. The existing system is limited in its ability to store and extract data, and the new system will reflect and report activity more accurately.

Risk	Key controls	Risk rating now	Risk rating year end
The NHS England review of the Quality Outcomes Framework results in changes that reduce the need for indicators developed by NICE.	Close involvement of the NICE Team in the QOF review process, including as part of the advisory board. Continuing to review opportunities for the role of NICE indicators in a range of external work programmes.	High	Moderate
There is a financial risk associated with the additional administrative capacity required to support the replacement of NICE's CRM system and an associated reputational risk as the existing system is unable to maintain accurate data.	Continue to contribute to the work required to introduce the replacement system. Additional administrative capacity provided during 2017-18 to enable more rigorous data verification.	Moderate	Moderate

Appendix 1 Guidance published since April 2017

The table below provides a list of guidance and advice produced between April and December 2017. For the Health and Social Care Directorate this includes adoption support products (ASP), evidence summaries (ES), IAPT assessment briefings (IAB), medicines evidence commentaries (MEC), mental health care pathways (MHCP), quality standards (QS) and social care quick guides (SCQG).

Guidance title	Publication date	Product
Virtual chromoendoscopy (VCE) using NBI, FICE or i-scan to assess colorectal polyps of 5 mm or less during colonoscopy [implementation statement]	Dec 2017	ASP
SecurAcath for securing percutaneous catheters	June 2017	ASP
Evidence review: Gemcitabine plus capecitabine for adjuvant treatment in resected pancreatic cancer	Dec 2017	ES
Antimicrobial prescribing: Ceftazidime/avibactam	Nov 2017	ES
Evidence review: Zinc salts for Wilson's disease	Sept 2017	ES
Early breast cancer (preventing recurrence and improving survival): adjuvant bisphosphonates	July 2017	ES
Preventing recurrence of Clostridium difficile infection: bezlotoxumab	June 2017	ES
Obese, overweight with risk factors: liraglutide (Saxenda)	June 2017	ES
Non-cystic fibrosis bronchiectasis: inhaled tobramycin	April 2017	ES
New MHRA drug safety advice: September to November 2017	Dec 2017	MEC
Chronic pain: patient outcomes with dose reduction or discontinua tion of long-term opioid therapy	Nov 2017	MEC
Effect of antibiotic stewardship on the incidence of infection and colonisation with antibiotic-resistant bacteria and Clostridium difficile infection: a systematic review and meta-analysis	Nov 2017	MEC
Antibiotic prescribing: adverse events with antibiotic use in people who are hospitalised	Nov 2017	MEC
Risk of death among users of Proton Pump Inhibitors: a longitudinal observational cohort study of United States veterans	Oct 2017	MEC
Topical Corticosteroid Phobia in Atopic Dermatitis: A Systematic Review	Oct 2017	MEC
Switching to biosimilar infliximab in people with stable disease	Sept 2017	MEC

Guidance title	Publication date	Product
New MHRA drug safety advice: June to August 2017	Sept 2017	MEC
Patient preferences for cardiovascular preventive medication: a systematic review	Aug 2017	MEC
Hyperlipidaemia: clinical outcome data for evolocumab	Aug 2017	MEC
Statin adverse effects: study suggests people are more likely to experience muscle aches and pains if they are expecting them	July 2017	MEC
Pain management: Initial opioid prescriptions and likelihood of long-term opioid use	July 2017	MEC
New MHRA drug safety advice: March to May 2017	July 2017	MEC
Medicines adherence: medicines problems associated with use of multicompartment compliance aids in a UK community setting	June 2017	MEC
Depression treatment and mortality after myocardial infarction	June 2017	MEC
Statin therapy: could liver function monitoring be reduced	May 2017	MEC
Stopping or reducing antipsychotics in people with learning disabilities who have challenging behaviour	May 2017	MEC
Bioequivalence between biosimilar and reference tumour necrosis factor–alpha inhibitors	April 2017	MEC
Biosimilar infliximab: a successful managed switch programme in people with inflammatory bowel disease	April 2017	MEC
Primary prevention of stroke and transient ischaemic attack: UK observational study suggests under-prescribing of prevention medicines	April 2017	MEC
Cerebral palsy in children and young people	Oct 2017	QS
End of life care for infants, children and young people	Sept 2017	QS
HIV testing: encouraging uptake	Sept 2017	QS
Physical health of people in prisons	Sept 2017	QS
Rehabilitation after critical illness in adults	Sept 2017	QS
Sepsis	Sept 2017	QS
Transition between inpatient mental health settings and community or care home settings	Sept 2017	QS
Low back pain and sciatica in over 16s	July 2017	QS
Chronic kidney disease in adults	July 2017	QS
Oral health in care homes	June 2017	QS
Haematological cancers	June 2017	QS

Guidance title	Publication date	Product
Liver disease*	June 2017	QS
Multimorbidity	June 2017	QS
Violent and aggressive behaviours in people with mental health problems	June 2017	QS
Osteoporosis	April 2017	QS
Discussing and planning medicines support	Nov 2017	SCQG
Understanding intermediate care, including reablement	Oct 2017	SCQG
Moving between hospital and home, including care homes	Sept 2017	SCQG
Recognising and preventing delirium	July 2017	SCQG
Building independence through planning for transition	June 2017	SCQG

*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.