PUBLIC BOARD MEETING

There will be a Public Board Meeting on the 20th January 2016 at 1.45pm
In the Alamein Room, City Hall, Malthouse Lane, Salisbury, Wiltshire, SP2 7TU

AGENDA

16/001 Apologies for Absence
To receive apologies for absence

16/002 Declarations of Interests
To record any conflicts of interest

16/003 Minutes of the Board Meeting
To approve the minutes of the meeting held on 18th November 2015

16/004 Matters Arising
To consider matters arising from the minutes of the last meeting

16/005 Chief Executive’s Report
To receive the Chief Executive’s report
Andrew Dillon, Chief Executive

16/006 Finance and Workforce Report
To receive a report on NICE’s financial position to the end of December 2015 and an update on the workforce strategy
Ben Bennett, Director, Business Planning and Resources

16/007 Annual Uptake Report
To approve the report on the uptake of NICE guidance
Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate

16/008 Accelerated Access Review: NICE Response to Interim Report
To note NICE’s response to the Review’s Interim Report
Andrew Dillon, Chief Executive

16/009 Resource Impact in Guidelines
To agree the advice and principles and approve the update to the guidelines manual
Professor Mark Baker, Director, Centre for Clinical Practice
Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate
16/010 **Board Effectiveness Review**
To agree the approach to the review
*Andrew Dillon, Chief Executive*

16/011 **Board Appointments**
To note the non-executive director appointment and agree the revised membership of the Remuneration Committee
*Professor David Haslam, NICE Chair*

16/012 **Rapid Reconsideration of Drugs Currently Funded through the Cancer Drugs Fund**
To note the proposed process and approve the constitution of an Appraisal Committee
*Professor Carole Longson, Director, Centre for Clinical Practice*

**Director's Report for Consideration**

16/013 Centre for Clinical Practice
*Professor Mark Baker, Director, Centre for Clinical Practice*

**Directors’ Reports for Information**

16/014 Centre for Health Technology Evaluation

16/015 Communications Directorate

16/016 Evidence Resources Directorate

16/017 Health & Social Care Directorate

16/018 **Any Other Business**
To consider any other business of an urgent nature

**Date of the Next Meeting**
To note the next Public Board meeting will be held on
Wednesday 16th March 2016 in the Education Centre, Morriston Hospital, Swansea, SA6 6NL
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
Dr Maggie Helliwell  Non-Executive Director
Professor David Hunter  Non-Executive Director
Tim Irish  Non-Executive Director
Professor Finbarr Martin  Non-Executive Director
Professor Rona McCandlish  Non-Executive Director
Andy McKeon  Non-Executive Director
Bill Mumford  Non-Executive Director
Linda Seymour  Non-Executive Director
Jonathan Tross  Non-Executive Director

Executive Directors

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

Directors in attendance

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

In attendance

David Coombs  Associate Director – Corporate Office (minutes)
Mirella Marlow  Programme Director – Centre for Health Technology Evaluation

15/091 APOLOGIES FOR ABSENCE

1. Apologies were received from Professor Carole Longson who was represented by Mirella Marlow.
15/092 CONFLICTS OF INTEREST

2. None declared.

15/093 MINUTES OF THE LAST MEETING

3. The minutes of the meeting held on 16 September 2015 were agreed as a correct record subject to a minor correction to paragraph 5.

15/094 MATTERS ARISING

4. The Board reviewed the actions arising from the Board meeting held on 16 September 2015. It was noted that:

- The Health and Social Care Directorate Report included further information on NICE’s working relationship with Public Health England and NICE’s support for disinvestment, and that activities in these areas remain ongoing.

- The actions relating to the equality objectives and the staff survey are in hand for future implementation.

- A number of initiatives are underway to develop NICE’s engagement with primary care, including the establishment of a GP advisory group led by David Haslam.

- A future Health and Social Care Directorate Report will include information on the forthcoming review of the implementation metrics.

15/095 CHIEF EXECUTIVE’S REPORT

5. Andrew Dillon presented his report, describing the main programme activities to the end of October 2015 together with a summary of NICE’s financial position for the same period. The report also included a six monthly progress update on the balanced scorecard. He highlighted minor formatting errors in graph 3 of the report.

6. Following a question from Linda Seymour, Jane Gizbert provided further information on the ‘RepTrack’ project. She confirmed that the pilot remains at an early stage and NICE is now the only participant. Further updates will be included in the Communications Directorate reports.

ACTION: Jane Gizbert
7. Maggie Helliwell referred to the balanced scorecard report and asked whether the targets on the publication of public health guidelines, local government briefings and evidence updates will be met at year-end. Gillian Leng confirmed that the public health guidelines target should be met, whilst there are forthcoming changes to NICE’s publications for local government. Mark Baker advised that evidence updates are now part of the guideline surveillance process, and the metric does not reflect the new process. The Board therefore agreed that the balanced scorecard measure should be updated accordingly.

**ACTION:** Andrew Dillon

8. In response to a question from David Hunter, Andrew Dillon provided further information on the proposed action to develop key performance indicators in response to a Triennial Review recommendation. He confirmed that the Board would be kept updated on progress with this.

9. The Board received the report.

**15/096 FINANCE AND WORKFORCE REPORT**

10. Ben Bennett presented the report which outlined the financial position as at 31 October 2015 and provided an update on the workforce strategy. He stated that the forecast underspend is likely to reduce from that in the report due to increased liabilities from the National Collaborating Centre reconfiguration, together with recent decisions by the Senior Management Team to utilise non-recurrent expenditure. He highlighted the mid-year position against the measures of financial control and confirmed that the aged debt analysis was broken down by the value and percentage of invoices.

11. Following a question from Tim Irish, Ben Bennett confirmed that the report reflects the staffing establishment in the financial plan. Any vacancies will be closely scrutinised as part of the budget setting process to ensure posts are removed from the establishment if they are no longer required.

12. Jonathan Tross, Chair of the Audit and Risk Committee, noted that forecast income is above plan which he felt is a positive indication of the regard in which NICE is held by those wishing to commission activity from NICE. He noted though, the potential risks should this reflect a wider shift away from general funding towards commissions for specific pieces of work.

13. The Board received the report and agreed that the Audit and Risk Committee should receive a further workforce update, particularly in relation to the initiatives to support middle management.

**ACTION:** Ben Bennett
15/097 INTERVENTIONAL PROCEDURES PROGRAMME MANUAL UPDATE

14. Mirella Marlow presented the proposed amendments to the Interventional Procedures (IP) Programme Manual following public consultation. She highlighted the group with health service and Government representatives from Scotland, Wales and Northern Ireland which is drafting a replacement for the Health Services Circular that established the function of the IP programme. The aim is to complete this work for April 2016.

15. Andy McKeon asked whether the requirements on companies to provide data should be strengthened, similar to those for other NICE programmes. Mirella Marlow advised that the approach within the manual reflects that the IP programme often assesses a procedure rather than a device.

16. The Board approved the amendments to the Interventional Procedures Programme Manual for publication and thanked the programme team for their work.

15/098 ACCELERATED ACCESS REVIEW: INTERIM REPORT

17. Andrew Dillon presented the interim report of the Accelerated Access Review and summarised the key implications for NICE. He confirmed that NICE will continue to actively engage with the review during the development of the final report.

18. The Board discussed a number of aspects of the report including patient engagement, potential changes to NICE’s technology appraisal programme, and the use of NICE’s recommendations by local Drugs and Therapeutics Committees. In relation to this latter point, it was noted that given current resources NICE cannot formally audit compliance with its recommendations, but the Field Team and the Medicines Prescribing Associates could provide useful insight into any particular concerns around uptake in a local area.

19. The Board noted the report and agreed that in addition to the ongoing engagement with the review, NICE should formally respond to the interim report.

ACTION: Andrew Dillon

20. The Board asked to be updated on the review’s emerging proposals as they may affect NICE, prior to the publication of the final report.

ACTION: Carole Longson

15/099 NICE RESPONSE TO THE TRIENNIAL REVIEW

21. Andrew Dillon presented the report that outlined the action taken, and that planned, in response to the Triennial Review of NICE.
ITEM 1

22. David Hunter asked about the extent to which the Field Team could increase its support to local providers and commissioners given its current resources. Gillian Leng stated that it will be challenging to secure a direct replacement for the team’s Associate Director who is leaving shortly; therefore the opportunity will be taken to review the team’s capacity and activities. Andrew Dillon outlined how the team has reallocated resources to support the Greater Manchester devolution, but noted the need to consider how to enable NICE to engage with new initiatives such as GP federations. David Haslam highlighted the Board’s support for the Field Team’s work and stated that it would therefore be interested in the outcomes of the review.

23. In response to a question from Bill Mumford, Gillian Leng updated the Board on engagement with the Social Care Institute for Excellence (SCIE). She noted the need to balance the contractual relationship regarding guidance development with SCIE’s potential broader support and advice to NICE on social care.

24. The Board noted the report and agreed that a further progress update should be brought to the March 2016 Board meeting, with an interim update included in the January Chief Executive’s Report as part of the update on consolidated priorities.

ACTION: Andrew Dillon

15/100 REVIEW OF THE BOARD COMMITTEES’ TERMS OF REFERENCE AND STANDING ORDERS

25. Ben Bennett presented the proposed amendments to the terms of reference and standing orders of the two Board Committees – the Audit & Risk Committee and the Remuneration Committee. Linked amendments have also been made to Institute’s standing orders and standing financial instructions.

26. The Board approved the amendments.

15/101 DIRECTOR’S REPORT FOR CONSIDERATION

27. Gillian Leng presented the update from the Health and Social Care Directorate, and outlined each programme’s progress against the business plan objectives and notable recent developments relating to the Directorate. She confirmed that the report on NICE’s support for disinvestment would be circulated to Board members and highlighted the work underway to review how this support is presented on NICE’s website.

28. Finbarr Martin asked whether the feedback from the consultation on the library of social care topics, together with NICE’s engagement with the NHS Five Year Forward View vanguards, provides an insight into how NICE’s guidance could evolve to support NICE adopting a broader system leadership role. Gillian Leng
confirmed that this analysis has not been formally undertaken, but agreed that it is important to ensure guidance is presented in a manner that supports its local implementation.

29. The Board noted the forthcoming improvements to the presentation of the quality standards on the website and agreed that the link would be circulated to Board members for information when launched.

**ACTION: Gillian Leng**

30. Jonathan Tross, Chair of the Audit and Risk Committee, highlighted the recent positive internal audit report on the quality standards programme. He stated that as part of its support for disinvestment, NICE should consider evolving its approach to recommendations to outline a range of prioritised options, taking account of the varying levels of available evidence.

31. The Board discussed NICE’s engagement and future relationship with Public Health England. Gillian Leng confirmed that the ‘Statement of Common Intent’ within the report remains draft, and that discussions continue on the respective roles and responsibilities of the two organisations.

32. Regarding the recent consultation on the library of social care related topics, Gillian Leng confirmed that criteria are in place to prioritise guidance topics. Finbarr Martin suggested that it would be helpful to communicate this process to stakeholders given the assurance it would provide.

33. The Board received the report and placed on record its thanks to Steve Sparks, Associate Director, Field Team who is shortly leaving NICE.

34. A member of the public asked about progress with the indicators in the report relating to Clinical Commissioning Groups and Health and Wellbeing Boards, and whether the engagement is desk-based. Gillian Leng confirmed that the Field Team will be focusing on this engagement in the remainder of the year, which is undertaken face-to-face.

**15/102-105 DIRECTORS’ REPORTS FOR INFORMATION**

35. The Board received the Directors’ Reports.

**15/106 COMMITTEE MINUTES**

36. The Board received the unconfirmed minutes of the Audit and Risk Committee held on the 28 October 2015. The Board noted that the strategic risks will be revised as part of the wider strategic planning process in light of the significant changes in NICE’s operating environment.
15/107 ANY OTHER BUSINESS

37. David Haslam noted this was Dr Maggie Helliwell’s last public Board meeting, and on behalf of the Board thanked Dr Helliwell for her significant contribution to NICE over the last eight years.

NEXT MEETING

38. The next public meeting of the Board will be held at 1.45pm, 20 January 2016 at City Hall, Malthouse Lane, Salisbury, SP2 7TU.
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CHIEF EXECUTIVE'S REPORT

This report provides information on the outputs from our main programmes for the 9 months to the end of December 2015, together with a summary of the financial position for the same period and comment on other matters of interest to the Board.

The Board is asked to note the report.

Andrew Dillon
Chief Executive
January 2016
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Chief Executive's report

1. This report sets out the performance of the Institute against its business plan objectives and other priorities, for the nine months ending 31 December 2015. It also reports on guidance published since the last public Board meeting in November and refers to business issues not covered elsewhere on the Board agenda.

Performance

2. The progress made against a consolidated list of objectives in our 2015/16 business plan, a list of priorities identified by the Department of Health, from the recommendations in the Triennial Review of NICE, published earlier this year, and from other sources, 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 2015 is set out in Graphs 1 and 2, below.

Graph 1: Main programme outputs: April to December 2015

Notes to Graph 1:

a) IP refers to Interventional procedures (minimally invasive surgery)
b) HST refers to the highly specialised technologies programme (drugs for very rare conditions)
c) Medicines summaries consist of both summaries (information on indications, harms and costs) of newly licensed medicines, and advice on the use of licensed medicines in diseases and conditions for which they are not licensed.

d) The variance is the difference between the target output for the reporting period, as set out in the business plan and the actual performance.

e) ‘Additional’ topics are either those which should have published in the previous financial year, or that have been added since the publication of the business plan.

4. Details of the variance against plan are set out at Appendix 3. Guidance quality standards and other advice published since the last Board meeting in November is set out Appendix 4.

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

Graph 2: Advice programmes main outputs: April to December 2015

Notes:

a) MIBs (medtech innovation briefings) are reviews of new medical devices
b) QP and Cochrane reviews report on opportunities for making better use of resources
c) Medicines summaries provide information on new medicines and on the unlicensed or off label use of medicine
Finance position (Month 9)

4. The financial position for the months from April to the end of December is an under spend of £3.8m (7.9%) against a budget of £37m (the position at the end of September was an under spend of £3.1m). £1.8m is attributed to the pay budgets with the remainder the result of under spending on the non-pay budgets. The forecast outturn is an under spend of £3.2m (5.1%). The position of the main budgets is set out in Graph 3. Further information is available in the Business Planning and Resources Director’s report.

Graph 3: Main programme spend: April to December 2015 (£m)
Appendix 1: Consolidated priorities for 2015-16

In managing its business during the 2015/16 financial year, NICE needs to take account of the objectives set out in its business plan, the organisational and policy priorities for NICE set out by the Department of Health, and the recommendations in the Triennial Review of NICE. In addition, NICE shares responsibility, with other national agencies, for the governance of NHS England’s Five Year Forward View. The Government’s spending review to 2020 and the development of a Shared Delivery Plan by the Department of Health and the Accelerated Access Review add additional tasks. The table below consolidates and tracks progress with the main elements of these influences on our work in 2015-16.

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<th>Theme</th>
<th>Source</th>
<th>Deliverable</th>
<th>Progress</th>
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<td>Impact</td>
<td>Triennial review</td>
<td>Work with the Department and NHS England to develop and publish a set of key performance indicators that reflect strategic objectives and assess the impact of the organisation, which are supported by appropriate input, output, or other performance targets.</td>
<td>There is unlikely to be an appetite to develop and allocate additional resources to maintain new indicators, given the current funding challenges and competing priorities in all three organisations. NICE will therefore undertake a piece of work to identify what existing data sources can be brought together to address this objective.</td>
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<td>NHS England Five Year Forward View</td>
<td>Share the stewardship of the Five Year Forward view with the other Arm’s Length Body signatories.</td>
<td>NICE joined the NHS Five Year Forward View Board in June. We have taken responsibility for sponsoring four of the national vanguards and are contributing to the majority of the programme boards. Through our membership of the Board we influenced the Department of Health’s Shared Delivery Plan, concentrating on those elements that relate to efficiency, quality and the use</td>
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<td>Business plan, DH balanced scorecard</td>
<td>Deliver NICE’s guidance, standards and services against the targets set out in the Business Plan and in accordance with the metrics in the balanced scorecard.</td>
<td>The performance of the main programmes, together with reasons for variances is set out elsewhere in the Chief Executive’s report.</td>
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<tr>
<td>Triennial review, DH priority, business plan, balanced scorecard</td>
<td>In order to work effectively in an evolving health and care system, NICE should increase its profile, work more flexibly and further develop relationships across the sector by; analysing awareness of its profile across the stakeholder landscape, including with patients, service users, their families and carers and in social care, developing actions to increase awareness of its role and functions.</td>
<td>Using the 2013 Reputation audit as a benchmark we will conduct a rolling programme to measure and analyse awareness across our stakeholder groups and to develop plans to address findings. Two new groups - the Cross Institute Primary Care group and GP Advisory Group led by NICE’s chairman have been established to help us monitor views of primary care stakeholders and to examine how NICE guidance can best meet the needs of the GPs. As part of the Cross Institute Primary Care Group our Audience insights team and the field team are offering assistance to two local initiatives in Cheshire and Mersey, and in Manchester where CCGs are undertaking work to explore barriers to implementation of guidance and solutions for improvement. An insights community database has been created and to date nearly 1000 volunteers have joined. The volunteers including GPs, nurses and midwives, and social care and public health have expressed interest in providing their views and feedback on a wide range of NICE products and</td>
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<td><strong>Triennial review, business plan</strong></td>
<td>Continue to improve communications and engagement work with social care stakeholders, including exploring whether alternative approaches to developing products would better fit the audience’s needs.</td>
<td>A prioritised social care engagement plan has been developed and is now being implemented. This builds on the existing work of the Field Team, the Social Care External Network and incorporates a broader approach from the Health and Social Care Directorate and the Communications Directorate so that social care engagement is aligned across NICE and a consistent priority for all relevant programmes.</td>
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<td><strong>DH priority, business plan</strong></td>
<td>Proactively seek evidence that NICE’s work is responsive to the local needs of the NHS at commissioner and provider level, as well as local government, by carrying out reputational surveys with local commissioners and providers.</td>
<td>As part of a Cabinet Office government-wide initiative we are working with the Reputation Institute on a project called RepTrack which measures on a rolling basis the reputation of government department and their ALBs amongst the informed public. NICE has been chosen to take part in a pilot project to explore how the RepTrak model could be used to track perceptions of key stakeholder groups. Following recent discussions with the Cabinet Office and the Reputation Institute, a full brief and project plan is now being prepared.</td>
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<td><strong>Adoption</strong></td>
<td>Working with other health and care leaders; especially NHS England, Public Health England and Care Quality Commission</td>
<td>We have ongoing work in place with PHE and CQC to facilitate the uptake of NICE guidance, and this is being reflected in updated partnership</td>
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<td>Priority</td>
<td>Business Plan</td>
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<td>DH priority, business plan</td>
<td>Consider out how NICE can better support the health and care sector with de-commissioning services and healthcare processes that are less effective and in order to make more space for more innovative services and processes. A report, for consideration by the Board and the Department of Health, on NICE support for disinvestment has been shared with the Board and the Department of Health. We are following up the recommendations in the report to enhance our offer to the NHS.</td>
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<td>DH priority, business plan</td>
<td>Support the more rapid introduction and diffusion of innovative and cost-effective medicines and technologies. NICE is actively engaging with the Accelerated Access Review, is reviewing and refining its adoption programmes and has developed the Office for Market Access, the details of which are set out below.</td>
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<td>DH priority, business plan</td>
<td>Develop plans to better support the medical technologies sector in understanding the needs and priorities of the NHS. The Office for Market Access, together with an expanded NICE Scientific Advice has increased our ability to engage proactively with the Life Sciences Industry. The Office is developing a range of fee for service activities to support life sciences companies in understanding the decision making processes, needs and priorities</td>
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of the NHS. Discussions are now taking place with individual companies to explore specific needs.

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<th>Programme development</th>
<th>DH priority</th>
<th>Provide strong project management support to facilitate delivery of the Innovation Scorecard, in addition to NICE’s expert analytical input to help further improve the Scorecard as an effective tool to address variation in the adoption of innovation in the NHS.</th>
<th>The May and October 2015 innovation scorecards were published as planned, and the next updated set of data is due to be published by the HSCIC on 12 January 2016. The data are also being converted into 'Heat maps' by NHS England, showing regional variation. NICE is part of ongoing discussion with NHS England, Office for Life Sciences and Department of Health to consider how the scorecard data can add most value.</th>
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<td>DH priority</td>
<td>Reflect the renewed focus on prevention across the health and care system, as set out in NHS England’s Five Year Forward View published alongside Public Health England’s strategic priorities for public health and the Department of Health’s corporate plan.</td>
<td>NICE is actively engaged in the FYFV Prevention Board and the PH systems Group. The diabetes prevention strategy and the new work to improve the health of NHS staff is all underpinned by NICE guidance. NICE is actively engaging with DH and PHE to prioritise topics for NICE guidance that support the national agenda.</td>
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<td>Triennial review</td>
<td>Work with the Department and the Cabinet Office Commercial Models team to explore opportunities for greater expansion of NICE International and NICE Scientific Advice and to consider whether these functions could be delivered more effectively through a different</td>
<td>The Board gave initial consideration to proposals for the future of NICE International and NICE Scientific Advice at a private session before its November meeting. The Board will consider further proposals for NICE International at its Strategy meeting in February.</td>
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<td>Model or change of sector.</td>
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<tr>
<td><strong>Triennial review, DH priority, business plan</strong></td>
<td>Actively engage with the Accelerated Access Review.</td>
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<td><strong>DH priority, business plan</strong></td>
<td>Develop proposals to improve awareness and uptake of the advisory services NICE offers to the life sciences industry.</td>
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<td><strong>DH priority, business plan</strong></td>
<td>Identify opportunities to evaluate digital health technologies and services within NICE’s guidance programmes, where evidence is available. Consider whether there is scope to develop a tailored assessment process within NICE for such technologies and what capabilities would be required for such a process.</td>
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We are working closely with the Review team, have seconded a senior member of staff to the Review and have responded to a set of targeted questions about the potential for NICE to enhance its contribution to securing faster access to innovate health technologies. The Board considered the interim report from the review at its November public meeting, and NICE submitted a formal response which is presented elsewhere on the January Board agenda.

A range of seminars and other activities have been delivered recently for the life sciences industry. Further awareness raising activities are ongoing through the Office for Market Access.

This is being undertaken as part of NICE’s role in supporting the National Information Board to develop a framework for assessing digital applications (‘apps’) in collaboration with Public Health England and the Health and Social Care Information Centre. NICE is focusing its efforts on determining the types of studies which can be used to assess the impact and value of apps whilst other partners are focusing on the technical assessment of apps. The NIB programme has received substantial funding from the...
<p>| Business plan | Continue to implement the digital strategy of NICE with emphasis on transforming internal guidance development systems while continuing to maintain and enhance our externally facing digital service. | Implementation of the digital strategy continues under the governance of the 5 Service Groups and SMT. NICE presented elements of its strategy to the Department of Health ‘ALB digital leaders’ forum’ in December 2015 and received positive feedback on the quality of its approach to managing information and the robustness of its management processes. |
| Business plan | Participate in the NHS England review of the management of the Cancer Drugs Fund. | We have engaged extensively with NHS England in the development of proposals which are currently subject to public consultation. |
| Business plan | Redesign and future-proof the clinical guidelines programme. | The tendering process for external contractors to develop clinical guidelines from 1 April 2016 is complete. Plans are in place, within the constraints of current capacity to maintain the currency of all published clinical guidelines. |
| Methodology | Triennial review | Continue to work with patient groups to make its approach to supporting patients more transparent and identifying where it can provide more support to those participating in | We have a full programme of active engagement with the organised patient advocacy movement and future work will be informed by a review of best practice in public involvement, for completion |</p>
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<th><strong>ITEM 2</strong></th>
<th><strong>the work of NICE.</strong></th>
<th><strong>by March 2016.</strong></th>
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<td><strong>Business plan</strong></td>
<td>Consolidate the integration of the methods and processes for the development of guidelines (clinical, public health and social care), and continue to consider improvements.</td>
<td>The implementation of the NICE ‘content strategy’ has resulted in a number of changes over recent months including new guideline overview pages launched for guidelines and the publication in September of the first guideline (Homecare) in a new unified template. The newly established content strategy governance group will identify and support the consistent implementation of changes to content on the basis of user research and other inputs from across NICE and the external environment. The NICE guidelines manual received accreditation from the NICE Accreditation Committee in November.</td>
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<td><strong>Partnership</strong></td>
<td>Work with the Medicines and Healthcare Products Regulatory Agency (MHRA) to review the partnership agreement and consider publicising both the agreement and steps taken to ensure the principles are put into practice throughout all levels of the organisations.</td>
<td>The Partnership Agreement has been reviewed and updated and regular meetings are taking place between the two organisations to identify and resolve operational and strategic issues.</td>
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<td><strong>Business plan</strong></td>
<td>Explore with CQC how to ensure that NICE quality standards and guidelines complement and reinforce essential standards, building on</td>
<td>A programme of work, to map NICE quality standards to CQC’s inspection framework is well advanced and will continue with support from</td>
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<td>Business plan</td>
<td>Engage with NHS England in the implementation of their 5 Year Forward View.</td>
<td>Clinical Fellows in both organisations. NICE is actively working with CQC to consider how the new CQC strategy should be best aligned with NICE products.</td>
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<td>Triennial review</td>
<td>Work with NHS England to identify systems and processes, with associated metrics where appropriate, to secure the application of the commitment in the Partnership Agreement between the two organisations to the use of NICE guidance in the centralised and devolved commissioning arrangements.</td>
<td>NICE guidance is already referenced in a range of central and devolved commissioning guidance. We are in discussion with them about extending our support to them in the development of their specialised commissioning policies.</td>
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<td>Triennial review</td>
<td>Work to further enhance relationships with organisations across health and care, clarifying areas where roles and responsibilities could be made clearer to stakeholders.</td>
<td>Work is underway to clarify the role of NICE guidance and standards, with involvement of colleagues at the DH, Skills for Care and the RCP. NICE is actively working with PHE to align our work programmes to be mutually supportive, and clear for the end user. As part of its strategy to 2020, NICE will undertake a programme by programme review of the alignment between its outputs and the health and care system they are designed for. This will include ensuring, over time</td>
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that each set of recommendations has a clear system owner or owners and a commitment from the system to manage the recommendations into practice.

| Financial | Business plan | Operate within resource and cash limits in 2015-16. Actively manage the appropriate application of any non-recurrent funding as early as practicable in the financial year. | The Institute is operating within its resource limits. Further information is available elsewhere in this report and in the Finance Report. |
| Business plan | Plan for a balanced budget for 2016-17, taking account of anticipated significant grant in aid reductions. | The Institute will be able to manage its budget for 2016-17 on the assumption that Department of Health income will reduce by a straight line proportion of a total reduction of 30% by April 2019. |
| Triennial review | Explore charging industry for health technology appraisals and medical devices and diagnostics evaluations. | As part of the longer term plans to address the 30% reduction in GIA income this is now being actively pursued. |
| DH priority, business plan | Explore opportunities for further efficiencies: making transactions digital and considering opportunities for back office efficiencies from synergies within your organisation or closer working with other system players. | Efficiencies continue to be sought from back office functions. Shared services arrangements and investment in IT solutions will continue to be used where they provide value. Co-location with other public bodies has provided an income stream and more efficient use of office accommodation in Manchester. A similar co-location arrangement has now been agreed for the London office which will commence April |

National Institute for Health and Care Excellence
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Date: 20 January 2016
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<table>
<thead>
<tr>
<th>Governance</th>
<th>Triennial review</th>
<th>A draft proposal for the Internal Auditors to undertake this work is considered elsewhere on the January Board agenda.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business plan</td>
<td>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.</td>
<td>All staff receive a set of personal objectives and a personal development plan.</td>
</tr>
<tr>
<td>Triennial review</td>
<td>Ensure that the arrangements for operating and quality controlling the work of NICE’s independent advisory committees are robust and transparent, publishing these arrangements where feasible.</td>
<td>The Board will be asked to consider a discussion paper on this at its March meeting.</td>
</tr>
<tr>
<td>DH priority</td>
<td>Promote a culture of continuous improvement within the organisation and uphold the ambition to remain a world-renowned organisation, benchmarking its systems, processes and outcomes against best players internationally, proactively thinking about succession planning and attracting and</td>
<td>All NICE’s methods and processes are reviewed regularly and are subject to public consultation. There is no obvious way of benchmarking our processes for producing guidance with other international organisations, but all NICE programmes are accredited using the NICE independent Accreditation Programme. The Board has considered and approved a workforce</td>
</tr>
<tr>
<td>retaining talent.</td>
<td>strategy.</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix 2: Extracts from the Directors’ reports

<table>
<thead>
<tr>
<th>Director</th>
<th>Featured section</th>
<th>Section reference</th>
</tr>
</thead>
</table>
| **Health and social care**      | The NICE guideline on asthma diagnosis and monitoring went out to consultation with stakeholders during the period 28th January – 11th March 2015. Following review of the comments, it was decided that a feasibility study would be carried out prior to publication. This study will address key areas raised by stakeholders relating to the use of objective tests in the different diagnosis algorithms, in particular the use of spirometry and fractional exhaled nitric oxide (FeNO) testing. The aims and objectives of the study are to:  
  - Assess the impact and feasibility of implementing, into primary care, the technical diagnostic tests (spirometry and FeNO) recommended in the asthma diagnostic guideline recommendations.  
  - Provide stakeholder assurance that the recommendations are able to be implemented, and to show that NICE has proactively responded to stakeholder comments.  
  - Gain ownership of the project outcomes from asthma experts and key stakeholders, via the proposed Steering Group, and to involve them in communicating these should feasibility be demonstrated.  
A report on the findings from the field testing will be provided by the end of November 2016 for consideration in time for publication of the guideline in July 2017. This will coincide with publication of the asthma management guideline. | Section/para 7 |
| **Clinical practice**           | We have developed a reference panel and database of topic experts for CCP activities. This will include former GDG members and new experts all recruited through open advert with the aim of improving timely access to expert advice for the surveillance programme and to speed up recruitment of topic specialist members to the new standing committees. Invitations have been sent out to all former GDG members for those topics prioritised for 2016/17. So far we have a positive response rate of almost 50%, although we anticipate this will increase with reminder emails. Only 2% of invitees have so far declined. | Section/para 10 |
| Technology evaluation | In November 2015, the highly specialised technologies programme published guidance on Elosulfase alfa for treating mucopolysaccharidosis type Iva. The guidance includes a Managed Access Agreement. This agreement, developed in collaboration with NHS England, Biomaarin and the MPS Society is the first of its kind for a HST product. It provides a platform for patients to obtain access to the drug while contributing to the collection of real world data that will inform the future evaluation of elosulfase in 5 years time. | Section/para 14 |
| Evidence resources | A strong relationship is being developed with Health Education England (HEE). Following the publication of ‘Knowledge for Healthcare; a Development Framework’ earlier in the year, HEE has set up a series of working groups to help define and deliver its framework’s objectives in the areas of resource discovery, workforce planning and development, quality and impact and service transformation. Where relevant NICE is working collaboratively with the working groups to help formulate the future strategy. A meeting was held in late November between NICE Evidence Resources, NICE Leadership and Engagement and HEE Director Alan Ryan- HEE Technology Enhanced Learning (TEL) Lead and e-LfH National Programme Director and his team to explore opportunities for joint working. As a result NICE will attend a clinical workshop in February 2016 and will coach HEE colleagues on how to get the most out of the NICE website, HEE has been granted a test syndication licence for NICE guidance, CKS and Evidence Search and the Memorandum of Understanding with HEE is being revised and updated. NICE and HEE are also working together on a project to redevelop HDAS (Healthcare Database Advanced Search). HDAS is a federated search service providing the NHS with access to the bibliographic databases that the NHS have paid for through a single search interface. | Section/para 7, bullet 5 |
| Communications | We completed work on the new website homepage which will go live during January 2016. In response to user feedback, the new homepage more clearly explains our role and provides users with faster access to the most popular areas of the website. Work is underway to create a new section on the website to support recruitment campaigns, in particular for specialist roles such as those in our digital service teams. The new section will promote the benefits of working | Section/para 27-29 |
for NICE using different media such as videos and blogs. During November and December the web team conducted a number of 1:1 sessions with users in response to feedback about the stakeholder registration process. The sessions highlighted a number of improvements needed to make the process more efficient and easier for stakeholders to complete.

| Finance and workforce | There are currently 49wte vacant posts from a budgeted establishment of 651wte, which equates to 7.5% of the total budgeted workforce. This is a change of 0.5% or 4wte compared to the last figure reported. It should also be noted that over half these vacancies are currently being actively recruited to and as such the level of under spend due to vacancies is expected to reduce. | Section/para: 3 |
### Appendix 3: Guidance development: variation against plan April – December 2015

<table>
<thead>
<tr>
<th>Programme</th>
<th>Delayed Topic</th>
<th>Reason for variation</th>
</tr>
</thead>
</table>
| Clinical Guidelines     | 3 topics delayed              | **Asthma diagnosis** - Delayed to enable an assessment of the impact and feasibility of implementing, into primary care, the technical diagnostic tests (spirometry and FeNO) recommended in the draft guideline recommendations. Due to publish in Q2 (July 2016).  
                                 |                                                                                             | **Neonatal jaundice** - In developing recommendations on treatment, it was recognised that additional work was required to produce recommendations on diagnosis. This work was then further extended to accommodate the need for an early consultation with an expert panel prior to stakeholder consultation to ratify the group’s recommendations. Due to publish Q1 2016/17.  
                                           |                                                                                             | **Tuberculosis (update)** – NICE Guidance Executive agreed changes to recommendations which required extended discussion with the advisory committee. Due to publish Q4 (January 2016). |
| Interventional procedures| 4 topics delayed              | **Endovascular aneurysm search for abdominal aortic aneurysm** – Delayed by consultation being re-run following an administrative error relating to the first consultation. Due to publish Q4 (February 2016).  
                                           |                                                                                             | **Percutaneous electrothermal treatment of the invertebral disc annulus for lower back pain and sciatica** - Delayed due to availability of lead committee member. Due to publish Q4 (January 2016).  
                                           |                                                                                             | **Percutaneous coblation of the invertebral disc annulus for lower back pain and sciatica** - Delayed due to the availability of a lead committee member. Due to publish Q4 (January 2016).  
                                           |                                                                                             | **Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain**. Delayed due to the availability of a lead committee member. Due to publish Q4 (January 2016). |
| Medical technologies    | 1 topic delayed               | **Heartflow FFRct for the estimation of fractional flow reserve from coronary CT angiography** - Paused due to the need for alignment with the update to clinical guideline 95: chest pain of recent onset, which has been delayed. Due to publish |
Sunlight exposure - Due to the nature of the feedback from the first guideline consultation and changes required, the guideline had to go out for a second stakeholder consultation. Due to publish Q4 (February 2016).

Antenatal and postnatal mental health - Delayed whilst awaiting publication in December 2015 of a report from the Chief Medical Officer relating to the use of prescription of valproate in pregnant women. Publication date to be confirmed.

Crohn’s disease – Tests for therapeutic monitoring of TNF inhibitors (LISA-TRACKER ELISA kits, TNF a-Blocker ELISA kits, and Promonitor ELISA kits) - Delayed as the first committee meeting was rescheduled due to a planned rail strike. Due to publish Q4 (February 2016).

Ovarian cancer (advanced - relapsed disease only) topotecan, pegylated liposomal doxorubicin hydrochloride and paclitaxel – delayed due to appeal being upheld. Therefore the appraisal will now be referred back to the committee. Due to publish Q1 2016/17 (April 2016).

Prostate cancer (hormone relapsed) – enzalutamide (chemotherapy naïve) – has been referred back to committee following submission of an amended patient access scheme and subsequent discussions with the Department of Health. Due to publish Q4 (January 2016).

Ovarian, fallopian tube, peritoneal cancer (relapsed, platinum sensitive, BRCA 1 or 2 mutations) – olaparib (maintenance) – delayed by the issue of a second ACD for consultation. Due to publish Q4 (January 2016).

Ankylosing spondylitis and axial spondyloarthritis – TNF inhibitors (inc review of TA143 & TA233) – An appeal was received and a hearing scheduled for 24 November 2015. The appellant subsequently withdrew their appeal on 20 November 2015. Due to publish Q4 (February 2016).

Systemic lupus erythematosus – belimumab – delayed due to ongoing discussions between NICE and external parties. Publication date to be confirmed.

Rheumatoid arthritis – adalimumab, etanercept, infliximab (TA 130), certolizumab pegol (TA 186), golimumab (TA 225 part review) and tocilizumab (TA 247) – an appeal has been lodged and the hearing held on 26 November 2015. Publication date to be confirmed.

Prostate cancer (advanced hormone dependent) – degarelix depot –
manufacturer has submitted additional evidence to be reviewed by ERG. The new evidence and the ERG review were considered by Committee on 4 November 2015. Due to publish in Q4 (February 2016).

Dupuytren’s contracture – collagenase clostridium histolyticum (1st line) – an appeal was lodged and the hearing was held on 30 November 2015. Publication date to be confirmed.

<table>
<thead>
<tr>
<th>3 topics planned for Q4 2015-16, published early</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphoma (mantle cell) - bortezomib (1st line) – This topic went straight to final draft following the first Appraisal Committee meeting. Published in Q3 (December 2015).</td>
</tr>
<tr>
<td>Juvenile idiopathic arthritis - etanercept, adalimumab, tocilizumab and abatacept - This topic went straight to final draft following the first Appraisal Committee meeting. Published in Q3 (December 2015).</td>
</tr>
<tr>
<td>Melanoma (unresectable, metastatic, ipilimumab naive) – pembrolizumab - This topic went straight to final draft following the first Appraisal Committee meeting. Published in Q3 (December 2015).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6 additional topics published in 2015-16, that were not planned for this financial year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cangrelor for reducing atherothrombotic events in people undergoing percutaneous coronary intervention or awaiting surgery requiring interruption of anti-platelet therapy (terminated appraisal) – Published in Q2 (July 2015) as a terminated appraisal.</td>
</tr>
<tr>
<td>Bevacizumab for treating relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer (terminated appraisal) – Published in Q2 (August 2015) as a terminated appraisal.</td>
</tr>
<tr>
<td>Pancreatic cancer (previously untreated, metastatic) - paclitaxel as albumin-bound nanoparticles (in combination with gemcitabine) – This was a post appeal publication. Following the appeal hearing held on 16 March 2015, the appeal was upheld and the appraisal went to Committee for further discussion. Following the release of a second FAD the guidance was published post appeal in Q3 (October 2015).</td>
</tr>
<tr>
<td>Non-small-cell lung cancer (untreated) - paclitaxel albumin-bound nanoparticles (with carboplatin) - Published in Q3 (October 2015) as a terminated appraisal.</td>
</tr>
<tr>
<td>Breast cancer (HER2 positive) - trastuzumab emtansine - Following the appeal against the final draft guidance for this appraisal, NICE developed a position statement on the relevance of the ‘PPRS Payment Mechanism’ of the</td>
</tr>
<tr>
<td>Highly Specialised Technologies (HST)</td>
</tr>
<tr>
<td>---------------------------------------</td>
</tr>
<tr>
<td>Accreditation</td>
</tr>
</tbody>
</table>

Pharmaceutical Price Regulation Scheme (PPRS) 2014 to the assessment of the cost effectiveness of branded medicines. An additional Committee meeting was held to discuss the outcome of the appeal and to reconsider the relevance of the PPRS in the light of the position statement. Published in Q3 (December 2015).

Non-small cell lung cancer (second line treatment) erlotinib (TA162) and gefitinib (TA175) - An additional committee meeting was held to reconsider the relevance of the PPRS in the light of NICE’s position statement for this appraisal. Published in Q3 (December 2015).

SIGN – delayed due to further information requested by the Accreditation Advisory Committee. Currently out for public consultation. Final decision planned for January committee. Due to publish Q4 (February 2016).
Appendix 4: Guidance published since the last Board meeting in November

<table>
<thead>
<tr>
<th>Programme</th>
<th>Topic</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Guidelines</strong></td>
<td>Type 2 diabetes (update)</td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td>Children’s attachment</td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td>Menopause</td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td>Pre-term labour and birth</td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td>Transfusion</td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td>Headaches (standing committee update)</td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td>Rheumatoid arthritis (standing committee update)</td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td>Venous thromboembolic diseases (standing committee update)</td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td>IV fluid therapy in children</td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td>Care of the dying adult</td>
<td>General guidance</td>
</tr>
<tr>
<td><strong>Interventional procedures</strong></td>
<td>Living donor liver transplantation</td>
<td>Normal arrangements</td>
</tr>
<tr>
<td></td>
<td>Electrical stimulation of the lower oesophageal sphincter for treating gastro-oesophageal reflux disease</td>
<td>Only in research</td>
</tr>
<tr>
<td></td>
<td>Insertion of a subretinal prosthesis system for retinitis pigmentosa</td>
<td>Only in research</td>
</tr>
<tr>
<td></td>
<td>Implantation of a corneal graft-keratoprosthesis combination for severe corneal opacity in wet blinking eyes</td>
<td>Normal arrangements</td>
</tr>
<tr>
<td></td>
<td>Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention</td>
<td>Normal arrangements</td>
</tr>
<tr>
<td></td>
<td>Repetitive transcranial magnetic stimulation for depression</td>
<td>Normal arrangements</td>
</tr>
<tr>
<td></td>
<td>Joint distraction for ankle osteoarthritis</td>
<td>Only in research</td>
</tr>
<tr>
<td></td>
<td>Transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis</td>
<td>Special arrangements</td>
</tr>
<tr>
<td></td>
<td>Radiofrequency ablation for symptomatic interdigital (Morton’s) neuroma</td>
<td>Special arrangements</td>
</tr>
<tr>
<td>Medical technologies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>No guidance published</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diagnostics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin cancer: the Vivascope 1500 and 3000 systems for detecting and monitoring skin lesions</td>
<td>Recommend further research</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Public Health</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Older people and mental wellbeing – primary, secondary and tertiary</td>
<td>General guidance</td>
</tr>
<tr>
<td>Oral health promotion approaches for dental teams</td>
<td>General guidance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality Standards</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute heart failure</td>
<td>Sentinal markers of good practice</td>
</tr>
<tr>
<td>Gallstone disease</td>
<td>Sentinal markers of good practice</td>
</tr>
<tr>
<td>Intrapartum care</td>
<td>Sentinal markers of good practice</td>
</tr>
<tr>
<td>Bladder cancer</td>
<td>Sentinal markers of good practice</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Technology Appraisals</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Major depressive disorder (moderate, severe) - vortioxetine</td>
<td>Recommended</td>
</tr>
<tr>
<td>Leukaemia (chronic lymphocytic, previously treated) – idelalisib</td>
<td>Recommended</td>
</tr>
<tr>
<td>Melanoma (unresectable, metastatic) – pembrolizumab (after ipilimumab)</td>
<td>Recommended</td>
</tr>
<tr>
<td>Atrial fibrillation (non-valvular, stroke and embolism prevention) – edoxaban tosylate</td>
<td>Recommended</td>
</tr>
<tr>
<td>Hepatitis C (chronic, genotype 1) – ledipasvir-sofosbuvir</td>
<td>Recommended</td>
</tr>
<tr>
<td>Hepatitis C (chronic) - daclatasvir</td>
<td>Recommended</td>
</tr>
<tr>
<td>Psoriasis (moderate to severe) - apremilast</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Psoriatic arthritis - apremilast</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Dry eye disease - ciclosporin</td>
<td>Recommended</td>
</tr>
<tr>
<td>Hepatitis C (chronic, genotype 1) – ombitasvir/paritaprevir/ritonavir (with or without dasabuvir)</td>
<td>Recommended</td>
</tr>
<tr>
<td>Lymphoma (mantle cell) – bortezomib (1st line)</td>
<td>Recommended</td>
</tr>
<tr>
<td>Condition and Medication</td>
<td>Recommendation</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Juvenile idiopathic arthritis – etanercept, adalimumab, tocilizumab and abatacept</td>
<td>Recommended</td>
</tr>
<tr>
<td>Melanoma (unresectable, metastatic, ipilimumab naïve) – pembrolizumab</td>
<td>Recommended</td>
</tr>
<tr>
<td>Breast cancer (HER2 positive) - trastuzumab emtansine</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Non-small cell lung cancer (second line treatment) erlotinib (TA162) and gefitinib (TA175)</td>
<td>Gefitinib – Not recommended Erlotinib – Optimised</td>
</tr>
</tbody>
</table>

### Highly Specialised Technologies (HST)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elosulfase alfa for treating mucopolysaccharidosis type IVA</td>
<td>Recommended</td>
</tr>
</tbody>
</table>

### Accreditation

<table>
<thead>
<tr>
<th>Programme</th>
<th>Accreditation</th>
</tr>
</thead>
<tbody>
<tr>
<td>NICE – Interventional Procedures Programme</td>
<td>Accredited</td>
</tr>
<tr>
<td>NICE – Guidelines</td>
<td>Accredited</td>
</tr>
<tr>
<td>NICE – Multiple Technology Appraisals</td>
<td>Accredited</td>
</tr>
</tbody>
</table>

### Evidence summaries – new medicines

<table>
<thead>
<tr>
<th>Medication</th>
<th>Summary of best available evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinecatechins for external genital and perianal warts</td>
<td></td>
</tr>
<tr>
<td>Cangrelor for reduction of thrombotic cardiovascular events in patients with coronary artery disease undergoing PCI</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td>High strength insulin glargine for diabetes mellitus Type 2</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td>Insulin glargine biosimilar</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td>Oxycodone / naloxone for restless leg syndrome</td>
<td>Summary of best available evidence</td>
</tr>
</tbody>
</table>

### Evidence summaries – unlicensed/off label medicines

<table>
<thead>
<tr>
<th>Medication</th>
<th>Summary of best available evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>C3 glomerulopathy in the native kidney: eculizumab</td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Medtech Innovation Briefings (MIB)</th>
<th>Adenoplus point-of-care test for diagnosing adenoviral conjunctivitis</th>
<th>Summary of best available evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TearLab osmolarity system for diagnosing dry eye disease</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td>Evidence Surveillance Reviews</td>
<td>Breast cancer (advanced)</td>
<td>Surveillance review decision</td>
</tr>
<tr>
<td></td>
<td>Early &amp; locally advanced breast cancer</td>
<td>Surveillance review decision</td>
</tr>
<tr>
<td></td>
<td>Depression in adults with a chronic physical health problem</td>
<td>Surveillance review decision</td>
</tr>
<tr>
<td></td>
<td>Familial breast cancer</td>
<td>Surveillance review decision</td>
</tr>
<tr>
<td></td>
<td>The management of hip fracture in adults</td>
<td>Surveillance review decision</td>
</tr>
<tr>
<td>Quality and Productivity case studies</td>
<td>Supply chain management and collaboration: cardiology device procurement</td>
<td>Examples of quality and productivity improvements</td>
</tr>
<tr>
<td></td>
<td>BRAF mutation testing for thyroid cancer: avoiding unnecessary surgery</td>
<td>Examples of quality and productivity improvements</td>
</tr>
<tr>
<td>Cochrane case studies</td>
<td>Robot-assisted surgery in gynaecology</td>
<td>Robot-assisted surgery (RAS) for hysterectomy or sacrocolpopexy should be limited to clinical research settings at present as it is unclear whether it is safer and more effective than conventional laparoscopic surgery (CLS).</td>
</tr>
</tbody>
</table>
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Finance and Workforce Report

This report gives details of the draft financial and workforce position as at 31 December 2015 and the forecast outturn for 2015-16.

The Board is asked to review the report.

Ben Bennett
Business Planning and Resources Director
January 2016
Summary

1. Table 1 summarises the provisional financial position as at 31 December 2015. There is a full analysis in Appendix A.

<table>
<thead>
<tr>
<th></th>
<th>Year to date</th>
<th>Estimated Outturn</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Budget £m</td>
<td>Expenditure £m</td>
</tr>
<tr>
<td></td>
<td>Budget £m</td>
<td>Expenditure £m</td>
</tr>
<tr>
<td>Guidance &amp; Advice</td>
<td>40.6</td>
<td>40.9</td>
</tr>
<tr>
<td>Corporate</td>
<td>6.7</td>
<td>9.6</td>
</tr>
<tr>
<td>NICE International</td>
<td>0.0</td>
<td>1.4</td>
</tr>
<tr>
<td>Scientific Advice</td>
<td>(0.0)</td>
<td>0.8</td>
</tr>
<tr>
<td>NICE Total</td>
<td>47.4</td>
<td>52.7</td>
</tr>
<tr>
<td></td>
<td>54.9</td>
<td>56.0</td>
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<tr>
<td></td>
<td>8.0</td>
<td>13.6</td>
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<tr>
<td></td>
<td>0.1</td>
<td>2.8</td>
</tr>
<tr>
<td></td>
<td>0.0</td>
<td>1.1</td>
</tr>
<tr>
<td></td>
<td>63.0</td>
<td>73.5</td>
</tr>
</tbody>
</table>

Table 1: Financial Position at 31 Dec 2015 (Tentative)

2. The current position shows an under spend of £3.8m (7.9%) for the first nine months of 2015/16. Of this, £1.8m is attributable to vacant posts and £2.0m relates to under spends on non-pay budget and additional income.

3. There are currently 49wte vacant posts from a budgeted establishment of 651wte, which equates to 7.5% of the total budgeted workforce. This is a change of 0.5% or 4wte compared to the last figure reported. It should also be noted that over half these vacancies are currently being actively recruited to and as such the level of under spend due to vacancies is expected to reduce.

4. The full year forecast outturn is a £3.2m (5.1%) under spend against the revenue resource limit. The reasons for material variances are detailed in this report.

5. Progress on the implementation of the workforce strategy is detailed in Appendix B. This week (18 – 22 January) is our Healthy Work Week with activities programmed throughout the week to encourage and inform staff about their own health and well being. Activities range from lunchtime runs to mindfulness sessions.
Financial Position as at 31 December 2015

6. Appendix A shows that the net operational expenditure for the first nine months of 2015-16 was £43.6m. This was a £3.7m (7.8%) under spend against budget. This is partly attributable to vacant posts (48% of under spend) resulting in lower pay costs. More detail on the pay expenditure is set out in the section below.

7. The non-pay and income budgets are currently showing an under spend of £1.9m, which is mainly due to under spends on contracts in the guidance producing centres, the Safe Staffing programme and a rates rebate relating to the Manchester office dating back a number of years.

Pay

8. Total operational pay expenditure for the first nine months of 2015/16 was £24.6m, which was £1.8m (6.8%) under spent against budget. Of this, £1.0m is currently allocated to pay reserves as part of the pay slippage exercise completed earlier in the year and the transfer of the Safe Staffing pay budget into reserves.

9. As at 31 December 2015 there were 597 whole time equivalent (wte) substantive employees on payroll (headcount of 653), plus 16wte agency and contractor staff in post. There were 54 vacant posts (48.9wte) as at this date, of which 30 are currently going through the recruitment process. The annualised budget value of these vacant posts is £2.03m, equivalent to a £169,000 under spend each month.

10. In addition to vacancies due to the normal turnover of staff, there are vacant posts relating to new work programmes (for example Observational Data Unit). As at 31 December there were also a number of vacant posts in the Communications directorate due to the recent management of change, although many of these posts have been ring-fenced for existing at risk.

Non-Pay expenditure

11. Total non-pay expenditure in the first nine months of 2015-16 was £25.6m, which was an under spend of £0.5m (2.0%) against budget.

12. Most sub-categories of non-pay are close to break-even, with the exceptions being under spends arising from the knock-on effect of vacancies. One notable example is lower than budgeted travel and subsistence costs (£0.2m under spent with 69% relating to non-staff budgets and 31% staff budgets). We have also received a multi-year rebate for Manchester business rates (£0.2m under spent) which contributes to the under spend.
13. There is an under spend of £0.3m for public health evidence reviews in the Public Health and Social Care programme. Evidence reviews work is being brought in-house, although there are a number of external contracts still in progress whilst new processes are bedded in. However, several contracts that were in the procurement pipeline during 2015-16 budget setting did not go out to tender because the new process was activated more rapidly than expected, resulting in the current under spend.

Other operating income

14. Other operating income is showing £1.4m of additional income for the first nine months of the year mainly due to funding we have received from NHS England (£1.2m) for work on Mental Health Access and Waiting Times Standards. The majority of the work associated with this income is subcontracted to the Royal College of Psychiatrists. Total income for this work in 2015/16 and subsequent years is expected to be £1.5m. We have also received additional unbudgeted income for the HDAS development work (£0.1m) from Health Education England and NHS England for an extra register associated with Commissioning Through Evaluation work (£0.1m).

15. NICE International is currently forecast to generate a small surplus of £27,000 by the year-end. An accumulated reserve of £431,000 has been carried over from previous financial years.

16. Scientific Advice is currently forecasting to generate a small surplus of £53,000 in 2015-16 as well as carrying an accumulated reserve of £137,000 from previous financial years. This projection includes Scientific Advice making a contribution to the Institute’s overheads of £130,000, equivalent to £13,000 per staff member in the team and a contribution to the OMA programme of £50,000.

Forecast outturn

17. The current forecast under spend for 2015/16 is £3.2m (5.1%). Of this, £1.5m relates to pay and the vacancies across the Institute noted above. At the start of the year any anticipated pay slippage is moved centrally to reserves and a part year effect pay budget is allocated to teams. This forecast makes assumptions about the likely dates posts will be recruited to, but if there is any slippage in these timescales, or teams recruit from elsewhere within the institute (therefore creating a knock-on vacancy), an under spend within the team’s pay budget arises.

18. Also adding to the under spend is the unused safe staffing budget, which has now been transferred into reserves.

19. Non-pay is expected to over spend by £0.3m by the end of the year. Although there are several areas of under spend such as Public Health evidence review
budget savings explained above (£0.5m); travel & subsistence budgets (£0.2m) and the rates rebate for the Manchester office (£0.3m) there are also some additional cost pressures. These include additional expenditure of £0.3m paid to the National Collaborating Centres for advancing guidance development; an additional £0.1m of under spend usage requested by the Centre for Health Technology Evaluation for a variety of different projects such as STAR, Meta Tool development and the MedTech Review; expenditure in the Centre for Clinical Practice relating to Access and Waiting Times (£1.1m). We have received equivalent income from NHS England to offset this cost.

20. The forecast assumes that £0.5m of reserves will be utilised in order to meet liabilities arising relating to uncertainties around ongoing consultations. It has also been assumed that an additional £0.2m will be required in order to upgrade IT equipment and software.

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

Capital

22. Capital funding of £0.5m was confirmed by the Department of Health in June 2015. This is unlikely to be fully utilised but there will be some expenditure on general upkeep and maintenance of the office facilities, installing a new meeting room system and some minor IT purchases.
### Appendix A – Summary of financial position as at 31 December 2015

#### Comparison of budget with expenditure and year end projection - 31st Dec 2015 (Tentative)

<table>
<thead>
<tr>
<th>Centre / Directorate</th>
<th>Year to Date</th>
<th>Year End Projection</th>
<th>Variance</th>
<th>Variance %</th>
<th>Variance</th>
<th>Variance %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Budget £000s</td>
<td>Expenditure £000s</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>4,103</td>
<td>4,085</td>
<td>(17)</td>
<td>(0.4%)</td>
<td>5,574</td>
<td>5,399</td>
</tr>
<tr>
<td>Non pay</td>
<td>9,850</td>
<td>10,828</td>
<td>979</td>
<td>9.9%</td>
<td>13,043</td>
<td>14,701</td>
</tr>
<tr>
<td>Income</td>
<td>(495)</td>
<td>(1,673)</td>
<td>(1,178)</td>
<td>(238.1%)</td>
<td>(654)</td>
<td>(2,232)</td>
</tr>
<tr>
<td>Total</td>
<td>13,457</td>
<td>13,241</td>
<td>(216)</td>
<td>(1.6%)</td>
<td>17,963</td>
<td>17,868</td>
</tr>
<tr>
<td>Pay</td>
<td>4,797</td>
<td>4,623</td>
<td>(174)</td>
<td>(3.6%)</td>
<td>6,434</td>
<td>6,234</td>
</tr>
<tr>
<td>Non pay</td>
<td>3,718</td>
<td>3,619</td>
<td>(100)</td>
<td>(2.7%)</td>
<td>4,958</td>
<td>4,938</td>
</tr>
<tr>
<td>Income</td>
<td>(248)</td>
<td>(231)</td>
<td>16</td>
<td>6.6%</td>
<td>(330)</td>
<td>(315)</td>
</tr>
<tr>
<td>Total</td>
<td>8,268</td>
<td>8,011</td>
<td>(257)</td>
<td>(3.1%)</td>
<td>11,062</td>
<td>10,857</td>
</tr>
<tr>
<td>Pay</td>
<td>6,909</td>
<td>6,391</td>
<td>(518)</td>
<td>(7.5%)</td>
<td>9,214</td>
<td>8,658</td>
</tr>
<tr>
<td>Non pay</td>
<td>2,962</td>
<td>2,568</td>
<td>(394)</td>
<td>(13.3%)</td>
<td>3,947</td>
<td>3,349</td>
</tr>
<tr>
<td>Income</td>
<td>(44)</td>
<td>(123)</td>
<td>(79)</td>
<td>(178.3%)</td>
<td>(56)</td>
<td>(86)</td>
</tr>
<tr>
<td>Total</td>
<td>9,827</td>
<td>8,835</td>
<td>(991)</td>
<td>(10.1%)</td>
<td>13,104</td>
<td>11,921</td>
</tr>
<tr>
<td>Pay</td>
<td>4,977</td>
<td>4,854</td>
<td>(124)</td>
<td>(2.5%)</td>
<td>6,745</td>
<td>6,798</td>
</tr>
<tr>
<td>Non pay</td>
<td>4,098</td>
<td>3,960</td>
<td>(138)</td>
<td>(3.4%)</td>
<td>6,054</td>
<td>5,945</td>
</tr>
<tr>
<td>Income</td>
<td>0</td>
<td>(9)</td>
<td>(9)</td>
<td>--</td>
<td>(15)</td>
<td>(130)</td>
</tr>
<tr>
<td>Total</td>
<td>9,075</td>
<td>8,805</td>
<td>(270)</td>
<td>(3.0%)</td>
<td>12,784</td>
<td>12,613</td>
</tr>
<tr>
<td>Subtotal</td>
<td>40,627</td>
<td>38,892</td>
<td>(1,735)</td>
<td>(4.3%)</td>
<td>54,913</td>
<td>53,259</td>
</tr>
<tr>
<td>Pay</td>
<td>2,808</td>
<td>2,728</td>
<td>(80)</td>
<td>(2.9%)</td>
<td>3,768</td>
<td>3,652</td>
</tr>
<tr>
<td>Non pay</td>
<td>360</td>
<td>310</td>
<td>(50)</td>
<td>14.0%</td>
<td>454</td>
<td>359</td>
</tr>
<tr>
<td>Total</td>
<td>3,168</td>
<td>3,037</td>
<td>(130)</td>
<td>(4.1%)</td>
<td>4,221</td>
<td>4,011</td>
</tr>
<tr>
<td>Business Planning and Resources</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>1,818</td>
<td>1,909</td>
<td>91</td>
<td>5.0%</td>
<td>2,430</td>
<td>2,508</td>
</tr>
<tr>
<td>Non pay</td>
<td>4,234</td>
<td>4,019</td>
<td>(215)</td>
<td>(5.1%)</td>
<td>5,765</td>
<td>5,621</td>
</tr>
<tr>
<td>Income</td>
<td>0</td>
<td>(8)</td>
<td>(8)</td>
<td>--</td>
<td>0</td>
<td>(5)</td>
</tr>
<tr>
<td>Total</td>
<td>6,052</td>
<td>5,919</td>
<td>(132)</td>
<td>(2.2%)</td>
<td>8,195</td>
<td>8,124</td>
</tr>
</tbody>
</table>

**Centre for Clinical Practice**

**Centre for Health Technology Evaluation**

**Health and Social Care**

**Evidence Resources**

**Subtotal Guidance and Advice**

**Communications**

**Business Planning and Resources**
### Appendix A (Continued)

<table>
<thead>
<tr>
<th>Centre / Directorate</th>
<th>Budget £000s</th>
<th>Year to Date Expenditure £000s</th>
<th>Variance £000s</th>
<th>Variance %</th>
<th>Budget £000s</th>
<th>Expenditure £000s</th>
<th>Variance £000s</th>
<th>Variance %</th>
</tr>
</thead>
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<tr>
<td><strong>Income / Overheads</strong></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overheads</td>
<td>(259)</td>
<td>(344)</td>
<td>(84)</td>
<td>32.6%</td>
<td>(346)</td>
<td>(450)</td>
<td>(104)</td>
<td>30.1%</td>
</tr>
<tr>
<td>Income</td>
<td>(4,404)</td>
<td>(4,539)</td>
<td>(136)</td>
<td>3.1%</td>
<td>(6,456)</td>
<td>(6,600)</td>
<td>(144)</td>
<td>2.2%</td>
</tr>
<tr>
<td>Total</td>
<td>(4,663)</td>
<td>(4,883)</td>
<td>(220)</td>
<td>4.7%</td>
<td>(6,802)</td>
<td>(7,050)</td>
<td>(248)</td>
<td>3.6%</td>
</tr>
<tr>
<td><strong>Depreciation / Capital Adjustments</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>750</td>
<td>671</td>
<td>(79)</td>
<td>10.5%</td>
<td>1,000</td>
<td>942</td>
<td>(58)</td>
<td>5.8%</td>
</tr>
<tr>
<td>Total</td>
<td>750</td>
<td>671</td>
<td>(79)</td>
<td>10.5%</td>
<td>1,000</td>
<td>942</td>
<td>(58)</td>
<td>5.8%</td>
</tr>
<tr>
<td><strong>Reserves</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>965</td>
<td>0</td>
<td>(965)</td>
<td>100.0%</td>
<td>948</td>
<td>300</td>
<td>648</td>
<td>68.3%</td>
</tr>
<tr>
<td>Non pay</td>
<td>438</td>
<td>0</td>
<td>(438)</td>
<td>100.0%</td>
<td>460</td>
<td>200</td>
<td>260</td>
<td>56.5%</td>
</tr>
<tr>
<td>Total</td>
<td>1,403</td>
<td>0</td>
<td>(1,403)</td>
<td>100.0%</td>
<td>1,407</td>
<td>500</td>
<td>(907)</td>
<td>64.5%</td>
</tr>
<tr>
<td><strong>NICE Operational Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>26,378</td>
<td>24,590</td>
<td>(1,788)</td>
<td>6.8%</td>
<td>35,111</td>
<td>33,549</td>
<td>(1,562)</td>
<td>4.4%</td>
</tr>
<tr>
<td>Non pay</td>
<td>26,149</td>
<td>25,630</td>
<td>(519)</td>
<td>2.0%</td>
<td>35,334</td>
<td>35,605</td>
<td>271</td>
<td>0.8%</td>
</tr>
<tr>
<td>Income</td>
<td>(5,190)</td>
<td>(6,583)</td>
<td>(1,393)</td>
<td>26.8%</td>
<td>(7,511)</td>
<td>(9,368)</td>
<td>(1,857)</td>
<td>24.7%</td>
</tr>
<tr>
<td>Total</td>
<td>47,336</td>
<td>43,636</td>
<td>(3,700)</td>
<td>7.8%</td>
<td>62,935</td>
<td>59,786</td>
<td>(3,149)</td>
<td>5.0%</td>
</tr>
<tr>
<td><strong>NICE International</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>1,437</td>
<td>910</td>
<td>(527)</td>
<td>36.7%</td>
<td>1,916</td>
<td>2,143</td>
<td>227</td>
<td>11.8%</td>
</tr>
<tr>
<td>Non pay</td>
<td>1,905</td>
<td>1,405</td>
<td>499</td>
<td>26.2%</td>
<td>(2,540)</td>
<td>(2,798)</td>
<td>(258)</td>
<td>(10.2%)</td>
</tr>
<tr>
<td>Total</td>
<td>3,342</td>
<td>2,315</td>
<td>(1,027)</td>
<td>40.4%</td>
<td>4,456</td>
<td>4,941</td>
<td>485</td>
<td>10.9%</td>
</tr>
<tr>
<td><strong>Scientific Advice</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>482</td>
<td>499</td>
<td>17</td>
<td>3.6%</td>
<td>643</td>
<td>712</td>
<td>69</td>
<td>10.8%</td>
</tr>
<tr>
<td>Non pay</td>
<td>199</td>
<td>259</td>
<td>59</td>
<td>29.7%</td>
<td>266</td>
<td>399</td>
<td>133</td>
<td>50.0%</td>
</tr>
<tr>
<td>Income</td>
<td>(682)</td>
<td>(814)</td>
<td>(132)</td>
<td>19.3%</td>
<td>(909)</td>
<td>(1,164)</td>
<td>(255)</td>
<td>(28.1%)</td>
</tr>
<tr>
<td>Total</td>
<td>(0)</td>
<td>(55)</td>
<td>(55)</td>
<td>n/a</td>
<td>0</td>
<td>(53)</td>
<td>(53)</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>NICE Grand Total</strong></td>
<td>47,374</td>
<td>43,603</td>
<td>(3,770)</td>
<td>8.0%</td>
<td>62,985</td>
<td>59,756</td>
<td>(3,229)</td>
<td>5.1%</td>
</tr>
</tbody>
</table>
Appendix B - Workforce strategy update at 31 December 2015

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

<table>
<thead>
<tr>
<th>Transformational change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enabling change</td>
</tr>
<tr>
<td>Business and workforce planning</td>
</tr>
<tr>
<td>Practical tools and training information that have been developed to help managers plan and facilitate change and to support staff experiencing change are currently being tested.</td>
</tr>
<tr>
<td>Following procurement of an e-learning function, these tools will be further developed into interactive training programmes which will be supported by 121 coaching. This work also feeds into the “NICE Manager” core competencies.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Resourcing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment</td>
</tr>
<tr>
<td>Retention</td>
</tr>
<tr>
<td>Innovation</td>
</tr>
<tr>
<td>The review of recruitment practices continues. The aim is to improve current recruitment practices and consider options for innovative ways of recruiting in the future.</td>
</tr>
<tr>
<td>Target date: late January 2016</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Maximising potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership and management</td>
</tr>
<tr>
<td>Managing performance</td>
</tr>
<tr>
<td>Succession planning and talent management</td>
</tr>
<tr>
<td>NICE manager</td>
</tr>
<tr>
<td>The core competencies of the ‘NICE manager’ are being piloted in some areas with the HR Business Partners supporting managers to undertake a skills gap analysis and where gaps are identified, managers will be directed to the learning programmes that have been developed to support the competency framework.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Learning management system</th>
</tr>
</thead>
<tbody>
<tr>
<td>The procurement of an electronic Learning Management System (LMS) is underway, with an anticipated contract being agreed in January 2016. This will provide a one-stop portal for managers and their staff to record and monitor training needs and to access training resources. It will also provide the platform for the change management and workforce planning tools and will include performance management training and a full e-appraisal module</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mentoring programme</th>
</tr>
</thead>
<tbody>
<tr>
<td>A formal mentoring programme has now been rolled out. In six months we will review its success and expand the scheme as required.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Department of Health Leadership Scheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>We continue to be actively involved in supporting this DH initiative which will give our most senior staff an opportunity to obtain a place on the new scheme for future Chief Executives.</td>
</tr>
</tbody>
</table>
The Health and Wellbeing Strategy group continue to support employee wellbeing at work, and to meet our obligations in line with NICE Guidance. An action plan is being worked through which aims to achieve improved wellbeing initiatives for staff in terms of the organisational commitment and leadership, line manager duties, employee engagement, the physical work environment, mental wellbeing and the prevention of health issues. Some actions that have been achieved and developed include:

- Organisational commitment and leadership - the development and implementation of a mentor scheme; Healthy Work Week
- Line manager duties – Resources and training for managers have been increased covering topics such as assessing against the Health and Safety Executive stress tool; guides to deal with stress; flexible working guidance for managers; HR drop in sessions
- Employee engagement – Partnership working group implemented; group of staff volunteers recruited to coordinate and promote activities; staff survey action plan development and ongoing implementation; partnership working with UNISON
- Physical work environment – weekly office inspections implemented; increased promotion on workstation assessments to improve posture and potential musculoskeletal problems; new toilet facilities being implemented
- Mental wellbeing – Increased resources made available for staff and managers including free online training for mental health awareness; ongoing promotion of employee assistance and counselling services
- Prevention of health issues – Development and implementation of smoke-free policy, including paid time off for evidence based smoking cessation; standing desk audits and promotion; factsheets and resources increased for staff on topics such as healthy eating and physical activity.

One initiative that the group has focussed on this quarter is Healthy Work Week which is taking place 18th – 22nd January 2016, during which many activities are planned. Each day focusses on a different area of the Five Ways to Wellbeing (connect, be active, take notice, keep learning and giving) and addresses need of our employees based on the responses from staff within the 2015 annual staff survey.

Activities taking place include:

- **Connect** – Free fruit drop at all desks; quiz on health for staff; promotion of partnership working and UNISON; promotion of actions completed following the staff survey
- **Be active** – lunchtime runs; healthy heart workshop (British Heart Foundation); staff blogs; promotion of facilities (standing desks, showers, cycle storage)
- **Take notice** – mindfulness sessions; promotion of employee assistance; factsheets and stress tools available
- **Keep learning** – promotion of online modules; healthy lunch sharing and recipe ideas; healthy options promotion; mental health awareness sessions (run by MIND)
- **Give** – mentoring scheme promotion; volunteering case studies and ideas; lunchtime guided walks.
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

ANNUAL UPTAKE REPORT

This Annual Uptake report provides the Board with an overview of the information NICE has about how our guidance and quality standards are being used.

The Board is asked to approve the report.

Professor Gillian Leng
Director, Health and Social Care
January 2016
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Preface

1. This annual report provides examples of published data about the uptake and use of NICE guidance and Quality Standards. The data are largely drawn from the Uptake Database on the NICE Website, which holds a comprehensive set of information about the use of NICE guidance.

2. The report includes examples of good uptake as well as some areas where further progress is desirable, providing a broadly representative overview of the way in which guidance and Quality Standards are used. NICE is continuing to look at ways to improve and expand the range of sources it uses to better evaluate uptake, including working with those organisations that manage the national audits.

3. NICE also undertakes other activities to determine how well guidance and standards are being used across the health and social care system. This includes collating ongoing feedback from the NICE Field Team against a range of metrics, such as whether local organisations have a standard process for looking at new NICE guidance.

4. In future, reports based on uptake data will be combined with other sources of feedback, and be presented to the Board as twice yearly progress reports. These will provide a coherent and overarching picture of the work being undertaken across health and social care to put NICE guidance into practice.
Executive summary

5. This report gives an overview of how NICE recommendations for effective and cost-effective practice are used in the NHS. It summarises the data recorded in the NICE uptake database by combining information from the database with examples of the uptake of NICE technology appraisals published by the Health and Social Care Information Centre. This is the second annual uptake report and includes data for 24 pieces of ‘active’ guidance published up to March 2015.

6. The uptake database contains published audit data that compares current practice against NICE recommendations. It contains information about the uptake of clinical guidelines and quality standards, with less about public health guidance, technology appraisals and interventional procedures guidance. Every month the Impact team at NICE search national audits and academic journals, sift through references, identify data that maps onto NICE recommendations or quality statements, extract the relevant data and upload this to the uptake database. The uptake database currently holds information on 1339 data points, compared with 614 data points held in January 2015. There is very little uptake data for social care, medical device or diagnostic guidance because these areas are generally under-reported in the published literature.

7. NICE uses uptake data to understand how guidance is currently used in the NHS and to identify areas of variation in care. The data can also inform decisions on updating guidance and to identify areas where uptake is low or under-reported. It is important to understand current practice during scoping and development of NICE guidance as this may affect how recommendations are implemented in practice.

8. This report summarises the uptake of recommendations from 24 pieces of NICE guidance. Guidance is selected based on a review of available data and aims to reflect a wide range of topic areas. Across the 24 pieces of NICE guidance that are included, uptake of NICE recommendations ranged from 38% to 82%. The results suggest that while uptake of NICE guidance has increased over time, further improvements could be achieved. In particular, this report highlights that the provision of transition handover clinics for young people with epilepsy, and
delivery of speech and language therapy in people with stroke are potential areas where uptake of NICE recommendations could be improved.

9. The uptake database continues to be developed in conjunction with other data collecting organisations, such as the Healthcare Quality Improvement Partnership (HQIP) and NHS England. Of the 27 national audits managed by HQIP, 10 have published reports since January 2015. Of the 10 national audits reported this year, 9 have data that maps to NICE recommendations and quality statements and this data has been included in the database. NICE is currently working with HQIP to encourage greater alignment between data collection for national audits and NICE quality standards.

10. NICE encourages organisations to submit audit data directly to the uptake database, and a quality standards service improvement template has been developed to enable organisations to measure their performance across a range of quality standard statements. Collecting more data on the uptake of NICE public health and social care guidance is also welcomed. We are working closely with manufacturers to enable more data to be collected from industry about the uptake of recommended medical devices and diagnostics.
Introduction

11. The Impact team at NICE identifies and extracts data examining the uptake of NICE guidance. This uptake report shares a number of examples from the information we have about how NICE evidence-based guidance is being used. NICE does not have a remit to directly collect data and therefore this report is based on information taken from a wide range of data sources including national and local audits, peer-reviewed publications and other externally produced reports.

12. The uptake of NICE guidance is one way of measuring variation in NHS care. NHS England’s Five Year Forward View (5YFV), published in October 2014, highlighted the need to reduce variations in the quality and safety of NHS care to ensure consistently high standards of care. Addressing variation is a common theme across NHS England’s business plan for 2015-2016. Sharing data on the uptake of evidence-based recommendations will help the NHS identify where it may need to focus to reduce these variations, and to narrow the gap between the best and the worst, whilst raising the quality bar for everyone. At a time when 66% of NHS trusts are forecasting that expenditure will exceed income by the end of 2015/16\(^1\) addressing variation may also help the NHS meet the challenges of rising costs and increasing demand.

13. To help maximise value, NHS England’s Right Care programme examines the distribution of care and relates routinely available data to investment, activity and outcomes to the whole population in need. In addition, working collaboratively with other healthcare organisations, this programme also seeks to underpin the identification of unwarranted variation and the actions needed to tackle it.

The uptake database and methodology

14. Our uptake database, which we have called ‘uptake data’, has been organised to allow users to see the data at individual recommendation or quality statement measure level to help them better understand how our guidance is being used and to see changes in uptake over time. We identify the data for inclusion in uptake data on a monthly basis by reviewing a wide range of sources including

\(^1\) The Kings Fund, Quarterly Monitoring Report 16
peer-reviewed publications and published national audits. We then check the
data to make sure it reflects our guidance and is new and original work. If it
meets these criteria it is entered into the database.

15. The criteria for inclusion are that the publication or audit must:

- contain new and original work (literature reviews are excluded)
- have findings and results that relate to populations resident in England,
  Scotland, Northern Ireland or Wales
- include quantitative data (reported as a compliance measure) and map to
  a specific recommendation or measure published in NICE guidance

16. The guidance and standards used as examples in this report were chosen to
reflect a broad range of topic areas and recommendations, and because each
reported at least 2 data points after publication. The examples have also been
chosen to show areas of low and high uptake.

17. Our first social care guideline was published in 2014 and we have very little
uptake data for it. Three social care guidelines will be published towards the end
of 2015. We will consider how to encourage more audits in social care and intend
to seek the views of people working in this sector on the best way to do this.

18. There is currently little uptake data for NICE-recommended medical devices and
diagnostics. This is partly because routinely collected data in the NHS rarely
includes information about the use of particular technologies. The NHS is working
with industry associations (Association of British Healthcare Industries and British
In Vitro Diagnostics Association) to find ways to collect this data. We are helping
in this by asking companies, whose products have been recommended by us, for
data about their sales.

19. Data from the Innovation Scorecard, have not been included in the uptake
database because the results are not reported as a compliance measure. The
Health and Social Care Information Centre (HSCIC) publishes the Innovation
Scorecard and makes use of data for NICE appraised medicines and medical
technologies currently available from a range of sources, both from the NHS and
the commercial sector. The scorecard was first published in January 2013 and is updated on a quarterly basis.

**Summary of uptake data**

20. Table 1 shows how much information we have on NICE guidance and quality standards published before March 2015. We have not included data for interventional procedures guidance because they do not include recommendations for practice. We define uptake data as a single piece of information about the uptake of a recommendation or quality statement measure.

<table>
<thead>
<tr>
<th>Number of published and</th>
<th>Proportion of products with uptake data (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘active’ NICE products by the end of March 2015</td>
<td></td>
</tr>
<tr>
<td>Clinical guidelines</td>
<td>152</td>
</tr>
<tr>
<td>Quality standards</td>
<td>86</td>
</tr>
<tr>
<td>Technology appraisal</td>
<td>214</td>
</tr>
<tr>
<td>Public health guidelines</td>
<td>56</td>
</tr>
<tr>
<td>Medical technologies guidance</td>
<td>19</td>
</tr>
<tr>
<td>Social care guidelines</td>
<td>1</td>
</tr>
<tr>
<td>Medicines practice guidelines</td>
<td>2</td>
</tr>
<tr>
<td>Safe staffing guidelines</td>
<td>2</td>
</tr>
<tr>
<td>Diagnostics guidance</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>545</td>
</tr>
</tbody>
</table>

21. We recognise that not all NICE guidance and quality standards have been implemented fully, and that the data collected to date has been drawn from published sources so does not represent the full picture. Figure 1 shows the number of reported data points broken down by 10% categories. For example, there are 201 data points with reported uptake results between 90% and 100%.

22. Figure 1 is a snapshot of the individual pieces of data held in the uptake database at the end of August 2015. It does not show change for individual pieces of guidance or timescales. For example, results in the lower bands could reflect that audits may be at an early stage of implementing the recommendations.
23. The number of data points held in the database has more than doubled since the last uptake annual board report. Around 95% of the data points relate to clinical guidelines and quality standards, with a fairly even split between the two. Much of this new data has come from national audits and reports. There is usually a break between the point of data collection and publication, leading to a delay in data availability.

Results: examples of uptake data

Epilepsy in adults and children and young people

24. Epilepsy is one of the commonest serious neurological disorders seen in primary care\(^2\). There are currently around 320,000 adults and 34,000 children and young people with epilepsy who are receiving anti-epileptic drugs\(^3\). Studies carried out

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\(^3\) NICE (2013) *Diagnosis and management of the epilepsies in adults, children and young people: commissioning guide*. Figures based on primary care data from IMS Disease Analyser.
in various settings have estimated that up to 30% of people are incorrectly
diagnosed with epilepsy⁴.

25. The need for continuity of care during transition from paediatric to adult services
is particularly important for young people. Good management during this period is
vital for developing and maintaining self-esteem and confidence. It also provides
an important opportunity to review the diagnosis, classification, cause and
management of a young person's epilepsy before they enter adulthood⁵ ⁶.

26. The NICE guideline on the epilepsies: the diagnosis and management of the
epilepsies in adults and children in primary and secondary care, published in
January 2012, recommends that during adolescence a named clinician should
take responsibility for the ongoing management of the young person with
epilepsy and ensure smooth transition of care to adult services.

27. NICE quality standards for the epilepsies in adults and the epilepsies in children
and young people published in February 2013 and prioritise 9 areas from relevant
guidance. Both quality standards state that young people with epilepsy should
have an agreed transition period during which their continuing epilepsy care is
reviewed jointly by paediatric and adult services. The Epilepsy12 national audit
reports on healthcare for children and young people with suspected epileptic
seizures. This includes data on the proportion of units that provide an epilepsy
handover clinic (a clinic where young people 'leave the paediatric service and join
an adult service' which comprises both adult and paediatric health professionals).

⁴ Chowdhury FA, Nashef L, Elwes RD (2008) Misdiagnosis in epilepsy: a review and recognition of
⁵ NICE (2013) The epilepsies in adults quality standard
⁶ NICE (2013) The epilepsies in children and young people quality standard
28. The chart shows an 8 percentage point increase in the proportion of units providing an epilepsy handover clinic, from 30% in 2011 to 38% in 2014. Unfortunately, data is not available before 2010 or after 2014. Similar results were found in the Epilepsy Action report A Critical Time for Epilepsy in England, published in January 2013. It reported that 35% of acute trusts offered transition clinics for young people moving from paediatric to adult services.

29. Epilepsy misdiagnosis is a costly problem, estimated at around £268 million a year\(^7\). Providing transition clinics where diagnosis is reviewed may help the NHS to reduce misdiagnosis rates and the associated costs.

30. In 2007 an All Party Parliamentary Group\(^8\) report established that 70% of people with epilepsy could be seizure-free with optimal treatment and that the case for improving epilepsy services was overwhelming. They received evidence that

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\(^7\) The Joint Epilepsy Council of the UK and Ireland. Epilepsy prevalence, incidence and other statistics. 2011

\(^8\) All Party Parliamentary Group on Epilepsy. The human and economic cost of epilepsy in England. 2007
transition services were not routine for people with epilepsy and, 8 years on, our uptake data suggests that this is still the case. Evidence from other studies, for different conditions, has shown that patient outcomes can be improved by providing transition services\textsuperscript{9}.

31. This area of epilepsy care warrants further quality improvement; therefore this data will inform the quality standards annual review process in summer 2016. The NICE guideline on transition from children’s to adult’s services is also in development and due to be published in February 2016. Improving the availability of transition clinics will provide better integrated services, having a significant impact on both the costs to the NHS as a whole and the individual management of epilepsy.

**Hip fracture**

32. There were around 65,500 emergency hospital admissions for hip fracture in adults\textsuperscript{10} in England in 2013/14\textsuperscript{11}, higher than the 61,772 reported in 2010/11\textsuperscript{12}. Hip fracture risk increases with age, and with an ageing population the total direct cost to the NHS is expected to rise. The total direct costs of all fragility fractures are forecast to rise, reaching £2.2 billion by 2020, with most of these costs relating to hip fracture care\textsuperscript{13}. The choice of procedure to treat hip fracture will need to take account of comorbid conditions, which may affect subsequent recovery and rehabilitation.

33. Traditional types of uncemented hemiarthroplasty are associated with a poorer functional outcome and increased risk of mortality compared with cemented implants. The use of cement reduces postoperative pain and aids recovery\textsuperscript{14}. The NICE hip fracture guideline, published in June 2011, recommends cemented implants in patients undergoing surgery with arthroplasty.

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10 Aged 18 years and over

11 Hospital Episode Statistics for financial year 2013-2014

12 Hospital Episode Statistics for financial year 2010-2011

13 Quality Watch (2013) *Focus on hip fracture*

14 Royal College of Physicians (2014) *National Hip Fracture Database extended report 2014*
34. The NICE quality standard on hip fracture, published in March 2012, prioritised 12 areas from relevant guidance, including a statement that people with displaced intracapsular fracture receive cemented arthroplasty, with the offer of total hip replacement if clinically eligible. The process measure is the proportion of people with displaced intracapsular fracture who have cemented arthroplasty.\(^{15}\)

35. The National Hip Fracture Database reports annually on all eligible hospitals in England, Wales and Northern Ireland. It describes care and outcomes for people admitted with a hip fracture, and is the largest database of its kind in the world. It reported on the proportion of people with displaced intracapsular fracture who had cemented arthroplasty between 2010 and 2014.

Figure 3 NICE quality standard on hip fracture, statement 7 (intracapsular fracture)

\(^{15}\) An audit standard of less than 100% should be expected for this process measure, to allow for cases where the practitioner considers it not in the best interests of the person to have surgery.
36. Figure 3 shows a 19.3% increase in the proportion of people who had a displaced intracapsular fracture with cemented arthroplasty between 2010 (63%) and 2014 (82.3%).

37. The NICE hip fracture guideline costing report estimated that a cemented arthroplasty saves £63.68 per procedure compared with the uncemented version. This could equate to an annual cost saving of £690,000 for the NHS. Although cemented arthroplasty is currently being used for 82% of appropriate hip fractures as shown above, there is room for further improvement to allow better functional outcomes for patients and generate potential cost savings for the NHS.

**Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure**

38. Arrhythmia is a term used to describe conditions where the heart contracts irregularly, or at a faster or slower pace than normal. Arrhythmias that arise from ventricles (ventricular arrhythmias) can occur unexpectedly and can cause sudden death when insufficient blood is pumped by the heart. Ventricular arrhythmias most commonly occur in people with underlying heart disease. Approximately 75% to 80% of the 70,000 sudden cardiac deaths in England and Wales in 2010 could be attributed to ventricular arrhythmias.  

39. Heart failure is a chronic condition predominately affecting people over 50 years old. It is estimated that there are about 900,000 people in the UK who have definite or probable heart failure. About two-fifths of people with heart failure will have left ventricular systolic dysfunction, a proportion of whom will be suitable for implantation of a cardiac rhythm management device. People with heart

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16 NICE *Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (review of TA95 and TA120)*

17 NICE *Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (review of TA95 and TA120)*


failure are at risk from sudden cardiac death; this is the most common cause of death in people with mild to moderate heart failure.\(^ {20} \)

40. The NICE technology appraisal guidance on implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (review of TA95 and TA120) was published in June 2014. Implantable cardioverter defibrillators (ICD) are recommended as an option for people who have had a serious ventricular arrhythmia, who have an inherited heart condition linked to a high risk of sudden death, or who have had surgery to repair congenital heart disease. For certain people with heart failure caused by left ventricular systolic dysfunction, ICDs, cardiac resynchronisation therapy with defibrillator (CRT-D) or with pacing (CRT-P) are recommended as treatment options.


42. The National Audit of Cardiac Rhythm Management Devices collects data on the implant rate for new implantable cardioverter defibrillators and the total cardiac resynchronisation therapy implant rate (including both new and replacement CRT-D and CRT-P).
43. The national audit shows an increase in implant rates for implantable cardioverter defibrillators and cardiac resynchronisation therapy in England between 2003 and 2013. The increase is more significant for cardiac resynchronisation therapy.

44. The national audit also compares implant rates with the Western European average. The cardiac resynchronisation therapy implant rate for England in 2013 was above the average (151 per million population compared with 119 per million population). This is mainly due to a higher than average implant rate of CRT-P devices. For implantable cardioverter defibrillators, the implant rate was below the average (72 per million population compared with 141 per million population). The results of the 2013/14 audit suggest that the 2014 NICE guideline is simpler and more closely aligned with international guidance, and it is hoped that future implant rates will continue to move closer to the Western European average.

45. Cardiac rhythm management devices have been shown to be an effective use of NHS resources in improving quality of life and survival for people with ventricular
arrhythmias and heart failure\textsuperscript{21}. The national audit shows that more people are having implantable cardioverter defibrillators and cardiac resynchronisation therapy implants. Progress appears good but this is against a background of an ageing population and an increase in heart disease and heart failure. In particular, further improvements could be made in respect of ICDs and CRT-D devices.

**Lung cancer (non-small cell, EGFR-TK mutation positive)**

46. Lung cancer is the second most common cancer in adults, with 36,653 cases registered in England in 2013\textsuperscript{22}. Non-small cell lung cancer (NSCLC) accounts for 85\% to 90\% of all lung cancers. Nationally it is estimated that one-third of people with NSCLC have chemotherapy, and of those it is expected that 16.6\% will have EGFR-TK mutation-positive tumours\textsuperscript{23}. This equates to an estimated treatment population of 1200 people each year. The 2014 National Lung Cancer Audit showed that the number of patients with histologically confirmed NSCLC tumours which are not further subtyped has fallen from 15.8\% to 12.9\%.

47. Treatment options differ depending on a person’s EGFR status as either positive or negative. Mutated EGFRs show an increased rate of uncontrolled tumour growth, which can speed up the cancer’s progression. People with mutation-positive tumours may gain more benefit from targeted therapies compared with standard chemotherapy. Although lung cancer is one of the more common cancers, survival is generally low (median survival 232 days)\textsuperscript{24}. This trend is similar for NSCLC, with median survival of 293 days\textsuperscript{25} and 100 days\textsuperscript{25} for stage 3 and 4 NSCLC respectively.

48. NICE recommends 3 biological therapies for NSCLC:

\begin{itemize}
  \item \textsuperscript{21} Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (review of TA95 and TA120)
  \item \textsuperscript{23} Health and social care information centre (2015) NICE Technology Appraisals in the NHS in England (Innovation Scorecard): to September 2014, Experimental Statistics. Estimates of predicted use compared to observed use.
  \item \textsuperscript{24} Public Health England (2015) National Cancer Intelligence Network Rare and less common cancers, Incidence and Mortality in England 2010 to 2013
  \item \textsuperscript{25} Health and Social Care Information Centre (2014) National Lung Cancer Audit Report 2014
\end{itemize}
• NICE technology appraisal guidance on afatinib for the treatment of epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small cell lung cancer (2014) recommends afatinib as an option for people with locally advanced or metastatic NSCLC if they test positive for EGFR-TK mutation, have not previously had a EGFR-TK inhibitor and the manufacturer provides the drug at the fixed price agreed under the patient access scheme.

• NICE technology appraisal guidance on erlotinib for the first line treatment of locally advanced or metastatic EGFR-TK mutation-positive non-small cell lung cancer (2012) recommends erlotinib as a first-line treatment option for people with locally advanced or metastatic NSCLC if they test positive for EGFR-TK mutation and the manufacturer provides the drug at the fixed price agreed under the patient access scheme.

• NICE technology appraisal guidance on erlotinib for the treatment of non-small cell lung cancer (2008) recommends erlotinib as a second-line treatment option for people with NSCLC.

• NICE technology appraisal guidance on gefitinib for the first-line treatment of locally advanced or metastatic non-small cell lung cancer (2010) recommends gefitinib as a first-line treatment option for people with locally advanced or metastatic NSCLC if they test positive for EGFR-TK mutation and the manufacturer provides the drug at the fixed price agreed under the patient access scheme.

49. During 2013, biological therapy treatment services for lung cancer patients in England and Wales were available on-site in 90% of trusts and off-site in 10% of trusts.

50. Uptake data for these medicines has been taken from the Innovation Scorecard (May 2015), which used primary and secondary care prescribing data from the

26 Health and Social Care Information Centre (2014) National Lung Cancer Audit Report 2014
PACT system and the Hospital Pharmacy Audit Index (HPAI) database from April 2010 to September 2014.

51. The data in figure 5 shows the number of defined daily doses (DDDs) per quarter for afatinib, erlotinib and gefitinib. (DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults.) It is important to note that erlotinib is also indicated for treatment of metastatic pancreatic cancer and it is not possible to establish proportional usage by indication.

**Figure 5 Defined daily doses of afatinib, erlotinib and gefitinib in primary and secondary care (April 2010 to September 2014)**

52. Figure 5 shows that the volume of all medicines prescribed increased from 77,965 DDDs in quarter 1 of 2010/11 to 103,632 DDDs in quarter 2 of 2014/15. This potentially equates to an additional 281 patients receiving treatment with these medicines over that period. These results suggest that more people are receiving treatment for NSCLC. In particular, there was a steady increase in
prescribing for gefitinib following publication of NICE technology appraisal guidance on *gefitinib for the first-line treatment of locally advanced or metastatic non-small cell lung cancer* in 2010. During the same time period, prescribing for erlotinib was decreasing. Afatinib prescribing shows a small increase following publication of the related technology appraisal guidance in 2014, but more data is needed to explore this in the future.

**Figure 6 Observed prescribing as a proportion of expected prescribing of afatinib, erlotinib and gefitinib in primary and secondary care (April 2010 to September 2014)**

53. Figure 6 shows that following publication of NICE technology appraisal guidance on *gefitinib for the first-line treatment of locally advanced or metastatic non-small cell lung cancer* in 2010, the observed use of treatments for NSCLC has become closer to predicted use. For the financial year 2013/14, the observed volume of these medicines was 5% higher than expected, with 397,645 daily doses (expected) and 418,847 daily doses (observed)\(^23\). However, given that erlotinib is
also used for the treatment of metastatic pancreatic cancer, it is likely that observed use is close to predicted use.

54. In summary, there has been a general increase in the volume of all 3 medicines prescribed for the treatment of NSCLC in England in 2014/15. These upward trends appear to follow publication of the associated NICE technology appraisals, which have provided more treatment options for people with NSCLC. Prescribing trends for the individual drugs for NSCLC vary over time but may reflect increased patient choice. Earlier treatment may have a beneficial impact on survival\textsuperscript{25}, and so the increasing trends in prescribing data are encouraging. However, it is important to note that erlotinib has licensed indications that have not been appraised by NICE.

**Non-vitamin K antagonist oral anticoagulants for atrial fibrillation**

55. Atrial fibrillation is the most common cardiac arrhythmia that affects about 1.6% of the population in England. The number of people in England with a diagnosis of atrial fibrillation has increased steadily from 823,000 in March 2012 to 883,938 in March 2014\textsuperscript{27}. Atrial fibrillation is a major cause of ischaemic stroke, with the risk of stroke being five times higher than in a person with a normal heart rhythm\textsuperscript{28}. Anticoagulation reduces the risk of stroke for people with atrial fibrillation. The Department of Health estimates that 7000 strokes could be avoided and 2100 lives saved each year in England if everyone with atrial fibrillation was appropriately managed\textsuperscript{29}.

56. The vitamin K antagonist warfarin is the main oral anticoagulant used in the UK, but a number of newer medicines are now available for stroke prevention in atrial fibrillation. Non-vitamin K antagonist oral anticoagulants (NOACs) do not need the same level of routine coagulation monitoring as warfarin. In 2012 and 2013, NICE positively appraised apixaban, dabigatran etexilate and rivaroxaban for use in the prevention of stroke in people with non-valvular atrial fibrillation.

\textsuperscript{27} Health and Social Care Information Centre (2014) *Quality and Outcomes Framework (QOF) - 2013-14*  
\textsuperscript{29} Department of Health (2013) *Cardiovascular Disease Outcomes Strategy: Improving outcomes for people with or at risk of cardiovascular disease*
57. NICE updated its clinical guideline on atrial fibrillation in June 2014. This stated that anticoagulation for atrial fibrillation may be with apixaban, dabigatran etexilate, rivaroxaban or a vitamin K antagonist. The clinical guideline also recommended that aspirin monotherapy should not be offered solely for stroke prevention to people with atrial fibrillation.

58. The NICE Implementation Collaborative published a consensus statement alongside the guideline which addressed some of the barriers to prescribing NOACs.

59. NICE published a quality standard on atrial fibrillation: treatment and management in June 2015. The quality standard prioritised the following areas for quality improvement: offering anticoagulation to reduce stroke risk; not using aspirin as monotherapy for stroke prevention; discussing options for anticoagulation (including vitamin K antagonists and NOACs); and reassessing anticoagulation for adults taking a vitamin K antagonist who have poor anticoagulation control.

60. Uptake data for the NOACs was taken from the October 2015 Innovation Scorecard, and provides primary care prescribing data from April 2011 to March 2015. This data shows the volume of medicine prescribed and dispensed in the community, measured in DDDs. Figure 7 includes use of these medicines for the prevention of stroke in atrial fibrillation and also for other licensed indications.
Figure 7 Defined daily doses of apixaban, dabigatran etexilate and rivaroxaban in primary care (April 2011 to March 2015)

61. Figure 7 shows an increase in the prescribing of these medicines following publication of the respective technology appraisals. Since quarter 4 of 2011/12 (when NICE technology appraisal guidance on dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation was published) to quarter 4 of 2014/15, the volume of medicine prescribed increased from 0.1 million to 20.3 million DDDs. This potentially equates to an additional 220,771 patients taking NOACs over this period. It is not known when these additional patients were diagnosed with atrial fibrillation or whether they were previously anticoagulated. In addition, these medicines may have been used for other licenced indications.

62. In primary care, over the same period of time, prescribing of warfarin increased from 35.8 million DDDs in quarter 4 of 2011/12 to 40.1 million DDDs in quarter 4 of 2014/1530.

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30 NHS Business Services Authority ePACT.net
National Institute for Health and Care Excellence
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Date: 20 January 2016
Ref: 16/007
63. NOACs do not require the same level of routine coagulation monitoring as warfarin and so they represent an attractive option for some people with atrial fibrillation. They are potential lifesavers for some people with atrial fibrillation, particularly those who find it difficult to control their blood clotting with vitamin K antagonists or those who are intolerant to them. NOACs also represent an option for people newly diagnosed with atrial fibrillation and for those currently taking aspirin for stroke prevention. Given the important role of NOACs in preventing stroke in people with atrial fibrillation, there will be significant health benefits from the observed improved uptake of these medicines.

**Quitting smoking in pregnancy and following childbirth**

64. Smoking during pregnancy can cause serious pregnancy-related health problems. These include complications during labour and an increased risk of miscarriage, premature birth, still birth, low birthweight and sudden unexpected death in infancy. Smoking during pregnancy increases the risk of infant mortality by an estimated 40%.

65. The NICE public health guideline on quitting smoking in pregnancy and following childbirth was published in June 2010. The guideline includes a recommendation to assist midwives in identifying pregnant women who smoke and referring them to NHS Stop Smoking Services. It recommends: assessing exposure to tobacco smoke through discussion and use of a carbon monoxide test; explaining the health benefits of stopping smoking for the woman and her baby and advising her to stop; referring all women who smoke to NHS Stop Smoking Services; checking if the referral was taken up; re-referring where appropriate; and at each stage recording smoking status, CO level, whether a referral is accepted or declined and any feedback given.

66. During guideline development, fieldwork was carried out to evaluate how relevant and useful NICE’s recommendations were for practitioners and how feasible it would be to put them into practice. During the workshops and focus groups

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midwives raised concerns about the impact of the guidance on their time and workload. However, it was established that most areas already made use of a referral system in relation to offering smoking cessation advice.

67. Publication of the guideline was followed, in September 2012, by a NICE quality standard on antenatal care. The quality standard prioritised 12 areas from relevant guidelines and includes a statement that pregnant women who smoke are referred to an evidence-based stop smoking service at the booking appointment. Smoking rates in pregnancy are an outcome measure for this statement.

68. The HSCIC Statistics on NHS Stop Smoking Services in England provide data on the number of pregnant women setting a quit date through NHS Stop Smoking Services.

**Figure 8 NICE quality standard on antenatal care, statement 5 (risk assessment – smoking cessation)**

69. Figure 8 shows that the number of pregnant women setting a quit date through NHS Stop Smoking Services peaked in 2011/12 but has since fallen, from 26,080 in 2011/12 to 18,887 in 2014/15.
70. Data for the quality statement outcome measure can be found in the HSCIC Statistics on Women’s Smoking Status at Time of Delivery, England. The data shows a small year-on-year reduction in the proportion of women smoking at time of delivery from 14% in 2009/10 to 11.4% in 2014/15. This is close to the national ambition of 11% or less women smoking at the time of delivery, outlined in the tobacco control plan for England. At the same time there has been a year-on-year reduction in the actual number of women smoking at time of delivery from 91,328 in 2009/10 to 70,879 in 2014/15.

71. Additional data in respect of the quality standard will be available from the new Maternity Service Data Set, which includes smoking status as recorded at the initial booking appointment. Data submission started on 1 June 2015.

72. Since publication of the NICE guideline on quitting smoking in pregnancy and following childbirth there has been a year-on-year reduction in the proportion of women smoking at time of delivery. However, the reduction is small and an initial peak in the actual number of pregnant women setting a quit date through NHS Stop Smoking Services has been followed by falling numbers. Given the poor maternal and infant outcomes associated with smoking in pregnancy, this remains a priority area.

Specialist neonatal care

73. Babies born prematurely, sick or with low birthweight need specialised care in their first hours, days and often months. In 2013, 80,000 babies received care in neonatal units in England and Wales33. Breastfeeding affects the incidence of certain childhood diseases, including gastroenteritis, otitis media and necrotising enterocolitis (a serious inflammatory condition of the gut) in pre-term babies34.

74. The Department of Health produced a toolkit for high quality neonatal services in 2009, recommending that neonatal services should provide dedicated support for breastfeeding and the expression of milk, and the provision of breast pumps for every mother who needs them.

33 National Neonatal Audit Programme
75. The NICE quality standard on specialist neonatal care, published in October 2010, prioritises 9 areas from relevant guidance and includes a statement that: mothers of babies receiving specialist neonatal care are supported to start and continue breastfeeding, including being supported to express milk. The quality statement outcome measure is the proportion of babies born at less than 33 weeks of gestation having specialist neonatal care who are breastfed when discharged from hospital. The Department of Health toolkit is a source document for the quality standard.

76. The National Neonatal Audit Programme (NNAP) considers care processes and outcomes of babies admitted to neonatal units in England and Wales. The audit provides data on the proportion of babies born at less than 33 weeks gestation who are discharged home and having breast milk.

Figure 9 NICE quality standard on specialist neonatal care, statement 6 (breastfeeding)

77. Figure 9 shows an increase following publication of the NICE quality standard from 44% in 2010 to 59% in 2013.
78. The Picker Institute survey of parents’ experiences of neonatal care reported on a number of processes relating to the proportion of babies receiving breastmilk on discharge. The 2014 survey found that different proportions of parents received support from neonatal staff to express breast milk (78%), were provided with breastmilk expressing equipment (83%), were given privacy for expressing milk (77%) and were offered support from neonatal staff for breastfeeding (75%). The results were similar to those from the 2011 survey.

79. Preventing disease and saving resources: the potential contribution of increasing breastfeeding rates in the UK referred to the cost of treating necrotising enterocolitis in infants in neonatal units. It estimated that if the rate of any breastfeeding/breastmilk feeding at discharge increased from 35% (reported in 2006) to 50% there would be a cost saving of £2.3 million per year. The data from the NNAP suggests that this saving is already being achieved. It also estimated that increasing the rate from 50% to 75% would result in additional savings of £3.8 million per year, and that a further £3.8 million per year would be saved by increasing the rate to 100%. Rates of 100% at discharge have been achieved in some European and US neonatal units.

80. The NNAP data shows an increase in the number of premature babies discharged home receiving breast milk between 2010 and 2013. Parents report high levels of support from staff with privacy and equipment for expressing and breastfeeding. This has remained stable between 2011 and 2014, although it is not known how many women decide to not breastfeed. The increase in babies discharged home receiving breastmilk can be expected to reduce the incidence of a number of childhood diseases, including necrotising enterocolitis, generating further cost saving for the NHS.

**Stroke**

81. More than 966,000 people living in England have had a stroke, including around 300,000 who live with moderate to severe disability as a result. Stroke is one of...
the top 3 causes of death and costs the NHS over £3 billion annually\textsuperscript{36}. Many people have a high burden of impairment, activity limitation and participation restriction after stroke, and much of the post-stroke care relies on rehabilitation services. Stroke rehabilitation delivered by a multi-disciplinary team including physiotherapists, occupational therapists and speech and language therapists plays a key role in care.

82. In addition to the clear benefits of stroke rehabilitation for people after stroke, there are also potential cost savings for the NHS. The Department of Health \textit{Impact Assessment: National Stroke Strategy} report (2007) estimated that full implementation of community-based rehabilitation would cost £11.4 million, leading to £38.2 million in savings and a net saving of £26.8 million or £53,025 per 100,000 population. It is likely that both the costs and savings estimated in the report have increased over time.

83. The NICE quality standard on \textit{stroke} published in June 2010 prioritises 10 areas from relevant guidance, including ongoing rehabilitation. The quality standard includes a statement that: patients with stroke are offered a minimum of 45 minutes of each active therapy that is required, for a minimum of 5 days a week, at a level that enables the patient to meet their rehabilitation goals for as long as they are continuing to benefit from the therapy, and are able to tolerate it\textsuperscript{37}.

84. The NICE guideline on \textit{stroke rehabilitation} published in June 2013 recommends initially offering at least 45 minutes of each relevant stroke rehabilitation therapy for a minimum of 5 days per week to people who have the ability to participate, and where functional goals can be achieved.

85. Uptake data for the quality standard is available from the Sentinel Stroke National Audit Programme (SSNAP). The audit measures the quality of care people living with stroke receive throughout the whole care pathway up to 6 months after admission. This includes data on the percentage of the required minutes of physiotherapy, occupational therapy and speech and language therapy which

\textsuperscript{36} National Audit Office (2010) \textit{Progress in improving stroke care}

\textsuperscript{37} The source guidance for this statement was the Royal College of Physicians National clinical guideline for stroke, published in 2008.
were delivered. The data reported is an indirect means of measuring the uptake of NICE stroke quality standard 2 statement 7, and is shown in figure 10.

Figure 10 NICE quality standard on stroke, statement 7 (ongoing rehabilitation)

86. Figure 10 shows an increase in the percentage of necessary minutes of therapy which were delivered following the publication of the NICE guideline on stroke rehabilitation in June 2013. There has been an increase from 24% in 2013 to 74% in 2015 for occupational therapy, from 19% to 69% for physiotherapy, and from 8% to 38% for speech and language therapy.

87. Speech and language therapy can help people after stroke if they have communication or swallowing problems. It is estimated that one-third of people will have some level of communication difficulty after stroke and at least 40% will initially experience some difficulty swallowing, although many recover their swallow quickly\(^{38}\). Difficulties with communication can make it harder for people

\(^{38}\) Stroke Association (2012) [Speech and language therapy after stroke](http://www.strokeassociation.org.uk)
to get help and information, affect their social relationships, limit their independence and reduce their self-confidence. Problems with swallowing can put people at risk of infection or spoil their enjoyment of food.

88. The data shows that following publication of the NICE guideline on stroke rehabilitation and the NICE stroke quality standard, progress has been made in the intensity of rehabilitation therapy delivered after stroke. This improvement has been lower for speech and language therapy and may reflect fewer speech and language therapy staff working in the NHS compared with other members of the stroke rehabilitation team. There is strong evidence that rehabilitation improves outcomes for people after stroke and demonstrates that further improvement could be made in this priority area for quality improvement.

The health and wellbeing of looked-after children and young people

89. Every year around 10,000 16- to 18-year olds leave foster or residential care in England. Children and young people in care must leave local authority care by their 18th birthday, although local authorities must support care leavers until they are 21 years of age. On leaving care, some young people return home to their families, but many start to live independent lives.

90. In 2014 the Department for Education introduced Staying Put, which offers care leavers the opportunity of staying with their former foster carers until they are 21-years old. The aim is to ensure that young people can remain with their former foster carers until they are prepared for adulthood, experience a transition akin to their peers, avoid social exclusion and be more likely to avert a subsequent housing and tenancy breakdown.

91. The NICE public health guideline on looked after children and young people, published in October 2010, includes a recommendation on preparation for the transition to adulthood and moving to independent living.

92. The guideline was followed, in April 2013, by a NICE quality standard on the health and wellbeing of looked-after children and young people. The quality standard includes a statement that care-leavers ‘move to independence at their own pace’

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39 National Audit Office (2015) Care leavers’ transition to adulthood Department for Education
own pace’. The focus is on young people having a pathway plan that prepares them for leaving care and equips them with the skills they need to live independently. The statement’s outcome measures are: feedback from care leavers that they felt supported to move to live independently at their own pace; care leaver satisfaction with their accommodation, and the accommodation status of young people leaving care.

93. The Children’s Care Monitor survey reported children’s views on the state of social care in England up to 2013. The Children’s Commissioner for England subsequently took over responsibility for the survey and amended the questionnaire.

Figure 11 NICE quality standard on looked-after children and young people, statement 8 (support to move to independence)

94. The Children’s Care Monitor survey showed a small increase in the number of care-leavers who reported having a pathway plan in place. In addition, there were increases in the number of care leavers who rated the support they were getting and their accommodation as good or very good.
95. The *Children’s Commissioner for England Children in Care and Care Leavers survey* published in July 2015 reported that 54% of care-leavers stated that they had left care at the right time. Where care-leavers felt that they had not left at the right time the main reasons were feeling settled in their placement and being forced to leave before they were ready.

96. The Department for Education publishes national statistics on *children looked after in England, including adoption*. In the financial year 2013/14, 77.6% of former care-leavers aged 19 to 21 years were in accommodation classed as suitable (5.7% in accommodation classed as unsuitable and 16.8% no information). Some types of accommodation were judged by the local authority as suitable when this would not be expected by the Department of Education, and work is being done to assess and improve the quality of the data for future publications.

97. The National Audit Office report *Care Leavers’ Transition to Adulthood* was published in July 2015 and concluded that the system for supporting young people leaving care was not working effectively. In respect of accommodation, it referred to the Staying Put policy as a positive step but noted that it was too early to assess its impact.

98. The Children’s Care Monitor survey showed a small improvement in outcomes in respect of care-leavers moving to independence at their own pace between 2010 and 2013. However, data from the other reports described now indicates that further improvements could be made in this area.

**How NICE is using the uptake data**

99. We have many examples where uptake data shows change over time, which helps us to better understand the factors that may influence uptake. Some of the examples included show occasions when uptake has reached a high level. It seems likely that rapid change has been influenced not only by our guidance but also by incentives in the NHS such as best practice tariffs and CQUIN payments.

100. The prescribing data, taken from the Innovation Scorecard, demonstrates uptake in the NHS after we have recommended the use of a medicine in a
technology appraisal. The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE’s technology appraisals within 3 months (unless otherwise specified) of the date of publication. The prescribing data allows us to observe pace and scale of uptake and to consider what might be influencing this. The Department of Health and the Office for Life Sciences are currently undertaking a review into plans to give NHS patients quicker access to innovative medicines and medical technologies. The use of uptake data to optimise the adoption and diffusion of innovations in the NHS is included in the Accelerated Access Review.

101. The Innovation Scorecard includes estimates of how many people might be prescribed a particular medicine, and based on this an expected volume of medicine is calculated. It can be difficult to estimate how many patients are likely to benefit from each treatment. When more than 1 treatment option is available for patients and clinicians to choose from, there may be a number of influences on the decision-making process including patient experience, how the medicine is administered, how frequently it needs to be taken, any monitoring requirements and a clinician’s familiarity with individual products. As part of our work to support the development of the Innovation Scorecard we are further developing and improving the ways in which we calculate estimates.

102. One of the most important uses of our uptake data is at the point when we are reviewing guidance or quality standards. In the last 12 months there have been 4 occasions when the use of uptake data has led to a recommendation to update quality standards. These were the quality standards for venous thromboembolism prevention, chronic kidney disease, end-of-life care for adults and lung cancer.

Future plans
103. This report has presented an overview of the information that we have about how our evidence-based guidance and quality standards are being used. The selected examples reflect the different types of guidance, the diversity of the information available and the different levels of uptake. It has provided examples of the areas that continue to be priorities for the NHS and social care.
104. Having access to data is an essential part of delivering service improvement and measuring changes in outcomes for people who use services. We intend to continue to publish and expand our uptake data to support both commissioners and providers of the prevention, care and treatments we recommend.

105. By assembling this data in one place we aim to provide an opportunity for organisations to compare their own uptake of our guidance or quality standards with others. This may help organisations identify warranted and unwarranted variation. The resource will become more useful over time as its content increases.

106. We want to encourage organisations to send their audit data related to our guidance and quality standards directly to us for inclusion in the uptake data. We are aware that many thousands of audits are conducted across the NHS and increasingly in social care every year, representing a potentially rich source of uptake data that will be of interest to those using our guidance. We have developed a quality standards improvement template to enable organisations to measure their performance across a range of quality standard statements. This will facilitate the measurement of uptake as the NHS moves to new models of care as part of delivering the Five Year Forward View. We expect that a tailored approach to assessment will encourage more organisations to review their progress against self-selected quality statements and that this will encourage them to submit this data to our uptake database.

107. We know that when the data we identify and include in our uptake data closely matches our recommendations it becomes more meaningful to organisations that are monitoring their use of our guidance. For this reason we intend to continue our discussions with the Healthcare Quality Improvement Partnership, and other teams that develop the datasets for national audits, to align with and to influence the metrics used in national audits.

108. We know that the Care Quality Commission (CQC) is increasingly using NICE guidance to help assess whether organisations are compliant with CQC standards. We are aiming to develop our uptake data into a resource that can be used by organisations to compare their own rate of implementation of NICE
guidance. We do not believe that our uptake data should be used by CQC inspectors because of the diversity of the data sources, the small sample sizes of local audits, and the fact that most data is at a national level lends itself only to general comparison.

109. We now meet each company whose medical device or diagnostic products we recommended for use 1 month after guidance is published and then about 6 months later. During these meetings a detailed discussion is held about how best to measure uptake. At the same time we are talking with the HSCIC to identify how data that is routinely collected in the NHS can help to evidence uptake.

110. We hope that you have found this report informative and interesting. We would be very pleased to receive ideas and suggestions about how our uptake data can be improved and expanded. Feedback from people working in the NHS, public health, social care and other health settings as well as the wider public is welcomed. Please send your ideas to uptake@nice.org.uk.
The last public Board meeting considered the Accelerated Access Review’s interim report from its independent Chair, Sir Hugh Taylor. The interim report presented Sir Hugh’s emerging thinking on speeding up access to transformative health technology that can help change the lives of NHS patients. It set out five propositions which would shape the review’s debate with stakeholders in the period prior to the publication of the review’s final report.

The Board discussed the report and agreed that in addition to NICE’s ongoing engagement with the review, NICE should formally respond to the interim report. This item presents the subsequent response.

The Board is asked to note NICE’s response to the Accelerated Access Review’s interim report.

Andrew Dillon
Chief Executive
January 2016
National Institute for Health and Care Excellence

Response to the Interim Report of the Accelerated Access Review

1. We broadly welcome the general direction of the review interim report, which, if implemented properly, will lead to a more co-ordinated approach to introducing innovation that benefits patients and the healthcare system. It has been helpful for NICE to have had a link to the review through the secondment of Nina Pinwill and to have had the opportunity to work closely with members of the review team. These discussions have given us an early view of the more detailed intentions of the review, and most of our comments relate to these detailed points.

2. Before turning to the detailed suggestions that have been made in discussions between the AAR and NICE teams, I would like to comment on the proposal for a National Innovation Partnership to oversee the delivery of change. Section 24 of the interim report says that the creation of new organisations should be avoided, and then goes on to suggest the creation of the National Innovation Partnership. We very much welcome the concept of a partnership, which, in our view should act as a means of ensuring that the main organisations involved in introducing innovation are held accountable for activities to promote the review’s aims. But we feel strongly that this should not involve a constituted body or structure with a chair, but rather that organisations should be held accountable via their normal departmental performance management relationships. This is, in our view, likely to be a more robust, sustainable and accountable way of meeting the review’s aims than setting up a new structure. The suggestion of a concordat to underpin the agreement of the main organisations to work together should be sufficient to ensure all are committed to meeting their responsibilities in the post-AAR landscape. These responsibilities need to be clear and transparent.

3. As regards the detailed discussions between the NICE and AAR team, a number of issues have been raised that will potentially affect NICE’s work in the future. We have seen various proposals about horizon scanning and managed access for promising products, as well as details of new potential outputs from NICE. Details of how the accelerated pathway could work have also been set out in the more recent draft document authored by PWC, and we have the following comments on them.
4. For horizon scanning, crucially, there is currently no link in the review between assessing value and budget impact. National-level horizon scanning could be developed to address the needs of the population and the system, with an assessment of the budget impact being done at this level, to inform the process for designating promising products that are thought likely to meet system and population needs in an affordable way. This could apply to medicines, medtech, diagnostics and digital products (though the review should also note that NICE and Public Health England are already collaborating on identifying digital products and introducing them into the system in an appropriate way, and it would be helpful for the AAR to reinforce this initiative, as it appears in the PWC report). Target product profiles could be developed, based on population health needs and system requirements, so that product developers and research funders can ensure they are developing products that meet the system's needs.

5. We think that the review offers a good opportunity for NICE to work with companies to make it more likely that they will have an evidence-based value proposition at an earlier stage in the product lifecycle, with advice from NICE targeted on system priorities that are likely to have the most impact in terms of clinical and population need, which could be achieved via the target product profile approach. If an organised approach is taken to identifying these priority technologies, then it should be less risky for investors and research funding bodies to commit resources to them. We suggest that this concept could be built more strongly into the final review report. This would support not only products with a promising designation, but also, potentially, those that still require a level of evidence for their adoption. NICE could collaborate on this with other bodies that advise companies on evidence development.

6. We agree with the proposal to extend the current approach to include potentially important technologies that are not covered in existing horizon scanning process for medicines via UK PharmaScan. Discussions have already begun with NHS England Specialised Services about a horizon scanning system to identify medtech products likely to appear in their commissioning policies. Although this needs to start with manageable ambitions, we think it could usefully be extended to include the broader population and system needs described above, as well as providing a single repository for all promising innovations that meet the system’s target product profiles. It could be fed primarily by NIHR Horizon Scanning and Research Intelligence, in collaboration with the medtech industry. The National Innovation Partnership could use it to label products with a “promising device designation” which would then proceed onto the accelerated access pathway. The PWC report suggests that this should be done at Innovation Exchange (i.e. local) level, but this does not seem as satisfactory as identifying these products at a national level. Disruptive technologies are highly likely to need national evaluation via NICE, to test their value proposition.
7. We shared our paper on a potential approach to managed access for medicines with the review team in October. We agree with the emerging findings of the review that this could helpfully be extended to medical and digital technologies and diagnostics, for products where there is general agreement on promise, but evidence is uncertain. To succeed for medical technologies, these schemes will need agreement by the payers to fund the treatment costs because normally these costs when associated for example with an implantable device, can be higher than standard treatment. This means that even if companies were willing to make devices available at preferential rates while evidence was still uncertain, this would not fully cover the cost of treatment, which would need to be met by NHS England Specialised Services or CCGs, depending on the treatment. This aspect of managed access schemes should be highlighted in the review final report to ensure the implications are clear for the payers, so that a realistic approach can be taken to affordability. We would be happy to share our experiences from running the current group of Commissioning through Evaluation projects for NHS England, which have raised a number of practical lessons that are likely to be generalisable to managed access schemes for medical technologies.

8. We welcome the fact that the review has focused on the possibility of additional outputs and roles for NICE, and in November 2015 we were asked to comment on a potential “enhanced health technology offer” from NICE. We shared comments with the review team at the time, chiefly suggesting that the review should avoid attempting to prescribe too much detail on what NICE’s guidance and advice outputs should look like, but instead, should focus on the top-level mechanisms needed to deliver its aims. This will then allow NICE to develop outputs that meet those needs that are deliverable in line with our resources and capabilities. We also need to develop any new outputs through our normal processes, in an open way, in collaboration with our stakeholders, who, because of the transparent way in which we work, have high expectations of how NICE conducts dialogue over any changes to our activities that we are committed to meet.

9. The PWC report on managed access is mainly helpful. We support the suggestion that the funding direction should be extended to all technologies that go through the accelerated pathway. The proposals for flexible pricing relating to evidence development seem helpful.

10. Firstly, commenting on the medicines aspects of the report, we welcome the proposal from PWC for near-parallel regulatory and HTA reviews as this is required to ensure NICE guidance being available at the time of licensing, whilst maintaining the rigorous principle of NICE guidance development. We also welcome the discussion about the MHRA’s EAMS in relation to the EMA PRIME designation, and agree that alignment of these two accelerated regulatory
schemes is crucial to companies and HTA agencies to navigate any new landscape in the future. The PWC recommended pathways include the development of real world data in parallel to regulatory clinical trials. This could prove problematic as no routine ‘real world’ patient would have access before Marketing Authorisation. It would be helpful if this could be elaborate more to enhance understanding of what is meant here (possibly just non-RCT data?). As far as the recommendation of the use of flexible pricing is concerned, this option has existed as part of the PPRS for many years not, and has not been used by companies. It may be helpful to reframe this recommendation to encouraging the use of the already exiting option. Finally, on medicines, there is a general confusion in the report about the concept of affordability (budget) and value-assessment (cost-effectiveness). NICE could certainly be more involved with advising at what prices medicines are likely to be cost effective (with NICE being transparent about its value assessment anyway), but NICE has no remit to advise on affordability. No conceptual link has been developed or proposed here between affordability and value-assessment, and this is definitely an important research subject for early consideration.

11. In relation to the PWC report’s treatment of non-medicines technologies, given the shorter product development timescales, the review should have realistic assumptions about the benefits of early access and what this might bring to patients and the healthcare system. As the regulatory process is short, the early access paradigm for technologies is different from that for medicines. Many devices are already brought to market with little being known about comparative effectiveness and significant remaining unknowns around longer term safety, for example for implantable devices. Using a promising device designation approach will help to flag those products in advance of their adoption, enabling a common understanding of what evidence is still required post-market. The accelerated pathway for these products in the PWC report looks broadly sensible, with the caveats covered elsewhere in this letter.

12. Finally, in view of the significant cost reductions NICE will need to make to meet the requirements of the CSR, any additional activity that might arise for NICE as a result of the review would need to be fully resourced, or else substituted for other outputs or activities at NICE, in the event that the whole system considers the activities recommended by the AAR to be a higher priority than NICE’s current portfolio.

National Institute for Health and Care Excellence

January 2016
In August 2015, as part of a wider discussion on how NICE can support disinvestment, the Board discussed how resource impact should inform the context in which Guideline Committees make their recommendations. The Board noted that the funding position for health and social care over the next 5 years means that service developments will be competing for scarce resources. NICE advisory Committees will need to be rigorous in considering and communicating the underpinning evidence and case for investment for all recommendations that add significant costs.

The Guidance Development Project (GDP) team has been working with the methods and economics working groups and the Resource Impact team to develop a set of principles and practical advice for guideline Committees, Developers and Quality Assurance teams in order to support this consideration. The advice and principles are included as appendix 1.

The Board is asked to review the advice and principles on resource impact in guidelines and:

- approve their distribution to Committees, Developers and Quality Assurance teams
- approve the changes to chapter 7 of the guidelines manual outlined in the appendix
- approve adoption of the principles for draft guidelines issued for consultation from April 2016.

Professor Mark Baker
Director, Centre for Clinical Practice
January 2016

Professor Gillian Leng
Director, Health and Social Care
Background

1. In August 2015, as part of a wider discussion on how NICE can support disinvestment, the Board discussed how resource impact should inform the context in which Guideline Committees make their recommendations. The Board noted that the funding position for health and social care over the next 5 years means that service developments will be competing for scarce resources. NICE advisory Committees will need to be rigorous in considering and communicating the underpinning evidence and case for investment for all recommendations that add significant costs.

Guideline methods

2. Developing NICE Guidelines: the manual (2014) includes the following section in Chapter 7 Incorporating economic evaluation:

7.2: Guideline recommendations should be based on the balance between the estimated costs of the interventions or services and their expected benefits compared with an alternative (that is, their ‘cost effectiveness’), rather than solely on the total cost or resource impact of implementing them. So, if the evidence suggests that an intervention, service or programme provides significant benefits at an acceptable cost per person, it is likely to be recommended even if it would be expensive to implement across the whole population. However, when implementing guideline recommendations, commissioners and decision-makers need to know the resource and cost implications for their organisations. Where appropriate, NICE carries out a separate cost–impact analysis and publishes this alongside the guideline, as part of its support for putting guidelines into practice.

It is proposed that this section should be updated as follows:

7.2: Guideline recommendations should be based on the balance between the estimated costs of the interventions or services and their expected benefits compared with an alternative (that is, their ‘cost effectiveness’). If there is likely to be a substantial cost increase overall the evidence supporting the recommendation must be robust and the Committee must be confident that any uncertainties are offset by a compelling argument in favour of the recommendation. The higher the...
likely cost of implementing a recommendation, the more certain the Committee will need to be of the cost effectiveness of the recommendations. However, the potential cost impact of the recommendations should not alone determine the Committee's decision.

rather than solely on the total cost or resource impact of implementing them. So, if the evidence suggests that an intervention, service or programme provides significant benefits at an acceptable cost per person, it is likely to be recommended even if it would be expensive to implement across the whole population. However, when implementing guideline recommendations, commissioners and decision-makers need to know the resource and cost implications for their organisations. Where appropriate, NICE carries out a separate cost–impact analysis and publishes this alongside the guideline, as part of its support for putting guidelines into practice.

Support for guideline Committees

3. A number of practical steps and principles will be put in place in future to support guideline Committees in their consideration of the likely cost impact of recommendations. These include:

- Guideline Committees currently identify areas that have the potential to result in substantial cost increases during guideline development. These areas are then prioritised, and economic analysis is undertaken in areas agreed by the Committee. In future, information on likely costs will be provided by the NICE Resource Impact team earlier in the guideline development process. Estimation of resource impact can be challenging. The assumptions on which the estimates are based will be discussed with the Committee, and documented in the guideline.

- It is acknowledged that economic analysis is currently not undertaken in all areas that have the potential to result in substantial cost increases – for example, the information needed to populate an economic model or analysis is not available or sufficient, or the economic resource available may be insufficient to cover all areas of potentially high cost. Cost pressures should not be introduced into the system unless the Committee is convinced of the benefits of the recommendation. In future, if the Committee wish to make a recommendation in an area that is anticipated to substantially increase costs, economic analysis must be undertaken. The balance of benefits and costs should be documented fully in the guideline.
• At present, information on likely resource impact is prepared for some recommendations towards the end of the guideline development process. 

In future the NICE Resource Impact team will establish a process to, throughout guideline development, provide information on costs for all recommendations that are likely to substantially increase costs, with final estimates being available to support implementation of the guideline.

• At present, NICE does not specifically engage with stakeholders regarding resource impact. 

In future when draft scopes are issued for consultation, NICE will ask stakeholders to suggest interventions or forms of practice where recommendations could result in cost savings. When guidelines are issued for consultation, NICE will ask stakeholders to comment on the recommendations identified as likely to substantially increase costs, and their justification, and to consider whether any other draft recommendations are expected to add substantial costs.

Following sections to be deleted from Committee versions

Advice for Developers and Quality Assurance teams

The practical advice for guideline Committees above has been developed from 5 detailed principles that outline the consideration of resource impact during guideline development. The principles are included below, together with a description of how methods meet these principles at present, and what changes are required.

These principles have been developed to guide the Committees' qualitative judgements. They should be considered alongside other relevant principles, including NICE's social value judgements.
<table>
<thead>
<tr>
<th>Principle</th>
<th>Existing process / methods that support the principle</th>
<th>Changes required</th>
</tr>
</thead>
</table>
| Principle 1 | Recommendations that are anticipated to substantially increase costs must be supported by economic analysis, as defined in Chapter 7 of the guidelines manual. In the absence of economic evidence, Committees should not make recommendations which are likely to substantially increase costs where there is no clear evidence of benefit to justify the expected cost. | Economic analysis
The guidelines manual includes the following on prioritisation of areas for economic analysis:

7.5 Prioritising questions for further economic analysis

Economic analysis is potentially useful for any question in which an intervention, service or programme is compared with another. It may also be appropriate in comparing different combinations or sequences of interventions, as well as individual components of the service or intervention. However, the broad scope of some guidelines means that it may not be practical to conduct de novo economic analysis for every component.

The decision about whether to carry out an economic analysis therefore depends on:

- the potential overall expected benefit and resource implications of an intervention both for individual people and the |

Detailed changes to the current approach to cost effectiveness are not proposed. Specifically, it is not proposed that a decision rule on cost impact is developed – no change to the cost effectiveness threshold is being made. The definition of a substantial increase in costs is left to individual Committees to determine given the perspective and budget relevant to each recommendation.
<table>
<thead>
<tr>
<th>Principle</th>
<th>Existing process / methods that support the principle</th>
<th>Changes required</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>population as a whole</em></td>
<td></td>
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<tr>
<td></td>
<td><em>the degree of uncertainty in the economic evidence review and the likelihood that economic analysis will clarify matters.</em></td>
<td></td>
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</table>

Guideline Committees therefore currently identify areas that have the potential to result in substantial cost increases early in guideline development. This assessment of resource impact is usually made qualitatively based on estimates of the size of the population affected by the recommendation and the difference in costs of the newly recommended interventions compared to usual care. These areas are then prioritised, and economic analysis is undertaken in areas agreed by the Committee.

Economic analysis will not be undertaken in all areas of high cost impact – for example, the area may not be deemed to be a priority area by the Committee, or information needed to populate an economic model or analysis is not available or sufficient.

In future, if the Committee wish to make a recommendation in an area that is anticipated to substantially increase costs, economic analysis must be undertaken. The balance of benefits and costs should be documented fully in the guideline.
<table>
<thead>
<tr>
<th>Principle</th>
<th>Existing process / methods that support the principle</th>
<th>Changes required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle</td>
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</tbody>
</table>
| Evidence  | The guidelines manual includes the following as an introduction to an extensive section on evidence: 4.4 Evidence used to inform recommendations  
  *In order to formulate recommendations, the guideline Committee needs to consider a range of evidence about what works generally, why it works, and what might work (and how) in specific circumstances. The Committee needs evidence from multiple sources, extracted for different purposes and by different methods.* | No changes are proposed to the definition of evidence that can be used to inform guideline recommendations. Certainty in the evidence should be valued over and above traditional views on the hierarchy of evidence. |
| Principle 2 | Committees should describe likely benefits for any recommendation anticipated to substantially increase costs. | In future, a greater level of information should be provided in the discussion section where recommendations are anticipated to substantially increase costs. This should be complemented with clearer identification of areas for cost savings, and the use of ‘do not do’ recommendations where appropriate. The guideline Committee should also clarify |
|           | The benefits associated with each recommendation are currently set out in the “discussion” section of the guideline (also known as LETR tables / considerations section).  
  *No distinction is systematically made between the level of information provided in this section for recommendations that substantially increase costs and* |                  |
<p>| | | |
|           |                                                      |                  |</p>
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<th>Principle</th>
<th>Existing process / methods that support the principle</th>
<th>Changes required</th>
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<tbody>
<tr>
<td>Principle 6</td>
<td>Recommendations that are cost-neutral or cost-saving.</td>
<td>Where the new practice ‘supersedes’ or replaces existing care. For example, Developers should provide information on interventions that should no longer be implemented if a new intervention is recommended.</td>
</tr>
<tr>
<td>Principle 3</td>
<td>When the Committee anticipates that costs will be substantially increased, information on resource impact should be presented to the Committee as early as possible in the development process.</td>
<td>The Committee will be presented with estimates of resource impact during the guideline development phase in future, and will need to consider resource impact when developing recommendations.</td>
</tr>
</tbody>
</table>

The proposals will have substantial implications for the Resource Impact Team who will need to undertake this work in a sufficiently timely fashion for Committees to consider during development across all guidelines. Guideline Developers do not have capacity to undertake this work. This will require a change in process and inputs into surveillance decisions.
<table>
<thead>
<tr>
<th>Principle</th>
<th>Existing process / methods that support the principle</th>
<th>Changes required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle 4</td>
<td>When the Committee anticipates that costs will be substantially increased, information on resource impact should</td>
<td>The guidelines manual includes the following on resource impact:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In light of the planned presentation of information on resource impact to guideline Committees early in development, section</td>
</tr>
</tbody>
</table>

scheduling for the Resource Impact team, and may also impact on the micro process and timeline for economic analysis. Micro process and methods of engagement / communication between the Resource Impact team, Developer and Commissioning team need to be agreed.

It is acknowledged that estimation of resource impact can be challenging. The assumptions on which the estimates are based should be made available to the Committee, and documented in the guideline.

The methods used to calculate resource impact are different from the approach used in economic analysis. This can lead to inconsistency and confusion in the presentation of the outputs of these different analyses. Work should be undertaken to discuss the different approaches used in economic analysis and calculation of resource impact, with the aim of bringing these closer together.
<table>
<thead>
<tr>
<th>Principle</th>
<th>Existing process / methods that support the principle</th>
<th>Changes required</th>
</tr>
</thead>
<tbody>
<tr>
<td>be published in the guideline. Where a positive recommendation is made, this should include the timing of the cost impact (e.g. up-front vs spread over a defined number of years).</td>
<td>Chapter 12: Resources to support implementation 12.2: NICE costing tools are intended to help organisations assess the potential costs and savings associated with implementing the guideline. A costing report and associated templates are produced for guideline publication if they add value. If no costing report or template is produced, a costing statement is used to explain the reason(s) for this.</td>
<td>12.2 of the manual will need to be updated, as detailed costing reports will no longer be required. This is not a material change to the manual, as it relates to supplementary information, and can be made without consultation. Updating resource impact information for all cost-increasing recommendation will have substantial implications for the Resource Impact Team who will need to undertake this work in a sufficiently timely fashion for Committees to consider during development across all guidelines. Guideline developers do not have capacity to undertake this work. In future, information on cost impact should be included in the discussion section of the guideline for recommendations which are anticipated to substantially increase costs. There is no fixed rule around the timeframe on which return on investment analysis should be based. However, feedback from the implementers of NICE guidance suggested that, typically, guidance will be most useful if return on investment will be</td>
</tr>
</tbody>
</table>

The guidelines manual includes the following on the presentation of results of economic evaluation:

7.6 Approaches to bespoke economic evaluation

Conventions on reporting economic evaluations should be followed (see Drummond and Jefferson 1996) to ensure that reporting of methods and results is transparent. For time horizons that extend...
<table>
<thead>
<tr>
<th>Principle</th>
<th>Existing process / methods that support the principle</th>
<th>Changes required</th>
</tr>
</thead>
</table>
|           | beyond 10 years, it may be useful to report costs and effects for the short (1–3 years) and medium (5–10 years) term. The following results should be presented where available and relevant:  
  - end points from the analysis, such as life years gained, number of events and survival  
  - disaggregated costs  
  - total and incremental costs and effects for all options. | felt within 5 years. |
| Principle 5 | When draft guidelines are issued for consultation, NICE should ask stakeholders to comment on cost impact and justification for draft recommendations, and consider whether any other draft recommendations are expected to add significant cost. | The new guidelines manual includes the option to ask questions of stakeholders during consultation on the draft guideline. In the past, questions were not asked about the cost impact of recommendations. | From September 2015, the draft guideline consultation form has included a standard question asking stakeholders: “Would implementation of any of the draft recommendations have significant cost implications?” |
Summary

The Triennial Review of NICE, published in July 2015 noted that the Board last assessed its effectiveness in 2013 and had independent input to a review in 2010. Noting best practice regarding Board evaluation, the review recommended that:

‘In order to ensure effective governance of the organisation, including its independent advisory committees, NICE should:

• Arrange an independent assessment of the effectiveness of the Board which gives consideration to whether additional expertise is required and how future thinking becomes an integral part of the Board’s activity [by April 2016].

• Ensure that the arrangements for operating and quality controlling the work of the independent advisory committees are robust and transparent, publishing these arrangements where feasible.’

This paper presents the proposed scope for the Board effectiveness review to address the first aspect of the recommendation for the Board’s approval.

The Board is asked to agree the proposed approach to undertaking the Board effectiveness review.

Andrew Dillon
Chief Executive
January 2016
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Board Effectiveness Review

Background
1. The report of the Triennial Review of NICE noted that NICE is compliant with the principles of good corporate governance. It though made several observations in respect of the Board and recommended these are considered as part of an independent assessment.

2. The relevant section of the Triennial Review is attached as an appendix, but in summary these observations included:
   - The size of the Board
   - Whether there are any gaps in skills or expertise on the Board, such as commercial expertise or health economics experience
   - A perception amongst stakeholders around the extent to which the Board is identifying and responding to future changes in the health and care landscape.

Proposed approach
3. PricewaterhouseCoopers (PwC) currently act as NICE’s internal auditors through the Health Group Internal Audit Service (HGIAS). PwC recently undertook a cross-cutting Board effectiveness review in four other Department of Health Arm’s Length Bodies (ALBs) – Health Education England, Health & Social Care Information Centre, Public Health England, and NHS Blood and Transplant.

4. It is proposed to commission PwC to undertake a similar review under the umbrella of the HGIAS. The review will include questionnaires and 1:1 interviews with Board members, meeting observation, and document review.

5. The proposed terms of reference are attached for the Board’s approval.

6. Undertaking this through the Health Group Internal Audit Service represents a cost effective approach and enables benchmarking with the other four ALBs.

7. Subject to approval by the Board, the review will commence in late January and will aim to conclude by April 2016.
Appendix A: extract of the Triennial Review

The role of the board, chair and non-executive members

7.15 NICE is compliant with the principles of good corporate governance.

7.16 NICE has an independent Chair who is appointed by the Secretary of State and who provides advice directly to the Secretary of State as required.

7.17 NICE’s board provides leadership and strategic direction for the organisation and is made up of non-executive and executive members. The joint board is collectively accountable, through the Chair, to the Secretary of State for the strategic direction of NICE, for ensuring a sound system of internal control through its governance structures and for putting in place arrangements for securing assurance about the effectiveness of that system.

7.18 The wide ranging and expert nature of NICE’s work is reflected in the knowledge and expertise brought by board members. For example, non-executive board members reflect the perspectives of primary care, social care, and public health as well as other areas. The board reviews its composition to ensure relevant areas are covered and works with the Department’s Public Appointments team to ensure there are no gaps.

7.19 The strategy of recruiting board members with specific areas of skill and knowledge can impact on two areas. The first area is the board’s diversity. Improving diversity in public appointments is a priority aimed at achieving equal representation of women and men in public appointments, pro rata representation of ethnic minority groups and increased participation of disabled people. Seven of the seventeen board members are women and there is no ethnic minority representation. The strategy on encouraging diversity (disability, BME and gender), includes an aspiration for 50% of new public appointees to be women. This is not just about gender; diversity is about encouraging applications from candidates with the widest range of backgrounds. A Centre for Public Appointments (CPA) has been established in the Cabinet Office to co-ordinate across Whitehall and promote roles on Public Boards to a range of candidates with diverse skills and backgrounds.

7.20 The second area is the size of the board. The NICE board is large but not necessarily too large to function. However, it would be good to assess whether other ways of accessing specific knowledge and expertise might offer advantages.

7.21 The review team asked stakeholders whether they felt the board demonstrated any gaps in skills or expertise. Many stakeholders did not feel equipped to judge, but for those who did, the most frequently mentioned omissions were commercial expertise and health economics experience.

7.22 We also asked stakeholders whether NICE could improve its performance in any specific areas. In relation to the board, there were suggestions that stakeholders did not see the board as actively identifying and responding to future changes in the health and care landscape and how it might impact NICE. The review team looked at minutes of board meetings and found that these issues were discussed,
nonetheless, the perception remains and this is an area that NICE will want to be aware of in the future.

7.23 Best practice is that a board should assess its effectiveness annually, with external facilitation every three years. The NICE board last assessed its effectiveness in 2013 and had independent input in 2010 and is awaiting the results of the Triennial Review before holding a further assessment of effectiveness. We recommend that the next assessment is carried out early in 2015/16 and includes independent assessment of the issues raised above.

7.24 NICE holds monthly board meetings, six of which are held in public. Meetings consider reports on strategic issues facing NICE and its performance against business targets. In addition, the board reviews finance reports, the business plan, project-specific papers on major developments, reports from all directors on activity within their departments and reports from board committees, such as the Audit and Risk Committee.
Health Group Internal Audit provides an objective and independent assurance, analysis and consulting service to the Department of Health and its arms length bodies, bringing a disciplined approach to evaluating and improving the effectiveness of risk management, control and governance processes.

The focuses on business priorities and key risks, delivering its service through three core approaches across all corporate and programme activity:

- **Review and evaluation** of internal controls and processes;
- **Advice to support management** in making improvements in risk management, control and governance; and
- **Analysis of policies, procedures and operations** against good practice.

Our findings and recommendations:

- Form the basis of an independent opinion to the Accounting Officers and Audit Committees of the Department of Health and its arms length bodies on the degree to which risk management, control and governance support the achievement of objectives; and
- Add value to management by providing a basis and catalyst for improving operations.

For further information please contact:
Bronwyn Baker - 01132 54 5515
1N16 Quarry House, Quarry Hill, Leeds, LS2 7UE

Our work has been conducted and our report prepared solely for the benefit of the Department of Health and its arms length bodies and in accordance with a defined and agreed terms of reference. In doing so, we have not taken into account the considerations of any third parties. Accordingly, as our report may not consider issues relevant to such third parties, any use they may choose to make of our report is entirely at their own risk and we accept no responsibility whatsoever in relation to such use. Any third parties, requiring access to the report may be required to sign ‘hold harmless’ letters.
Distribution List – Draft Terms of Reference

Main recipient(s)
Professor David Haslam  Chair
Board members
David Coombs  Board Secretary

cc:
Catherine Wilkinson  Associate Director of Finance and Estates
Natalie Sargent  Head of Financial Accounting

Distribution List – Final Terms of Reference

Main recipient(s): Professor David Haslam  Chair
Board members
David Coombs  Board Secretary

cc:
Catherine Wilkinson  Associate Director of Finance and Estates
Natalie Sargent  Head of Financial Accounting

NAO can request copies of final reports should they wish to do so.
1. INTRODUCTION

1.1 The National Institute for Health and Care Excellence (NICE) is an executive non-departmental public body established under the Health and Social Care Act 2012. Its purpose is to improve the quality and productivity of clinical practice, public health and social care.

1.2 The Report of the Triennial Review of NICE published in July 2015 concluded that: “Overall, the report considered that NICE performed well in the delivery of necessary functions and was highly valued by stakeholders. We found that it is an efficient organization that compares well with other public bodies and which identifies issues and seeks to address them early. The tenor of the evidence gathered throughout the review was that NICE is a respected and valued organisation with an important role to play, particularly in financially constrained times. Most of the comments were made in the context of the organisation not being considered ‘broken’ in any way but with the ability to enhance what it does and how it operates further”.

1.3 The report raised 14 recommendations for NICE to address within a nine to twelve month timeframe including a specific recommendation relating the Board as follows:

a. “Recommendation 13: In order to ensure effective governance of the organisation, including its independent advisory committees, NICE should:

i. Arrange an externally facilitated assessment of the effectiveness of the Board which gives consideration to whether additional expertise is required and how future thinking becomes an integral part of the Board’s activity. [by April 2016]”.

1.4 As a result we have been commissioned to undertake a board effectiveness review of NICE to address the recommendation above. The review will be undertaken as part of an extension of the Internal Audit plan for 2015/16.

2. KEY RISKS, OBJECTIVES AND SCOPE

Key Risks

2.1 Failure to address the recommendations of the Triennial Review could expose NICE to the risk that is unable to meet the challenges of the future in its current form. Specifically, the risks around Board effectiveness include:

- The Board may not consist of the right level of skills and expertise and have the right style of leadership;
- Board members may not be fully aware of their statutory duties;
- An effective and efficient induction and on-boarding process may not be in place for board membership;
- Sub-committees of the Board may not have clear lines of accountability and scheme delegation;
- Duplication may exist between the activities of the Board and its sub-committees;
- Roles and responsibilities for the Non-Executive Directors and Directors and management may not be clearly defined;
- The Board may not exhibit the right values and behaviours;
- The focus and content of Board meetings may not be appropriate;
- Issues and actions may not be escalated appropriately and dealt with in a timely manner;
- The Board may not receive the right level and quality of information to make the right decisions;
- Risk management at Board level may not operate effectively;
- The Board may not receive the right levels of assurance;
- Stakeholder management may not be effective;
- The performance and effectiveness of the Board and individual Board members is not monitored or measured; and
- There may not be appropriate arrangements in place for induction of new Board members; development and training; and succession planning.

**Objectives**

2.2 The objective of our review is to assess the effectiveness of the NICE Board in the context of the recommendation of the Report of the Triennial Review with a specific focus on the skills and expertise of the Board and how the Board ensures future thinking becomes an integral part of its activity.

**Scope**

2.3 A three step approach will be used to undertake this review:

*Figure 1. High Level Audit Approach*
Step 1 of 3. Board Effectiveness Assessment

- We will issue an electronic questionnaire to all board members under the six framework headings.
- This will be followed up through a series of interviews which will include all board members, the senior management team and other key staff and stakeholders, including the DH sponsorship team.
- We will observe the March 2016 Board meeting, both private and public sessions and observe the Board Strategy day in February 2016.
- We will also perform a review of key documents, Board and subcommittee papers covering a 12 month period.
- Based on the information provided and the interviews, we will complete the assessment and identify the strengths and areas for improvement of the organisation’s board effectiveness.
- The methodology being adopted includes a measure of maturity for each area to facilitate quantification of what would be expected, as well as comparison against similar organisations.

<table>
<thead>
<tr>
<th>Assessment Areas</th>
<th>Key Elements</th>
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<tbody>
<tr>
<td>Composition, leadership and structure</td>
<td>• Statutory duties and obligations; and roles and responsibilities</td>
</tr>
<tr>
<td></td>
<td>• Board size, right blend of skills and expertise</td>
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<tr>
<td></td>
<td>• Appointment of Board members</td>
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<td></td>
<td>• Chairmanship and leadership of the Board</td>
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<tr>
<td>Roles and responsibilities</td>
<td>• Subcommittees of the Board have clear and appropriate schemes of delegation</td>
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<tr>
<td></td>
<td>• Roles and responsibilities and lines of accountability are clear</td>
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<td></td>
<td>• Escalations processes</td>
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<tr>
<td>Board focus</td>
<td>• Strategic direction and performance management</td>
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<td></td>
<td>• Financial management &amp; performance</td>
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<td></td>
<td>• Risk management and assurance</td>
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<td></td>
<td>• Key developments and emerging issues</td>
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<tr>
<td>Board in action</td>
<td>• Timing of board meetings</td>
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<td></td>
<td>• Quality of board agenda and papers</td>
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<td></td>
<td>• Decision making and achievement of outcomes</td>
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<tr>
<td>Relationships and engagement</td>
<td>• The relationships between the board members is constructive</td>
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<td>• Behavioural values for the Board</td>
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<td>• Internal and external stakeholder management</td>
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<tr>
<td>Performance and development</td>
<td>• Performance and effectiveness of the Board</td>
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<td>• Board member performance monitoring</td>
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<td></td>
<td>• Induction process</td>
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<td></td>
<td>• Training and development</td>
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<td></td>
<td>• Succession planning</td>
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Steps 2 and 3. Reporting, Analysis and Feedback

- NICE will receive an individual internal audit report which will include the outcome of their assessment.
The findings within the report will be discussed with the Chair, Chief Executive and other individuals as required.
Analysis will be conducted to draw out key themes, risks, issues and areas of good practice compared with other ALBs.

3. GOVERNANCE OF THE REVIEW

3.1 The review will be undertaken by the senior members of the internal audit team to reflect the seniority of the stakeholders involved.

3.2 Karen Finlayson will be the Head of Internal Audit and will have overall responsibility for the quality of service as well as conducting some interview. Mark Wood will undertake the majority of the work and also manage and co-ordinate the work of Steve Clarke in reviewing key documents.

3.3 This review is due to commence in January 2015 following formal approval by the Board at their meeting to be held on 20 January 2016. However, the exact timing of the commencement of fieldwork and length of this review will be agreed with management following sign-off of the terms of reference but we will complete the review by April 2016 in accordance with the Triennial Review recommended timeframe.

3.4 The sponsors for this review are Professor David Haslam, Chair and Sir Andrew Dillon, Chief Executive. Their key role and responsibility is to provide sign-off of terms of reference as well as agree the outcomes detailed in the audit report. This will include brokering recommendation owners, coordinating and consolidating customer responses, where necessary, and to provide final sign-off for the report. David Coombs, Board Secretary, will be our key contact for the review.

4. DELIVERABLES

4.1 The deliverable from this review will be a report on the principle findings and implications arising from the review. The findings will be discussed with the Chair and Chief Executive prior to issuing the draft report, including any themes that may be outlined in the overarching report and how they would be positioned and presented.

4.2 An overarching report will cover analysis of key themes, risks, issues and areas of good practice.

4.3 The report will specifically address the key requirements of the Triennial Review.

5. FEEDBACK

On completion of the audit, we will seek feedback on our performance from the customer in the form of a Client Satisfaction Questionnaire.
6. TIMING & RESPONSIBILITY

<table>
<thead>
<tr>
<th>Objective</th>
<th>Responsibility</th>
<th>Completed by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terms of Reference agreed</td>
<td>Board/Karen Finlayson/Mark Wood</td>
<td>20 January 2016</td>
</tr>
<tr>
<td>Commencement of Fieldwork</td>
<td>Steve Clarke / Mark Wood</td>
<td>January 2016</td>
</tr>
<tr>
<td>Completion of Fieldwork</td>
<td>Steve Clarke / Mark Wood</td>
<td>March 2016</td>
</tr>
<tr>
<td>Discussion of draft findings</td>
<td>David Haslam/Andrew Dillon/Mark Wood</td>
<td>March 2016</td>
</tr>
<tr>
<td>1st Draft Report issued</td>
<td>Mark Wood</td>
<td>March 2016</td>
</tr>
<tr>
<td>Management Responses received</td>
<td>David Haslam/Andrew Dillon/David Coombs</td>
<td>March 2016</td>
</tr>
<tr>
<td>Final Report issued</td>
<td>Karen Finlayson</td>
<td>By April 2016</td>
</tr>
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</table>

7. KEY CONTACTS & AUDIT BUDGET

<table>
<thead>
<tr>
<th>Audit Team</th>
<th>Name</th>
<th>Title</th>
<th>Telephone no.</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Karen Finlayson</td>
<td>Head of Internal Audit</td>
<td>07881 805552</td>
<td><a href="mailto:karen.finlayson@uk.pwc.com">karen.finlayson@uk.pwc.com</a></td>
</tr>
<tr>
<td></td>
<td>Mark Wood</td>
<td>Senior Manager</td>
<td>07739 874338</td>
<td><a href="mailto:mark.a.wood@uk.pwc.com">mark.a.wood@uk.pwc.com</a></td>
</tr>
<tr>
<td></td>
<td>Steve Clarke</td>
<td>Lead Auditor</td>
<td>07764 958045</td>
<td><a href="mailto:steve.clarke@uk.pwc.com">steve.clarke@uk.pwc.com</a></td>
</tr>
<tr>
<td></td>
<td>Tbc</td>
<td>Senior Auditor</td>
<td>Tbc</td>
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</tr>
</tbody>
</table>

We anticipate a budget of 12 days to complete this review.

Terms of Reference have been agreed by:

Professor David Haslam, NICE Chair                        Date: …..  
Karen Finlayson, NICE Head of Internal Audit                Date: 22/12/2015
As the Board is aware, Dr Maggie Helliwell’s term of office as a Non-Executive Director ended on 31 December 2015. Recruitment for Dr Helliwell’s successor is now complete and Dr Rosie Benneyworth has been appointed on a term of office running from 1 January 2016 to 31 December 2019.

Dr Benneyworth is currently the Managing Director of the South West Academic Health Science Network (AHSN). She has spent many years as a GP principal in Somerset and she currently works for Somerset Doctors Urgent Care Service. Prior to joining the AHSN, Dr Benneyworth worked for several years as a clinical commissioner. She was on the Governing Body of Somerset CCG and was the vice-chair of Somerset Health and Wellbeing Board. She has also been a NICE Fellow since 2013, and was a member of the group that developed the NICE guideline on Urinary Incontinence in Women. Dr Benneyworth has declared the following interests:

- Salaried out of hours GP, Vocare (Somerset Doctors)
- Managing Director, South West Academic Health Science Network (SW AHSN)
- NICE Fellow (to finish March 2016).

In addition, she has declared a non-personal interest in that the SW AHSN has received payments from four pharmaceutical companies to progress project work in the areas of management of Atrial Fibrillation and rheumatology.

Dr Helliwell was a member of the Board’s Remuneration Committee. Under NICE’s Reservation of Powers it is the Board’s responsibility to appoint its committees. The Board is therefore asked to appoint Tim Irish to the Remuneration Committee to fill the position vacated by Dr Helliwell.

Recruitment for a Non-Executive Director with a background in nursing, midwifery, or an allied health profession, remains underway. This role is to succeed Rona McCandlish whose term of office ends on 31 March 2016.

The Board is asked to:
1. Note the appointment of Dr Rosie Benneyworth as a Non-Executive Director of NICE.
2. Agree to appoint Tim Irish to the Remuneration Committee.

Professor David Haslam  
NICE Chair  
January 2016
RAPID RE-CONSIDERATION OF DRUGS CURRENTLY FUNDED THROUGH THE CANCER DRUGS FUND

The Board has been briefed previously on NICE’s activities in relation to the Cancer Drugs Fund (CDF) and its transition to a new operational model.

NICE and NHS England have agreed a transition plan for products currently on the CDF. As part of the transition plan, a process has been developed for re-consideration of drug-indication pairs that are on the CDF, and for which NICE has published guidance.

In order for NICE to deliver on the transition activities before 31 March 2017 for the above-mentioned group of products, companies have already been asked by NICE to express an interest in providing an evidence submission to support the re-consideration process.

The process included in this paper is currently out for consultation with all stakeholders in the re-consideration of the above-mentioned products.

The Board is asked to:

1. Note the re-consideration process to be used for drug-indication pairs currently funded by the CDF and for which NICE has published guidance.

2. Approve the constitution of a separate Appraisal Committee, using the existing terms of reference and standing orders, and with membership drawn from the existing Appraisal Committees.

Professor Carole Longson
Director, Centre for Health Technology Evaluation
January 2016
Rapid re-consideration of drugs currently funded through the Cancer Drugs Fund

Introduction

1 All cancer drugs that are funded through the current Cancer Drugs Fund (CDF) will be considered in line with the proposed new CDF criteria.

2 This document sets out the proposed rapid reconsideration process necessary to support the re-consideration of drugs that have previously been appraised by NICE and are currently funded through the CDF.

3 In order to allow for the transition of drugs currently in the CDF to take place before 31 March 2017, NICE needs to prepare for the re-consideration in parallel with consultation on the new CDF arrangements, without prejudging the outcome of that consultation. The proposals in this paper are therefore provisional and subject to change if the proposed CDF arrangements are amended after the consultation.

Rapid re-consideration process

Scope and evidence submission

4 The scope for re-consideration will remain the same as the final scope used for the published guidance. NICE will re-issue the scope at the start of the re-consideration process.

5 A decision problem meeting (see 3.2.2 of the Guide the processes of technology appraisal) will be held only on request from a company, and NICE will judge the need for a meeting taking into account the details of the request.

6 The company evidence submission should focus on cost effectiveness analyses using the new cost of the drug, either as a consequence of an amendment to the existing patient access scheme or as a ‘commercial access agreement’ (see proposed new paragraphs 5.31 – 5.33).

7 The analyses included in the evidence submission must use the assumptions that determined the most plausible incremental cost effectiveness ratio as presented by the Appraisal Committee in the published guidance. Only in exceptional circumstances and with prior agreement with NICE should new clinical evidence be included. Submission of new clinical evidence must not lead to structural changes in the approach to cost effectiveness.

8 The submission should take account of the proposed changes to NICE’s methods of technology appraisal set out in the CDF consultation, in particular those concerning the appraisal of life-extending products at the end of life (proposed amended paragraph 6.2.10), and including those for use through the Cancer Drugs Fund (proposed new paragraphs 6.5.1 – 6.5.4).

9 If the evidence submission is to include a new patient access scheme, an amendment to an existing patient access scheme, or a commercial access
arrangement, each of these must have been formally agreed with the relevant organisation (that is, the Department of Health or NHS England), by the time the Appraisal Committee meets.

10 Companies will have the opportunity to change their evidence submissions to NICE in case substantial changes are required to the proposals currently included in the CDF consultation.

11 No statements from non-company consultees are to be sought.

12 The Evidence Review Group (ERG) critically evaluates the evidence submission.

13 NICE sends the ERG report to the company before it is presented to the Appraisal Committee. The company has 5 working days from the date of sending to check that the report (including confidential information provided by the company) does not contain factual errors, for example, errors in the figures, incorrect quotes from the evidence submission or text that does not describe the facts accurately. NICE prepares a document highlighting any factual errors for the Appraisal Committee and publishes the document on its website as part of the committee papers. The company cannot submit additional evidence during the evidence review phase unless NICE has agreed to this before the main evidence submission, or NICE asks for more evidence. The company is also required to check that the ERG has accurately marked confidential information within the report. This again provides an opportunity for the company to reconsider and update the confidential status of information before the Appraisal Committee meeting.

14 All other relevant sections of the Guide to the processes of Technology Appraisal apply.

Appraisal Committee

15 The Appraisal Committee used for the re-consideration of CDF products will be drawn from the 4 Appraisal Committees with the same membership composition as the existing Committees. The terms of reference and standing orders for this Appraisal Committee will be available separately.

16 The Committee discussion will be held in public in as much as is possible. Considering the likely commercial nature of the discussion, it will be necessary to hold the discussions largely in private, with only company and evidence review group representatives attending.

17 Clinical experts, patient experts and commissioning experts will be invited to attend the Appraisal Committee meeting.

18 The Appraisal Committee can make one of the following recommendations:

• **Recommended for routine commissioning**

• **Not recommended**

• **Recommended for use within the CDF**
19 Scheme proposals submitted through the rapid re-consideration process are treated by NICE as commercial in confidence and all matters about the proposed scheme (except the existence of the scheme proposal) will usually remain confidential unless consideration by the Appraisal Committee results in a change to guidance recommendations. In this situation, NICE will issue an Appraisal Consultation Document (ACD) for consultation (see section 3.7.21 onwards in the Guide to the processes of technology appraisal) or a Final Appraisal Determination (FAD) for appeal. NICE releases information during the ACD consultation or FAD for appeal consideration so that the proposed scheme and its impact on the clinical effectiveness, cost effectiveness and the recommendations can be understood.

20 Appeals following the rapid re-consideration of guidance, when consideration of the impact of patient access scheme/commercial access arrangement proposals on current guidance has resulted in a change to the guidance, will only be accepted on points relating to the new or amended patient access scheme or commercial access arrangement proposal. The Appeal Panel will not consider points previously raised or points that could have been raised at earlier appeals. Subject to any appeal by consultees, the FAD forms the basis of NICE guidance on the use of the technology.
### Table 1 Expected timelines for the rapid reconsideration process*:

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Weeks (approx.) since process began</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>NICE invites organisations to participate in the rapid CDF reconsideration process as consultees or commentators</td>
<td>0</td>
</tr>
<tr>
<td>Step 2</td>
<td>NICE receives evidence submissions from company</td>
<td>4</td>
</tr>
<tr>
<td>Step 3</td>
<td>NICE invites clinical experts, patient experts, commissioning experts and company representatives to attend the Appraisal Committee meeting</td>
<td>4</td>
</tr>
<tr>
<td>Step 4</td>
<td>ERG delivers the critique of the company submission to NICE</td>
<td>7</td>
</tr>
<tr>
<td>Step 5</td>
<td>NICE sends the ERG report to the company for fact checking</td>
<td>8</td>
</tr>
<tr>
<td>Step 6</td>
<td>NICE compiles the supporting documentation (see section 3.7.3 of the Guide to the processes of technology appraisals) and sends it to the Appraisal Committee</td>
<td>9</td>
</tr>
<tr>
<td>Step 7</td>
<td>Appraisal Committee meeting</td>
<td>11</td>
</tr>
<tr>
<td>Step 8</td>
<td>The ACD is produced. NICE distributes the ACD and publishes it on the website 5 working days later</td>
<td>14</td>
</tr>
<tr>
<td>Step 9</td>
<td>Fixed 4-week consultation period on the ACD</td>
<td>14-18</td>
</tr>
<tr>
<td>Step 10</td>
<td>Appraisal Committee meeting to consider comments on the ACD from consultees and commentators, and comments received through the consultation on the NICE website. Appraisal Committee agrees the content of the FAD</td>
<td>19/20</td>
</tr>
<tr>
<td>Step 11</td>
<td>The FAD is produced. NICE distributes the FAD and publishes it on the website 5 working days later</td>
<td>25</td>
</tr>
</tbody>
</table>

*Timelines may change in response to individual appraisal requirements.
Table 2 Expected timelines for the rapid reconsideration process if an ACD is not produced*  

<table>
<thead>
<tr>
<th>Step 7</th>
<th>semanas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appraisal Committee meeting to develop a FAD</td>
<td>11</td>
</tr>
<tr>
<td>Step 8</td>
<td>semanas</td>
</tr>
<tr>
<td>The FAD is produced. NICE distributes the FAD and publishes it on the website 5 working days later</td>
<td>16</td>
</tr>
</tbody>
</table>

*Timelines may change in response to individual appraisal requirements.
Figure 1 – Summary of the reconsideration process

CDF re-consideration scheduled

Reconsideration begins (week 0)
NICE invites consultees and commentators to take part in the CDF reconsideration process

Evidence Review Group (ERG)

ERG reviews company submission and produces ERG report (week 7).
Company receive the ERG report for factual error check

Consultees and commentators

Company submission (week 4)

Conference papers

Pre meeting briefing

Appraisal Committee meeting to develop the FAD or ACD (week 11)

FAD produced

ACD produced

Committee papers

ACD finalised

Confidential information redacted

ACD sent to consultees, commentators, clinical, commissioning and patient experts and ERG (week 14)

4-week consultation
3-week consultation (on web)

Consultee and commentator comments
Public comments

Appraisal Committee meeting to develop the FAD (week 20)
Appraisal Committee meeting to develop the FAD (week 20)

NICE Guidance Executive approves and finalises FAD

NICE sends FAD to consultees for appeal (15 working days) (week 16 or 25)

NICE sends FAD to commentators (week 16 or 25)

NICE publishes FAD on its website for information (week 17 or 26)

FAD produced

NICE asks Appraisal Committee to reconsider the evidence

Factual error

No appeal or factual errors

Appeal received

Not upheld

Guidance published

Upheld

NICE Guidance Executive amends errors and approves FAD

Editorial changes

NICE January 2016
The Centre for Clinical Practice (CCP) develops and maintains high quality, timely, evidence based, cost effective clinical guidelines that are easily accessible to a range of users on the treatment and care of people with specific diseases and conditions and service delivery within the NHS.

The Centre for Clinical Practice also includes the NICE Medicines and Prescribing Programme, which provides a range of advice to prescribers and organisations responsible for medicines optimisation together with Evidence Summaries on new medicines and unlicensed and off-label medicines and guidance and advice on medicines optimisation. The Programme also manages the contract for the BNF.

The Centre for Clinical Practice has hosted the Institute-wide review of methods and processes for the clinical, public health and social care guidelines and maintains the Unified Manual. It is leading the development of digital strategies to improve the efficiency of guideline processes and the effectiveness of presentation.

The Board is asked to review the progress report.

Professor Mark Baker
Director, Centre for Clinical Practice
January 2016
Centre for Clinical Practice 2015/16

1. This report provides the Board with a summary of the progress the Centre for Clinical Practice made against the business plan objectives for 2015/16.

Clinical Guidelines

2. The purpose of the clinical guidelines programme is to develop and maintain high quality, timely, evidence based, cost effective clinical guidelines that are easily accessible to a range of users on the treatment and care of people with specific diseases and conditions and service delivery within the NHS. The Centre for Clinical Practice business plan objectives for 2015/16 and delivery of the progress to date is as follows:

3. To publish 34 clinical guidelines including updates. Of the 34 planned topics, 24 have been published up to the end of December. The 24 publications are:
   - Anaemia management in people with chronic kidney disease (NG8)
   - Bronchiolitis in children (NG9)
   - Violence and aggression: short-term management in mental health, health and community settings (NG10)
   - Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges (NG11)
   - Lower urinary tract symptoms in men: assessment and management (standing committee update) (CG97)
   - Suspected cancer: recognition and management of suspected cancer in children, young people and adults (update) (NG12)
   - Venous Thromboembolism - Reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients admitted to hospital (standing committee update) (CG92)
   - Melanoma: assessment and management (NG14)
   - Diabetes in children and young people: diagnosis and management of type 1 and type 2 diabetes in children and young people (NG18)
- Diabetic foot problems: prevention and management of foot problems in people with diabetes (NG19)
- Type 1 diabetes: the diagnosis and management of type 1 diabetes in adults (update) (NG17)
- Prophylaxis against infective endocarditis: Antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures (standing committee update) (CG64)
- Coeliac disease: recognition, assessment and management (NG20)
- Menopause: diagnosis and management (NG23)
- Blood transfusion (NG24)
- Preterm labour and birth (NG25)
- Headaches in over 12s: diagnosis and management (standing committee update) (CG150)
- Venous thromboembolic diseases: diagnosis, management and thrombophilia testing (standing committee update) (CG144)
- Children’s attachment: attachment in children and young people who are adopted from care, in care or at high risk of going into care (NG26)
- Type 2 diabetes in adults: management (NG28)
- Rheumatoid arthritis in adults: management (standing committee update) (CG79)
- Intravenous fluid therapy in children and young people in hospital (NG29)
- Care of the dying adult (NG31)
- Tuberculosis - clinical diagnosis and management of tuberculosis, and measures for its prevention and control, incorporating PH37 Tuberculosis - Hard to reach Groups (update) (due to be published 13 January 2016)

4. The Asthma diagnosis and monitoring guideline was not published as planned. This was because it was decided to allow additional time to work with commissioners and healthcare professionals in asthma care on the feasibility of implementation. Following discussions with Professional
Associations and NHS England it is planned to carry out field testing before publishing the final guideline.

5. The Neonatal jaundice update by standing committee has been delayed. One review question required the updating of the threshold table for intervention from the original guideline. This required a more intensive update with the need to involve additional neonatal topic experts, and a targeted consultation to consult on the updated threshold table prior to formal consultation.

Surveillance Reviews

6. Surveillance reviews, undertaken at intervals during the life of a published clinical guideline, enable decisions to be taken on whether or not to update existing clinical guidelines.

7. To publish 45 surveillance reviews. Of the 45 planned surveillance reviews, 20 have been published up to the end of November. In addition, we have also undertaken 5 ad hoc or exceptional reviews. These were due to challenges to decisions or as a result of identified safety issues being raised. The 20 planned publications are:

Two year reviews:
- Antisocial behaviour and conduct disorders in children and young people (CG158)
- Crohn’s disease (CG152)
- Familial breast cancer (CG164)
- Fertility (CG156)
- Idiopathic pulmonary fibrosis (CGG163)
- Psychosis and schizophrenia in children and young people (CG155)
- Social anxiety disorder (CG159)
- Ulcerative colitis (CG166)

Four year reviews:
- Alcohol-use disorders: diagnosis and clinical management of alcohol-related physical complications (CG100)
- Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence (CG115)
- Generalised anxiety disorder (CG113)
- Hip fracture (CG124)

Six year review:
- Advanced breast cancer (CG81)
- Early and locally advanced breast cancer (CG80)
• Depression in adults with a chronic physical health problem (CG91)
• Glaucoma (CG85)
• Inadvertent perioperative hypothermia (CG65)

Eight year review:
• Dementia (CG42)

Ten year reviews:
• Post-traumatic stress disorder (CG26)
• Service guidance on improving outcomes in head and neck cancer (CSGHN)

8. Twelve surveillance reviews are in progress and a further 3 have been scheduled. This is below the planned output, due to the postponement in recruitment of new technical staff in quarters 1 and 2 and subsequent resignations. All of the vacant analyst posts have now been filled with 2 analysts due to start in February. Plans are being finalised to prioritise key topics for review and to explore options for using underspend to deliver more surveillance reviews in this financial year.

9. Work is ongoing to develop a process to allow a rapid response to anticipated new research. We have agreed with both NIHR and the NCRI a process to identify key trials that are anticipated to impact our guidance and agreement to receive pre-publication copies so we can respond as soon as key research is published. We have set up a database to track these key trials and a pilot topic (depression in children) has been identified to test the new processes and methods.

10. We have developed a reference panel and database of topic experts for CCP activities. This will include former GDG members and new experts all recruited through open advert with the aim of improving timely access to expert advice for the surveillance programme and to speed up recruitment of topic specialist members to the new standing committees. Invitations have been sent out to all former GDG members for those topics prioritised for 2016/17. So far we have a positive response rate of almost 50%, although we anticipate this will increase with reminder emails. Only 2% of invitees have so far declined.

11. The new processes and methods incorporating both surveillance reviews and evidence updates are now operational and the first surveillance reports in the new format were published in September.

12. We continue to evaluate and streamline these methods and processes to deliver an efficient programme. A workshop was held within the team to
identify areas for improvement and these will be taken forward over the next quarter.

Clinical Guideline Updates – standing committee

13. Build capacity to increase the number and frequency of published updated clinical guidelines. The progress to date is as follows:

- Two update standing committees (Committee A and B) are operating fully.

- Committees A and B will focus on updates where the surveillance team have identified new evidence which is less than 4 review questions in size. These committees will continue to update the more generalist topics.

- The composition and constituency of the committees has been reviewed and proposals for revised committee structures and constituency was approved by NICE Senior Management Team in November. These include:
  
  - Committees A and B will include 10 core standing members each. These members will be drawn from a range of NHS, lay and academic backgrounds. Up to a maximum of 6 topic expert members will join the core standing members to inform the development of each guideline update.
  
  - Committees C and D will focus on updates of specialist guidelines with each committee being made up of the following:
    
    - 7 core standing members recruited for three years
    - 5 condition specific standing members recruited for three years to participate in updates relevant to their area of expertise in a certain area
    - Up to 4 topic expert members recruited specifically for individual updates.

- Recruitment of members for Committee’s C and D will commence in January 2016. The topics will cover broad disease or population areas starting with:
  
  - Cancer
  - Mental health
  - Diabetes and other endocrine disorders
ITEM 10

- Cardiovascular

- 23 topics in total have now been referred to the programme for updating of which 12 have published to date. Six topics have been published this year.

14. A process and methods working group will be responsible for overseeing and agreeing any required process and methodological developments for the updates programme.

New Contracts

15. The Centre for Clinical Practice has tendered for 2 new contracts for the development of clinical guidelines and 1 new contract for the Technical Support Unit this year. Progress to date is as follows:

- Following an EU wide tendering process, the contracts for Development Centre 1, and Development Centre 2 were awarded to the Royal College of Physicians (RCP) London and the Royal College of Obstetricians & Gynaecologists (RCOG).

- The contract negotiations for DC1 are completed, and the contract is agreed and awaiting signatories. The Statement of Transfer has been agreed by current host organisations (RCOG, RCPsych and Valindre NHS Trust) and signatories are in progress. Contract negotiations for DC2 are completed and are awaiting signatories. A Transition contract with the RCOG has been agreed and awaiting signatories. The new contract will come into effect on 1 April 2016.

- RCOG continue to take forward transition plans in collaboration with the specialist National Collaborating Centres to ensure business continuity for all current guidelines in development.

- The NICE steering group meets monthly to oversee governance and risk management and ensure business continuity. Once the formal one-to-one interviews have been conducted through the TUPE process we will be in a better position to understand the impact of the transition on the work programme.

- The contract for the Technical Support Unit contract has been awarded to the University of Bristol, continuing our collaboration. The new contract will commence on the 1 April 2016.

16. We are required to operate the Centre within budget and ensure that the contractors and other developers maintain and improve the quality and
efficiency of their processes to deliver consistently high quality work, to time and budget. The progress to date is as follows:

- The quarter 2 review meetings with contractors are completed. Estimated year-end financial positions are being monitored and actioned.

- The current end of year position is predicted to report an underspend position. We have commissioned two additional guidelines in year, Chest pain (update) and Heavy menstrual bleeding (update), utilising underspend.

- The developers in the specialist National Collaborating Centres are reporting medium risk to business continuity due to the transition to Development Centre 2.

17. We are developing the methods of clinical guideline development to maintain and enhance the Centre's reputation for methodological quality and efficiency. Progress to date is as follows:

- The Centre is continuing to support the implementation of the new guidelines manual for those clinical guidelines in development from 1 January 2015.

- The development of service delivery guidance continues to raise technical and methodological challenges. The Centre has established an external service delivery methods reference group to support the development of its service guidance.

- The service guidance on acute medical emergencies is helping to populate six quality standards which are; urgent and emergency care, out of hours care, seven day working, consultant review within 12 hours, medical admissions in the first 48 hours and readmissions. This work is challenging in terms of its scope and methodology and in the longer term, implementation.

- In May, June and July we met economists and operational researchers at Monitor and NHS England to discuss their economic and modelling work on accident and emergency services and to discuss their learning with respect to methods for simulation modelling from their projects. They have agreed to share their work and models with the developers of the the Acute Medical Emergencies service guidance.

- In July, we presented and facilitated at the MRC Beyond the QALY workshop organised by NICE’s Science Policy and Research Team
and attended by leading academics to inform the MRC’s future research agenda addressing the development of new quality of life instruments to better capture benefits across health and social care.

- In October, we presented and contributed to a workshop organised by the MRC Network of Hubs for Trials Methodology Research on Health Economic Analysis Plans, with respect to their current usage in terms of their structure, content and purpose.

- We continue to contract the Technical Support Unit (TSU) to provide specialist technical and methodological advice for guideline-specific issues and on-going training and development sessions for staff in the Centre for Clinical Practice, National Collaborating Centres and members of Guideline committees. The contract has been awarded to the University of Bristol being re-appointed to continue to undertake the function from 1 April 2016.

- We have maintained involvement with the international Grading of Recommendations Assessment Development and Evaluation (GRADE) working group. The Centre has submitted a proposal to the GRADE Guidance Group to co-lead with University College London, a UK GRADE Network which will include partners from the Scottish Intercollegiate Guideline Network (SIGN), Cochrane UK and BMJ Evidence amongst others.

- During quarter 1, 2 and 3 we have been a partner organisation on the European-funded project: Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence (DECIDE). DECIDE is examining different presentation formats and dissemination approaches for guidelines and project updates are regularly provided for the Guidance Development Project (GDP). Results from the various work packages are being published and the final report is due in early 2016.

- We continue to attract interest from students and researchers seeking short-term placements to gain experience in clinical guideline development. In collaboration with 7 groups from across Europe we have been awarded an EU grant to host up to 3 PhD students for short-term placements to undertake studies on “Methods In Research On Research” (MIROR project).

- We have agreed with the European Respiratory Society to host, with the Cochrane Collaboration, 2 research fellows for 3-6 month placements in 2016. They will pursue a guideline-related research
project of their choosing while being exposed to as many NICE activities as possible.

- We continue to co-lead the Manchester Evidence Synthesis Network in collaboration with the University of Manchester. The network organises regular educational workshops on topical subjects with high profile speakers. A workshop on surveillance and updating was held in May 2015 and was attended by NICE staff.

- We continue to promote the advance of methodological and process innovation in guideline development. A total of 17 abstracts submitted by CCP staff (6 in collaboration with NCC or TSU staff) were accepted for presentation at the 2015 Guidelines International Network conference.

**Medicines and Prescribing Programme (MPP)**

18. The purpose of the Medicines and Prescribing Programme is to provide a comprehensive suite of guidance, advice and support for delivering quality, safety and efficiency in the use of medicines. This includes evidence summaries, Medicines Practice Guidelines (formerly Good Practice Guidance) and providing access to the British National Formulary (BNF) and British National Formulary for Children (BNFc) in digital and print formats for prescribers working in the NHS in England. The business plan objectives for MPP were as follows:

19. To publish 30 Evidence Summaries, including New Medicines, Unlicensed/off-label medicines and one Medicine and Prescribing briefing. Of the 30 planned topics, 18 have been published up to the end of December.

The following 11 Evidence summaries new medicines have been published:

- ESNM 57: Chronic obstructive pulmonary disease: aclidinium/formoterol
- ESNM 58: Ulcerative colitis: budesonide multimatrix (Cortiment)
- ESNM 59: Type 2 diabetes: dulaglutide (Trulicity)
- ESNM 60: Type 2 diabetes: insulin degludec/liraglutide (Xultophy)
- ESNM 61: Orthostatic hypotension due to autonomic dysfunction: midodrine
• ESNM 62: Type 1 diabetes mellitus in adults: high-strength insulin glargine 300 units/ml (Toujeo)
• ESNM 63: Coronary revascularisation: Cangrelor
• ESNM 64: Diabetes mellitus type 1 and type 2: insulin glargine biosimilar (Abasaglar)
• ESNM 65: Type 2 diabetes mellitus in adults: high-strength insulin glargine 300 units/ml (Toujeo)
• ESNM 66: External genital and perianal warts: green tea (Camellia sinensis) leaf extract 10% ointment
• ESNM 67: Restless legs syndrome: Oxycodone/naloxone prolonged release

20. The following 7 Evidence summaries unlicensed or off-label medicines have been published:

• ESUOM 43: Interstitial cystitis: oral pentosan polysulfate sodium
• ESUOM 44: Prevention of recurrence of C3 glomerulopathy post-transplant: eculizumab
• ESUOM 45: Symptoms of peripheral arterial disease: Ramipril
• ESUOM 46: Hypersexuality: fluoxetine
• ESUOM 47: Infantile haemangioma: topical timolol
• ESUOM 48: Excessive daytime sleepiness in Parkinson’s disease: modafinil
• ESUOM 49: C3 glomerulopathy in the native kidney: eculizumab

NHS England commissioned a second rapid evidence summary (RES) on eculizumab in a related indication in November following the publication of ESUOM 44 in June. NHS England is planning to develop national commissioning policy based on these evidence summaries in early 2016.

ESUOM Hormone-sensitive metastatic prostate cancer: docetaxel was shared with NHS England (embargoed copy) ahead of publication on 5 January to accommodate a request to have the summary available to inform the Clinical Panel’s commissioning policy decision-making in early January 2016.
21. To publish 2 Medicines Practice Guidelines. Of the 2 planned topics, 1 has been published up to the end of December.

- Antimicrobial Stewardship (AMS) (NG15)

22. Ensure that the BNF contract delivers quality and timely products within budget. Progress to date is as follows:

BNF Print and Distribution:

- Revamped print editions of BNF 70, BNFC 2015 and NPF 2015 were distributed to eligible NHS staff throughout the UK in October and November. They were the first editions to include the new content structure, which has been designed to deliver digital and print products, improve consistency in the presentation of information and offer the scope to deliver new functions and features. As a result there have been changes to the way the content is organised. A small number of factual errors, including dosage errors were identified in the print BNF and BNFC, causing some Trusts to instruct staff not to use them and instead refer to the digital formats where the errors had been corrected. The BNF Publisher has advised that this small number of errors is the norm in each new print edition, and has disseminated joint communications with UK Medicines Information (UKMI) and the National Paediatric Prescribing Group to reassure users that the print formats are safe to use. It has also issued information on clinically important corrections.

- The supply of the service to manage the BNF mailing database and enquiry handling has been tendered and won by the incumbent supplier on a three year contract delivering equivalent service with annual cost savings peaking at 25% in 2018.

BNF Online:

- The BNF Publisher released enhanced BNF and BNFC platforms on www.medicinescomplete.com in November which utilise the new content structure and presentation.

- We have been working with NHS stakeholders which utilise the old BNF content structure for reporting on medicines usage, such as the Health and Social Care Information Centre, NHS Business Services Authority, Department of Health and the Devolved Administrations to ensure they receive adequate support from the BNF Publisher to continue reporting.
- Usage of NICE’s BNF and BNFC sites, hosted on NICE Evidence Services continues to grow, peaking at 177,000 visits in November 2015, more than double the equivalent in 2014. The joint project between MPC, IM&T and M&AI teams to develop an enhanced BNF/BNFC platform, based on the new BNF content structure continues.

Apps:

- The BNF Publisher submitted a prototype of its new app to NICE for approval to launch in October 2015. Testing by NICE indicated good progress towards the required specification.
- We are collaborating with IM&T and Communications Directorates to prepare for the eventual release of the new BNF app, and subsequent withdrawal of the NICE BNF and BNFC apps. The NICE BNF app receives over 400,000 visits each month.

Cross Institute Work

Guidance Development Project (GDP)

23. The purpose of the GDP is to lead on the accreditation, maintenance and updating of the guidelines manual, and support its implementation. In addition, the project seeks to improve the efficiency of development and functionality of presentation of NICE guidance, through implementation of the NICE content strategy and investment in technology through the transforming guidance development programme. The business plan objective for the GDP is as follows:

24. Support the Implementation of the unified manual and the NICE content strategy. Progress to date is as follows:

25. The application seeking NICE accreditation status for the guidelines manual was considered by the Accreditation Committee in November 2015. The Committee recommended that Developing NICE Guidelines: The manual should be awarded NICE accreditation status.

26. NICE is in discussions with the EPPI Centre/UCL to develop a strategic partnership which will enable NICE to use the EPPI-Reviewer tool to support systematic review and other evidence management tasks across NICE programmes.

27. The transformation of NICE guidance involves breaking down NICE content into elements that can be discovered outside the document in which they were created. The first project in the knowledge base stream has
succeeded in demonstrating that this can help meet the needs of our users; feedback on the new searchable dataset of quality statements has been positive, and the system will go live at the end of January 2016.

Recent developments

Access and Waiting Times - working in Partnership with NHSE

28. The access and waiting times work programme is in partnership with NHS England and the Royal College of Psychiatrists on the delivery of a set of commissioning guides amongst other deliverables, based on published NICE clinical guidelines to support the achievement of the objectives in Achieving Better Access to Mental Health Services by 2020.

29. In August 2015, NHS England referred the access and waiting times work programme for a further four more years. On 8 September 2015, the Senior Management Team discussed a paper from CCP on the referral, and agreed that it should continue within the Health and Social Care Directorate. Handover of the work is in progress.

30. CCP has retained management of the current contract until March 2016 and is agreeing the call off on the current contract with NHSE and the Royal College of Psychiatrists for 2016/17. Handover of contract management from CCP to H&SC directorate will occur on 1 April 2016. Negotiations on the call off contract are ongoing with NHSE and RCPsych and significant progress was made in December with the RCPsych Trust board agreeing to continue with the contract.

Contract with BPACnz to contextualise clinical guidelines for New Zealand

31. The Centre continues to work with Best Practice Advocacy Centre New Zealand (BPACnz) to contextualise NICE clinical guidelines for the New Zealand health care system. NICE receives an income from BPACnz. Methods and processes for the contextualisation of NICE clinical guidelines for use in New Zealand have been developed and agreed.

32. The approach is consistent with the approach developed by the ADAPTE collaboration. However, some key differences - restricting source guidelines to NICE guidelines and inclusion of an independent quality assurance review by the CCP QA team, have ensured that the process is more efficient and robust. An oral presentation showcasing this work was presented at the Guidelines International Network (GIN) conference in October. The first two clinical guidelines to be contextualised - Respiratory Tract Infections and Urinary Tract Infections are completed and we are in discussion with BPACnz about future topics.
Implementing changes

33. The phased implementation of new ways of working are in progress following agreed changes through the guidance development project; the changes will improve consistency and ensure best practice is used by all developers.

Workforce

34. The Commissioning team have a number of vacancies. Recruitment and retention of some posts continues to be challenging.

Medicines and Prescribing Programme (MPP)

35. In September the MPC consulted on proposed changes to management responsibilities within the team to facilitate greater flexibility; to allow better use of skills in the team across the Institute; to be more responsive to changing needs; and to provide continuity of expert medicines advice. The proposal also included the recommendation to change the name from Medicines and Prescribing Centre (MPC) to Medicines and Prescribing programme (MPP) to better align with other teams in NICE. The proposed changes were accepted by SMT on 29 September, and were implemented during November and December 2015.

Associates and associate recruitment

36. The associate network operates in a wide range of settings to influence medicines and prescribing strategies and local practice. These include academia, clinical commissioning groups, commissioning support units, defence medical services, general practice, hospitals providing secondary and tertiary care, mental health services, prisons, social enterprises, and specialised commissioned services.

37. The programme aims to broaden the professional mix of associates as well as their geographical spread. A 3 day training and assessment course was held in November to recruit 18 new associates. Candidates were identified by existing associates and through the promotional work of the 4 regional technical advisers. There are now 79 associates in England, Wales, Northern Ireland, Guernsey and Jersey. Most are pharmacists but there are also 3 nurses, a hospital physician, and a general practitioner.

Associate development

38. The associate programme involves 5 contact days each year, held concomitantly at the NICE offices in Manchester and London. These focus on training and sharing of good practice in medicines optimisation and
implementation of relevant NICE guidance. Materials are produced and delivered by the medicines education team. Regional technical advisers help associates develop local implementation plans following the training days. Four events were held between April and December 2015.

**Associate and NICE work programmes**

39. Associates act as a valuable link between NICE and frontline clinical practice, offering the opportunity to align guidance and advice with the needs of the service.

**Presentations**

40. Members of the medicines education team have given presentations at over 40 national and regional events. The programme continues to thrive; the 2016-17 strategy will be developed in January (in collaboration with the associates), and launched at the final 2015-16 training day in February.

41. As part of the weekly medicines awareness service the MPP produces Medicines Evidence Commentaries (MECs). These help to contextualise important new evidence on medicines and prescribing, highlighting areas that could signal a change in clinical practice. The MPP has published 31 MECs to date in 2015/16 against a target of 40 with a further 10 topics identified for development.

42. The MPP is working in collaboration with the NHS England Medicines Optimisation Intelligence group to update the Medicines optimisation: key therapeutic topics (MOKTT). The MOKTT provides localities with summaries of evidence on topics where there are potential opportunities for maintaining or improving quality and improving value from our use of medicines. The resource also includes comparative data to illustrate the variation in prescribing over a period of time, produced in collaboration with the Health and Social Care Information Centre (HSCIC).

43. The 2015/16 update includes 3 new topics: biosimilar medicines, non-vitamin K antagonist anticoagulants (NOACs) and acute kidney injury. The draft key therapeutic topics were consulted on in November and December and the final update will publish in February 2016.

44. The MPP published a patient decision aid (PDA) on 2 December, alongside the updated Type 2 Diabetes guideline to support the implementation of the guidance.

45. Throughout 2015/16 the MPP has been working with colleagues across the wider CCP to develop and agree systems and processes to identify how the medicines advisers can best add value to the existing surveillance, guideline
development and validation and endorsement programmes by providing structured but flexible advice around medicines. Formal arrangements will be agreed and fully implemented during 2016/17.

46. The MPP will also provide formal targeted support to CGUT for standing committee updates. Currently support is requested in a less formal way on an ad hoc basis. Where the updates are already in the later stages of development MPP have a process in place to identify key topics for comment at the consultation stage where medicines are involved.

**Endorsement**

47. To date the MPP have assessed 8 tools/resources submitted via the NICE Endorsement programme. This work was carried out in line with the assessment criteria developed by the Accreditation and Quality Assurance team.

**Implementation**

48. The MPP have started work on the development of an implementation tool to support the Care of the Dying Adult guideline. The guideline published in December 2015.

**Rapid evidence summaries**

49. We have agreed in principle with NHS England a proposal to develop up to 10 rapid evidence summaries in 2016/17 on a fee-based model. The topics are likely to be mainly unlicensed/off label use of medicines that have been the subject of frequent individual funding requests and will be used to inform NHS England commissioning policy.

50. The programme will displace existing ESUOM slots, and is expecting to begin from 1 April 2016, subject to contract agreement with NHS England.
Key indicators

CCP Activity Summary

Clinical Guidelines Activity Summary

Published clinical guidelines

![Cumulative Clinical Guideline Publications 2015/16](chart1)

Published Surveillance Reviews of Clinical Guidelines

![Cumulative Surveillance Review Publications 2015/16](chart2)
Medicines Prescribing Programme Activity Summary

Published Evidence Summaries

Cumulative Evidence Summaries Publications 2015/16

- Planed
- Actual
- Variance

April May June July Aug Sept Oct Nov Dec Jan Feb March
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION PROGRESS REPORT

The Centre for Health Technology Evaluation develops guidance on the use of new and existing medicines, including highly specialised technologies, treatments, medical technologies, diagnostics and surgical procedures within the NHS. In addition to its guidance producing activities, the Centre is responsible for the Patient Access Scheme Liaison Unit, the Science Policy & Research Programme, NICE Scientific Advice, the Office for Market Access and the NICE Topic Selection Programme.

The Board is asked to note the report.

Professor Carole Longson
Director, Centre for Health Technology Evaluation
January 2016
Centre for Health Technology Evaluation

1. This report provides the Board with a narrative progress report on the main business plan objectives the Centre for Health Technology Evaluation for 2015-16, and highlights recent developments for the months of April 2015 to January 2016

Business Plan Objectives 2015-16

2. Based on the latest information on the regulatory status of relevant medicines, technology appraisals is currently on target to publish 45 pieces of final guidance and the patient access scheme liaison unit will exceed the target of 12 pieces of advice to Ministers and provide advice on 26 patient access schemes.

3. Based on the selection and routing decisions of the Medical Technologies Advisory Committee, 8 medical technology guidance documents were expected to be published during 2015/16. Four topics have needed to be rescheduled and are now due to publish in 2016/17:
   - after selection by MTAC, one topic was subject to further regulatory status change and the company was acquired;
   - one topic is rescheduled pending availability of key UK clinical effectiveness study findings;
   - one topic is rescheduled to allow alignment with the planned partial update to clinical guideline 65: inadvertent perioperative hypothermia;
   - one topic is paused due to the need for alignment with the update to clinical guideline 95: chest pain of recent onset, which has been delayed.

4. The medical technologies programme is forecast to publish at least 36 medtech innovation briefings.

5. The interventional procedures programme is expected to publish 34 pieces of guidance.

6. The diagnostics assessment programme has published 3 pieces of guidance in the business year to date. The programme expects to publish 6 pieces of diagnostics guidance in the business year. A second consultation has been initiated for one topic which will now publish in the 2016/17 business year.

7. The highly specialised technologies programme expects to publish 2 pieces of final guidance.

8. The Observational Data Unit, commissioned and funded by NHS England, is working on 6 projects, all of which are progressing to target.
9. Based on the current schedule, NICE Scientific Advice anticipates full recovery of all programme and overhead costs and will meet, or exceed, its annual business targets. Since April 2015, 32 projects have been initiated and 1 additional project has been booked to complete before the end of the financial year. There are a further 7 projects booked that will fall into the 2016/17 financial year.

Science Policy and Research Programme

10. The SP&R Programme at NICE is participating in the EU Innovative Medicines Initiative (IMI) project: Accelerated Development of Appropriate Patient Therapies: a Sustainable, Multi-stakeholder Approach from Research to Treatment-outcomes (ADAPT-SMART). ADAPT-SMART will provide a ground-breaking opportunity for the project consortia to design new operational procedures for the development of medicines as part of the ‘Medicines Adaptive Pathways to Patients (MAPPs) initiative. ADAPT–SMART will establish a forum with relevant stakeholders for the coordination of MAPPs related activities within IMI 2. NICE, in collaboration with Astra Zeneca (AZ), is co-leading work package 1 (WP1) of the project. NICE is also coordinating the contribution and activities of the four participating European health technology assessment (HTA) organisations (NICE, HAS, ZIN, DACEHTA). The 30-month project started in July 2015 with a Scientific Advisor post fully funded to deliver NICE’s work.

11. A Citizens Council meeting was held in early November which asked the Council members to explore the use of anonymised information from personal records. The meeting was attended by two non-executive NICE Board members. A report on the meeting is being prepared.

Strategic Technology Appraisals Review

12. Elisabeth George, Associate Director, continues to lead the strategic review of the technology appraisal programme. The review will develop proposals to respond to several external developments likely to affect how we produce guidance in the future. The review will focus on three areas: managing uncertainty and risk, value assessment and responding to increases in demand.

Cancer Drugs Fund proposals

13. The technology appraisals team have been working closely with NHS England to plan the operation of the new Cancer Drugs Fund (CDF) from Aril 2016. A business case for funding of the work NICE is expected to do as a consequence of the new plans for CDF has been submitted NHS England. Work is also underway to implement transition arrangements for drugs that are currently on the CDF.

Highly Specialised Technologies

14. In November 2015, the highly specialised technologies programme published guidance on Elosulfase alfa for treating mucopolysaccharidosis type Iva. The guidance includes a Managed Access Agreement. This agreement, developed in collaboration with NHS England, Biocare and the MPS Society is the first of its
kind for a HST product. It provides a platform for patients to obtain access to the drug while contributing to the collection of real world data that will inform the future evaluation of elosolfase alpha in 5 years’ time.

The Office for Market Access (OMA)

The OMA team are developing final details of their initial suite of chargeable services towards and aim to launch them towards the end of January 2016.
Key indicators

Figure 1 highlights programme activity for guidance producing teams for the months of April 2015 to January 2016.

![Figure 1. Programme activity April 2015 - January 2016](image)

<table>
<thead>
<tr>
<th>Ref</th>
<th>Programme</th>
<th>Unit of output</th>
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</thead>
<tbody>
<tr>
<td>TA</td>
<td>Technology Appraisal</td>
<td>Final Published Guidance</td>
</tr>
<tr>
<td>IP</td>
<td>Interventional Procedures</td>
<td>Final Intervention Procedures Document</td>
</tr>
<tr>
<td>DAP</td>
<td>Diagnostics Assessment</td>
<td>Diagnostics Guidance Document</td>
</tr>
<tr>
<td>MTEP</td>
<td>Medical Technologies Evaluation</td>
<td>Medical Technology Final Guidance Document</td>
</tr>
<tr>
<td>HST</td>
<td>Highly Specialised Technologies</td>
<td>Final Published Guidance</td>
</tr>
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</table>
The Communications Directorate at NICE is made up of a number of teams:

- Enquiry handling
- Audience Insights
- Internal communications
- Website
- External communications which includes media, public affairs, stakeholder engagement, and events and exhibitions,
- Publishing.

Together we use a variety of channels to communicate with a wide range of audiences in the NHS, in social care and beyond. We contribute to the core work of producing guidance through our roles in editing, production, distribution and promotion. And we help to protect and enhance the reputation of NICE through daily contact with the public, media, parliamentarians and other key groups.

The Board is asked to review the progress report.

Jane Gizbert
Communications Director
January 2016
Communication directorate’s plans for 2015-16

1. This paper covers the period between 1 November and 31 December 2015. It highlights our business plan objectives, which have been developed to support the organisation’s strategic objectives. It demonstrates how our activities during the past 2 months have aligned to these objectives.

Business plan objectives for 2015-16

2. Our main objectives that we intend to deliver this year are listed in the boxes below. Under each we have provided a narrative on our progress in meeting the objectives during this reporting period.

<table>
<thead>
<tr>
<th>Objective 1</th>
</tr>
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<tr>
<td><strong>NICE’s offer</strong>: Communicate the narrative about NICE’s role (USP) within the health and social care system</td>
</tr>
</tbody>
</table>

Media relations

Menopause guideline

3. Our embargoed press conference for the clinical guideline, Menopause: diagnosis and management generated blanket positive media coverage in November.

The NICE guideline headlined all morning national and regional news broadcasts and included additional interviews and features on BBC Breakfast, BBC News, Sky News, ITN, Good Morning Britain and Victoria Derbyshire TV programmes. Radio 4 Today programme, Radio 5 Live, Radio 4 Woman's Hour and range of BBC regional radio stations also featured interviews on top of running it as their lead story. Daytime TV magazine shows discussed the guideline, including Loose Women and The Wright Stuff.

The guideline was the front page story on the Daily Telegraph and The Times, and featured in all national newspapers, as well as a range of regional titles and health trade journals and magazines. [There is a diary of the coverage on Storify](https://storify.com) which gives details of the story through social media – especially Twitter.
Type 2 diabetes guideline update

4. The press coverage for this guideline in early December was positive and balanced despite the previous concerns about specific proposed recommendations which led to a second consultation. The announcement in the press release, that NICE is setting up a standing committee to ensure that the guideline remains up to date, was well received.

Care of the Dying Adult

5. Our guideline on delivering high-quality care for those in their final days of life was launched in December. Aware of the sensitivities surrounding this new guideline replacing the Liverpool Care Pathway, we worked closely with the committee and the press to ensure our key messages were consistent and reported accurately. The guideline received national, regional and social media attention. It was the top story for the BBC’s morning news outlets and secured sustained coverage throughout the day into evening news. There was also widespread coverage for our key audiences through GP Online, the BMJ, Care Management Matters and EHospice. A diary of the coverage is available via Storify.

Independence and well-being

6. Launched in the same week as the Care of the Dying Adult guideline, Public Health Guidance on older people - independence and mental wellbeing was also well received. It coincided with a focus by Channel 4 News on loneliness in older people. Gillian Leng took part in a studio discussion on the issue.

   The guideline was also covered by The Daily Telegraph (Join a choir to stave off dementia, says health watchdog Nice) and the Daily Mail: Lonely OAPs 'should join a choir or read to children in schools'; Health watchdog says elderly need to be told of activities in their area to help increase independence.

Cancer drugs fund

7. We worked alongside NHS England to announce the consultation on proposed changes to the Cancer Drugs Fund by providing a supportive quote from Andrew Dillon to be included in their press release. Coverage has so far been positive with articles widely promoting the opportunity for people to comment.
Cancer drug appraisals

8. Draft decisions for enzalutamide and abiraterone to treat prostate cancer were published in December. Both were assessed for treating prostate cancer that has spread in people whose first treatment has failed, who have no or mild symptoms, and for whom chemotherapy is not yet clinically indicated. Enzalutamide was a positive draft recommendation, abiraterone was negative due to cost. Prostate Cancer UK and Janssen PR released statements of disappointment over the abiraterone decision. This was reported in Pharma Times and the European Pharmaceutical Review.

We received a lot of interest over two negative cancer drug appraisals, nivolumab (Opdivo) for lung cancer and trastuzumab emtansine (Kadcyla) for breast cancer. A proactive press release was issued for Kadcyla whilst a reactive statement was prepared for Opdivo. We also worked with the Institute of Cancer Research and Breast Cancer Now to issue statements in line with our rationale that the treatments were not cost-effective. As a result the majority of coverage was neutral for us, with the Daily Mail and The Times writing wider pieces on the rising cost of cancer drugs.

Intrapartum care QS

9. The publication of our quality standard on intrapartum care received a good level of coverage across national and regional media. All coverage focused on the key message set out in our press release to offer women more choice on place on birth with the provision of information on local outcomes to be made a priority. The story appeared online on the Daily Mail and Telegraph websites; with print coverage in the Daily Telegraph and the Sun.

Head of media

10. Following interviews in December, Rebecca Smith, a former medical editor at the Daily Telegraph and Evening Standard, was appointed to lead the media team. She will develop our work with the traditional press and with digital outlets – continuing to improve our multimedia activities.

Coverage

11. Because of the large volume of coverage about NICE, we are now targeting our evaluation more specifically at proactive media work. Over
the period there were 624 articles and broadcasts rated. (84% positive, 13% neutral and 2% negative). Guidelines on Menopause, Care of the Dying Adult, and the appraisal of Vimizim (to treat a very rare genetic disorder, Morquio A syndrome) were very positively received. Coverage of the cancer drug appraisals was largely neutral with some negative pieces.

Year in review

12. A summary of the guidance and advice that generated the most interest during 2015 can be found in 2 parts on the NICE website. This infographic shows the highlights:
External events and speaking engagements

13. In November, Professor David Haslam gave a keynote speech at the opening of the FT Global Pharmaceutical Biotechnology conference on 'Market access, towards a sustainable solution to the challenge of rising drug costs'.

14. We also supported speaking engagements for SMT, Board members and other NICE colleagues at almost 30 events, including:
• **Increasing and improving workplace wellbeing and health – 25 November 2015, London:** Gillian Leng spoke about putting senior management at the heart of workplace wellbeing

• **Commissioning Live – 24 November 2015, Manchester:** David Haslam took part in a panel debate on 'managing long term illness in the patient population'.

• **The Care and Dementia Show – 4 November 2015, Birmingham:** Bridget Warr (chair of the Home Care guideline committee) presented on the guideline and Fiona Glen presented on ‘setting the standards for integrated care’.

**Enquiry handling**

15. From 1 November to 31 December the enquiry handling team responded to 1715 enquiries.

16. The popular areas of enquiry were clinical guidelines products (23%), technology appraisals (7%), OpenAthens (6%) and PharmaScan (7%). 13% of the enquiries in this period concerned guidelines that NICE had not produced or raised questions outside of NICE’s remit. The origin of enquiries remained broadly the same, with the NHS accounting for 34% and members of the public accounting for 36% of enquiries received. Enquiries from international organisations and individuals remained at 5%.

17. Following publication of the care of the dying adult guideline, enquirers praised our focus on the importance of individual decision-making and also prompted a number of calls from the public regarding their previous experiences. The team responded to a number of queries regarding treatment options for hepatitis C due to confusion about what drug treatments have been recommend for different genotypes. The volume of enquiries urging NICE to issue final positive guidance on the drug elosulfase alfa (Vimizim) for treatingucopolysaccharidosis idosis type IVa (also known as MPS IVa and Morquio A syndrome) and on ataluren (Translarna) for treating a type of Duchenne muscular dystrophy remained high, especially from MPs on behalf of their constituents.

18. The enquiry team responded to 18 Freedom of Information requests. These included several requests for information about contract management for both IT services and facilities, a request for all internal correspondence relating to the removal of a recommendation within guidance on dementia, disability and frailty in later life and information about whether NICE pays for private healthcare or insurance for any member of staff.
Objective 2

We produce high quality products: NICE products are high quality, readily understood and presented in formats and through channels that meet the needs of our audiences.

Documents from development to launch

19. November and December were busy months for guidance publication, with 38 topics published, including 23 CHTE items and 11 NICE guidelines. Two of the guidelines included tools to support shared decision making. We worked with the developers of the menopause guideline on risk tables to help healthcare professionals explain to women absolute rates of coronary heart disease, stroke, breast cancer and fragility fractures for different types of HRT compared with no HRT. We also provided input to the MPC’s patient decision aid to help adults with type 2 diabetes think about their options for controlling their blood glucose to try to reduce the long-term risks of diabetes.

20. In November and December we prepared and digitally published 97 documents. The digital publishing team are continuing work on improving the overview pages.

NICE Pathways

21. In November and December, we:

- Published 6 new pathways
- Fully updated 7 pathways
- Updated 25 pathways to take account of new guidance (for example, adding new health technology guidance)
- Updated a further 56 pathways to add related pathway links or as maintenance updates.

22. The updates included the diabetes pathway, which was changed to include the recommendations in the new guideline on type 2 diabetes in adults (the last in the suite of diabetes guidelines published this year).

Guidance transformation project

23. The Publishing team is involved in most of the workstreams to transform the way NICE develops guidance.
24. In November, we completed the series of workshops on user-focused writing for colleagues across the Communications team. The workshops focused on writing content that meets the needs of our users and communicates our information clearly. There was very positive feedback on the training, with comments that the workshops were useful not only to get us thinking about how we can improve communication with our audiences but also to share ideas and knowledge across the communications team. This theme was also picked up at the directorate awayday in November.

25. Communications team nominees on the Content Strategy Governance Group attended its first meeting. The publishing team also gave support and feedback on the quality standards knowledge base project.

**NICE website**

26. The graphs below contain a standard at-a-glance view of website and Pathways statistics and data for December for 3 key metrics:

- visits for the last full calendar month
- the percentage of visits that completed a meaningful interaction such as a user clicking to download a guideline or fill in a form
- the percentage of returns within 10 days

![Graphs showing NICE and Pathways statistics](image)

27. We completed work on the new website homepage which will go live during January 2016. In response to user feedback, the new homepage
more clearly explains our role and provides users with faster access to the most popular areas of the website.

28. Work is underway to create a new section on the website to support recruitment campaigns, in particular for specialist roles such as those in our digital service teams. The new section will promote the benefits of working for NICE using different media such as videos and blogs.

29. During November and December the web team conducted a number of 1:1 sessions with users in response to feedback about the stakeholder registration process. The sessions highlighted a number of improvements needed to make the process more efficient and easier for stakeholders to complete.

### Objective 3

**Engagement:** Engage with our partners and stakeholders to successfully reset our offer in the new system and to encourage widespread adoption of our new and improved products

### Reaching primary care, local government & social care audiences

30. The external communications team has been working the RCGP to plan articles on upcoming guidance. In November, a piece by David Haslam on kindness and trust with insights from the annual NICE conference led the College’s Clinical News newsletter. It includes articles on the Care of the Dying Adult guideline as well as a piece by a member of the NICE obesity guideline development group on resources to help GPs support people who want to manage their weight.

31. In December, an article by Gillian Leng was published in the Local Government Chronicle on social care guidance to improve the transition to and from inpatient hospital settings and community or care home settings.

32. A piece by Jane Silvester on new social care guidance at NICE was placed in Care England’s magazine in November (p18).

### Audience and user research

33. Work is continuing with the Reputation Institute on the Cabinet Office-sponsored pilot stakeholder reputation survey. Following discussions with the Cabinet Office a full brief and project plan is now being prepared.
34. We have been approached by several local CCGs who are keen to work with us on market research into the use of NICE guidance at a local level and in particular any barriers to implementation amongst primary care audiences. Plans are at an early stage but a partnership approach will have many benefits for our audience insights programme.

35. We are supporting the NICE savings and productivity steering group with user research on how the savings and productivity resources are currently being used and what improvements our users would like to see to increase their effectiveness. An online survey opened in December and will be followed by in-depth 1:1 interviews.

36. Audience research was conducted during December to find out more about how our Medtech Innovation Briefings (MIBs) are being used. A survey was sent to 280 stakeholders including CCGs and specialist commentators who had been involved in the development of the MIBs. The results have been analysed and are currently being considered by the team responsible for developing the briefings.

37. During November and December we provided advice and practical support for a number of surveys carried out by other teams. These included a survey on how we involve patients and the public in our work, and an internal staff survey on a quiet zone for the Health and Social Care directorate.

**Objective 4**

*Internal communications:* Ensure all employees have a shared understanding of our vision and work.

38. During November and December the Internal Communications team made a number of improvements to NICE Space in response to staff feedback. These included the ability to subscribe to individual blogs, and the ability to edit and delete comments posted. To inform future developments staff were asked to complete a short survey during December, about NICE Space. Over 200 staff have responded and the results are currently being analysed.

39. In recognition of the contributions made to NICE Space, by teams across NICE we ran a content contributor award. The resource impact assessment team won the award as they demonstrated how they have embraced the functionality provided by NICE Space, keeping their pages up to date and informative through a variety of media.
40. The internal communications team has been asked by our intranet software provider Sorce, to present NICE Space at the national conference, as an example of best practice. We were selected from a wide range of high profile private and public sector organisations.

41. During this reporting period we engaged staff on a range of topics which included the new smoke free policy, launch of the new room booking system, and the Evidence Information Services consultation.

42. We also published a number of blogs including the popular David’s diary from David Haslam, and non-executives Maggie Helliwell and Jonathan Tross.

**Objective 5**

**Resource management**: Identify and implement efficiencies and savings while ensuring communications support and advice to the organisation.

43. During the reporting period we continued to look at ways to find savings and efficiencies within the directorate. Following our recent restructure which identified significant overall savings, we are recruiting to a number of newly created posts. The changes will support our strategic approach to communicating with our key stakeholders through relevant channels, including social and multi-media.
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

EVIDENCE RESOURCES DIRECTORATE PROGRESS REPORT

The Evidence Resources directorate comprises two teams which provide a range of functions to NICE:

- The Digital Services team (formally referred to as Information Management and Technology (IM&T)) delivers NICE’s digital transformation programme and maintains all 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 commissions key items of content made available to the NHS via the NICE Evidence Services.

The directorate manages the NICE Evidence Services, a suite of evidence services including a search portal (Evidence Search), the Clinical Knowledge Summary service (CKS), access to journals and bibliographic databases via a federated search (HDAS), and a range of evidence awareness products (including newsletters and bulletins).

The Board is asked to review the progress report.

Alexia Tonnel
Director, Evidence Resources
January 2016
Progress update against business plan objectives for 2015/16

1. The Evidence Resources business plan objectives for 2015/16 serve the four strategic objective categories of the Institute: product quality, system partnerships, adoption and impact and resource management. These objectives, and progress with delivery as of the end of December 2015, are presented in this section of the report.

**Product quality**

2. In 2015/16, the directorate has retained the objective to ‘deliver and continue to improve the suite of digital evidence services and evidence awareness products that constitute the NICE Evidence Services’. Progress to date has been as follows:

- The Eyes on Evidence e-bulletin and the Public Health Awareness Bulletin have been produced on a monthly basis as planned and the Medicines Awareness Daily and Weekly bulletins were published on schedule as well.
- Following public consultation on the updated process and methods manual for the Evidence Search service, 73 comments from 5 external stakeholders were reviewed. The responses to feedback and changes made as a result of feedback were reviewed by SMT. The revised manual was published on the NICE website in November 2015.

3. Similarly, the objective to ‘develop Information Services (IS) capacity and support for programmes of work that have been brought in-house, or are new or expanding for 2015/16’ was carried over from the previous year. In 2015/16, the focus will be on developing capacity and support for public health guidelines. There is also a strong focus on providing expert user leadership to the Evidence Management project of the Transforming Guidance Development programme. Progress to date has been as follows:

- Guidance Information Services (gIS) is now supporting the in-house development of evidence reviews for public health guidelines and additional capacity to meet this requirement is now in place.
- Information support has been provided to the Centre for Clinical Practice for the newly expanded surveillance programme according to schedule.
- Information support is also being provided to CCP to pilot processes for live guidance development. This includes the provision of continuous searches.
- Work with the Health and Social Care Directorate is now in progress to agree a process for their surveillance programme. Four public health topics were piloted during the autumn and the pilots are being assessed.

4. The Information Resources team continues to co-sponsor and provide stakeholder input to the Evidence Management digital project. A primary objective of the directorate continues to be to ‘implement the key digital strategy and service
development projects planned for 2015/16’, supporting digital product and service delivery across the whole of NICE. Progress with the programme of work in the third quarter of 2015/16 has been as follows:

- The HDAS Performance and Stability project is progressing well. Users have provided feedback on a prototype. A live service will be tested with users in January 2016. Two-way communication about the project and the test versions is being managed via a dedicated online space called NICE Labs at http://labs.nice.org.uk/hdas-redevelopment.

- The BNF Extended Feed project will provide alternative ways for users to access BNF content using the enhanced digital feed to be provided by the BNF publishers. The project is in development and is expected to deliver a product that can be made available for user testing in January 2016.

- Digital projects supporting the broader Transforming Guidance Development programme of work are progressing well. A 12-month rolling plan is continuing to be iterated every 3 months that maps out the key work streams required to achieve the vision for future Guidance Development. Projects in progress include the Evidence Management and Knowledge Base projects.
  - The Evidence Management project is currently considering the options for sourcing a product to meet NICE’s current and future needs. The favoured option is through the development of a strategic partnership and discussions about this are nearing conclusion with the agreement of software licensing arrangements. This project will bring together all the information underlying the evidence review process from across NICE and presents a significant opportunity for future efficiencies in surveillance based evidence reviews.
  - The Knowledge Base project is developing the first iteration of the strategic NICE ‘Knowledge Base’. This system will enable NICE to create guidance in a structured format, using common elements that can be described using metadata and presented in a flexible way. This first iteration is focussing on Quality Standards and their quality statements. The beta release of the quality statements discovery tool has been well received and can be found at http://ld.nice.org.uk/qs.

5. Alongside new projects, it is essential that ‘live services are maintained and continuously improved based on service performance against agreed key indicators’. This continues to be a core function of the digital strategy team in 2015/16. As of the end of December 2015, the following activity had taken place:

- In total, 43 continuous improvement change requests were completed in quarter 3 2015/16 and 139 maintenance / defect interventions were delivered across the 5 digital service areas.

- The ‘Insights Group’ for the NICE website is operating and taking data and user feedback about the performance of the website from a number of sources and
investigating issues identified and areas for performance improvement. Work has commenced on establishing capabilities to test changes with users using different approaches, this includes establishing the underlying skills and infrastructure required. A tool has been identified to enable the detailed analysis and feedback on user experience of NICE Digital Services.

- The re-procurement of hosting capability (data centres, infrastructure and servers) for NICE Digital Services is now expected to complete in January 2016. This will enable the migration of the services to a new platform, currently targeted for the end of the financial year.

6. A new objective for the Directorate was introduced for 2015/16, to ‘implement a consistent and streamlined mechanism for dealing with user feedback from web based channels and other user contacts with NICE regarding Digital Services’. The requirements for tools to support this objective have been considered by the Design Authority. A project will now be established under the Web Service Group that will further refine the business requirements and priorities and establish the type of solution required.

### System partnerships

7. In 2015/16 the team will continue to work on the objective to ‘put in place arrangements to collaborate with key stakeholder organisations on the provision of evidence services to their users’. Progress to date has been as follows:

- Links with the Health and Social Care Information Centre (HSCIC) continue to develop on several fronts including continued input into the NICE/HSCIC strategic partnership meetings and discussions with the NHS Choices’ team on semantic capabilities and the use of linked data technology. The HSCIC have been granted a test licence for the syndication service for NICE Guidance, Pathways and CKS.

- The NICE Digital Services team is attending regular showcases of the nhs.uk new platform for healthcare transactions and will be meeting with the development team to explain and support the re-use of NICE content in the development of nhs.uk.

- PHE has been granted a test licence to the syndication service for both NICE guidance and Evidence Search content for use in their Resource Discovery System. A meeting was held in late November between NICE Information Resources and PHE’s Knowledge Management teams to explore opportunities for joint working and information sharing. A number of actions were identified for NICE Information Resources to share information with PHE.

- A relationship with Government Digital Services information architects has been started around sharing of taxonomies and technologies. NICE has also been approached by a number of organisations to share its taxonomy assets. NICE is
exploring these opportunities including ways to open up its metadata repository and taxonomies, for discovery by interested parties.

- A strong relationship is being developed with Health Education England (HEE). Following the publication of ‘Knowledge for Healthcare; a Development Framework’ earlier in the year, HEE has set up a series of working groups to help define and deliver its framework’s objectives in the areas of resource discovery, workforce planning and development, quality and impact and service transformation. Where relevant NICE is working collaboratively with the working groups to help formulate the future strategy. A meeting was held in late November between NICE Evidence Resources, NICE Leadership and Engagement and HEE Director Alan Ryan- HEE Technology Enhanced Learning (TEL) Lead and e-LfH National Programme Director and his team to explore opportunities for joint working. As a result NICE will attend a clinical workshop in February 2016 and will coach HEE colleagues on how to get the most out of the NICE website, HEE has been granted a test syndication licence for NICE guidance, CKS and Evidence Search and the Memorandum of Understanding with HEE is being revised and updated.

- NICE and HEE are also working together on a project to redevelop HDAS (Healthcare Database Advanced Search). HDAS is a federated search service providing the NHS with access to the bibliographic databases that the NHS have paid for through a single search interface. Progress is reported in section 4 above.

8. Through 2015/16, NICE has continued to ‘support the implementation of the National Information Board (NIB) ‘Personalised Health and Care 2020 – A Framework for Action’ and specifically contribute to the development of a framework for the assessment of digital applications’. In October 2015, Workstream 1.2. of the NIB, that is co-chaired by NICE and PHE, updated its high level ‘roadmap’ proposals for the assessment of digital applications. The proposals are being further developed using an iterative pilot-based approach. The NIB programme has received substantial funding from the Comprehensive Spending Review. NICE is awaiting confirmation of the funding which the app workstream will receive and the governance arrangements which will be put in place by NHS England going forward.

Adoption and impact

9. The key objective of the directorate with regard to Adoption and Impact is to ‘formally launch and scale-up the NICE syndication service’. The resources for scaling up syndication activities are in place and recent achievements and developments include:

- Ongoing discussions taking place with an international commercial organisation to use only NICE content in their product(s) with the possibility of income generation outside of syndication;

- One of the NICE MTEP Evidence Evaluation Centres has been commissioned to review the market for clinical decision support systems and make contact with key
providers who may have an interest in accessing NICE’s syndication service with initial findings being reported early in January 2016;

- Test licences have been approved for HSCIC and HEE (e-Learning for Health) and a further application for a full licence was received from Public Health England;

- Discussions with NHS England are ongoing and include follow up activity with ‘GP Supplier of Choice Lot 1’ suppliers and about how NICE content could be used within the next iteration of NHS Choices;

- There is a firm indication that 3 applicants using the short-term ‘test’ licence for evaluation purposes will now apply for either a pilot or full licence indicating the success of this approach.

10. As of the end of December 2015, there had been 97 expressions of interest to access content via the NICE syndication service. Out of these expressions of interest, 14 syndication licences have now been issued and signed. These comprise 6 full licences (permitting use of NICE content in live products and systems), 2 pilot licences (allowing the applicant to test the market with a newly developed product) and 6 current test licences (allowing the applicant to test the feasibility of developing a product). The latter includes a reissued HSCIC licence not used previously. Licences have been issued to a further 9 organisations which are being followed up (signature pending).

Resource management

11. The objective to ‘operate within the approved 2015/16 IM&T budget’ will continue to be carefully managed through the year.

- Recruitment continues to be challenging for the most technical roles (developers) but the budget position is being closely monitored to align demand with budget capacity. A recruitment campaign is being planned for January 2016 covering all vacant roles across the Digital Services teams, this will be accompanied by ‘Working for NICE’ information on the website and other advertising and social media prompts.

- Savings will not be achieved on the NICE’s hosting contract until later in this financial year following the termination of the new hosting contract awarded in the spring and the need for re-procurement. The re-procurement of Hosting Services is expected to complete in January enabling migration to commence in the final quarter of FY15/16.

12. The Information Resources team will continue with the objective to ‘explore new methods and approaches, and where suitable deliver service improvement in the provision of information services across NICE’. In 2015/16, the focus will be placed on:

- Monitoring the delivery of savings from using the Royal Society of Medicine’s (RSM)
document delivery service;

- Participating in the Copyright Licensing Agency’s (CLA) ‘Content’ pilot and monitor the cost savings;

- Exploring the viability of creating full-text electronic repositories for NICE guidance, and the potential for cost saving.

13. Finally, in 2015/16, the Digital Services team will ‘explore new methods and approaches, and where suitable deliver improvement in the provision of NICE Digital Services’. Specific effort will be placed on:

- Reducing the end to end delivery time of small changes to NICE Digital Services ensuring shorter cycles of improvement and learning. Tools have been implemented across the Digital Services team to enable the tracking of cycle times for changes. This has enabled the team to improve the throughput of continuous improvement change and defect resolution;

- Translating data and observations about the performance of NICE Digital Services into actionable improvements in the usability of the Digital Services reducing user support needs. The Insights Group is a key enabler of this objective and is now operational and generating change to the presentation and content on the Website. The Insights Group has identified a number of areas for improvement including in the stakeholder registration process;

- Developing a greater depth of understanding of user needs and behaviours through the use of specific tools and techniques ensuring new skills are embedded within the Digital Services team. This objective is being delivered through the development and use of user research and user testing capabilities, particularly in the Discovery phase of projects and in new user testing techniques. A review of tools available to support the collection of data on user experience for both live services and services in development has recently been concluded and a product is on trial.

**Selected activity indicators – Two months 1\textsuperscript{st} July 2015 to 31\textsuperscript{st} August 2015**

**NICE Evidence Services: statistics**

14. In line with performance reporting across the board at NICE, this document now contains a simplified yet informative view of NICE Evidence Services statistics. Each digital service has been separated to allow the reader to focus on three key metrics:

- The first metric is ‘visits for the last full calendar month’. This is the metric which had been reported to the Board in the past.

- The second metric is ‘meaningful interactions’, which, as the name suggests, is a
percentage of visits that completed one or more meaningful interactions for that digital service. These ‘meaningful’ interactions are agreed by the Service Group and are the basis for any continual improvement to the digital service. For example, for Evidence Search, a meaningful interaction is a user clicking on a search result following a search or scrolling down the page to assess results.

- Lastly we indicate the ‘% of returns within 10 days’, which again is a percentage of visits and is a metric used by the Service Group to monitor engagement in the digital service.

These dashboards and similar dashboards including online versions provide a consistent framework or recording digital services performance.
NICE Apps: statistics

15. The reporting for NICE Apps follows the same new performance reporting model. Downloads are now omitted from this report.
**Information Services: activity levels**

16. The activities undertaken by guidance Information Services (gIS) to support teams across NICE are summarised in the graph below.
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE PROGRESS REPORT

The Health and Social Care directorate covers a range of work: public health and social care guidelines, quality standards, indicators, accreditation, the Public Involvement Programme (PIP), external engagement and support for the adoption of NICE guidance and standards.

Quality standards are developed for healthcare, public health and social care, alongside associated indicators to inform the Quality and Outcomes Framework (QOF) and the Clinical Commissioning Group Outcomes Indicator Set (CCG OIS).

This report provides the Board with an overview of the Health and Social Care directorate’s achievement against its main objectives for 2015/16. The report also highlights notable developments for the period April 2015 to December 2015 alongside key programme indicators.

The Board is asked to review the progress report.

Professor Gillian Leng
Director, Health and Social Care
January 2016
Progress against business plan objectives for 2015/16

1. The following sections, by programme, provide the Board with an overview of achievement of the business plan objectives from April 2015 to December 2015.

Public Health and Social Care guidance

2. The overall objective of this programme is to publish guidelines relevant to public health and social care. Overall progress to date against deliverables includes publishing:
   - Two social care guidelines: Older people with social care needs and multiple long-term conditions and Transition between inpatient hospital settings and community or care home settings for adults with social care needs.
   - Two review decisions for public health guidelines on preventing unintentional injuries in under 15s: strategies (PH29) and home (PH30).

Leadership & Engagement Programme

3. This programme is central to supporting NICE’s engagement with external organisations, and coordinating cross-Institute functions for the Health and Social Care directorate. Progress against deliverables during the second quarter of 2015/16 includes:
   - Hosting 19 student champion training events to date, above the predicted target of 15 events annually. This reflects ongoing enthusiasm in the system for these events.
   - Identifying 34 examples of Local Authority public health teams using NICE public health related quality standards in their contracts, April and November.
   - Identifying only 19 examples of Health and Wellbeing Boards using NICE guidance, advice and quality standards to improve population health during the same period. This target is harder to measure because NICE’s work may not be explicitly mentioned. NICE’s Field team are in the process of undertaking a desk based exercise to consider this further.
   - Visiting Clinical Commissioning Groups (CCGs), of which 63 are using at least 1 piece of NICE guidance or a quality standard to inform their quality improvement work in primary care.
• Tracking the use of quality standards within hospital trusts. 116 trusts have been identified as using quality standards to improve clinical services between April and November.

• Maintaining 99% of NICE guidance being available via NICE Pathways.

Public Involvement Programme
4. The overall objective of this programme is to support opportunities for public involvement across all of NICE’s work programmes, and to encourage lay stakeholder organisations to support implementation. Overall progress against deliverables includes:

• Receiving 338 applications for 64 vacancies across 41 guideline and standing committees. Of these:
  − 66 places were offered, slightly more than anticipated because of the exceptional quality of applications.
  − A further 27 lay people were invited to join the Quality Standards, Public Health, Diagnostics and Guidelines Update Committees as specialist members.
  − 82 people gave testimony to the Technology Appraisals and Highly Specialised Technologies Committees as patient experts.

• Developing web-based resources for future training packages. In addition, the following training events were provided:
  − 5 training sessions for guideline committee members.
  − 2 masterclasses for North West HealthWatches.
  − 1 ‘Introduction to NICE’ masterclass.
  − 2 training sessions for Guideline Committee Chairs (co-delivered with the Centre for Clinical Practice).

Quality Programme
5. The overall objective of this programme is to develop and publish quality standards and indicators, and manage the accreditation and quality assurance programmes. Overall progress against deliverables includes: publishing as planned:

• 21 quality standards. The following quality standards have been published since the last board report: Acute heart failure in adults; bladder cancer; gallstone disease; and intrapartum care. Publication of the antenatal and postnatal mental health quality standard was due in December, but has been
deferred until publication of a report from the Chief Medical Officer relating to the prescription of valproate to pregnant women.

- 10 final accreditation decision reports published. NICE has been accredited since the last report to the Board for Multiple Technology Appraisals, Interventional Procedures Guidance and for the Guidelines (the new Manual) processes.
- The following additional outputs: 13 endorsement decisions; 6 quality and productivity case studies; 5 Cochrane reviews that highlight ineffective interventions; and 38 shared learning examples.

Adoption and Impact

6. The objective of the programme is to support the adoption and use of NICE guidance and quality standards. This includes providing implementation support, costing tools and responsibility for tracking the uptake of NICE guidance. Overall progress against deliverables includes:

- Producing 11 adoption scoping reports for guidance teams to advise them of the likely barriers to adoption and completing 48 ‘first adoption engagements’. These engagements are the first point of contact (telephone or face to face) that the Adoption team has with health and social care organisations to understand how they have implemented a specific piece of medical technology or diagnostic equipment into their practice.

- Publishing 5 ‘Insights from the NHS’ adoption support resources for selected technology appraisals, medical technology and diagnostic guidance. These contain practical solutions and advice that enable NHS organisations to promote the sustainable uptake of NICE guidance. They describe the experiences of health and social care organisations that have already put a product or technology into routine practice.

- Continuing to develop NICE’s uptake resource. 1339 new data points have been identified in 2015. This resource is being used to support guidance and quality standard reviews.

- Continuing to work with the Office of Life Sciences and NHS England to support the development of the Innovation Score Card. NICE remains a key stakeholder in the work to expand its content and improve the presentation. This has included detailed analytical work estimating uptake of NICE appraised medicines.

- Developing a new quality standards service improvement template informed by feedback from clinical audit teams and clinicians. This was profiled at the NICE conference and will be published in January 2016. It allows people to
select individual statements from all quality standards to target their service improvement activities to their own area of practice.

Notable recent developments

Asthma guideline implementation feasibility project

7. The NICE guideline on asthma diagnosis and monitoring went out to consultation with stakeholders during the period 28th January – 11th March 2015. Following review of the comments, it was decided that a feasibility study would be carried out prior to publication. This study will address key areas raised by stakeholders relating to the use of objective tests in the different diagnosis algorithms, in particular the use of spirometry and fractional exhaled nitric oxide (FeNO) testing.

8. The aims and objectives of the study are to:
   - Assess the impact and feasibility of implementing, into primary care, the technical diagnostic tests (spirometry and FeNO) recommended in the asthma diagnostic guideline recommendations.
   - Provide stakeholder assurance that the recommendations are able to be implemented, and to show that NICE has proactively responded to stakeholder comments.
   - Gain ownership of the project outcomes from asthma experts and key stakeholders, via the proposed Steering Group, and to involve them in communicating these should feasibility be demonstrated.

9. A report on the findings from the field testing will be provided by the end of November 2016 for consideration in time for publication of the guideline in July 2017. This will coincide with publication of the asthma management guideline.

Mental health access and waiting time standards

10. NICE is being funded by NHS England to support their work on improvement of mental health services. The work is being carried out via the Collaborating Centre for mental health, and particularly includes the development of an indicator set and an accreditation scheme, as part of an overall standards package. The operational responsibility for the Mental Health access and waiting times standards programme of work will move from the Centre for Clinical Practice to the Health and Social Care Directorate in January, however the Quality team has been involved with the work over the past couple of months. CCP will continue to support the contractual arrangements with the Collaborating Centre until the end of March 2016. Recent activity has included agreement of the topic schedule for 2016/17, formalisation of the NICE governance
arrangements and agreement about how NICE and NHS England will work in partnership on this programme.

Supporting disinvestment

11. Since the last report to the Board, work has been done to improve presentation of the Savings and Productivity Collection on the NICE website, including amendments to the filters and removal of older content. The ‘Do not Do’ section is now fully up to date, and discussions are in hand to improve presentation of these recommendations. A user survey is collecting information about what people want from the Collection that will feed into further changes and refinements.

12. The forward planner is being updated to produce a guidance planner consistent with health and social care financial planning time frames. The new planner profiles resource impact over the next five financial years. It includes specific help on disinvestment by enabling users to look at cost saving guidance only, Quality and Productivity case studies and Cochrane case studies. The costs and savings from implementing guidance are identified separately and then added together to give the overall resource impact.

13. The medicines and prescribing programme and clinical fellows are working to identify expenditure on potentially inappropriate medicines prescribing in the NHS. The approach is to match primary and secondary care data on medicines expenditure and usage, to medicines identified in NICE ‘Do not Do’ recommendations and the STOPP/START (screening tool of older people’s prescriptions/screening tool to alert to right treatment) list. The use of the STOPP/START list, a validated tool, is recommended in NICE’s guideline on medicines optimisation. The result will show expenditure (actual or estimate) against potentially inappropriate medicine use that can be used to develop a comprehensive position on NICE guidance and inappropriate medicines expenditure.

Indicator development

14. The Indicator team has established a new approach to developing indicators for a topic across the whole care pathway, rather than developing separate indicators for primary and secondary care and public health. This approach was used for the first time at the December Indicator Advisory Committee meeting, when discussing potential indicators for diabetes and atrial fibrillation. This approach reflects the greater emphasis on integration of care and the need for joint management of care across sectors.

15. The Indicator team is also working with NHS England to confirm the future purpose of the Clinical Commissioning Group Outcome Indicator Set and how
NICE can support the development of appropriate indicators for it, along with contributing to the national CCG assessment framework.

**Involving primary care**

16. The internal primary care/general practice group is being refreshed. The new group will provide more focussed, strategic engagement and communications between NICE and the primary care community, and support NICE in producing outputs that address their needs. An engagement strategy is being developed to help govern future areas of work. In addition, a GP advisory group is being formed to consider the views of GPs, and the NICE response to those views. The advisory group will be chaired by Professor David Haslam and its membership will comprise key opinion leaders from the GP community.

**Public involvement review**

17. An internal review of NICE’s approach to engagement with patients and the public has been initiated. The aim of the review will be to ensure that the service we deliver is efficient and in line with best practice. The review will map the full picture of public involvement across NICE, identify priority areas of work and areas where the programme can divest its efforts. It will also consider possible ways of capacity building whilst ensuring that the public voice remains central to NICE’s decision making.

18. The findings of the literature review were presented at the Board Strategy meeting in December 2015. A short survey was launched in early January 2016 and a consultation meeting with stakeholders will be held on 26th January 2016. Proposals and considerations on the future shape of public involvement at NICE will be presented at the March public Board meeting.

**Shared decision making**

19. NICE has been commissioned by the Patients and Information directorate at NHS England to explore a mechanism for updating a suite of patient decision aids (http://sdm.rightcare.nhs.uk/pda), including the possibility of embedding this function within NICE linking to the routine surveillance process for guideline updates. NHS England has provided additional resources for a fixed-term internal NICE secondment to support this work until the end of March 2016. This post has now been filled and the work is underway.
Key programme indicators

20. The following charts provide a visual depiction of progress towards key objectives for each of the programmes. In some cases progress is expected to be linear, whereas in other cases it might be affected by variable factors.

Public Health and Social Care Centre

**SC and PH Guidelines**

Leadership and Engagement Programme

**Examples of Trusts using QS to improve clinical service**

*Data not available for December*
**LA and NHS visits**

*Data not available for December*

**Examples of Local Authorities using NICE outputs**

*Data not available for December*
Public Involvement Programme

Lay member recruitment summary - April-December 2015

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Quality Programme

Quality Standards
Accreditation reports

Adoption and Impact

Adoption

Conduct a minimum of 30 first adoption engagements with Health and Social Care organisations.

Provide a minimum of 12 adoption scoping reports to DAP, MTEP and TA scoping meetings.

Complete a minimum of 6 adoption support products to support the uptake of new technologies.

Annual Target | Actual to date