AGENDA

16/019 **Apologies for Absence**  
To receive apologies for absence  
(Oral)

16/020 **Declarations of Interests**  
To record any conflicts of interest  
(Oral)

16/021 **Minutes of the Board Meeting**  
To approve the minutes of the meeting held on 20 January 2016  
(Item 1)

16/022 **Matters Arising**  
To consider matters arising from the minutes of the last Meeting  
(Oral)

16/023 **Chief Executive’s Report**  
To receive the Chief Executive’s report  
*Andrew Dillon, Chief Executive*  
(Item 2)

16/024 **Finance and Workforce Report**  
To receive a report on NICE’s financial position to the end of January 2016 and an update on the workforce strategy  
*Ben Bennett, Director, Business Planning and Resources*  
(Item 3)

16/025 **Business Plan 2016-17**  
To approve the business plan  
*Andrew Dillon, Chief Executive*  
(Item 4)

16/026 **Cancer Drugs Fund**  
To consider the response to the public consultation  
*Professor Carole Longson, Director, Centre for Health Technology Evaluation*  
(Item 5)

16/027 **Cancer Drugs Fund: Update on Transition Arrangements**  
To consider the transition arrangements  
*Professor Carole Longson, Director, Centre for Health Technology Evaluation*  
(Item 6)
16/029 Triennial Review Recommendation: Governance of NICE’s Independent Advisory Committees
To consider the response to the issues raised in the Triennial Review
Andrew Dillon, Chief Executive

16/030 Engagement Success Criteria
To consider the criteria
Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate

16/031 NICE and Public Health England: Partnership Agreement
To note the partnership agreement
Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate

16/032 Revisions to the NICE Standing Orders, Standing Financial Instructions and Reservation of Powers to the Board and Scheme of Delegation
To agree the amendments to the governance documents
Ben Bennett, Director, Business Planning and Resources

16/033 Director’s Report for Consideration
Centre for Health Technology Evaluation
Professor Carole Longson, Director, Centre for Health Technology Evaluation

16/034 Directors’ Reports for Information
Centre for Clinical Practice

16/035 Communications Directorate

16/036 Evidence Resources Directorate

16/037 Health & Social Care Directorate

16/038 Committee minutes
To receive the unconfirmed minutes of the Audit and Risk Committee held on 27 January 2016

16/039 Any Other Business
To consider any other business of an urgent nature (Oral)
**Date of the Next Meeting**
To note the next Public Board meeting will be held on
Wednesday 18 May 2016 in the Deafblind UK Conference Centre, The National Centre for Deafblindness, Cygnet Road, Hampton, Peterborough, PE7 8FD
National Institute for Health and Care Excellence

Public Board Meeting held on the 20 January 2016 at City Hall, Malthouse Lane, Salisbury, Wiltshire SP2 7TU

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 Rosie Benneyworth 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
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

16/001 APOLOGIES FOR ABSENCE

1. Apologies were received from Linda Seymour and Professor Carole Longson, with the latter represented by Mirella Marlow.
16/002 CONFLICTS OF INTEREST

2. David Hunter stated that he is a specialist advisor to the House of Commons Health Select Committee’s public health inquiry. David Haslam confirmed that this did not represent a conflict of interest given the items before the meeting.

16/003 MINUTES OF THE LAST MEETING

3. The minutes of the meeting held on 18 November 2015 were agreed as a correct record.

16/004 MATTERS ARISING

4. The Board reviewed the actions arising from the Board meeting held on 18 November 2015. It was noted that:
   - Information on the ‘RepTrak’ pilot was included in the Communications Directorate Report and further updates will be provided in future reports.
   - The balanced scorecard has been updated to reflect the revised evidence update process.
   - A further workforce briefing is scheduled for the April Audit and Risk Committee meeting.
   - NICE’s response to the Accelerated Access Review is presented as a subsequent agenda item and the Board will be updated on the emerging proposals in the spring.
   - The link to the revised presentation of the quality standards on the NICE website will be circulated to Board members shortly.

ACTION: Gillian Leng

16/005 CHIEF EXECUTIVE’S REPORT

5. Andrew Dillon presented his report, describing the main programme activities to the end of December 2015 together with a summary of NICE’s financial position for the same period.

6. Finbarr Martin noted and welcomed that almost 1000 volunteers, including health and social care professionals, have joined the insights community database. He asked whether the database could be a source of feedback on the adoption and uptake of NICE guidance. Jane Gizbert stated that the initial focus has been to seek feedback on changes to NICE’s website, however there could be scope to consider whether the database could be utilised more broadly.

7. Following a question from David Hunter, Gillian Leng confirmed that NICE is establishing links with NHS Improvement (NHSI), building on existing relationships with the staff in the bodies transferring into NHSI.
8. Following a question from Bill Mumford, the Board discussed NICE’s relationship with the Care Quality Commission (CQC) and the current work to map NICE quality standards to the CQC’s inspection framework. Gillian Leng stated that she would clarify whether the mapping will be made available to providers and how the uptake of NICE guidance will feed into the CQC assessment process.

**ACTION:** Gillian Leng

9. The Board received the report.

10. A member of the audience from the pharmaceutical industry asked about the current work to explore the scope to charge industry for health technology appraisals and medical devices and diagnostics evaluations. Andrew Dillon stated that the possibility of charging formed a recommendation in NICE’s 2015 Triennial Review. Initial discussions have been held with the Association of the British Pharmaceutical Industry and detailed proposals will be developed over the coming six months.

**16/006 FINANCE AND WORKFORCE REPORT**

11. Ben Bennett presented the report which outlined the draft financial position as at 31 December 2015 and provided an update on the workforce strategy. He stated that the financial position is consistent with that previously reported to the Board and the forecast underspend, £3.2m, provides a sound base to respond to the significant reductions in NICE’s Grant in Aid income in 2016-17. He highlighted the activities underway as part of ‘Healthy Work Week’.

12. Jonathan Tross, chair of the Audit and Risk Committee, noted that recruitment is underway for 30 of the 54 currently vacant posts. He asked for assurance that this takes account of the impact of the forthcoming reductions in headcount following the reductions in NICE’s income. Ben Bennett stated that this is a challenging issue in that additional staff are required for new activities, prior to the likely reductions in other areas of activity. This is being closely managed and he is chairing a group that is planning the implementation of the required savings.

13. The Board received the report and thanked those involved in organising the Healthy Work Week.

**16/007 ANNUAL UPTAKE REPORT**

14. Gillian Leng presented the annual report which provided an overview of the information NICE has about how its guidance and quality standards are being used. She stated that in future, this information, which is taken from the uptake database, will be combined with other sources of feedback such as from the Field Team, and be presented to the Board as twice yearly progress reports.
These will then provide a coherent and overarching picture of the work being undertaken across health and social care to put NICE guidance into practice.

15. Rosie Benneyworth suggested that it would be helpful to include information on outcomes alongside uptake. Also, greater information on cross-system impact would reflect the current drive to integrate care.

16. Finbarr Martin and Andy McKeon suggested exploring whether the National Clinical Audit and Patient Outcomes Programme (NCAPOP) and the Care Quality Commission (CQC) could provide information on the uptake of NICE guidance.

17. David Hunter noted the low level of uptake data available for public health guidance. Gillian Leng stated that NICE has been engaging with the Local Government Association on this matter; however the localised nature of local government affects the ability to collate national data. NICE will continue to engage with Public Health England to encourage further audits of guidance.

18. The Board approved the report. Board members highlighted the need to note that the report is based on information in the uptake database and that other sources of information are available on the uptake of NICE guidance. The Board therefore welcomed the proposal to combine the report with other sources of feedback for future six monthly reports.

16/008 ACCELERATED ACCESS REVIEW: NICE RESPONSE TO THE INTERIM REPORT

19. Andrew Dillon presented the submission to the Accelerated Access Review (AAR) in response to the review's interim report that was discussed at the last Board meeting. He confirmed that NICE continues to be closely involved in the review and has been asked to make a further submission to inform the development of the review's final report.

20. Andrew Dillon highlighted that the central thrust of the review is to speed up the process for innovative health technologies being available to patients. He noted that this may entail additional activities for NICE, and if so, NICE will need to discuss the implications of this with the Department of Health given the reductions in NICE’s overall funding.

21. The Board noted the submission.

16/009 RESOURCE IMPACT IN GUIDELINES

22. Mark Baker and Gillian Leng presented the proposed advice and principles on resource impact in guidelines, and the accompanying proposed amendments to the guidelines manual. Mark Baker stated that cost impact is currently part of the guideline process and is undertaken after recommendations have been formulated. Given the need to be sensitive to the environment in which
recommendations will be implemented, it is proposed to undertake this cost impact analysis at an earlier stage in the guideline development process. Under the proposals, the resource impact team will undertake an analysis of the recommendations prior to, rather than post, consultation.

23. Mark Baker stated that the proposals do not seek to prevent recommendations that increase costs. Rather, they confirm that such cost must be justified. Where recommendations have a high cost impact then there must be a higher degree of assurance on evidence. Also, it is proposed that when draft scopes are issued for consultation, NICE will ask stakeholders to suggest interventions or forms of practice that could result in cost savings.

24. Mark Baker stated that these amendments may increase the legitimacy of NICE’s guidance and increase the uptake of recommendations. He stated that some existing recommendations may be stood down when the guidelines are subject to future review under the amendments proposed to the manual.

25. The Board discussed the proposals at length. Gillian Leng confirmed that there is sufficient capacity within the Resource Impact team to deliver the proposals. She also highlighted the importance of recognising the legitimacy of current guideline recommendations which had been developed in accordance with a robust process and subject to consultation. The amendments should not be seen as undermining these recommendations or discourage their implementation.

26. In particular, the Board discussed the proposed amendments to section 7.2 of the guidelines manual. It was noted that the final sentence of the proposed amendment – ‘...the potential cost impact of the recommendations should not alone determine the Committee’s decision’ reflects NICE’s role in reviewing evidence rather than solely considering cost. However there were concerns that this sentence could undermine the preceding amendments. Board members also queried whether the preceding proposed amendments implied that the evidence must be robust only when there is a substantial cost increase overall. The Board agreed that the wording should be revised to make clear that the Committee must be increasingly certain of the cost effectiveness of a recommendation as the cost of implementation increases.

27. The Board delegated to Andrew Dillon the authority to revise the relevant section of chapter 7 of the guideline manual in line with the Board’s discussion.

ACTION: Andrew Dillon

28. The Board agreed that given the amendments to the guidelines manual clarify, rather than substantively amend the existing manual, consultation was not required. Therefore, once the wording had been amended by Andrew Dillon, the Board agreed that:

- The advice and principles on resource impact in guidelines should be distributed to Committees, Developers and Quality Assurance teams.
• The revised guideline manual and principles should be adopted for draft guidelines issued for consultation from April 2016.

**ACTION:** Mark Baker / Gillian Leng

### 16/010 BOARD EFFECTIVENESS REVIEW

29. Andrew Dillon presented the proposed terms of reference for the Board effectiveness review that will seek to address a recommendation within the Triennial Review of NICE. He outlined the proposal to undertake the review as an extension of the internal audit plan.

30. The Board approved the terms of reference for the review to be undertaken by NICE’s internal auditors. The Board agreed that the findings should be presented to the April Board Strategy meeting.

### 16/011 BOARD APPOINTMENTS

31. The Board received the paper from David Haslam and:

- Noted the appointment of Dr Rosie Benneyworth as a Non-Executive Director of NICE and Dr Benneyworth’s declared interests.

- Agreed to appoint Tim Irish to the Remuneration Committee following Dr Maggie Helliwell’s retirement from the Board.

### 16/012 RAPID RECONSIDERATION OF DRUGS CURRENTLY FUNDED THROUGH THE CANCER DRUGS FUND

32. Andrew Dillon presented the paper that outlined the proposed process for the re-consideration of drug-indication pairs that are currently funded through the Cancer Drugs Fund (CDF), and for which NICE has published guidance. He highlighted that these appraisals can be undertaken relatively quickly given that only in exceptional cases will new clinical evidence be considered.

33. Andrew Dillon also asked for the Board’s approval to amend the Terms of Reference and Standing Orders of the Technology Appraisal (TA) Committees to refer to five TA committees, to accommodate the establishment of an additional committee which will reconsider these drugs.

34. The Board:

- Supported the proposed process to reconsider drug-indication pairs currently funded by the CDF and for which NICE has published guidance.

- Approved the constitution of a separate Appraisal Committee, by amending the existing terms of reference and standing orders, and with membership drawn from the existing Appraisal Committees.
35. A member of the audience from the pharmaceutical industry asked about the arrangements for the drugs currently funded through the CDF, which have not been subject to a NICE appraisal. Andrew Dillon confirmed that it is his understanding that these drugs will be subject to a full NICE appraisal, and continue to be funded by the CDF until such appraisal is completed.

16/013 DIRECTOR’S REPORT FOR CONSIDERATION

36. Mark Baker presented the update from the Centre for Clinical Practice (CCP). He drew the Board’s attention to key items of note in the report, including the field work to test the feasibility of implementing aspects of the asthma diagnosis and monitoring guideline; the recruitment of a reference panel and database of topic experts for CCP activities; and the changes to the Clinical Guideline Updates Standing Committees, which enhance the ability to update guidelines in a cost effective and timely manner.

37. Mark highlighted the dissonance between NICE’s guidance on foetal monitoring contained within the Intrapartum Care (low risk) guideline and the recent guidance from the International Federation of Gynaecology and Obstetrics (FIGO). He stated that given the professions are split in terms of which to follow, NICE is expediting a review and update of its guidance during the development of the sister guideline on Intrapartum Care (high risk). Rona McCandlish noted stakeholders’ positive feedback to this decision and asked this is fed back to the staff involved.

38. The Board received the report.

16/014-16/017 DIRECTORS’ REPORTS FOR INFORMATION

39. Andy McKeon referred to the Evidence Resources Directorate Progress Report and asked for further information on the re-procurement of the digital services hosting capability. Alexia Tonnel and Ben Bennett outlined the background to the procurement and noted the learning points.

40. The Board received the Directors’ Reports.

16/018 ANY OTHER BUSINESS

41. None.

NEXT MEETING

42. The next public meeting of the Board will be held at 1.45pm, 16 March 2016 at Morriston Hospital, Swansea, SA6 6NL.
This report provides information on the outputs from our main programmes for the 11 months to the end of February 2016, together with a summary of the financial position for the 10 months to the end of January 2016 and comment on other matters of interest to the Board.

The Board is asked to note the report.

Andrew Dillon
Chief Executive
March 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 29 February 2016 (31 January, in the case of the finance report). It also reports on guidance published since the last public Board meeting in January and refers to business issues not covered elsewhere on the Board agenda.

Performance

2. The 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 2015 and February 2016 is set out in Graphs 1 and 2, below.

Graph 1: Main programme outputs: April 2016 to February 2016

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 2015 to February 2016

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 10)

4. The financial position for the months from April to the end of January is an under spend of £3.8m (7.3%) against a budget of £52m (the position is unchanged from that reported for the end of December). £1.9m 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 £3.8m (6%). 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 2015 to January 2016 (£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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<tr>
<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 conventional and digital technologies.</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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<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 services.</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 (CQC), to align the approach to implementation of NICE guidance and recommendations in order to support</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 agreements. Work with NHS England relates primarily to the National Quality Board’s new strategy, and the use of indicators and metrics. NICE is actively engaging with the national group</td>
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<td>Priority</td>
<td>Business Plan</td>
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<td>DH</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.</td>
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<td>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 and took part in a recent Department of Health ‘deep dive’ to identify what further contribution we might be able to make. As a result, we are undertaking further work on identifying in appropriate prescribing amongst the elderly.</td>
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<td>DH</td>
<td>Support the more rapid introduction and diffusion of innovative and cost-effective medicines and technologies.</td>
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<td>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</td>
<td>Develop plans to better support the medical technologies sector in understanding the needs and priorities of the NHS.</td>
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<td>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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<td>Programme development</td>
<td>DH priority</td>
<td>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.</td>
<td>The May and October 2015 innovation scorecards were published as planned, and an updated set of data was 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.</td>
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<td>Programme development</td>
<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 model or change of sector.</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 considered further proposals for NICE International at its Strategy meeting in February and has established a working group, which make recommendations on</td>
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<td>1</td>
<td>Triennial review, DH priority, business plan</td>
<td>Actively engage with the Accelerated Access Review.</td>
<td>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.</td>
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<td>DH priority, business plan</td>
<td>Develop proposals to improve awareness and uptake of the advisory services NICE offers to the life sciences industry.</td>
<td>A range of seminars and other activities have been delivered for the life sciences industry. Further awareness raising activities are ongoing through the Office for Market Access.</td>
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<td>3</td>
<td>DH priority, business plan</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>
<td>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 Comprehensive Spending Review. NICE and</td>
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<td>Business plan</td>
<td>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.</td>
<td>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.</td>
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<td>Business plan</td>
<td>Participate in the NHS England review of the management of the Cancer Drugs Fund.</td>
<td>The joint NHS England and NICE proposals for the future management of the CDF were the subject of public consultation and have been considered and approved by the NHSE Board. The NICE Board will consider its response to consultation at this (March) meeting. Meanwhile, we are engaging with companies who have products in the CDF to assess and make recommendations on their future funding, subject to the outcome on both Board’s consideration of the responses to consultation.</td>
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<td>Business plan</td>
<td>Redesign and future-proof the clinical guidelines programme.</td>
<td>The tendering process for external contractors to develop clinical guidelines from 1 April 2016 is complete. Plans are in place, within the</td>
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<td><strong>Methodology</strong></td>
<td>Triennial review</td>
<td>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 the work of NICE.</td>
<td>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 by March 2016.</td>
</tr>
<tr>
<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>
<td></td>
</tr>
<tr>
<td><strong>Partnership</strong></td>
<td>Triennial review</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</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. Discussions on issues such as the Early Access to Medicines scheme, the Accelerated Access Review, the Cancer Drugs Fund and joint</td>
</tr>
</tbody>
</table>

*National Institute for Health and Care Excellence*
*Chief Executive’s Report*
*Date: 16 March 2016*
*Ref: 16/023*
| Business plan | Explore with CQC how to ensure that NICE quality standards and guidelines complement and reinforce essential standards, building on existing work to map NICE Quality Standards into the CQC inspection work. | A programme of work, to map NICE quality standards to CQC’s inspection framework is well advanced and will continue with support from 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. |
| Business plan | Engage with NHS England in the implementation of their 5 Year Forward View. | NICE is now a member of the NHS Five Year Forward View Board, sharing responsibility with the other national agencies in the delivery of its objectives, including sponsorship of four of the new models of care vanguards. |
| Triennial review | 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. | 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. |
| Triennial review | Work to further enhance relationships with organisations across health and care, clarifying areas where roles and responsibilities could be made clearer to stakeholders. | 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 that each set of recommendations has a clear system owner or owners and a commitment from the system to manage the recommendations into practice.

<p>| 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. |
| 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. A project group, chaired by the Chief Executive and including DH membership has been established. |
| 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 | 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 |</p>
<table>
<thead>
<tr>
<th></th>
<th>working with other system players.</th>
<th>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 2016.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Governance</td>
<td>Triennial review</td>
<td>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.</td>
</tr>
<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 consider a discussion paper on this at this (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</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</td>
</tr>
<tr>
<td>organisation, benchmarking its systems, processes and outcomes against best players internationally, proactively thinking about succession planning and attracting and retaining talent.</td>
<td>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 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>
<tbody>
<tr>
<td>Health and social care</td>
<td>An Economic and Methodological Unit (EMU) has been commissioned to support the development of guidelines in public health and social care. After a tender process during which 3 bids were submitted, York Health Economics Consortium (YHEC) has subsequently been awarded the contract. YHEC has experience in developing economic models and reviews for NICE public health guidelines, and their core team will include the Centre for Health Economics (CHE) at the University of York, who will lead the methodological work. The contract is due to start in April.</td>
<td>Section/para 7</td>
</tr>
<tr>
<td>Clinical practice</td>
<td>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.</td>
<td>Section/para 10</td>
</tr>
<tr>
<td>Technology evaluation</td>
<td>Given the intense life science and healthcare system interest in diagnostics, the programme has significantly increased external engagement activities during 2015/16. This has resulted in an increased awareness of NICE’s diagnostics capability and expertise and has provided the opportunity for NICE to participate in key policy discussions and influence the development of national policy. Interactions have included regular formal dialogue with the Chief and Deputy Chief Scientific Officer for NHS England, resulting in a proposal to initiate a NHS England/NICE diagnostics liaison group, membership of the NHS England Personalised Medicine Strategy Board, membership of the NIHR Diagnostics Evidence Cooperatives methodology group, participation in the NHS England Specialised Services group that introduced changes to the funding mechanism for molecular genetic tests associated with a companion drug or chemotherapy treatment, dialogue with the Prime Minister Review on Antimicrobial</td>
<td>Section/para 10</td>
</tr>
</tbody>
</table>
Resistance and advice on the economic assessment of diagnostics to inform antimicrobials prescribing and identification of resistance, and routine engagement with diagnostics related professional bodies resulting in the identification of diagnostics assessment of topics of high clinical interest e.g. Molecular testing for Lynch syndrome in people with colorectal cancer.

### Evidence resources

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. Work is continuing to Quality Assure content, develop the user presentation and integrate the solution into the NICE Website. Further work is planned to develop the ability to highlight recent changes to Quality Standards.

### Communications

We are currently working on 2 guidelines for people with learning disabilities. These are in development, and we prepared specially written and designed slides for committee meetings to explain the role of the editors and what makes a good recommendation. We had very good feedback from the committee chair, the programme manager and the committee members who have learning disabilities. The editors will need to make sure all of the information we give throughout the whole process is understandable by the whole committee, including the members with learning disabilities. One of the editors is currently writing an easy read version of our information for the public to explain the forthcoming guideline on mental health problems in people with learning disabilities.

### Finance and workforce

The current forecast under spend for 2015/16 is £3.8m (6.1%). Of this, £1.8m 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.
## Appendix 3: Guidance development: variation against plan April 2015 – February 2016

<table>
<thead>
<tr>
<th>Programme</th>
<th>Delayed Topic</th>
<th>Reason for variation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Guidelines</strong></td>
<td>2 topics delayed</td>
<td>Asthma – Delayed following a request to discuss funding to roll out FeNO with NHS England and get support from RCGP and Asthma UK. Publication date to be confirmed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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 (May 2016).</td>
</tr>
<tr>
<td><strong>Interventional procedures</strong></td>
<td>3 topics delayed</td>
<td>Percutaneous endoscopic laser lumbar discectomy for sciatica - Delayed due to availability of lead committee member being unable to attend the committee meeting. Further delayed by committee decision to return the procedure to an earlier stage in the process to change the scope for inclusion. Due to publish Q2 2016/17 (August 2016).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Percutaneous transforaminal endoscopic lumbar discectomy for sciatica - Delayed due to the availability of a lead committee member being unable to attend the committee meeting. Due to publish Q1 2016/17 (April 2016).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Percutaneous interlaminar endoscopic lumbar discectomy for sciatica - Delayed due to the availability of a lead committee member being unable to attend the committee meeting. Due to publish Q1 2016/17 (April 2016).</td>
</tr>
<tr>
<td></td>
<td>1 topic planned for March 2016 (Q4 2015-16), published early</td>
<td>Angioplasty and/or stenting to treat peripheral arterial disease causing refractory erectile dysfunction - IP1138 was brought forward by one month.</td>
</tr>
<tr>
<td><strong>Medical technologies</strong></td>
<td>2 topics delayed</td>
<td>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 Q3 2016/17 (October 2016).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spectra Optia apheresis system for automated red blood cell exchange in patients with sickle cell disease – Programme timeline re-profiled in year. Due to publish in Q4 (March 2016).</td>
</tr>
<tr>
<td>Public Health</td>
<td>No variation against plan 2015-16</td>
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<td></td>
</tr>
<tr>
<td>Quality Standards</td>
<td>No variation against plan 2015-16</td>
<td></td>
</tr>
<tr>
<td>Diagnostics</td>
<td>1 topic planned for March 2016 (Q4 2015-16), published early</td>
<td></td>
</tr>
<tr>
<td>Technology Appraisals</td>
<td>7 topics delayed</td>
<td></td>
</tr>
</tbody>
</table>

**Sepsis:** The LightCycler SeptiFast Test MGRADE, SepsiTest and IRIDICA BAC BSI assay for rapidly identifying bloodstream bacteria and fungi – This topic published one month earlier than planned. Published February 2016.

**Technology Appraisals**

1. **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).
2. **Systemic lupus erythematosus (active seropositive) – belimumab** – delayed due to ongoing discussions between NICE and external parties. Due to publish in Q4 (March 2016).
3. **Prostate cancer (advanced hormone dependent) – degarelix depot** – the manufacturer has submitted additional evidence. The new evidence was considered by Committee on 4 November 2015. Publication date to be confirmed.
4. **Dupuytren’s contracture – collagenase clostridium histolyticum (1st line)** – an appeal was lodged against this topic. The hearing was held on 30 November 2015. Publication date to be confirmed.
5. **Lung cancer (non-small cell, anaplastic lymphoma kinase positive, metastatic) - ceritinib (post chemotherapy)** - The Final Appraisal Determination for this appraisal has been withdrawn and the appraisal suspended because an error has been identified in External Review Group’s exploratory scenarios that were fundamental to decision making. Publication date to be confirmed.
6. **Myelofibrosis (disease-related splenomegaly or symptoms in adults with myelofibrosis)** – ruxolitinib (review of TA289) - Following a request from the company to submit new evidence at ACD stage as part of their response and in order to allow ERG critique, the second Appraisal Committee Meeting was rescheduled. Due to publish in Q4 (March 2016).
7. **Primary hypercholesterolaemia (heterozygous, familial and non familial) and mixed dyslipidaemia – evolocumab** - Following the release of a second ACD the anticipated publication date is now June 2016 (Q1 2016-17).
### 8 additional topics published in 2015-16, that were not planned for this financial year

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cangrelor for reducing atherothrombotic events in people undergoing</td>
<td>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</td>
<td>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</td>
<td>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 final draft, the guidance was published post appeal in Q3 (October 2015).</td>
</tr>
<tr>
<td>Non-small-cell lung cancer (untreated) - paclitaxel albumin-bound</td>
<td>nanoparticles (with carboplatin) - Published in Q3 (October 2015) as a terminated appraisal.</td>
</tr>
<tr>
<td>Breast cancer (HER2 positive) - trastuzumab emtansine - Following the</td>
<td>appeal against the Final Appraisal Determination (FAD) for this appraisal, NICE developed a position statement on the relevance of the 'PPRS Payment Mechanism' of the 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).</td>
</tr>
<tr>
<td>Non-small-cell lung cancer (second line treatment) erlotinib (TA162)</td>
<td>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).</td>
</tr>
<tr>
<td>Eltrombopag for treating severe aplastic anaemia refractory to</td>
<td>immunosuppressive therapy – Published in Q4 (January 2016) as a terminated appraisal.</td>
</tr>
<tr>
<td>Melanoma (unresectable or metastatic) – nivolumab - This appraisal</td>
<td>went straight to FAD. Originally planned for May 2016 (Q1 2016-17). Published February 2016.</td>
</tr>
</tbody>
</table>

### Highly Specialised Technologies (HST)

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Ataluren</td>
<td>for treating Duchenne muscular dystrophy caused by a nonsense mutation in the dystrophin gene - Additional information submitted by the</td>
</tr>
<tr>
<td>Accreditation</td>
<td>No variation against plan 2015-16</td>
</tr>
</tbody>
</table>
## Appendix 4: Guidance published since the last Board meeting in January

<table>
<thead>
<tr>
<th>Programme</th>
<th>Topic</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Guidelines</strong></td>
<td><strong>Tuberculosis (update)</strong></td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td><strong>Motor neurone disease: assessment and management</strong></td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td><strong>Transition from children’s to adults’ services for young people using health or social care services</strong></td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td><strong>Fractures (non-complex): assessment and management</strong></td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td><strong>Fractures (complex): assessment and management</strong></td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td><strong>Major trauma: assessment and initial management</strong></td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td><strong>Major trauma: service delivery</strong></td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td><strong>Spinal injury: assessment and initial management</strong></td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td><strong>Myeloma: diagnosis and management</strong></td>
<td>General guidance</td>
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<tr>
<td></td>
<td><strong>Cancer of the upper aerodigestive tract: assessment and management in people aged 16 and over</strong></td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td><strong>Attention deficit hyperactivity disorder: diagnosis and management (update)</strong></td>
<td>General guidance</td>
</tr>
<tr>
<td><strong>Interventional procedures</strong></td>
<td><strong>Percutaneous coblation of the intervertebral disc for low back pain and sciatica</strong></td>
<td>Normal arrangements</td>
</tr>
<tr>
<td></td>
<td><strong>Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica</strong></td>
<td>Special arrangements</td>
</tr>
<tr>
<td></td>
<td><strong>Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain</strong></td>
<td>Special arrangements</td>
</tr>
<tr>
<td></td>
<td><strong>Angioplasty and stenting to treat peripheral arterial disease causing refractory erectile dysfunction</strong></td>
<td>Only in research</td>
</tr>
<tr>
<td></td>
<td><strong>Endovascular aneurysm sealing for abdominal aortic aneurysm</strong></td>
<td>Special arrangements</td>
</tr>
<tr>
<td></td>
<td><strong>Mechanical clot retrieval for treating acute ischaemic stroke</strong></td>
<td>Normal arrangements</td>
</tr>
<tr>
<td></td>
<td><strong>Normothermic extracorporeal preservation of hearts for transplantation following donation after brainstem death</strong></td>
<td>Normal arrangements</td>
</tr>
<tr>
<td><strong>Medical technologies</strong></td>
<td><strong>No publications</strong></td>
<td></td>
</tr>
<tr>
<td>Diagnostics</td>
<td>Therapeutic monitoring of TNF-alpha inhibitors in Crohn’s disease (LISA-TRACKER ELISA kits, IDKmonitor ELISA kits, and Promonitor ELISA kits)</td>
<td>Not recommended</td>
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<td>-------------------------------------------------</td>
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<tr>
<td></td>
<td>Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system)</td>
<td>Recommended</td>
</tr>
<tr>
<td></td>
<td>Tests for rapidly identifying bloodstream bacteria and fungi (LightCycler SeptiFast Test MGRADE, SepsiTest and IRIDICA BAC BSI assay)</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Public Health</td>
<td>Sunlight exposure: risks and benefits</td>
<td>Develop and support population level initiatives</td>
</tr>
<tr>
<td>Quality Standards</td>
<td>Gastro-oesophageal reflux in children and young people</td>
<td>Sentinal markers of good practice</td>
</tr>
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<td></td>
<td>Diabetes in pregnancy</td>
<td>Sentinal markers of good practice</td>
</tr>
<tr>
<td></td>
<td>Pneumonia in adults</td>
<td>Sentinal markers of good practice</td>
</tr>
<tr>
<td></td>
<td>Obesity in adults: prevention and lifestyle weight management programmes</td>
<td>Sentinal markers of good practice</td>
</tr>
<tr>
<td></td>
<td>Preventing unintentional injury in under 15s</td>
<td>Sentinal markers of good practice</td>
</tr>
<tr>
<td></td>
<td>Multiple sclerosis</td>
<td>Sentinal markers of good practice</td>
</tr>
<tr>
<td></td>
<td>Domestic violence and abuse</td>
<td>Sentinal markers of good practice</td>
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<tr>
<td></td>
<td>Antenatal and postnatal mental health</td>
<td>Sentinal markers of good practice</td>
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<tr>
<td></td>
<td>Healthcare-associated infections</td>
<td>Sentinal markers of good practice</td>
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<tr>
<td></td>
<td>Irritable bowel syndrome in adults</td>
<td>Sentinal markers of good practice</td>
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<tr>
<td></td>
<td>Chronic obstructive pulmonary disease in adults (update)</td>
<td>Sentinal markers of good practice</td>
</tr>
<tr>
<td>Technology Appraisals</td>
<td>Chronic heart failure in adults (update)</td>
<td>Sentinal markers of good practice</td>
</tr>
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</tr>
<tr>
<td><strong>Ramucirumab</strong> for treating advanced gastric cancer or gastro–oesophageal junction adenocarcinoma previously treated with chemotherapy</td>
<td></td>
<td>Not recommended</td>
</tr>
<tr>
<td><strong>Enzalutamide</strong> for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated</td>
<td></td>
<td>Recommended</td>
</tr>
<tr>
<td><strong>Radium-223 dichloride</strong> for treating hormone-relapsed prostate cancer with bone metastases</td>
<td></td>
<td>Recommended</td>
</tr>
<tr>
<td><strong>Nintedanib</strong> for treating idiopathic pulmonary fibrosis</td>
<td></td>
<td>Recommended</td>
</tr>
<tr>
<td><strong>Panobinostat</strong> for treating multiple myeloma after at least 2 previous treatments</td>
<td></td>
<td>Recommended</td>
</tr>
<tr>
<td><strong>Olaparib</strong> for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy</td>
<td></td>
<td>Recommended</td>
</tr>
<tr>
<td><strong>Eltrombopag</strong> for treating severe aplastic anaemia refractory to immunosuppressive therapy</td>
<td></td>
<td>Terminated guidance (no guidance issued)</td>
</tr>
<tr>
<td><strong>Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept</strong> for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed</td>
<td></td>
<td>Recommended</td>
</tr>
<tr>
<td><strong>Ezetimibe</strong> for treating primary heterozygous-familial and non-familial hypercholesterolaemia</td>
<td></td>
<td>Recommended</td>
</tr>
<tr>
<td><strong>Nivolumab</strong> for treating advanced (unresectable or metastatic) melanoma</td>
<td></td>
<td>Recommended</td>
</tr>
<tr>
<td><strong>TNF-alpha inhibitors</strong> for ankylosing spondylitis and non-radiographic axial spondyloarthritis</td>
<td></td>
<td>Recommended</td>
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</tbody>
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<thead>
<tr>
<th>Highly Specialised Technologies (HST)</th>
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<tbody>
<tr>
<td><strong>No publications</strong></td>
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<tr>
<th>Accreditation</th>
<th>SIGN</th>
<th>Accredited</th>
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<tr>
<th>Evidence summaries – new</th>
<th>Inflammatory lesions of papulopustular rosacea: ivermectin 10 mg/g cream</th>
<th>Summary of best available evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>medicines</td>
<td>Evidence summaries – unlicensed/off label medicines</td>
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<tr>
<td></td>
<td>Hormone-sensitive metastatic prostate cancer: docetaxel</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td>Medtech Innovation Briefings (MIB)</td>
<td>EarlySense for heart and respiratory monitoring and predicting patient deterioration</td>
<td>Summary of best available evidence</td>
</tr>
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<td>CORTRAK 2 Enteral Access System for placing enteral feeding tubes</td>
<td>Summary of best available evidence</td>
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<td>BladderScan BVI 9400 3D portable ultrasound scanner for measuring bladder volume</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>Xpert Carba-R to identify people carrying carbapenemase producing organisms</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>MiniMed 640G system with SmartGuard for managing blood glucose levels in people with type 1 diabetes</td>
<td>Summary of best available evidence</td>
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<td>Varicose veins in the legs</td>
<td>Surveillance review decision</td>
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<td>The assessment and prevention of falls in older people (update)</td>
<td>Surveillance review decision</td>
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<td>Improving outcomes in colorectal cancer</td>
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<td>Quality and Productivity case studies</td>
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<td>Cochrane case studies</td>
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</table>
This report gives details of the financial and workforce position as at 31 January 2016 and the forecast outturn for 2015-16.

The Board is asked to review the report.

Ben Bennett
Director, Business Planning and Resources
March 2016
Summary

1. Table 1 summarises the financial position as at 31 January 2016. 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>
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<tr>
<td>Guidance &amp; Advice</td>
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<td>45.4</td>
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<td>Corporate</td>
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<td>NICE International</td>
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<td>Scientific Advice</td>
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<td>NICE Total</td>
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</table>

Table 1: Financial Position at 31 Jan 2016

2. The current position shows an under spend of £3.8m (7.3%) for the first ten months of 2015/16. Of this, £1.9m is attributable to vacant posts and £1.9m relates to under spends on non-pay budget and additional income.

3. During February 2016 there were 44 (40.7wte) vacant posts from a budgeted establishment of 651wte, which equates to 6.7% of the total budgeted workforce. These are posts that are not currently covered by agency staff or bank / fixed term employees.

4. The full year forecast outturn is a £3.8m (6.1%) under spend against the revenue resource limit. The reasons for material variances are detailed in this report.

5. A summary of progress against the workforce strategy is included as Appendix B.
6. Appendix A shows that the net operational expenditure for the first ten months of 2015/16 was £48.5m. This was a £3.8m (7.3%) under spend against budget. This is partly attributable to vacant posts (50% 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 under spend generated by stopping 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 ten months of 2015/16 was £27.3m, which was £1.9m (6.7%) 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 29 February 2016 there were 599 whole time equivalent (wte) substantive employees on payroll (headcount of 653). There were 44 vacant posts (40.7wte) as at this date, of which 20 (45%) are currently going through the recruitment process. The annualised budget value of these vacant posts is £1.65m, equivalent to a £137,000 under spend each month.

Non-Pay expenditure

10. Total non-pay expenditure in the first ten months of 2015/16 was £28.4m, which was an under spend of £0.4m (1.3%) against budget.

11. 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 73% relating to non-staff budgets and 27% staff budgets). We have also received a multi-year rebate for Manchester business rates (£0.2m under spent) which contributes to the under spend.

12. There is an under spend of £0.4m 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

13. Other operating income is showing £1.5m of additional income for the first ten months of the year mainly due to funding we have received from NHS England (£1.3m) 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).

14. 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.

15. Scientific Advice is currently forecasting to generate a surplus of £73,000 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.

Forecast outturn

16. The current forecast under spend for 2015/16 is £3.8m (6.1%). Of this, £1.8m 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.

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

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

19. The forecast assumes that £0.5m of reserves will be utilised in order to meet liabilities arising relating to uncertainties around ongoing consultations. This is the best current estimate and may change in value. The maximum liability is estimated at £0.65m.

20. 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

21. 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 January 2016

<table>
<thead>
<tr>
<th>Centre / Directorate</th>
<th>Year to Date</th>
<th>Estimated Outturn</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>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Centre for Clinical Practice</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>4,589</td>
<td>4,541</td>
<td>(49)</td>
<td>(1.1%)</td>
</tr>
<tr>
<td>Non pay</td>
<td>10,843</td>
<td>12,089</td>
<td>1,245</td>
<td>11.5%</td>
</tr>
<tr>
<td>Income</td>
<td>(548)</td>
<td>(1,837)</td>
<td>(1,289)</td>
<td>(235.3%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>14,885</td>
<td>14,792</td>
<td>(93)</td>
<td>(0.6%)</td>
</tr>
<tr>
<td><strong>Centre for Health Technology Evaluation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>5,249</td>
<td>5,141</td>
<td>(108)</td>
<td>(2.1%)</td>
</tr>
<tr>
<td>Non pay</td>
<td>4,132</td>
<td>4,030</td>
<td>(102)</td>
<td>(2.5%)</td>
</tr>
<tr>
<td>Income</td>
<td>(275)</td>
<td>(274)</td>
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<td>0.3%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>9,106</td>
<td>8,896</td>
<td>(209)</td>
<td>(2.3%)</td>
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<tr>
<td><strong>Health and Social Care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>7,677</td>
<td>7,135</td>
<td>(542)</td>
<td>(7.1%)</td>
</tr>
<tr>
<td>Non pay</td>
<td>3,290</td>
<td>2,739</td>
<td>(550)</td>
<td>(16.7%)</td>
</tr>
<tr>
<td>Income</td>
<td>(48)</td>
<td>(93)</td>
<td>(45)</td>
<td>(92.7%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>10,919</td>
<td>9,782</td>
<td>(1,137)</td>
<td>(10.4%)</td>
</tr>
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<td><strong>Evidence Resources</strong></td>
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<tr>
<td>Pay</td>
<td>5,565</td>
<td>5,342</td>
<td>(223)</td>
<td>(4.0%)</td>
</tr>
<tr>
<td>Non pay</td>
<td>4,558</td>
<td>4,352</td>
<td>(206)</td>
<td>(4.5%)</td>
</tr>
<tr>
<td>Income</td>
<td>(25)</td>
<td>(35)</td>
<td>(10)</td>
<td>(41.9%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>10,098</td>
<td>9,658</td>
<td>(440)</td>
<td>(4.4%)</td>
</tr>
<tr>
<td><strong>Subtotal Guidance and Advice</strong></td>
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</tr>
<tr>
<td>Pay</td>
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<tr>
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<td>3,128</td>
<td>3,010</td>
<td>(118)</td>
<td>(3.8%)</td>
</tr>
<tr>
<td>Income</td>
<td>391</td>
<td>331</td>
<td>(60)</td>
<td>15.4%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>3,519</td>
<td>3,341</td>
<td>(178)</td>
<td>(5.1%)</td>
</tr>
<tr>
<td><strong>Communications</strong></td>
<td></td>
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<tr>
<td>Pay</td>
<td>2,022</td>
<td>2,110</td>
<td>93</td>
<td>4.4%</td>
</tr>
<tr>
<td>Non pay</td>
<td>4,744</td>
<td>4,534</td>
<td>(201)</td>
<td>(4.4%)</td>
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<tr>
<td>Income</td>
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<td>(7)</td>
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</tr>
<tr>
<td><strong>Total</strong></td>
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<td>6,637</td>
<td>(129)</td>
<td>(1.9%)</td>
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<tr>
<td><strong>Business Planning and Resources</strong></td>
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<tr>
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<th>Centre / Directorate</th>
<th>Year to Date</th>
<th>Estimated Outturn</th>
<th>Variance</th>
<th>Variance</th>
</tr>
</thead>
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<td></td>
<td>Budget £000s</td>
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<tr>
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<td>43,128</td>
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<td>4,534</td>
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<td>(4.4%)</td>
</tr>
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<td>Income</td>
<td>0</td>
<td>(7)</td>
<td>(7)</td>
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</tr>
<tr>
<td><strong>Total</strong></td>
<td>6,766</td>
<td>6,637</td>
<td>(129)</td>
<td>(1.9%)</td>
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</tbody>
</table>
### Appendix A (Continued)

<table>
<thead>
<tr>
<th>Centre / Directorate</th>
<th>Income / Overheads</th>
<th>Depreciation / Capital Adjustments</th>
<th>Reserves</th>
<th>NICE Operational Total</th>
<th>NICE International</th>
<th>Scientific Advice</th>
<th>NICE Grand Total</th>
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<td></td>
<td>Budget £000s</td>
<td>Year to Date</td>
<td>Expenditure £000s</td>
<td>Variance £000s</td>
<td>Variance %</td>
<td>Budget £000s</td>
<td>Expenditure £000s</td>
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<tr>
<td>Overheads</td>
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<td>(383)</td>
<td>(95)</td>
<td>(32.8%)</td>
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<td>(450)</td>
</tr>
<tr>
<td>Income</td>
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<td>(5,008)</td>
<td>(137)</td>
<td>(2.8%)</td>
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<td>(6,426)</td>
<td>(6,600)</td>
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<td>Total</td>
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<td>(5,391)</td>
<td>(232)</td>
<td>(4.5%)</td>
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<td>(7,050)</td>
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<tr>
<td>Non pay</td>
<td>833</td>
<td>746</td>
<td>(88)</td>
<td>(10.5%)</td>
<td></td>
<td>1,000</td>
<td>895</td>
</tr>
<tr>
<td>Total</td>
<td>833</td>
<td>746</td>
<td>(88)</td>
<td>(10.5%)</td>
<td></td>
<td>1,000</td>
<td>895</td>
</tr>
<tr>
<td>Pay</td>
<td>994</td>
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<td>33,302</td>
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<tr>
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<td>28,437</td>
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<td>(7,511)</td>
<td>(9,572)</td>
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<tr>
<td>Total</td>
<td>52,263</td>
<td>48,461</td>
<td>(3,802)</td>
<td>(7.3%)</td>
<td></td>
<td>62,935</td>
<td>59,145</td>
</tr>
<tr>
<td>Pay</td>
<td>561</td>
<td>579</td>
<td>18</td>
<td>3.2%</td>
<td></td>
<td>673</td>
<td>678</td>
</tr>
<tr>
<td>Non pay</td>
<td>1,597</td>
<td>963</td>
<td>(634)</td>
<td>(39.7%)</td>
<td></td>
<td>1,916</td>
<td>2,193</td>
</tr>
<tr>
<td>Income</td>
<td>(2,116)</td>
<td>(1,451)</td>
<td>665</td>
<td>31.4%</td>
<td></td>
<td>(2,540)</td>
<td>(2,794)</td>
</tr>
<tr>
<td>Total</td>
<td>42</td>
<td>91</td>
<td>49</td>
<td>n/a</td>
<td></td>
<td>50</td>
<td>77</td>
</tr>
<tr>
<td>Pay</td>
<td>536</td>
<td>553</td>
<td>17</td>
<td>3.2%</td>
<td></td>
<td>643</td>
<td>691</td>
</tr>
<tr>
<td>Non pay</td>
<td>222</td>
<td>277</td>
<td>55</td>
<td>24.8%</td>
<td></td>
<td>266</td>
<td>367</td>
</tr>
<tr>
<td>Income</td>
<td>(757)</td>
<td>(868)</td>
<td>(111)</td>
<td>(14.7%)</td>
<td></td>
<td>(909)</td>
<td>(1,131)</td>
</tr>
<tr>
<td>Total</td>
<td>(0)</td>
<td>(39)</td>
<td>(39)</td>
<td>n/a</td>
<td></td>
<td>0</td>
<td>(73)</td>
</tr>
<tr>
<td>NICE Grand Total</td>
<td>52,305</td>
<td>48,513</td>
<td>(3,792)</td>
<td>(7.2%)</td>
<td></td>
<td>62,985</td>
<td>59,149</td>
</tr>
</tbody>
</table>
Appendix B - Workforce strategy update at 29 February 2016

The workforce strategy was approved at the July 2015 Board meeting. We are progressing 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 has been developed to help managers plan and facilitate change has been tested and is now being used to support the planning of changes that are currently underway across the organisation. Feedback to date has been excellent.</td>
</tr>
<tr>
<td>An e-learning platform has been procured and is in development which will enable these tools to 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>Initial analysis indicates potential efficiencies can be achieved through more coordinated recruitment activity to common roles that are advertised frequently. We are also investigating an alternative approach to assessing potential candidates and will be piloting an assessment centre model in March 2016.</td>
</tr>
<tr>
<td>We continue to develop our talent management and succession planning work-streams which will enable us to better map career pathways and plan resourcing strategies in future.</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 used 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 programs that have been developed to support the competency framework.</td>
</tr>
<tr>
<td>Learning management system</td>
</tr>
<tr>
<td>An electronic Learning Management System (LMS) is currently being built which 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</td>
</tr>
</tbody>
</table>
performance management training and a full e-appraisal module, which will be piloted this year with a number of teams.

**Leadership**
We continue to be actively engaged in leadership development and are currently participating as part of the steering group for the DH's health system-wide senior talent programmes and have one Band 9 staff member taking part in the Aspiring Directors Leadership Development Programme. We are going through a process of selection for the next cohort of this programme due to commence later this year.

In addition, we have obtained places on the SHINE REACH Higher programme for two employees and are putting another three employees forward for this programme in 2016. SHINE REACH Higher is a programme specifically designed to develop and implement leadership strategies that reflect the unique challenges and experiences of BAME employees. Participating in this programme enables us to start to address under representation of BAME leaders in management and leadership positions and continued participation will in time increases the size and diversity of the senior leader talent pool across NICE and the ALB/NHS community.

**Culture**

<table>
<thead>
<tr>
<th>Engaged workforce</th>
<th>Inclusive workforce</th>
<th>Wellbeing at work</th>
</tr>
</thead>
<tbody>
<tr>
<td>In January 2016 we held our annual Healthy Work Week which included a wide selection of events and activities planned around the 5 ways of well-being.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

We continue to progress the actions under the staff survey 2015 action plan with development and implementation of a number of initiatives including introduction of the NICE mentor scheme; increased offering of e-learning for staff on a variety of topics including data analysis, logical and critical thinking and mental health and wellbeing; development of the partnership working group and plans to update and improve office toilet facilities.
The business plan sets out our business objectives and performance measures for 2016-17. It has been updated since the version reviewed by the Board in January to reflect feedback from the Board and the Department of Health.

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

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

BUSINESS PLAN

2016 - 2017
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Introduction

1. This plan sets out our business objectives and performance measures for 2016-17. It has been informed by our engagement with the Department of Health, NHS England, Public Health England, and our other national partners, in the NHS, local government, social care, and in the life sciences industries. It supports the ambitions set out in the Department of Health’s Shared Delivery Plan, NHS England’s ‘Five Year Forward View’, the implementation of which is being managed by five other national agencies; NICE, NHS Improvement, Public Health England, Health Education England and the Care Quality Commission, and the planning guidance for 2016-17, issued by the six national agencies in December 2015.

2. Our purpose is to help improve the quality, sustainability and productivity of health and social care. We do this by producing guidance and information on effective practice, which enables people working in health and social care to make better decisions with and for those for whom they are providing services. We take account of value for money in developing our guidance, by recognising that new forms of practice need to demonstrate the benefits they bring against what they displace, and by recommending better targeting of interventions of limited value and opportunities for disinvesting from ineffective practice. We promote our guidance and information using our own as well as a range of third party channels, including digital media and we help people to use it by providing practical support tools. NICE has a unique role in health system transformation given its remit across health care, public health and social care. NICE is therefore well placed to adopt such a system-wide perspective.

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

4. Our strategic and business objectives are framed around four themes which bring together our priorities:

   - Content: guidance, standards and evidence services, to enable high quality, sustainable care and support the efficient use of resources;
• Engagement: working effectively with organisations, inside and beyond the public sector, to shape and drive the use of our guidance, standards and evidence services;

• Adoption and impact: providing practical tools and other support to help users make the most of our work and to measure its uptake;

• Productivity: using our staff and our other resources efficiently and effectively, acting sustainably and building future resilience to climate change where needed.

Our objectives also take into account and support the Secretary of State for Health’s priorities for the NHS, which are:

• Transforming out-of-hospital care;
• Creating the safest, highest quality health and care service;
• Maintaining and improving performance against core standards while achieving financial balance;
• Driving improvements in efficiency and productivity;
• Preventing ill health and supporting people to live healthier lives;
• Supporting research, innovation and growth, and influencing global health priorities.

The context in which we work

The health and care system

5. Demographics, constrained resources, public expectation and a wave of new technologies are combining to present the health and care system with both challenges and opportunities. The NHS Five Year Forward View and the Department of Health’s Shared Delivery Plan recognise that while some of what is needed can be done by the NHS, much will require collaboration with local government, voluntary organisations and employers. This argues for a renewed effort to do what we know will help to promote good health and prevent ill-health, support patients to gain control of their care through using shared budgets, and promote better integration of care between hospitals and general practitioners and between the NHS and social care. The Department of Health is supporting the move to better integrate services, supporting local councils to help them work more effectively with health and social care organisations. The Care and Support White Paper set out the Department of Health’s plans for removing barriers to integrated care, better coordination of care and providing more support for people moving from one service to another.

The 2015-20 Comprehensive Spending Review

6. The Comprehensive Spending Review, published in November 2015, sets a challenging agenda for the public sector. Although the NHS settlement provides for small real terms growth and some front loaded investment in service
transformation, the outlook is still difficult and the position for local government is even more so, with funding reductions likely to impact significantly on those aspects of social care for which we are producing guidance. NICE, too, is affected by the Review. The Department of Health has confirmed that our strategic savings challenge will be a real terms reduction of 30% in our Grant-in-Aid administration funding and a 10% reduction in our programme funding, from our 2015-16 baseline to be achieved by 1 April 2019. This amounts to a reduction of around £14m off our projected 2016-17 baseline. Although achieving savings of this magnitude will require significant changes to the nature and extent of what we can offer, we believe that we can nevertheless keep the essential shape of our offer, combining a range of guidance, standards and indicators, with an array of evidence services, adoption support and added value, fee for service programmes. The Board has developed a strategic savings programme, covering the three financial years from April 2017, which will be considered with our principal sponsors during 2016. This programme is based on the assumption that the cost of the technology appraisal programme will be recovered from companies whose products are appraised in it. This proposal, based on a recommendation in the Triennial Review of NICE, undertaken by the Department of Health in 2015, will need to be developed and tested with stakeholders during the first half of 2016.

Working with our system partners

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

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

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

Digital health and care services

9. In November 2014, the National Information Board (NIB) published a new Framework for Action, entitled ‘Personalised Care 2020 - Using Data and Technology to Transform Health and Care’. The Framework identifies core priorities for delivering a modern digital health and care services, for use by the public, patients, carers and health and care professionals. Through 2015, NICE has contributed to the delivery of this agenda, leading with Public Health England on a programme designed to help people identify good quality apps to help manage their mental and physical health. The nature of NICE’s continued engagement with the NIB work in 2016 will be dependent on the funding and governance arrangements which are put in place at system level to implement the NIB agenda. Close collaboration with Public Health England, NHS England and the HSCIC will be required to deliver the app assessment programme which is ultimately a multi-agency endeavour. We are also exploring how we can further support innovation and demand for the right digitally enabled services through our guidance development programmes. We are already evaluating eHealth technologies and apps within our guidance programmes, where evidence is available.

Public expectations of NICE

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

11. The Government is committed to enabling the public to influence the development and delivery of health and social services. NICE has, from its inception, actively encouraged and supported the involvement of patients, service users, carers and the public (organisations and individuals) in the development and implementation of its guidance and advice, and in providing versions of this guidance and advice in accessible formats. Over the years, NICE has broadened opportunities for public scrutiny of our decisions by providing access for the public to the meetings of our advisory bodies. During the first half of 2016, we are conducting a review of our arrangements for engaging patients, service users and the public. The actions arising from this review will be implemented during 2016-17.
12. What we offer is enhanced by the NICE Evidence Services. This programme has extended our functions beyond guidance production to providing a comprehensive evidence and information service for healthcare, public health and social care. This includes an on-line portal for easy access to evidence, accredited guidance and other products, an evidence service targeted at primary care and specialist information services for accessing bibliographic content purchased by the NHS.

13. Work to develop the digital presentation of all NICE products, including standards, will continue to improve and widen access to our content. This includes a pathway presentation on the NICE website and facilitating access through third party information intermediaries.

Public health

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

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

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

17. We will work with Public Health England to help them to produce ‘return on investment’ tools, drawing on the evidence from NICE guidance. These tools help local government make the business case for investment in key strategic areas, such as reduction in tobacco use, alcohol consumption and encouraging
physical activity and we will look to Public Health England to ensure that these are promoted effectively at a local level.

18. We will work closely with Public Health England to ensure NICE public health evidence resources are integrated into the Public Health England online information services. This includes a clear, shared description of the different information resources being made available, and supporting Public Health England in ‘syndicating’ evidence content from NICE.

19. Our links with the Manchester Academic Health Science Centre, the School for Public Health Research, King’s College London, the National Institute of Health Research, the Medical Research Council and the Academic Health Sciences Networks will continue to be maintained. And we will work with the Local Government Association and other representative bodies in public health, including the Faculty for Public Health and the Society of Local Government Chief Executives.

Social care

20. NICE guidance and quality standards for social care, are commissioned by the Secretary of State for Health and, in the case of children’s social care, the Secretary of State for Education. The first of these quality standards for social care was published in 2013. The Department of Health does not intend our guidance and quality standards for social care to be prescriptive or directive. Instead, they and their associated supporting material will be tools for use in commissioning and providing social care, dependent on circumstances and in conjunction with professional judgement. They are intended for use in conjunction with the frameworks and regulation already in place, providing practical support to help drive up the quality of adult and children's care. They will also support the work of local Health and Wellbeing Boards and help local people hold commissioners and providers to account.

21. The Department of Health recognises that resource allocation decisions are a matter for local councils and believes that using an evidence-based approach to cost-effectiveness can assist local commissioners in making these decisions. This highlights the importance of ensuring that quality standards describe cost effective practice.

22. Ministers also want the standards to be flexible enough to support the ‘social care context’. Our social care quality standards will therefore need to take account of personalisation, so that the evidence and the standards are accessible enough to inform the choices of the personal budget-holder as commissioner. They will need to be designed and presented in a way that meets the needs of the individuals who deliver social care and the organisations they work for.

23. The social care community has long been an important audience for any NICE guidance and advice that impacts on broader health issues, particularly from our public health programme and NICE Evidence Services, which has been
making social care information available as part of its online portal for six years. NICE has experience in developing guidance across the health and social care interface in areas such as dementia. In the next three years, as arrangements for CCGs and their relationship with local authorities develop, stronger mechanisms for joint working between healthcare, public health and social care will emerge. We can support this important emphasis on integration with our guidance and standards.

Health care industries

24. Much of what NICE does has an impact on the health care industries that supply the NHS. We are very conscious of the responsibility we have when we advise the NHS on the use of health technologies and we know that what we say about new technologies is often taken into account in health systems beyond the United Kingdom. For these reasons we regard the relationship we have with the industries and individual companies as having equal importance with our other stakeholders and we will continue to work with the industry associations in this country and abroad to build mutual respect and trust.

25. In 2014, we consulted on terms of reference provided by the Department of Health for broadening of the methods for value assessment of branded pharmaceuticals. It was clear from the response to this consultation that much of what concerns those interested in the rapid adoption of effective and cost effective health technologies is beyond the reach of changes to our methods. As a result, we called for a wider conversation about broader system changes, and in this context we welcome the Accelerated Access Review announced by the Department of Health in late 2014, the final report of which is expected in spring 2016. The review will look at the development, regulation, evaluation and adoption of life sciences products. We are enthusiastic participants in this review.

26. In November 2015, NICE and NHS England published a joint consultation on the future of the Cancer Drugs Fund. The consultation document presented compelling arguments for change, based on the need to ensure that only those drugs with real promise but uncertainty as to their value to patients and to the wider NHS are admitted to the Fund. Both organisations are engaged in managing the transition arrangements, as the new Fund comes into place in July 2016. NICE has significantly increased its capacity to play its part in appraising all new cancer drugs and indications and in making conditional recommendations, as a new appraisal outcome, which will form the basis of potential admission to the Fund.

27. We will continue to develop NICE Scientific Advice which covers its costs through charges made to companies which take advantage of it. This programme, through early interaction allows developers to better prepare for assessment of their products under NICE technology evaluation programmes. We now offer the option for pharmaceutical companies to request parallel advice meetings with the Medicines and Healthcare Regulatory Agency (MHRA) or the European Medicines Agency (EMA). We are actively engaged in the
multi-HTA agency Shaping European Early Dialogues (SEED) initiative and we have developed a programme of seminars tailored to the needs of the medical technology and pharmaceutical sectors, and we work closely with the UK medicines regulator on the operation of the Early Access to Medicines Scheme. In addition, we have created an Office for Market Access which will consolidate these resources, with other, added value services to provide additional support to companies with good value products for the NHS and social care.

28. NICE is conscious of the impact it has on the life sciences industries that support the delivery of high quality care. We are aware of the extent to which the guidance we produce, particularly on new health technologies influences reimbursement decisions in other parts of the world. We will make sure that the way we work contributes to the long term health of the UK life sciences industries, through fair and objective evaluation of their products, and by stimulating the NHS to adopt effective and cost effective products and services.

NICE’s unique offer

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

- **Unique**: clarity about the nature and purpose of the evidence-based products we provide;
- **Aligned**: products that address the needs of the people, inside and outside the NHS, local government and social care, and which meet the needs of patients, service users, carers and the public who use the NHS, public health and social care services;
- **Robust**: securing transparency, rigour, inclusiveness, contestability;
- **Efficient**: providing guidance, related products and services in a timely and accessible fashion;
- **Flexible**: the ability to respond flexibly to changes in the needs of the people and organisations we serve.

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

Strategic Objectives

31. Our strategic objectives for 2016-20 are summarised below. Appendix 1 sets them out alongside their success criteria, and the section below provides detail of our plans for 2016/17 (Programmes, products and services).

Content: guidance, standards and evidence services, to enable high quality, sustainable care: Maintain NICE as the national point of reference for advice on effective and cost effective practice in health and social care, with guidance, standards, advice and evidence aligned with the needs of its users and the demands of a resource constrained system.

Engagement: working effectively with organisations, inside and beyond the public sector, to shape and drive the use of our guidance, standards and evidence services: Create and manage effective partnerships with national and local organisations in the health and social care system, including patients and service users and their associated professional bodies, and use them to inform and promote our guidance and advice. Work with government and industry to help promote innovation and growth in the life science industries, and with the research communities to ensure they are aware of the gaps in the evidence base underpinning our recommendations and of our methodological.

Adoption and impact: providing practical tools and other support to help users make the most of our work and to measure its uptake: Enable and promote access to NICE guidance, advice and evidence, at the point of need and in formats that users want. Use conventional and innovative ways to support the adoption of our guidance and advice, and assess the impact it has on improving quality of care and outcomes.

Productivity: using our staff and our other resources efficiently and effectively: Secure the effective management of NICE’s resources, exploring appropriate income generating opportunities and delivering the savings required to operate within a reducing resource envelope. Act sustainably in our delivery and policy objectives, building in future resilience to climate change where needed.

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

34. The Institute’s planning principles are set out below and the business objectives together with the outputs for 2016-17 are in table 3. The ‘balanced scorecard’, which sets specific targets based on the objectives agreed by the Board with the Department of Health and monitored on a quarterly basis, is attached as Appendix 1. Details of the publication outputs for each programme are provided in Appendix 2.

Programmes, products and services

Content

35. **Quality standards**: NICE quality standards provide clear, concise statements of high-priority areas for quality improvement. In 2013, following publication of the Health and Social Care Act, the scope of our quality standards grew to encompass public health and social care. They help organisations improve quality by providing measures of best practice to support ongoing performance improvement, and can provide information both for commissioners and providers. The programme supports the integration of services by covering topics in health, public health and social care. Over 60 standard topics are in development at any one time, through a process that actively involves those with expertise and understanding of current services. Quality standards include
content related to all three dimensions of quality – safety, effectiveness and patient experience – and take into account overall cost impact.

36. Although quality standards are not mandatory, they are an important driver for change within the arrangements for commissioning and service delivery in health and social care. Both the Secretary of State and NHS England must have regard to NICE quality standards. In public health, NICE is working with Public Health England to support their use in local government, including actively encouraging an ongoing process of data collection. To facilitate use of quality standards by commissioners, in response to feedback, we are reformatting quality standards to enable them to more easily be aligned to local priorities.

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

38. **Guidance on health technologies**: technology appraisals develop recommendations for the NHS and patients on drugs and treatments based on their clinical and cost effectiveness. We review only a subset of all new technologies offered to the NHS and we select them using criteria we have agreed with the Department of Health. Regulations provide for the mandatory funding of drugs and treatments which are recommended in a technology appraisal and that funding must normally be available within 3 months of a positive appraisal. Patient entitlement to these drugs is set out in the NHS Constitution.

39. Medical technologies (devices and diagnostics) are notified directly to NICE, usually by commercial sponsors and sometimes by clinical leads, and the Medical Technologies Advisory Committee (MTAC) decides which technologies should be evaluated, and by which guidance programmes. Our medical technologies guidance aims to identify cost saving interventions and recommends them to the NHS when the sponsor’s case for adoption is supported by the evidence. The guidance is based on advantages to patients and to the NHS, compared with current practice, and it includes detailed consideration of costs, care settings and of the whole patient pathway.

40. **Our diagnostics guidance** advises the NHS and patients on the clinical and cost effectiveness of diagnostic technologies. The Diagnostic Advisory Committee produces guidance on a range of related technologies that have the potential to transform clinical diagnosis pathways to achieve better outcomes. The potential of technologies to provide a diagnosis at the “point of care” and to avoid attendances in secondary care is often an important consideration.
41. In 2014, NICE began to produce **Medtech Innovation Briefings (MIBs)** to provide the NHS and social care with objective information on promising medical technologies as an aid to local decision making by clinicians, commissioners and procurement professionals, and to inform patients about new technologies. We will work collaboratively, particularly with NHS England, to develop MIBs as a rapid responsive resource where the need for information has been identified directly from the NHS. We will also exploit the potential of MIBs to address technologies across the whole spectrum of NHS and social care settings.

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

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

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

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

- The current portfolio of clinical guidelines is approximately 170; the largest collection of clinical guidelines in the world. A further 25 topics have been referred to the programme by NHS England and these will be commissioned over the next two years. At any given time, between 60 and 70 guidelines (including updates) are in development.

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

- **Social care guidelines:** The 2012 Health and Social Care Act established a new responsibility for NICE to develop guidance and quality standards for social care in England. This provides an opportunity to apply an evidence-based system to decision-making in the social care sector, similar to that provided for the NHS. It will also allow us to produce guidance that promotes better integration between health, public health and social care services, and will be developed in close partnership with, rather than imposed upon, service users and carers, practitioners and organisations working in social care. The programme currently has between 7 and 10 guidelines for social care in development at one time. 2016 will see the programme develop to take into account new social care topics, identified following significant engagement with stakeholders to understand their priority areas and adapting to the specific needs of our social care audiences.

- **Public health guidelines** NICE guidance in public health cover a range of topics largely addressing health improvement and wider determinants, such as tobacco cessation services and prevention of obesity. It is a significant programme of work that has between 20 and 24 topics under development at any one time. In 2014, we were referred a library of over 60 public health topics to inform future quality standards and guidance. These will cover a broad range of topics that will be prioritised with partners, including Public Health England, in the next three years.

- **Medicines Practice Guidelines** provide advice for the NHS and social care on the safe and effective management of medicines. This programme addresses some of the most pressing challenges facing health and social care including medicines optimisation and antimicrobial stewardship. The programme will merge with the clinical guidelines programme at the end of its current commissions in early 2017.
45. **Medicines and prescribing**: We provide a comprehensive portfolio of medicines information to the NHS. This includes a horizon scanning function for new drugs (UK Pharmascan), plus information about new medicines, drug safety alerts, the off label and unlicensed use of medicines and best practice prescribing advice. Most of this information is provided by functions that have transferred to NICE (from the National Prescribing Centre and the National Electronic Library for Medicines). Prescribing advice is commissioned through the British National Formulary (BNF), and information about licensed drugs is available through NICE’s digital evidence resource. A programme of revisions to the structure and accessibility of the BNF was implemented during 2015.

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

47. **Decommissioning**: In the next 5 years, as the health and care system faces significant financial challenges, NICE will continue to help drive the optimal use of resources. To do this, we will build on the existing portfolio of disinvestment work. This will include developing our online offer on savings and productivity to improve its visibility on the NICE website, and actively working with partner organisations to improve uptake of disinvestment opportunities. We will continue to support the optimal use of medicines and ‘deprescribing’ through the work of the Medicines and Prescribing Centre, including focussed work on specific medicines. We will also provide a ‘forward view’ that will show anticipated costs, by quarter, for future technology appraisal guidance. This will support the commissioning process, particularly for specialised products.

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

49. Indicators provide a mechanism to incentivise general practitioners and the health professionals who work with them to improve the quality and consistency of the services they provide. NICE will work closely with NHS England to support planned changes to primary care indicators in England and the Devolved Administrations in Scotland, Wales and Northern Ireland.

50. **NICE also produces indicators for public health, and to help Clinical Commissioning Groups identify areas for improvement, to enable them to compare with other groups, locally and nationally. NICE will work closely with NHS England to ensure indicator development reflects plans for this framework, and to develop additional indicators to reflect other priority areas.**

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

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

Engagement

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

54. We will continue the work of understanding our audiences and helping them to access the NICE products and services they need. We have improved the NICE website to give users the opportunity to personalise and tailor information of most relevance to them; and we are developing ways to use new digital platforms, including social media and digital devices, to communicate with old and new audiences as people change the way they access information.

55. We are developing a new audience insight programme to gather data on the views of our audiences and about how they engage with us to help inform what we do and spark new ways of working.
56. In all areas of communications work – from writing and editing guidance, responding to enquiries about our work, developing and maintaining digital content, through to our public affairs work with government, and engagement with the press and other media as well as internal audiences – we will ensure that guidance and advice is easily accessible, simple to use and readily understood. Our aim is to explain NICE’s key role in delivering excellence in health and social care.

57. **Involving patients, services users and the public:** We have a service user and public-centred approach in the development of our methodologies across all our programmes. Our processes are designed to enable organisations that represent patients, service users, carers and the wider public to submit evidence, alongside health professionals and others, and to influence the formulation of guidance and other products and services. Individual patients, service users, carers and community members are involved in the development of each piece of NICE guidance, and other products. In addition, patients, service users and the public and the organisations representing their interests, are increasingly supporting the implementation of our guidance and advice. We are committed to seeking improvements in how we can better incorporate the views of lay people into our work and in disseminating our recommendations to a public audience. To this end, we are undertaking a review of our approach to engaging with the public and service users and will implement the recommendations from this review during 2016-17.

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

59. We are also committed to encouraging and advising voluntary and community sector organisations to support the use of NICE guidance and standards. We will continue our work to include patient and voluntary sector organisations’ contact details in our Information for the Public, to provide readers with additional sources of support. Voluntary and community sector organisations have formal agreements with NICE to support the use of NICE quality standards and we will continue to work with NICE Implementation Programme and Healthwatch England to provide advice to local Healthwatch organisations on supporting the use of NICE guidance and standards.

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

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

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

63. The programme also leads on managing NICE’s relationship with the MHRA. Good collaboration has been established through quarterly meetings and ongoing engagement in several areas of mutual interest. We now have a much greater understanding of interactions between the two organisations. Real value is also derived from a key issues log which is kept up to date with review at the quarterly meetings. We also have clear agreement of the mechanisms and contacts for collaboration between NICE and the Commission on Human Medicine (CHM) as recommended in the Triennial Reviews of both organisations. These arrangements allow NICE to actively seek CHM input on NICE guidance and evidence summaries. Moving forward, we anticipate further collaborative work, including joint work to implement recommendations from the Accelerated Access Review. Through European collaborative activities, we are also developing strong links with the European Medicines Agency.

64. In recent years the Science Policy and Research programme has also focussed on playing a more direct role in delivering NICE’s research needs through seeking funding to set up research projects within the programme. Strong
progress has been made and we currently have a team of 5 staff working on research projects fully funded through research grant income. A major focus currently is exploring methods for the timely managed access to high value health technologies and support for broader life-sciences innovation strategy. Current activities include two European Innovative Medicines Initiative (IMI) funded projects – “GetReal”, a pan-European consortium of medicines regulators, HTA bodies, pharmaceutical companies, patients and other stakeholders to explore the role of real-world evidence (RWE) for informing decision making during drug development and in evaluation by regulators and HTA bodies; and “ADAPT-SMART” which provides an opportunity to design new collaborative approaches to the development of medicines through Medicines Adaptive Pathways to Patients (MAPPs). In addition, a study exploring the appraisal of regenerative medicines was undertaken in collaboration with the University of York in response to a recommendation from the DH Regenerative Medicines Expert Group. Learning from these projects is translated to practice through the guidance producing teams and life sciences companies engaged in developments through the Office for Market Access and NICE Scientific Advice. The team is currently engaged in developing proposals for further IMI funded projects and exploring other research funding opportunities.

Adoption and impact

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

66. The implementation strategy has four broad aims to: raise awareness of NICE guidance and other related resources; motivate and encourage change in practice by working through other organisations and systems within health and local government and their partner organisations to generate ‘leverage’; provide practical support; and monitor and evaluate uptake of the recommendations to inform future work.

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

68. We also have a team of implementation consultants to provide practical support and advice to NHS trusts, networks, CCGs, local authorities and social care providers, particularly in relation to effective processes for implementation and information about NICE. The NICE Board will continue to receive an overview, through six monthly reports, of the information that NICE has about how our recommendations for evidence-based and cost effective care are being used. As our own resources become more constrained, we will apply a greater proportion of our implementation resources on local engagement, including through our Implementation Consultants. We will work more actively with partner organisations to use their enthusiasm and support to encourage adoption of NICE recommendations. We will pay particular focus to challenging areas for implementation, highlighting them clearly in guidelines, and where quality standards point to key improvement areas support the work of others.

69. **Adoption of Health Technologies:** We facilitate the adoption of selected medical device and diagnostic technologies guidance across the NHS through engagement with clinical teams, commissioners, patients groups and social care. Included in this is focused practical advice about how to measure impact. There are two types of practical adoption support: the first consolidates the learning that has taken place from a significant number of NHS sites that have already adopted the technology; the second focuses on technologies that are not widely used in the NHS or where complex redesign to services is required to successfully implement the technology.

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

71. **Endorsement and accreditation:** To support users of NICE Evidence, we introduced a formal accreditation programme, enabling ‘kite-marking’ of high quality independent guidance producers. We now also have a process of formally endorsing externally produced implementation tools and resources, where these are in line with NICE recommendations. This process helps users of guidance to identify high quality resources, recognising the potential power of these channels and the lack of capacity to produce all that we might want to ourselves. Examples of new and existing collaborations to develop this approach include with the BMJ through their improvement and information platforms, and organisations or alliances representing the public, professional
associations and networks such as AHSNs. In 2016/17 we will be considering whether these programmes can operate on a fee-for-service basis.

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

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

74. A key component of our Digital Strategy is to improve the efficiency and productivity of NICE guidance development processes. Over the next 3 to 5 years, NICE intends to move away from managing its content in large ‘document’ format, towards managing smaller pieces of information and the relationships between them. This will allow our recommendations, evidence statements, and the underpinning evidence to be queried, updated, shared and repurposed more effectively, with benefits to internal and external users of NICE’s content alike. Achieving this vision will require significant changes in the way content is developed, written and managed in guidance development systems.

75. Other key objectives of digital transformation include the need to widen and improve access and distribution of NICE guidance and evidence-based products and services to NICE core audiences using a range of digital channels including mobile platforms and third party platforms. Finally, we strive to continually improve our website, to ease the navigation of NICE’s complex portfolio of products and services, and facilitate access to relevant and related content for users.

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

**NICE International**

77. **NICE International**, established in 2008, offers fee for service advice to governments and government agencies outside the UK on building capacity for assessing and interpreting evidence to inform health policy and practice, and on using methods and processes to apply this capacity to their local setting. The
primary objective of NICE International is to contribute to better health around the world through the more effective and equitable use of resources. It does this on a full cost recovery basis by providing advice on the use of evidence and social values in making clinical and policy decisions. The service is aligned with both the Department of Health and the Department for International Development’s ambitions for improving global health, particularly in low and middle income countries, as well as wider Government policy to engage with emerging economies. We will review the future of this work, along with our other international activity, during 2016.

**Core principles for product development**

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

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

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

**Resource assumptions**

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

81. The majority of NICE’s activity (and funding) is classified as Administration – the exceptions are funding for supplying the British National Formulary (BNF) publications to the NHS and some costs associated with the Medical Technologies Evaluation Pathway programme.
82. The Table below shows the planned sources of funds for 2016-17 and how they will be applied. It also shows how these compare with the 2015-16 plan.

Table 1: Sources and applications of funds

<table>
<thead>
<tr>
<th>Sources of Funding</th>
<th>2015-16 £m</th>
<th>2016-17 £m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration - GIA</td>
<td>53.1</td>
<td>49.4</td>
</tr>
<tr>
<td>Programme - GIA</td>
<td>8.9</td>
<td>8.7</td>
</tr>
<tr>
<td>Income from Devolved Administrations</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Income from Health Education England</td>
<td>3.6</td>
<td>3.7</td>
</tr>
<tr>
<td>Income from NHS England (confirmed)</td>
<td>1.1</td>
<td>5.5</td>
</tr>
<tr>
<td>Other income</td>
<td>1.8</td>
<td>2.9</td>
</tr>
<tr>
<td>Non-Cash Funding - Depreciation</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Total Sources of Funding</strong></td>
<td><strong>71.5</strong></td>
<td><strong>73.2</strong></td>
</tr>
</tbody>
</table>

| Application of Funds | | |
|----------------------|------------|
| Guidance and Advice | 57.7 | 59.1 |
| Corporate | 12.5 | 12.4 |
| Contingency reserve | 0.3 | 0.7 |
| Depreciation Charges | 1.0 | 1.0 |
| **Total Applications of Funding** | **71.5** | **73.2** |

Sources of funds

83. It has been confirmed that the 2016-17 administration funding will fall by 7% (£3.7m) in cash terms. The programme budget will also reduce from £8.9m to £8.7m giving a total reduction in GIA funding of £3.9m (6%). This is the first stage of an overall straight line phased real terms reduction of 30% in our administration funding over the current Spending Review (SR) period to 2019-20. It has been indicated to us that the programme element will reduce over the period to £8m (10%) and this will also be phased.

84. In addition to GIA funding there are a number of other sources of income. In total these are projected to increase by £5.6m in 2016-17 to £14.1m. The increase is mainly due to new commissions from NHS England as follows:

- **Cancer drugs fund £2.0m** income to support the cost of administering the fund and associated increase in appraisal activity
- **Commissioning support documents £0.8m** cost of producing up to 25 documents annually
- **Rapid evidence summaries** £0.1m cost of producing up to 10 per year
- **Mental Health Access and Waiting times** £1.5m Primarily pass through cost of work being commissioned by NICE on behalf of NHSE

85. It is assumed that NHS England will continue to provide £1.0m to fund Medical Technology Innovation Briefings and support the Observational Data Unit.

86. Other income sources will increase from £1.8m to £2.9m. These sources include the Scientific Advice and international programmes of work which are self-funding activities. Scientific Advice provides early advice to the pharmaceutical and medical technology industries. NICE International supports health system capacity building in low and middle income countries. These activities will generate £1.8m to cover their direct costs and contribute to overheads where appropriate.

87. Rental income in also included in other income and will increase to £0.8m. There will be a new income stream as a result of the co-location arrangement that has been agreed with the Human Fertilisation and Embryology Authority (HFEA) in our London office and we will continue to generate income from the sub-lets in our Manchester office to the Homes and Communities Agency and the Care Quality Commission.

88. Income of £3.7m will come from Health Education England under the service arrangements in place whereby NICE procures and provides the national core content for the NHS.

89. It is assumed that the income from the devolved administrations (Wales, Scotland and Northern Ireland) will be maintained at £2m in accordance with the current Service Level Agreements (SLAs). This contributes to the cost of selected guidance production, producing the BNF and some supporting services depending on which products and services they make use of locally. SLAs set out the level of funding that will be provided and which outputs can be used by each country or support to be provided.

90. In addition to the grant-in-aid funding that we receive from the Department of Health, we also bid for capital funding on an annual basis. Although subject to confirmation, the assumed capital requirement for 2016-17 is £0.5m.

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

92. There are small amounts of income from other sources. This includes a licensing arrangement for clinical guidelines adapted in New Zealand and the syndication of NICE content overseas for a fee.
How we apply our resources

93. The proposed reduction in GIA funding over the SR period presents a significant challenge to the organisation. During 2015-16 the Senior Management Team and the Board have been reviewing the organisation’s strategic direction in the light of anticipated reductions of this scale. Now that the likely impact of the SR on NICE has been confirmed the Board is engaged in the process of agreeing a strategic plan covering the period to 2019-20. This plan will be finalised early in 2016-17. It will set out how NICE will re-shape its activities and use of resources to manage this reduction in GIA funding.

94. We continue to review the costs and resources applied to the corporate 'back-office' functions with the aim of remaining below all the Government best practice benchmarks as well as maintaining the quality of the corporate functions provided. The finance and HR teams are located in Manchester where costs are lower. We take advantage of shared services where appropriate. Our finance systems and payroll are provided by NHS Shared Business Services and we transferred the administration of recruitment to NHS Business Services Authority during 2015. We continue to seek opportunities for co-location with other public bodies and the HFEA will be co-locating with us in London from April 2016.

95. NICE is committed to staff training and development and will allocate £0.4m in 2016-17 to staff training.
Table 2: Benchmarking the back office

<table>
<thead>
<tr>
<th>Function</th>
<th>Indicator (Benchmarking the back office: Central Government)</th>
<th>2016-17 plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR</td>
<td>Number of wte staff per member of HR staff. Mean 50, adjusted average 51</td>
<td>Current plan is for 8 wte HR staff which equates to a ratio of 81:1 ratio of staff to HR employee. (Based on 647wte – final headcount figure tbc).</td>
</tr>
<tr>
<td>Finance</td>
<td>Cost of finance function as a percentage of total cost. Mean 2.2%, adjusted average 1.9%</td>
<td>Cost of finance function is £0.74m which equates to 1.0% of total expenditure.</td>
</tr>
<tr>
<td>Estate</td>
<td>GPU requirement is for 8m2 per desk, with an 8:10 ratio of desks per staff.</td>
<td>During 2016-17 we will achieve or exceed this across all the estate. A key contributor to this is the colocation arrangement agreed in London with the HFEA from April 2017.</td>
</tr>
<tr>
<td>IT</td>
<td>Cost of IT as a percentage of total cost. The mean is 6.1% of the total, adjusted average is 4%</td>
<td>Cost of IT is £1.3m which equates to 1.8% of total expenditure.</td>
</tr>
</tbody>
</table>

Human Resources

96. There are two members of staff expected to earn more than £142,500 during 2016-17. Overall, the ratio of staff on the very senior managers (VSM) pay framework to total staff complement is 1 VSM for 90 staff.

97. A new structure and service arrangements for the HR function were implemented during 2015. The Board also approved a new workforce strategy in July 2015. This was developed in the context of the anticipated workforce challenges associated with the funding reductions expected. The strategy recognises issues associated with such significant change and has been developed to provide the support that managers will need.

98. As part of the implementation of the strategy each Centre/Directorate will develop workforce plans that identify where improvement can be achieved through more efficient resourcing, role redesign, change management and the use of low cost, high impact training and development options.

99. We will be taking forward our work on developing talent, engaging in sector wide talent management programmes and introducing graduate training programmes into roles that NICE has found hard to recruit to in the past.

100. We have been increasing our use of apprenticeship schemes and this will continue. We expect to achieve the target of 14 wte apprentices during 2016.

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

**Estate**

102. All NICE’s office facilities now operate on a totally flexible working model with ratios that achieve or exceed the Government Property Unit metrics. From April 2016 the Human Fertilisation and Embryology Authority will be collocated in our London office. This will provide an income stream to offset against our savings targets.

103. The lease on the London office runs through to end of 2020 when it is expected that the freeholder will redevelop the site. At that point NICE would expect to move to one of the London public sector ‘hub’ sites. The lease on our Manchester office comes up for renewal at the end of 2017. The GPU considers that the colocation arrangements we currently have in place in Manchester with the Home and Communities Agency and with CQC puts us in a good position to seek a renewal of the lease as part of the strategic ‘hub’ arrangements for public bodies in Manchester. In the longer term (10 years) this may involve a super-hub arrangement at an alternative site which NICE would be in a good position to participate in.

**Procurement**

104. We aim to comply with the Government’s policy objectives in relation to procurement and efficiency controls. We already comply with the target of 18% of procurement spend to be with small and medium enterprises (SMEs) by 2015, use Government LEAN sourcing principles for all significant procurements and undertake most procurements within 120 days. We are aware of the Greening Government agenda and comply with Government buying standards as well as using central contract solutions where appropriate for procurement of common goods and services. We also conform to the Efficiency Reform Group controls and procedures where applicable.

**Sustainable development**

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

106. We will continue to consider our own direct impact, focusing our efforts on areas where carbon impact is most significant. These include: electricity use, staff and non-staff business travel, printing of guidance and the British National Formulary (BNF), office waste and recycling. We will update our Sustainable Development Management Plan through our cross-institute ‘green group’
107. In addition, we intend to explore ways in which the sustainability of health interventions we are asked to consider might feature in the guidance we produce. A sustainability steering group will be established that will develop a generic statement on sustainability to be incorporated in NICE products. It will also consider how sustainability factors (social and environmental) can be incorporated into the cost impact analysis work. We will do this in conjunction with the Centre for Sustainable Healthcare and the Sustainable Development Unit. Any changes to our methods or for the presentation of guidance would need to be the subject of discussion and consultation. We will also develop a Board-Approved, Sustainable Development Management Plan (SDMP).

Equality

108. In April 2013, NICE’s Board approved a policy statement for the period 2013 to 2016 setting out its approach to complying with the Public Sector Equality Duty, and agreed two equality objectives. Central to compliance is an equality analysis process for each item of NICE guidance (which includes quality standards and indicators for the Quality and Outcomes Framework and Clinical Commissioning Group Outcomes Indicator Set). The purpose of the process is to try and ensure that, wherever there is sufficient evidence, NICE’s recommendations support local and national efforts to advance equality of opportunity and narrow health inequalities.

109. NICE meets the Equality Act’s specific duty on publication of information through its annual equality report on the impact of its equality programme. The Board will consider the next annual equality report in September 2016. In March 2016 the Board will consider new objectives for the period 2016 – 2019 in accordance with the Public Sector Equality Duty.

Risk management

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

111. The Board receives assurance on these from a number of sources but primarily through the Chief Executive’s regular report. The Department of Health regularly assesses the extent to which NICE has met its statutory obligations at quarterly accountability meetings.
### Principal business objectives 2016-17

**Table 3: Principal business objectives for 2016/17**

<table>
<thead>
<tr>
<th>Objective</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content</td>
<td>Guidance, standards and evidence services published and provided in accordance with the schedule set out in Appendix 2 and the balanced score card</td>
</tr>
<tr>
<td></td>
<td>Delivery within the range allowed for in the balanced scorecard</td>
</tr>
<tr>
<td>Publish guidance, standards and indicators, and provide evidence services</td>
<td></td>
</tr>
<tr>
<td>against the targets set out in the Business Plan and in accordance with</td>
<td></td>
</tr>
<tr>
<td>the metrics in the balanced scorecard.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop plans to ensure that NICE’s guidance products meet the needs of</td>
<td>Continue to engage with the social care and public health sectors to understand their needs and expectations of NICE guidance</td>
</tr>
<tr>
<td>social care providers and commissioners. This includes adapting NICE’s</td>
<td></td>
</tr>
<tr>
<td>methods and processes to ensure that they are appropriate in a social</td>
<td></td>
</tr>
<tr>
<td>care context and, for public health, ensuring alignment with PHE priorities</td>
<td></td>
</tr>
<tr>
<td>and ensuring NICE guidance supports local public health services.</td>
<td>Redesign processes and methods to better deliver against these expectations and produce definitive plans by September 2016</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop and then implement the first year of a three year strategy to</td>
<td>Strategy agreed with the Board and principal stakeholders by July 2016</td>
</tr>
<tr>
<td>reshape the offer from NICE, to take account of the reduction in</td>
<td>Actions monitored through regular reports to the Senior Management Team and the Board</td>
</tr>
<tr>
<td>Department of Health Grant-in Aid funding.</td>
<td>Balanced budget set for 2017-18</td>
</tr>
<tr>
<td></td>
<td>CDF transition arrangements completed, in accordance with the schedule for 2016-17 agreed with NHS England</td>
</tr>
<tr>
<td></td>
<td>New methods and processes operational from April 2016</td>
</tr>
<tr>
<td></td>
<td>Additional capacity in place by end July 2016</td>
</tr>
<tr>
<td>Objective</td>
<td>Actions</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Manage the change from the existing to the new commissioning             | • Agree the terms of the transition process with the current contractor by July  
| arrangements for social care guidance efficiently and sympathetically.   | • Put in place the 2016-17 actions in the transition process                                                                 |
| Implement the relevant recommendations in the final report of the        | • Assess and report to the Board on the financial, operational and reputational implications of the final report for NICE guidance programmes  
| Accelerated Access Review                                                | • Develop an implementation plan and report to the Board on progress with its implementation                                           |
| Review options for the long term development of NICE International's     | • Identify and evaluate the options for the long term future of NICE International  
| health systems development work in low and middle income economies       | • Board consideration of the preferred option in June  
|                                                                          | • Complete the actions for the preferred option by December                                                                           |
| Engagement                                                               |                                                                                                                                 |
| Share the stewardship of the Five Year Forward View with the other Arm's | • Regular participation in the governance arrangements (the main Board and its programme groups) of the Five Year Forward View  
| Length Body signatories.                                                 | • Strategies and policies, developed by the Five Year Forward View Board are informed, where appropriate, by NICE and its outputs |
|                                                                          |                                                                                                                                 |
| Ensure that all new guidance topics that are commissioned align with a    | • Each topic associated with a system priority, strategy or policy  
| health and care system priority, strategy or policy and that each         | • System owner identified for each topic  
| guidance publication clearly articulates the case for adoption for its    | • The case for adoption published for each topic  
| key audiences.                                                           |                                                                                                                                 |
|                                                                          |                                                                                                                                 |
| Identify and operate systems and processes, with NHS England and Public  | • Identify the key business relationships between the two organisations by April 2016                                               |
| Health, which ensure that business critical functions are                 |                                                                                                                                 |

March 2016
<table>
<thead>
<tr>
<th>Objective</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>delivers, duplication avoided and opportunities for contribute to and participate in complementary activity are identified and acted on.</td>
<td>• Develop and track metrics to assess and monitor the successful operation of these relationships in line with updated partnership agreements</td>
</tr>
<tr>
<td>Work with the MHRA, the Office for Life Sciences and NIHR to ensure timely technology appraisal guidance on EAMS products is delivered on the timeline agreed with the Department of Health</td>
<td>• Ensure the timeline for all EAMS designated products in the technology appraisal programme is consistent with the Scheme’s expectations</td>
</tr>
<tr>
<td>Ensure that NICE is compliant with its duties under the Equalities Act 2010</td>
<td>• Publish annual equality report in September 2016 • Develop action plan to deliver equality objectives</td>
</tr>
</tbody>
</table>

**Adoption and Impact**

<p>| Develop a consolidated set of metrics and data to assess the uptake and impact of the guidance and evidence services provided by NICE. | • Measure and report against a set of indicators that enable the Senior Management Team and the Board to exercise a judgement about the uptake and use of a defined range of guidance and evidence services. |
| Continue to work with CQC to ensure that NICE quality standards and guidelines complement and reinforce essential standards, building on existing work to map NICE Quality Standards into the CQC inspection work. | • Agree with CQC on the extent of use of relevant guidance and quality standards in their inspection regime. • Put in place a process for sampling the use made of the guidance and standards |
| Redesign and promote, in conjunction with NHS Improvement, NHS England and the Local Government Association, a comprehensive resource for commissioners and providers on the use of NICE guidance to help make savings, improve productivity and promote optimal use of interventions. | • Redesigned resource available from April 2016 • Usage monitored and reported to the senior Management Team and the Board |
| Subject to the release of budget for this programme of work, Contribute to the National Information Board Framework for Action through the development of an endorsement scheme for health apps, | • Secure the resources necessary for NICE to be able to make a meaningful contribution to the work • Subject to adequate resourcing, agree a programme of work |</p>
<table>
<thead>
<tr>
<th>Objective</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>working closely with Public Health England and HSCIC.</td>
<td>with the key partners</td>
</tr>
<tr>
<td></td>
<td>• Deliver against the 2016-17 elements of the agreed work plan</td>
</tr>
<tr>
<td>Take into account the views and concerns expressed by key stakeholders</td>
<td>• Report RepTrak metrics to the Senior Management Team and the Board</td>
</tr>
<tr>
<td>through the government-wide RepTrak reputation research project</td>
<td></td>
</tr>
<tr>
<td>Productivity</td>
<td></td>
</tr>
<tr>
<td>Operate within resource and cash limits in 2016-17. Actively manage</td>
<td>• Performance against plan for all budgets monitored and</td>
</tr>
<tr>
<td>the appropriate application of any non-recurrent funding as early as</td>
<td>reported to the Senior Management Team and the Board</td>
</tr>
<tr>
<td>practicable in the financial year.</td>
<td></td>
</tr>
<tr>
<td>Complete the implementation of the Cabinet Office’s Triennial Review</td>
<td>• Review progress and complete a ‘one year on’ report in July 2016</td>
</tr>
<tr>
<td>recommendations published in July 2015</td>
<td>• Complete all actions by December 2016</td>
</tr>
<tr>
<td>Promote a culture of continuous improvement within the organisation</td>
<td>• Identify the programmes which might be suitable for</td>
</tr>
<tr>
<td>and uphold the ambition to remain a world-renowned organisation,</td>
<td>benchmarking and assess what, if any, international</td>
</tr>
<tr>
<td>benchmarking where possible its systems, processes and outcomes</td>
<td>benchmarking is possible by September</td>
</tr>
<tr>
<td>against best players internationally</td>
<td>• Identify 10 publications in peer reviewed international journals</td>
</tr>
<tr>
<td></td>
<td>which assess and provide an opinion on one or more aspects of NICE’s</td>
</tr>
<tr>
<td></td>
<td>work and submit to the Board for consideration in March</td>
</tr>
<tr>
<td>Implement the first year of a three year strategy to manage the</td>
<td>• Centres and directorates identify savings in order enable the</td>
</tr>
<tr>
<td>reduction in the Department of Health’s Grant-In-Aid funding and plan</td>
<td>Institute to manage within the reduced Grant in aid funding it</td>
</tr>
<tr>
<td>for a balanced budget in 2017-18.</td>
<td>received from DH by April</td>
</tr>
<tr>
<td></td>
<td>• Management of change exercises completed in accordance</td>
</tr>
<tr>
<td></td>
<td>with a schedule agreed and monitored by the SMT</td>
</tr>
<tr>
<td>Objective</td>
<td>Actions</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>
| Put in place arrangements to charge the cost of the technology appraisal programme to industry users, from April 2017 | - Key stakeholder agreement to charging obtained by September  
- Board regularly appraised of the financial, operational and reputational risks  
- Financial and operational arrangements designed and tested by April 2017  
- Charging arrangements are able to go live from September 2017 at the latest |
| Develop a strategic plan to grow the commercial activity over the next 10 years. This should explore, for example, offering advice, digital protocols, assessments or a subscription service to other countries. | - Identify and evaluate the options for increasing income from non-Grant-in-Aid sources, inside and beyond the UK  
- Evaluate the options for the most effective vehicle for delivering this activity, by June 2016  
- Prepare business cases for each element of the programme by December 2016 |
| Enthuse and enable staff to deliver on the Institute’s objectives, ensuring that every member of staff has a clear set of personal objectives, a personal development plan and an annual appraisal. | - All staff have clear objectives supported by personal development plans  
- Staff are fully briefed on the strategy to manage the changes needed to reshape NICE as a consequence of the reduction of Department of Health Grant-in-Aid funding  
- Current global job satisfaction index in the annual staff survey is maintained or improved |
| Develop an approach to succession planning and attracting and retaining talent and recruiting appropriately skilled staff to key posts, including achieving the specified 2.3% of apprenticeships | - As an addition to the workforce strategy, develop a proposal for the Board which defines succession planning as it should apply to NICE, together with a set of actions to deliver on its objectives  
- Secure compliance with the target for apprentices by July 2016 |
APPENDICES

1. Balanced Scorecard for 2016-17
2. Activity Analysis for 2016-17
3. Revenue budget allocations for 2016-17
4. Board and Senior Management Team
5. Organisational Chart
Appendix 1 - Balanced Scorecard 2016-17

The structure of the balanced scorecard as determined by the Department of Health and is set out into four domains. These are then supported by strategic objectives and specific measures, which will be reported on throughout the year. The four domains are:

- Outcomes: Delivering services and improvements
- Investment: Investing in the organisation
- Reputation: Improving stakeholder satisfaction
- Change and Business Improvement: Improving the way we work

The proposed objectives and measures are set out in the tables below.

Outcomes: Delivering services and improvements

<table>
<thead>
<tr>
<th>Success Criteria</th>
<th>Key Measures</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Development and publication of guidance and evidence outputs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publish 34 guidelines</td>
<td>Publication within stated quarter</td>
<td>75%</td>
</tr>
<tr>
<td>- Clinical areas, including updates (25)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Public health (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Medicines practice guidelines (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Social care (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publish 50 technology appraisals guidance (including up to 15 CDF reconsiderations)</td>
<td>Publication within stated quarter</td>
<td>75%</td>
</tr>
<tr>
<td>Publish 35 interventional procedures guidance</td>
<td>Publication within stated quarter</td>
<td>75%</td>
</tr>
<tr>
<td>Publish 6 diagnostics guidance</td>
<td>Publication within stated quarter</td>
<td>75%</td>
</tr>
<tr>
<td>Publish 3 highly specialised technologies guidance</td>
<td>Publication within stated quarter</td>
<td>100%</td>
</tr>
<tr>
<td>Success Criteria</td>
<td>Key Measures</td>
<td>Target</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------</td>
<td>------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Publish 7 medical technologies guidance</td>
<td>Publication within stated quarter</td>
<td>75%</td>
</tr>
<tr>
<td>Publish 40 medtech innovation briefings (MIBs)</td>
<td>Publication within stated quarter</td>
<td>75%</td>
</tr>
<tr>
<td>Submit advice to Ministers on 12 Patient Access Schemes</td>
<td>Publication within stated quarter</td>
<td>75%</td>
</tr>
<tr>
<td>Deliver up to 14 Commissioning Support Documents to NHS England</td>
<td>Publication within stated quarter</td>
<td>75%</td>
</tr>
<tr>
<td>Publish 40 evidence surveillance reviews</td>
<td>Publication within stated quarter</td>
<td>75%</td>
</tr>
<tr>
<td>Publish 20 evidence summaries – new medicines, unlicensed and off-label medicines</td>
<td>Publication within year</td>
<td>80%</td>
</tr>
<tr>
<td>Publish 33 quality standards</td>
<td>Publication within stated quarter</td>
<td>75%</td>
</tr>
<tr>
<td>Publish 1 indicator set</td>
<td>Publication within year</td>
<td>100%</td>
</tr>
<tr>
<td>Publish 10 new quality and productivity case studies</td>
<td>Publication within stated quarter</td>
<td>80%</td>
</tr>
<tr>
<td>Publish at least 6 Cochrane quality and productivity commentaries</td>
<td>Publication within stated quarter</td>
<td>80%</td>
</tr>
<tr>
<td>Publish 30 endorsement statements</td>
<td>Publication within stated quarter</td>
<td>80%</td>
</tr>
</tbody>
</table>

**Provision of support products for the effective implementation of guidance**

<table>
<thead>
<tr>
<th>Provision of support products for the effective implementation of guidance</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Conduct a minimum of 30 first adoption engagements</td>
<td>Publication within year</td>
</tr>
<tr>
<td>Publish 80 Resource impact assessment products</td>
<td>Publication within year</td>
</tr>
<tr>
<td>Complete a minimum of 5 adoption support products</td>
<td></td>
</tr>
</tbody>
</table>

**Development and publication of evidence awareness services**

<table>
<thead>
<tr>
<th>Development and publication of evidence awareness services</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish 12 monthly updates of the BNF and BNF C content</td>
<td>Publishing within stated quarter</td>
</tr>
<tr>
<td>Publish a regular medicine awareness service</td>
<td>Publishing to regular weekly and daily (working day) schedule</td>
</tr>
<tr>
<td>Publish 16 Medicines optimisation key therapeutic topics</td>
<td>Publishing within stated quarter</td>
</tr>
<tr>
<td>25 medicines evidence commentaries</td>
<td>Publishing within stated quarter</td>
</tr>
<tr>
<td>5 education and dissemination events for NICE medicines and prescribing associates</td>
<td>Publishing within stated quarter</td>
</tr>
</tbody>
</table>
### Investment: Investing in the organisation

<table>
<thead>
<tr>
<th>Critical Success Factors</th>
<th>Key Measures</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Delivering programmes and activities on budget</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effective management of financial resources</td>
<td>Revenue spend</td>
<td>To operate within budget</td>
</tr>
<tr>
<td>Effective management of Scientific Advice income generated activity</td>
<td>Net income and expenditure total</td>
<td>To recover all direct costs and overheads</td>
</tr>
<tr>
<td>Effective management of other non-exchequer income sources such as NICE International</td>
<td>Expenditure within anticipated income from grants and other sources</td>
<td>To operate within allocated resource</td>
</tr>
<tr>
<td>Produce the annual report and accounts within the statutory timeframe</td>
<td>Publications</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Maintaining and developing a skilled and motivated workforce</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Management of recruitment</td>
<td>Proportion of posts appointed to within 4 months of first advertisement</td>
<td>80%</td>
</tr>
<tr>
<td>Management of sickness absence</td>
<td>Quarterly sickness absence rate is lower than NHS average rate (3.7% Apr-Jun 2011) or general rate for all sectors (2.8%)</td>
<td>90%</td>
</tr>
<tr>
<td>Management of training</td>
<td>% of allocated funds for training spent within the year on identified personal development needs</td>
<td>90%</td>
</tr>
<tr>
<td>Staff satisfaction</td>
<td>Proportion of staff reporting in staff survey that the Institute is a good, very good or excellent place to work (global job satisfaction index)</td>
<td>75%</td>
</tr>
<tr>
<td>Staff involvement</td>
<td>Hold monthly staff meetings</td>
<td>80%</td>
</tr>
</tbody>
</table>
## Sustainable Development

<table>
<thead>
<tr>
<th>Critical Success Factors</th>
<th>Key Measures</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recycled waste</td>
<td>% of total waste recycled</td>
<td>50%</td>
</tr>
</tbody>
</table>

### Reputation: Improving stakeholder satisfaction

<table>
<thead>
<tr>
<th>Critical Success Factors</th>
<th>Key Measures</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improving stakeholder satisfaction</td>
<td>Complaints fully responded to in 20 working days</td>
<td>80%</td>
</tr>
<tr>
<td></td>
<td>Enquiries fully responded to in 18 working days</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>Number of Freedom of Information requests responded to within 20 working days</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>PQs contribution provided within requested time frame</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>DPA requests responded to within 40 calendar days</td>
<td>100%</td>
</tr>
<tr>
<td>Ensuring stakeholders have access to our websites as the main communication channel</td>
<td>Percentage of planned availability, not including scheduled out of hours maintenance</td>
<td>98%</td>
</tr>
<tr>
<td>Interest in opportunities for lay people (patients, carers, service users, community members) to sit on our advisory reflected by ratio of applications to positions</td>
<td>2 to 1 (or greater) each quarter</td>
<td>100%</td>
</tr>
<tr>
<td>To support the HTAP ambition to the expand the Medical Technologies Industry in the UK by providing advice to suppliers that helps them to identify market opportunities, improve outcomes for patients and benefit from the use of their products in the NHS</td>
<td>A minimum of 16 engagements with suppliers undertaken</td>
<td>100%</td>
</tr>
</tbody>
</table>
### Critical Success Factors

<table>
<thead>
<tr>
<th>Maintaining and developing recognition of the role of NICE</th>
<th>Key Measures</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social care providers and commissioners gaining understanding of using NICE guidance and quality standards</td>
<td>Local Authorities, authorities with a social care commissioner role have a policy for working with NICE social care guidance and quality standards. 10 examples of social care providers prioritising, using and auditing against NICE quality standards.</td>
<td>50%</td>
</tr>
<tr>
<td>Ensure ongoing awareness of NICE equality strategy and implementation across all programmes</td>
<td>Produce an annual Equality Report</td>
<td>100%</td>
</tr>
<tr>
<td>Coverage of NICE in the media</td>
<td>% of positive coverage of NICE in the media resulting from active programme of media relations</td>
<td>80%</td>
</tr>
</tbody>
</table>

### Change and Business Improvement: Improving the way we work

<table>
<thead>
<tr>
<th>Improving efficiency and speed of outputs</th>
<th>Key Measures</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speed of production</td>
<td>% STAs for all new drugs issuing an ACD or FAD within 6 months of the product being first licensed in the UK</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>' % of multiple technology appraisals from invitation to participate to ACD in 41 weeks, or where no ACD produced to FAD in 44 weeks</td>
<td>85%</td>
</tr>
<tr>
<td></td>
<td>% of Appeal Panel decisions received within 3 weeks of the hearing</td>
<td>80%</td>
</tr>
</tbody>
</table>
# Appendix 2 - Activity Analysis 2016-17

<table>
<thead>
<tr>
<th>Programme</th>
<th>2015-16 published outputs</th>
<th>2016-17 planned outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social care guidelines¹</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Clinical guidelines, including rapid updates²</td>
<td>34</td>
<td>25</td>
</tr>
<tr>
<td>Public health guidelines</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Medicine practice guidelines</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Quality standards (including Social Care and Public Health)</td>
<td>36</td>
<td>33</td>
</tr>
<tr>
<td>Technology appraisals (including Cancer Drugs Fund reconsiderations)</td>
<td>45</td>
<td>50</td>
</tr>
<tr>
<td>Highly specialised technologies guidance</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Medical technologies guidance</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Medtech Innovation Briefings</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>Diagnostics guidance</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Commissioning Support Documents</td>
<td>n/a</td>
<td>Up to 14</td>
</tr>
<tr>
<td>Interventional procedures guidance</td>
<td>34</td>
<td>35</td>
</tr>
<tr>
<td>Evidence Summaries - New Medicines, Unlicensed / Off label Medicines</td>
<td>25</td>
<td>20</td>
</tr>
<tr>
<td>Indicator menu (QOF and CCGOIS)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Adoption support products</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Resource impact assessment products³</td>
<td>90</td>
<td>80</td>
</tr>
<tr>
<td>Quality and productivity case studies</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Shared learning examples</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Endorsement statements for guidance support tools/ resources</td>
<td>16</td>
<td>30</td>
</tr>
<tr>
<td>Guidance producer accreditations</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Guidance surveillance reviews – clinical</td>
<td>30</td>
<td>40</td>
</tr>
<tr>
<td>Guidance surveillance reviews – public health</td>
<td>Inc above</td>
<td>12</td>
</tr>
<tr>
<td>New Cochrane topics</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

Notes:

1. Reduction in outputs due to sequencing of workload, and not a reduction in capacity.
2. The number of publications in 2015/16 was inflated by the inclusion of two series of guidelines (diabetes and trauma). The number for 2016/17 is also higher than the historical norm due to the use of a shortened update process.
3. Reduction in outputs reflects a reduction in guidance outputs.
### Appendix 3.1 - Centre and directorate budget allocations 2016/17

<table>
<thead>
<tr>
<th>Directorate</th>
<th>2016-17 Pay</th>
<th>2016-17 Non-pay</th>
<th>2016-17 Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>wte</td>
<td>£'000</td>
<td>£'000</td>
</tr>
<tr>
<td>Guidance and advice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Centre for Clinical Practice</td>
<td>97</td>
<td>5,671</td>
<td>11,935</td>
</tr>
<tr>
<td>Centre for Health Technology Evaluation</td>
<td>160</td>
<td>10,175</td>
<td>4,903</td>
</tr>
<tr>
<td>Health and Social Care Directorate</td>
<td>166</td>
<td>9,279</td>
<td>4,653</td>
</tr>
<tr>
<td>Evidence Resources Directorate</td>
<td>102</td>
<td>6,276</td>
<td>5,425</td>
</tr>
<tr>
<td>NICE International¹</td>
<td>12</td>
<td>782</td>
<td>0</td>
</tr>
<tr>
<td>Corporate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communications Directorate</td>
<td>78</td>
<td>3,824</td>
<td>432</td>
</tr>
<tr>
<td>Business Planning and Resources Directorate</td>
<td>53</td>
<td>2,579</td>
<td>5,594</td>
</tr>
<tr>
<td>Contingency Reserves</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Budget</strong></td>
<td><strong>668</strong></td>
<td><strong>38,586</strong></td>
<td><strong>34,645</strong></td>
</tr>
</tbody>
</table>

**Note:**

1. The NICE International pay budget for 2016-17 is included here. The corresponding income target to offset this expenditure is not shown, but is included in the sources of income figures discussed in the resource assumptions section of this business plan.
### Appendix 3.2 - Revenue projections in financial statements format

#### Statement of comprehensive net expenditure

<table>
<thead>
<tr>
<th>Year</th>
<th>£'000</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016-17</td>
<td></td>
</tr>
<tr>
<td><strong>Expenditure</strong></td>
<td></td>
</tr>
<tr>
<td>Staff costs</td>
<td>38,586</td>
</tr>
<tr>
<td>Depreciation &amp; Amortisation</td>
<td>1,000</td>
</tr>
<tr>
<td>Other expenditure</td>
<td>33,645</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>73,231</strong></td>
</tr>
<tr>
<td><strong>Income</strong></td>
<td></td>
</tr>
<tr>
<td>Income from activities</td>
<td>-14,180</td>
</tr>
<tr>
<td>Other income</td>
<td></td>
</tr>
<tr>
<td><strong>Net Expenditure</strong></td>
<td><strong>59,051</strong></td>
</tr>
</tbody>
</table>

#### Note 3 - Staff numbers and related costs

<table>
<thead>
<tr>
<th>Year</th>
<th>£'000</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016-17</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Employed</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salaries and wages</td>
<td>30,461</td>
<td>1,100</td>
</tr>
<tr>
<td>Social security costs</td>
<td>3,132</td>
<td></td>
</tr>
<tr>
<td>Employer contributions to NHSPA</td>
<td>3,993</td>
<td></td>
</tr>
<tr>
<td><strong>Total net costs</strong></td>
<td><strong>37,586</strong></td>
<td><strong>1,100</strong></td>
</tr>
<tr>
<td>Less recoveries in respect to outward secondments</td>
<td>-100</td>
<td>-100</td>
</tr>
</tbody>
</table>

---

March 2016
## Appendix 3.3 - Balance sheet projection

### Statement of Financial Position to 31 March 2017

<table>
<thead>
<tr>
<th></th>
<th>31 March 2017</th>
<th>£000</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-current assets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property, plant and equipment</td>
<td>3,000</td>
<td></td>
</tr>
<tr>
<td>Intangible assets</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>Non Current Receivables</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Total non-current assets</strong></td>
<td></td>
<td>3,150</td>
</tr>
<tr>
<td>Current assets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>2,000</td>
<td></td>
</tr>
<tr>
<td>Other current assets</td>
<td>2,000</td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>2,500</td>
<td></td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td></td>
<td>6,500</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td></td>
<td>9,650</td>
</tr>
<tr>
<td>Current liabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>-4,000</td>
<td></td>
</tr>
<tr>
<td>Provisions for liabilities and charges</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td></td>
<td>-4,000</td>
</tr>
<tr>
<td><strong>Non-current assets less net current liabilities</strong></td>
<td></td>
<td>5,650</td>
</tr>
<tr>
<td>Non-current liabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provisions for liabilities and charges</td>
<td>-1,000</td>
<td></td>
</tr>
<tr>
<td>Financial Liabilities</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Total non-current liabilities</strong></td>
<td></td>
<td>-1,000</td>
</tr>
<tr>
<td><strong>Assets less liabilities</strong></td>
<td></td>
<td>4,650</td>
</tr>
<tr>
<td>Taxpayers’ equity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General fund</td>
<td>3,900</td>
<td></td>
</tr>
<tr>
<td>Non-exchequer trading reserves</td>
<td>750</td>
<td></td>
</tr>
<tr>
<td><strong>Taxpayers’ equity</strong></td>
<td></td>
<td>4,650</td>
</tr>
</tbody>
</table>
## Appendix 3.4 - Cash flow projection

<table>
<thead>
<tr>
<th>Projected cash flow statement for year ending 31 March 2017 (£'000)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cash flows from operating activities</strong></td>
</tr>
<tr>
<td>Net surplus after cost of capital and interest</td>
</tr>
<tr>
<td>Adjustments for non-cash transactions</td>
</tr>
<tr>
<td>(Increase)/Decrease in trade and other receivables</td>
</tr>
<tr>
<td>Increase/(Decrease) in trade and other payables</td>
</tr>
<tr>
<td>Use of provisions</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td><strong>Cash flows from investing activities</strong></td>
</tr>
<tr>
<td>Purchase of property, plant and equipment</td>
</tr>
<tr>
<td>Purchase intangible assets</td>
</tr>
<tr>
<td>Proceeds of disposal of property, plant and equipment</td>
</tr>
<tr>
<td>Proceeds of disposal of intangibles</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td><strong>Cash flows from Financing Activities</strong></td>
</tr>
<tr>
<td>Payments in respect of finance leases and PFI contracts</td>
</tr>
<tr>
<td><strong>Net Cash inflow/(outflow) before financing</strong></td>
</tr>
<tr>
<td><strong>Net Parliamentary Funding</strong></td>
</tr>
<tr>
<td><strong>Net increase/(decrease) in cash equivalents</strong></td>
</tr>
<tr>
<td>Cash and cash equivalents at the beginning of the period</td>
</tr>
<tr>
<td>Cash and cash equivalents at the end of the period</td>
</tr>
</tbody>
</table>
Appendix 4: Board and Senior Management Team

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

Professor David Haslam CBE  Chair
Dr Rosie Benneyworth  Non-Executive Director
Mr Tim Irish  Non-Executive Director
Professor Finbarr Martin  Non-Executive Director
Professor Rona McCandlish  Non-Executive Director
Mr Andy McKeon  Non-Executive Director
Mr Bill Mumford  Non-Executive Director
Ms Linda Seymour  Non-Executive Director
Mr Jonathan Tross CB  Non-Executive Director

Sir Andrew Dillon CBE*  Chief Executive
Professor Mark Baker  Director: Centre for Clinical Practice
Mr Ben Bennett*  Director: Business Planning and Resources
Ms Jane Gizbert  Director: Communications
Professor Gillian Leng CBE*  Director: Health and Social Care
Professor Carole Longson MBE*  Director: Centre for Health Technology Evaluation
Ms Alexia Tonnel  Director: Evidence Resources

Note: * Executive Directors
Appendix 5 – Organisational Chart

Chief Executive

- Centre for Clinical Practice
  - Clinical guidelines, Medicines and prescribing, BNF

- Centre for Health Technology Evaluation
  - Technology appraisals, Interventional procedures, Medical devices and diagnostics, Scientific Advice, Science policy and research, Topic Selection, Highly Specialised Technologies, Office for Market Access

- Health and Social Care
  - Adoption and uptake, public health and social care guidelines, leadership and engagement, public involvement, and quality

- Business Planning and Resources
  - Finance and facilities, Human resources, IT and procurement, business planning, Corporate Office

- Communications
  - Media relations, Corporate communications, enquiry handling, website and editorial

- Evidence Resources
  - Information services, On-line evidence services, Digital transformation, Syndication services

- NICE International
  - Capacity-building and technical support in low and middle income economies
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

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.

This paper presents the relevant themes for NICE that have been extracted from the analysis of comments received in the joint consultation with NHS England. It includes responses to the issues raised, and a list of next steps.

The appendices to the paper include the NHS England Board paper of 25 February 2016 and the NEL Commissioning Support Unit report presenting an analysis of responses to the consultation of 24 February 2016.

The Board is asked to consider the following questions and to authorise the Director of the Centre for Health Technology Evaluation to engage with NHS England to establish the methods, processes and joint working arrangements in support of the new CDF:

- Is the Board content with the proposals, set out in paragraphs 22 to 37 below, for handling the issues raised by consultees, relating to NICE’s methods and processes?
- Is the Board content with the response to consultation and the actions proposed set out in paragraph 38 below?
- Is the Board content for NICE to engage with NHS England in the implementation of the proposed arrangements for the Cancer Drugs Fund, from 1 July 2016, subject to the resolution of the matters identified as outstanding for resolution in the CDF Standard Operating Procedure?

Professor Carole Longson
Director, Centre for Health Technology Evaluation
March 2016
Introduction

2. This paper provides a covering note for, and draws out relevant themes from the analysis of the responses to consultation on the joint proposal for new arrangements for the Cancer Drugs Fund (CDF), put forward by NICE and NHS England. The public consultation, which closed on 11 February, received 286 responses through both the consultation hub and in written submissions. In addition, four webinars for stakeholders (85 attendees) and two face-to-face events in London and Manchester (115 attendees) were organised, along with a number of individual meetings with key stakeholder groups.

3. The consultation document sets out how NHS England (NHSE) will rely on NICE to undertake the evaluation of new licensed cancer medicines and to make recommendations as to whether they should be made available for routine use, for conditional use for a limited period in the CDF, or not recommended.

4. The Board of NHS England met on 25 February to consider its response to consultation and to make decisions about the future of the CDF. It considered the consultation response paper set out at Appendix A and agreed:

   • To the implementation of a new managed access fund, with clear entry and exit criteria;
   
   • That the new scheme should go live from 1 July 2016 to allow for further work on the operational detail;
   
   • That existing CDF drug indications should continue to receive transitional funding, subject to certain conditions, from 1st April 2016 until the point that NICE is able to complete their appraisal or reconsideration of these drugs;
   
   • To implement the proposed financial control mechanisms as described in the consultation document; and
   
   • To fix the overall budget for the CDF to a maximum of £340m per annum.

5. NHS England also identified a number of matters, which need further consideration, in discussion with NICE and which it has remitted to its executives for resolution. The final position on a number of these issues will
be set out in a new Standard Operating Procedure (SOP) for the new CDF, to be published by June 2016.

6. The NHS England Board paper specifically highlighted the following areas as requiring further consideration as the operational detail of new CDF is developed:

- The practical aspects of publishing initial NICE recommendations prior to marketing authorisation.
- The risk of providing interim funding for drugs from the point of marketing authorisation if a NICE draft recommendation has not been produced.
- Ensuring that rarer cancers are not overlooked. This includes recognising the importance of off-label drugs and considering what the role of NICE could be in the evaluation of off-label treatments in the future.
- The proposal to limit funding to the number of patients required to support evaluation.
- Alternative approaches to limiting the total cost of any single drug or indication while in the CDF (the consultation document contained a proposal to limit funding to the number of patients required to support evaluation).
- The importance of securing accurate data collection on key clinical outcomes.

Changes to NICE’s processes and methods

7. The consultation document set out the process and methods that NICE will use to make recommendations on the use of cancer drugs in the future. The principal changes to our current processes relate to the timing of the start of our cancer drug appraisals, relative to the receipt by a company of the marketing authorisation for its cancer drugs, and the establishment of joint arrangements, with NHSE, to determine the basis on which drugs recommended for the new CDF are entered into it. The comments and challenges to these proposals are considered in the NHS England Board paper on the Cancer Drugs Fund of 25 February (Appendix A), and in the NEL Commissioning Support Unit report ‘consultation on proposals for a new cancer drugs fund (CDF) operating model from 1 April 2016; analysis of responses to the consultation (Appendix B).

8. Importantly, no significant change to our methods of appraisal were sought by NHSE or proposed in the consultation. This matters because both before and during the consultation, concern was expressed by some stakeholders that
the proposals may not go far enough in securing an appropriate level of access to new cancer medicines, citing the fact that NICE’s methods were not substantively changing as evidence for their concerns.

9. The Board will know that NICE does not unilaterally decide what treatments should be provided by the NHS. The Department of Health and NHS England are primarily responsible for determining the ambition for access to care and the outcomes that the NHS should achieve. Our role is to help the NHS deliver on the ambition set for it through the guidance and standards we produce. We cannot, therefore, change our methods without a signal from the Department of Health and NHS England that they want us to do so. Other than the changes to our End of Life treatments protocol that were proposed in the consultation document, no other modifications to our methods and processes have been requested.

Consultation response

10. Respondents to consultation were asked to answer 14 questions, of which 10 had three options; agree, disagree or unsure. Space for a free text response was provided for all of the questions.

11. The questions with implications for NICE’s methods and processes were:

- **Question 2**: Do you agree with the proposal that all new cancer drugs and significant new licensed indications will be referred to NICE for appraisal?

- **Question 3**: Do you agree with the proposal that the NICE Technology Appraisal Process, appropriately modified, will be used to evaluate all new licensed cancer drugs and significant license extensions for existing drugs?

- **Question 4**: Do you agree with the proposal that a new category of NICE recommendations for cancer drugs is introduced, meaning that the outcome of NICE Technology Appraisal Committee’s evaluation would be a set of recommendations falling into one of the following three categories: i.) Recommended for routine use, ii.) Recommended for use within the Cancer Drugs Fund, iii.) Not recommended?

- **Question 5**: Do you agree with the proposal that “patient population of 7000 or less within the accumulated population of patients described in the marketing authorisation” be removed from the criteria for the higher cost effectiveness threshold to apply?
• **Question 6**: Do you agree with the proposal for draft NICE cancer drug guidance to be published before a drug receives its marketing authorisation?

• **Question 7**: Do you agree with the process changes that NICE will need to put in place in order for guidance to be issued within 90 days of marketing authorisation, for cancer drugs going through the normal European Medicines Agency licensing process?

12. The next set of paragraphs broadly describes the feedback received for each of these questions, organised in four themes.

**Referral of all new cancer drugs and significant license extensions (Q2&3)**

13. The majority of respondents agreed with the proposal for NICE to appraise all new cancer medicines and significant license extensions (67% in Q2 and 60% in Q3).

14. Concerns were raised about the workload for NICE, and in particular whether enough resources will be made available to ensure that the process of appraisal would not take too long as a consequence. Some consultees raised concern about the appropriateness of the NICE process for the appraisal of rarer cancers in particular, signalling that they feel the changes do not go far enough to ensure rare cancers and cancers of unmet need will receive a better chance of being recommended.

15. A large proportion of the respondents from pharmaceutical industry, companies and representative bodies, 62%, either disagreed or were unsure about the proposal, mostly because they want ‘NICE ‘reform’ and a ‘broader value assessment’ framework.

**New ‘recommended for use in the CDF’ category (Q4)**

16. Between two thirds and three quarters of respondents indicated support for a new category of recommendations to allow products to be considered for use within the CDF. Some of those disagreeing expressed the view that cancer should not be treated differently, and that therefore there should not be a CDF at all.

17. One respondent called for more specificity in guiding the appraisal committees in their decision making around the parameters of uncertainty that need to be considered, including what level of uncertainty would be acceptable, how the committee is to determine whether the uncertainty has the potential to be resolved, and what timeframes for evidence generation would be considered acceptable.
Changes to ‘end of life’ criteria (Q5)

18. Most of those responding for pharmaceutical companies and industry bodies agreed with the proposal to remove the restriction of ‘size of the patient population to 7000’ from the ‘end of life’ criteria, but also noted that, in their view, removing this criterion is likely to make little difference in practice to the number of medicines NICE is likely to recommend.

19. Comments received from patients and the public, as part of a large proportion (43%) stating that they were ‘unsure’ about the proposals, suggested that the question was phrased in a way that didn’t make it clear what the consequence of the change would be.

Guidance publication within 90 days of marketing authorisation (Q6&7)

20. Responses to the two questions directed at the proposal for NICE to produce guidance within 90 days of marketing authorisation were mixed. A majority of the patient and public respondents (58 and 80%, respectively, when answering question 6) agreed with the proposal for draft NICE guidance to be published before a drug receives its marketing authorisation, while over 60% of pharmaceutical companies and industry bodies did not.

21. Industry’s concern was directed at issues such as: NICE’s processes will need to be reformed, and this is not possible within the timeframe (of implementation of the new CDF); ‘the UK price of a medicine is not set until immediately prior to licensing, so how would NICE undertake an assessment of cost effectiveness’; ‘some companies don’t have the resources to submit early’; ‘as new data becomes available after the original submission, this will need to be inputted’.

22. For what concerns the specific process changes that NICE will need to put in place in order to meet the target of issuing guidance within 90 days of marketing authorisation, many respondents continued to express concern that 90 days was still too long, and that NICE would not be able to cope and make decisions in a timely manner.

Response to issues relating to NICE’s methods and processes

Capacity

23. A key question raised by many in consultation, during engagement sessions, and by the Public Accounts Committee is whether NICE has the capacity to deliver on the expected increase in the number of topics to be appraised, especially when guidance is to be produced earlier than now is the case.
24. In 2015, NICE submitted a business case to NHSE for the additional resources needed in the Technology Appraisal programme and in supporting functions at NICE required to support the expected increase in workload. The business case envisages the following key activities for NICE:

- manage the operational and strategic interface between NICE and NHS England;
- support the Cancer Drugs Fund Investment Group (a joint group of NHS England and NICE) in its governance role for the new CDF;
- support the activities related to data collection governance, synthesis and interpretation;
- monitor the use of drugs included in the CDF over time;
- plan, administer and coordinate all the procedures necessary to deliver technology appraisals in the context of the CDF;
- deliver an increase in output of cancer technology appraisals;
- accommodate an increase in Patient Access Schemes and to provide advice on the feasibility of Commercial Access Arrangements to NHS England.

25. The funding for staff, non-pay resources and overheads, amounts to approximately £2m in the first year, and £1.9m in steady state. NHS England has indicated that they will make these resources available. Recruitment has started for key positions, at risk but underwritten by NHS England for 2016-17, and will continue from 1 April 2016, once approval for the full business case has been received. Specific funds to support the transition work for the group 1 products are included in the business case. Separate funds are allocated for the National Institute for Health Research (NIHR) to commission Evidence Review Groups (ERGs) to support the increase in demand for technology appraisals and the transition work.

**Timeliness**

26. As indicated in the consultation document, NICE’s ability to produce guidance within 90 days of marketing authorisation is largely a function of topics having been identified early enough to enable us to do so, and companies keeping NICE informed of the plans for regulatory approval, including the exact date/month in which European Medicines Agency’s Committee for Human Medicinal Products (CHMP) opinion is expected. Experience teaches us that individual companies will deal with this requirement differently, and therefore it will not be possible to unequivocally state that we will succeed in doing so for
all cancer products, which is why the consultation proposal used the word ‘normally’ when referring to the publication of draft guidance before Marketing Authorisation is granted.

27. A key potential constraint for NICE in being able to publish guidance within 90 days of marketing authorisation will be the approval of any Patient Access Schemes, by the Department of Health. The Patient Access Scheme Liaison Unit (PASLU) is already facing a very significant workload, and although extra resources are included in the business case for NICE, these do not extend to the team within the Department of Health that processes PASLU advice and seeks Ministerial approval.

28. Similarly, the process and procedures for the development of ‘commercial access agreements’ are still under consideration within NHS England, and the role of the CDF Investment Group in this regard will need further exploration.

29. At least one respondent has asked for consideration to be given to allowing individual companies the flexibility to determine the most appropriate timeline for a NICE submission; jointly agreed where necessary between NICE, NHS England and the company.

30. Finally, the commitment to producing guidance within 90 days of marketing authorisation will only apply to topics referred to NICE for appraisal by Ministers after 1 April 2016. Attempting to apply this to topics already referred, would mean a complete overhaul of the existing work programme, and will lead to questions about fairness to stakeholders in technology appraisals whose slots would have to be used for this purpose.

31. NICE expects to work through these issues with colleagues in NHS England in the context of development of the SOP. It is unlikely that this is able to provide the flexibility for individual companies to determine the timing of their submission to NICE, unless the company at the same time commits to not launching the product in the NHS in England in the immediate future (some companies may consider this to be an appropriate commercial strategy).

‘End of life’

32. Although consultation responses indicated broad support for the proposed changes to the end of life criteria, some respondents suggested further amendments. The Association of the British Pharmaceutical Industry, in particular, asked us to consider:

- an extension of the life expectancy criterion to 36 months (in line with that used by the Scottish Medicines Consortium);
- making overall survival benefit proportional to average length of life;
• attributing value to medicines where a sizeable proportion of patients have significantly more than 3 months overall survival benefit;

• implementing a higher cost-effectiveness threshold for all breakthrough medicines;

• implementing a higher cost-effectiveness threshold for rarer cancers and orphan medicines.

33. None of these suggested changes formed part of the consultation proposals and whatever their merit, NICE cannot unilaterally give consideration to them, for the reasons set out in paragraph 9.

Recommendations for use in CDF

34. Respondents generally welcomed the introduction of a further category of recommendations to be used by the Appraisal Committee to allow for managed access in the context of the CDF, although some indicated that its introduction had to go hand-in-hand with broader NICE reform as patients would otherwise be no better off.

35. One respondent suggested that more specificity is needed to guide the Appraisal Committee in their decision making. For example, what level of uncertainty would be acceptable, how would the Committee determine whether the uncertainty as the potential to be resolved and what timeframes for data generation would be considered acceptable for each case.

36. Work is already underway in the context of the NICE strategic technology appraisal review to address specifically the direction given to the Appraisal Committees on what consideration needs to be given to the potential for formulating recommendations with evidence collection or managed access.

Data collection

37. Respondents have noted the fact that the consultation document did not include much detail of what is expected of data collection during the managed access period. Some argued that the restriction to two years is not reflective of what is likely to be needed for individual technology appraisals, and therefore would advocate flexibility on a case-by-case basis. In addition, agreeing data collection protocols, receiving ethical and R&D approval will take months to deliver an acceptable outcome for all parties involved.

38. Further detail on data collection will need to be worked through in development of the SOP with NHS England, Public Health England (as this houses the Systemic Anti-Cancer Therapy dataset team) and will involve NICE’s Observational Data Unit.
Next steps

39. Taking into account the response to consultation, it is proposed NICE takes the following actions:

- Recruit to the full complement of staff as listed in the business case submitted to NHS England, with the aim of having most in place by September 2016;

- Publish the amendments to the Technology Appraisal processes and methods, as presented in appendix B of the consultation proposals, on the NICE website on 1 April 2016;

- Work through the operational arrangements for producing guidance within 90 days of marketing authorisation, and liaise with NHS England on how to reflect these arrangements in the SOP by June 2016;

- Develop further detailed instructions for Appraisal Committees on the considerations to be taken into account in formulating recommendations for use within the CDF;

- Use the experience of the NICE Observational Data Unit in the consideration of arrangements for data collection to inform inclusion in the SOP by June 2016.

Decisions for the Board

40. The Board is asked to consider the following questions and to authorise the Director of the Centre for Health Technology Evaluation to engage with NHS England to establish the methods, processes and joint working arrangements in support of the new CDF:

- Is the Board content with the proposals, set out in paragraphs 22 to 37 above, for handling the issues raised by consultees, relating to NICE’s methods and processes?

- Is the Board content with the response to consultation and the actions proposed set out in paragraph 38 above?

- Is the Board content for NICE to engage with NHS England in the implementation of the proposed arrangements for the Cancer Drugs Fund, from 1 July 2016, subject to the resolution of the matters identified as outstanding for resolution in the CDF Standard Operating Procedure?
Professor Carole Longson
Director, Centre for Health Technology Evaluation
March 2016


Appendix B - Consultation on proposals for a new cancer drugs fund (CDF) operating model from 1 April 2016; analysis of responses to the consultation. NEL Commissioning Support Unit for NHS England. 24 February 2016
Title:
Cancer Drugs Fund

Lead Director:
Bruce Keogh, National Medical Director / Paul Baumann, Chief Financial Officer

Purpose of Paper:
A 12 week public consultation on proposals for reforming the Cancer Drugs Fund (CDF) closed on 11th February 2016. In light of consultation responses received, the Board is asked to consider and agree proposals for a phased and managed transition from the current CDF to a new operating model. In particular this includes:

- Agreeing the implementation of a new managed access fund, with clear entry and exit criteria;
- Agreeing that the new scheme should go live from 1 July 2016 to allow for further work on the operational detail;
- Agreeing that existing CDF drug indications should continue to receive transitional funding, subject to certain conditions, from 1st April 2016 until the point that NICE is able to complete their appraisal or reconsideration of these drugs;
- Agreeing the financial control mechanisms set out in this paper; and
- Agreeing the overall budget for the CDF of £340m.

For patients, the new CDF will help provide faster access to the most promising new cancer treatments.

For taxpayers, the new CDF will drive stronger value for money in drugs expenditure.

For drug companies willing to price their products responsibly, the new CDF offers a new fast-track route to NHS funding for promising drugs at the point of marketing authorisation, with a speeded up and more transparent NICE assessment process.

The Board is invited to:
The Board is asked to approve the proposal set out in this paper.
CANCER DRUGS FUND

PURPOSE

1. The Board concluded in late 2015 that the current arrangements for the Cancer Drugs Fund (CDF) were unsustainable and inappropriate, and that there was a need for fundamental and urgent change to the fund’s operating model; this need was also underlined by the National Audit Office (NAO), the Public Accounts Committee (PAC) and the independent Cancer Taskforce in recent reports. They and others argued that while the current CDF has produced meaningful benefits, it also has badly overspent—thereby subtracting funding from other aspects of cancer care and other patient services. In part this has been because the current CDF has led to potentially inflated drug prices for sometimes limited efficacy, offering poor value for money. With the approval of the Board, we therefore initiated a joint 12 week public consultation with the National Institute for Health and Care Excellence (NICE) regarding a new CDF operating model, and this closed on 11 February 2016. In the light of this consultation, the Board is asked to consider and agree proposals for a phased and managed transition from the current CDF to a new operating model. NICE will be taking those aspects of the proposals that are relevant to their processes and methods to their Board for approval on 17 March 2016.

2. The consultation report at Annex A includes details of the number of responses by stakeholder type and responses to each consultation question. The original text of replies is available to the Board on request. The published consultation document is included at Annex B.

OVERVIEW

3. The proposal, aspects of which have been amended in the light of consultation, is as follows:

- The CDF becomes a new managed access fund with clear entry and exit criteria, in line with the proposals set out in the consultation document;

- The new scheme will ‘go live’ from 1 July 2016. From this point, new drugs will be able to enter the CDF under the terms of the new scheme;

- The operational detail of the new scheme will be developed over the coming months, informed by further detailed analysis and consideration of the consultation responses received. A new Standard Operating Procedure will be published by June;

- On 1 April 2016 the current CDF list will be rolled over but will remain closed to new drugs pending the start of the new scheme in July 2016. All existing CDF drugs will continue to receive funding until the point that NICE has been able to appraise / re-consider them (unless their manufacturer/sponsor does not co-operate promptly with the appraisal process). Off-label drugs will also continue to receive funding until such time as a routine funding decision can be taken;

- Any existing CDF drug that is not recommended for continued use within the new CDF or for routine commissioning as a consequence of this appraisal / re-consideration process will be given a notice period. However, patients in receipt of those drugs will continue to receive them. This period of notice will not be given any earlier than 1 July 2016. Ahead of these appraisal / re-considerations, relevant companies will have had, where clinically appropriate, the opportunity to review their pricing levels with a view to their product either continuing to receive CDF funding or being approved for “routine commissioning” by NICE;
• In preparation for the operational start of the new scheme, NICE will begin using their proposed new methodology for appraisals from 1 April 2016, subject to consideration and approval by the NICE Board; and

• The fixed financial limit of £340m for the CDF will fund both new and transitional CDF drugs. Should the need arise, the same financial control mechanisms will be applied to both new drugs and existing CDF drugs awaiting appraisal / re-consideration. Acceptance of those controls will be made a condition of existing drugs awaiting appraisal / re-consideration remaining in the CDF after 1 July 2016.

CONTEXT

4. The CDF was developed in 2010 to improve access to cancer drugs that had not been adopted for routine use in the NHS. It provided the capability to fund drugs that were not eligible to go through the NICE appraisal process, such as drugs for rare conditions. It was only ever intended as a temporary measure and, as such, no clear criteria to allow drugs to exit the fund were developed. The current version of the CDF was set to expire in April 2016.

5. The annual budget for the CDF has been increased from £200m in 2011/12 to £340m in 2015/16. Despite this, the CDF has exceeded its allocated budget each year since 2013/14, primarily because more and more drugs have entered but few have had issues of clinical and cost effectiveness uncertainty resolved. The National Audit Office and Public Accounts Committee have both criticised these overspends.

6. Two delisting exercises have been undertaken in order to help bring significant budget overspends under control, but these have not had sufficient impact and the current approach represents a completely unsustainable way of commissioning cancer drugs.

7. The NAO, Public Accounts Committee and the independent Cancer Taskforce have all recognised in recent reports that there is a need for the CDF to change. In particular, the PAC indicated that ‘NHS England should set clear objectives for what the fund is seeking to achieve, and be prepared to take tough decisions to ensure the Fund does not overspend’. This requires an improved methodology for budget management, an efficient means of evaluating the effectiveness of drugs and transparency for pharmaceutical companies.

8. In addition to CDF reform, the Department of Health is developing proposals for its Accelerated Access Review (AAR) which is seeking to develop sustainable ways of increasing the uptake of transformative drugs and technologies, including ‘Breakthrough’ drugs, across all conditions. There will be opportunities to further consider alignment here providing the conclusions and recommendations of the AAR are available in advance of finalising the new CDF Standard Operating Procedure.

CONSULTATION

9. An analysis of the consultation responses is provided at Annex A. We received 286 responses in total through both the consultation hub and written submissions. In addition we held four webinars for stakeholders (85 attendees) and two face-to-face events in London and Manchester (115 attendees) alongside a number of individual meetings with key stakeholder groups. The table below outlines the response rates for each question.

10. Three key themes emerged from the consultation:

• Firstly, there was significant support for change, including specifically a move to a managed access process;

• Secondly, stakeholders suggested that there was a need to conduct further work to refine
and clarify the operational detail with regard to the management of the new CDF, particularly entry & exit criteria and financial control mechanisms; and,

- Thirdly, respondents were keen to understand more about the transition between the old and new operating models.

11. Some consultees expressed concern about whether the proposals would lead to more or less access to cancer drugs for patients when compared to the current system. In contrast, the consultation also produced strong views from some respondents that prioritising cancer drugs through the CDF was not equitable when compared to other conditions. There were also calls for broader and more general reform of NICE in order to improve access to and evaluation of all treatments.

12. 264 of the consultation responses provided quantifiable information. The breakdown of responses is summarised in figures 1 and 2 below (please note not all respondents replied to all 14 questions) and the list of questions asked is included at Appendix 1.

**Figure 1: Overall summary of responses to all questions**

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**Figure 2: Breakdown of responses by stakeholder group**

- Patients
- Members of the public
- Pharmaceutical companies and industry bodies
- Patient and voluntary groups
- NHS organisations
- Healthcare professionals
- Other
A NEW MANAGED ACCESS PROCESS

13. The consultation indicated support for the implementation of a managed access process. This process will utilise the clinical and health economics expertise of NICE and fulfil NHS England’s requirement to manage the budget efficiently by providing a clear basis for decisions about what enters and exits the CDF. **Appendix 2** presents the new CDF process as a diagram with supporting narrative.

14. The key aspects of the managed access process are:

- A change to existing process, meaning that all new licensed cancer drugs (including those that were previously not appraised due to small population size) will be referred to NICE for appraisal;

- A much faster NICE process such that NICE will make a draft recommendation before marketing authorisation. Any drugs that receive either a draft recommendation for routine commissioning or, where uncertainty exists, a recommendation for use within the CDF will receive interim funding from the CDF from the point of marketing authorisation;

- NICE will then normally issue final guidance within 90 days of marketing authorisation. If drugs are recommended for routine commissioning at this point, they will be funded by normal commissioning budgets. If drugs are recommended for substantive entry into the CDF, a joint NHS England and NICE CDF Investment Group will meet to agree the terms of any commercial access agreement, including evaluation criteria and a timescale for evaluation to complete;

- At the end of the CDF evaluation period NICE will re-appraise the drug with the aim of making a final positive or negative assessment as to whether the drug should be routinely commissioned. Any patients still in receipt of treatment with drugs not recommended for routine commissioning at this point will continue to be treated, but with the funding provided by the relevant drug company until their treatment is completed.

15. The NICE process leading to guidance normally being issued within 90 days of receipt of marketing authorisation will be put in place for topics referred by Ministers after 1st April 2016. This will only apply to products referred to NICE early enough to allow the commitment to be met.

16. It should be noted that the new process will satisfy one of the ambitions of the Early Access to Medicines Scheme, which rests on the earliest possible start for NICE technology appraisal. This should have a positive impact in terms of ensuring earlier funding of and patient access to those drugs that NICE consider to be clinically and cost effective or demonstrate the potential to be clinically and cost effective. This benefit would also be felt by those cancer drugs that had obtained a ‘Breakthrough’ designation. However, this also represents an additional demand upon NICE and consultation respondents were concerned regarding the capacity within NICE to undertake assessments in a timely manner. Following detailed discussions between NHS England and NICE, resource is being put in place to ensure delivery of the number of additional appraisals required within the stated timescales, and NICE has committed to these timescales accordingly.

**Recommendation 1:** The Board agrees to establish the CDF as a new managed access process with clear entry and exit criteria as set out in the consultation document and summarised at **Appendix 2**.
DETAILED OPERATING PROCEDURE

17. The consultation identified a number of different opinions on how to operationalise a reformed CDF, and our stakeholder engagement events highlighted the need to take time to ensure an orderly transition to the new arrangements. As a result, we propose to implement a phased transition and begin the new CDF operating model from 1 July 2016. This gives NHS England and NICE time to refine and clarify the operational detail, taking into account relevant considerations arising from the consultation responses received during the consultation exercise just closed. The initial analysis indicates that it will be particularly important to consider carefully the following:

- The practical aspects of publishing initial NICE recommendations prior to marketing authorisation. Several pharmaceutical companies indicated that these would need to avoid pre-empting final wording within the marketing authorisation.

- The risk of providing interim funding for drugs from the point of marketing authorisation if a NICE draft recommendation has not been produced. Respondents indicated that this should be avoided by maintaining sufficient capacity within NICE. However, if a draft recommendation is not produced there is a danger of funding ineffective treatments which become difficult to withdraw from the CDF at a later date should the NICE evaluation be negative. This could create pressure on the CDF budget.

- Ensuring that rare cancers are not overlooked. This includes recognising the importance of off-label drugs and considering what the role of NICE could be in the evaluation of off-label treatments in the future.

- The proposal to limit funding to the number of patients required to support evaluation. Whilst this proposal was intended to maximise the number of drugs able enter the fund before further financial control mechanisms might need to be applied, 45 respondents questioned whether this was the best approach. Further consideration as to how best to maximise the breadth and depth of access, whilst remaining within the fixed financial envelope, will be important as the detailed operating procedure is developed.

18. Furthermore, the need for accurate data collection in terms of measuring key clinical outcomes will be critical to the success of the new CDF. The PAC has asked NHS England to report by June 2016 on what measures are being taken to improve data completeness. As such, and as part of the work to develop the operational detail, the Board is asked to note that it is our current intention that for drugs given substantive entry into the new CDF, any hospital trust wishing to administer such new CDF drugs must:

- have electronic prescribing systems in place and used for the prescribing of all intravenous and oral chemotherapy; and,

- be fully compliant with the collection of the Systemic Anti Cancer Therapy dataset for all its patients having intravenous and oral chemotherapy

19. A detailed standard operating procedure (SOP) will be submitted to the Specialised Services Commissioning Committee for approval and published by June 2016.

Recommendation 2: The Board agrees that the new scheme should go live from 1 July 2016, allowing time to work through important operational details, informed by relevant responses to the consultation, and that authority to agree the standard operating procedure and to make any other necessary arrangements and changes to the operational introduction or timing of the new scheme should be delegated to the Specialised Services Commissioning Committee.
TRANSITION ARRANGEMENTS – EXISTING CDF DRUGS

20. The consultation indicated that respondents wanted clear transition arrangements between the old and new CDF operating models. The following paragraphs set out the proposed arrangements, which will be further developed as part of the new Standard Operating Procedure between now and June.

21. In order to ensure a smooth and fair transition to the new scheme, it is proposed that the existing CDF list should “roll over” from 1 April 2016, with all drug indications continuing to receive funding until the point that NICE is able to issue a final appraisal / re-consideration decision (providing their manufacturer/sponsor co-operates with the NICE appraisal process). The current CDF scheme would continue to remain closed to new drugs pending the introduction of the new CDF operating model from 1 July 2016.

22. NICE will apply the new decision making methodology referred to in Appendix 2 to existing CDF drug indications, and could propose to the CDF Investment Group that the drug should be considered for the new CDF. NICE will set out its final appraisals and re-considerations timetable in March.

23. It is proposed that two conditions should apply to existing CDF drugs receiving transitional funding from 1 April 2016:

- Firstly, that reimbursement of each drug indication is no higher than the level as at 31 March 2016; and
- Secondly, that from 1 July 2016 existing CDF drugs receiving transitional funding (i.e. pending NICE appraisal / re-consideration) will be liable to the same financial control mechanisms as new drugs entering the new CDF (see affordability and financial control section below).

24. Any existing CDF drugs that are subsequently recommended for routine commissioning will cease to receive CDF funding, as their costs will be picked up as part of routine baseline commissioning. For existing CDF drugs appraised or re-considered as part of transition that are not recommended for routine commissioning, having taken account of the pricing that drug companies propose, companies will be given a notice period, but all patients already in receipt of these drugs will continue to get them.

25. In addition to the above process, we recognise that for certain rare cancers the provision of off-label drugs remains an important issue. The work to clarify the operational detail will consider the views of consultation respondents on how this should be addressed, but in the meantime existing CDF off-label drugs will continue to receive funding.

Recommendation 3: The Board agrees that, from 1 April 2016, the current CDF list should be rolled over but remain closed to new drugs, with funding made available until the point of NICE issuing guidance. The Board also notes the broader transitional arrangements proposed for existing CDF drugs and agrees to delegate final decisions on their application to the Chief Executive, National Medical Director and Chief Financial Officer, in partnership with NICE.

AFFORDABILITY AND FINANCIAL CONTROL

26. The CDF needs to be affordable. We recognise that consultation responses were uncertain regarding the proposal to fix the annual CDF budget but most comments indicate recognition of the need for improved budgetary control and a requirement to limit the impact of the CDF on
wider NHS services. The operational detail regarding financial control is still to be finalised and will explain clearly how the arrangements will work.

27. Based on the above proposals there is a period between 1 April 2016 and 30 June 2016, where the only call on the fixed CDF budget will come from existing drugs (transitional drugs). Financial modelling indicates that this restriction, coupled with expected NICE appraisal recommendations over this period, will ensure there is sufficient funding available in the first quarter share of the annual CDF funding for all transitional drugs.

28. The operational mechanisms regarding financial control are being put in place to allow for the flow of eligible new drugs into the CDF whilst ensuring that the CDF does not overspend. The published SOP will clearly describe these financial control mechanisms based on the following principles:

- the incremental cost effectiveness ratio of any new CDF drugs must potentially fall within the standard NICE range, if any reasonable uncertainty in the drug’s cost effectiveness were eventually to be resolved in the drug’s favour;

- the total cost of each individual drug to the CDF will be limited via the terms of the commercial access agreement put in place;

- a prospective contingency will be put in place whereby:
  - the amount paid by the CDF to all companies during the year is set at a consistent level below 100% of the sums otherwise due, with the remainder retained as a contingency;
  - if the CDF stays within the resulting net budget, the contingency will be released to companies;
  - if the CDF exceeds the net budget, the contingency will be retained as necessary to balance the budget, with the remainder paid to companies proportionately;
  - if the CDF exceeds the net budget and the contingency, the whole contingency will be used to reduce the overspend, and, exceptionally, a further across the board rebate for each CDF drug will be applied. (There are some parallels with the voluntary PPRS scheme rebate. However, at the request of the ABPI, spending on the CDF over and above £320m in 2016/17 will not be captured by the existing PPRS rebate mechanism, further underlining why other budget control mechanisms are needed).

29. The need to utilise the prospective contingency mechanism will depend on several factors, including the outcome of NICE appraisals on both existing CDF drugs and new drugs and the commercial arrangements put forward by drug manufacturers. Supplier agreement to all of the above mechanisms will be a condition of funding under the new arrangements from 1 July 2016 for both new drugs and those transferred from the existing CDF pending appraisal or re-consideration under the new scheme.

30. The operation of the financial control mechanisms will be the responsibility of the proposed CDF Investment Group, a joint committee of NHS England and NICE.

**Recommendation 4:** The Board approves the methodology for keeping CDF expenditure in line with the budget, including the transition from the old to new CDF operating models, confirms a fixed annual budget of £340m for the CDF, and agrees to delegate final decisions on the detail of the methodology to the Chief Executive, National Medical Director and Chief Financial Officer.
CONCLUSION

31. The Board is asked to consider and agree proposals for a phased and managed transition from the current CDF to a new operating model. In particular this includes:

- Agreeing the implementation of a new managed access fund, with clear entry and exit criteria;
- Agreeing that the new scheme should go live from 1 July 2016 to allow for further work on the operational detail;
- Agreeing that existing CDF drug indications should continue to receive transitional funding, subject to certain conditions, from 1st April 2016 until the point that NICE is able to complete their appraisal or reconsideration of these drugs.
- Agreeing the financial control mechanisms set out in this paper;
- Agreeing the delegations of authority described above; and,
- Confirming the overall budget for the CDF of £340m.

Author: Bruce Keogh, National Medical Director / Paul Baumann, Chief Financial Officer
Date: 25 February 2016
Appendix 1 – List of Consultation Questions

Question 1: Do you agree with the proposal that the CDF should become a ‘managed access’ fund for new cancer drugs, with clear entry and exit criteria?

Question 2: Do you agree with the proposal that all new cancer drugs and significant new licensed cancer indications will be referred to NICE for appraisal?

Question 3: Do you agree with the proposal that the NICE Technology Appraisal Process, appropriately modified, will be used to evaluate all new licensed cancer drugs and significant licence extensions for existing drugs?

Question 4: Do you agree with the proposal that a new category of NICE recommendations for cancer drugs is introduced, meaning that the outcome of the NICE Technology Appraisal Committee’s evaluation would be a set of recommendations falling into one of the following three categories:
   i. Recommended for routine use;
   ii. Recommended for use within the Cancer Drugs Fund;
   iii. Not recommended.

Question 5: Do you agree with the proposal that “patient population of 7000 or less within the accumulated population of patients described in the marketing authorisation” be removed from the criteria for the higher cost effectiveness threshold to apply?

Question 6: Do you agree with the proposal for draft NICE cancer drug guidance to be published before a drug receives its marketing authorisation?

Question 7: Do you agree with the process changes that NICE will need to put in place in order for guidance to be issued within 90 days of marketing authorisation, for cancer drugs going through the normal European Medicines Agency licensing process?

Question 8: Do you agree with the proposal that all drugs that receive a draft NICE recommendation for routine use, or for conditional use within the CDF, receive interim funding from the point of marketing authorisation until the final appraisal decision, normally within 90 days of marketing authorisation?

Question 9: What are your views on the alternative scenario set out at paragraph 38, to provide interim funding for drugs from the point of marketing authorisation if a NICE draft recommendation has not yet been produced, given that this would imply lower funding for other drugs in the CDF that have actually been assessed by NICE as worthwhile for CDF funding?

Question 10: Do you have any comments on when and how it might be appropriate for the CDF in due course to take account of off-label drugs, and how this might be addressed?

Question 11: Do you agree with the proposal to fix the CDF annual budget allocation and apply investment control mechanisms within the fixed budget as set out in this consultation document?

Question 12: Do you consider that the investment control arrangements suggested are appropriate for achieving transparency, equity of access, fair treatment for manufacturers and operational effectiveness, while also containing the budget? Are there any alternative mechanisms which you consider would be more effective in achieving those aims?

Question 13: Are there any other issues that you regard as important considerations in designing the future arrangements for the CDF?

Question 14: Do you agree that, on balance, the new CDF arrangements are preferable to existing arrangements, given the current pressures the CDF is facing?
Appendix 2 – The Managed Access Process

1: All new cancer drugs expecting to be licensed are referred to NICE for appraisal prior to marketing authorisation
2: NICE makes an initial recommendation based on clinical and cost effectiveness
3: Interim funding is provided by the CDF whilst NICE undertake their full appraisal
4: NICE makes a final recommendation. Drugs recommended to enter the CDF must meet NHS England commercial requirements
5: CDF drugs are evaluated against specific criteria for a set period. After the evaluation period they are given a ‘yes’ or ‘no’ recommendation by NICE
6: Light blue shading denotes where CDF funding applies (subject to financial controls & £340m budget)
CONSULTATION ON PROPOSALS FOR A NEW CANCER DRUGS FUND (CDF) OPERATING MODEL FROM 1 APRIL 2016

Analysis of responses to the consultation

24 February 2016
1. Introduction

This report covers the responses received to the consultation on the proposals for a new Cancer Drugs Fund operating model which ran from 19 November 2015 to 11 February 2016.

The use of quotes throughout the document is to illustrate some of the main issues raised. They do not necessarily reflect a balance of opinions.

2. The consultation in numbers

The consultation received 264 online responses and 22 written submissions. We are aware that there is some duplication; for example organisations which responded online, but also sent in a written submission.

3. Who responded to the consultation?

Responses were received from:

- 23 pharmaceutical companies, including:
  - AbbVie
  - Amgen
  - ARIAD
  - Astellas
  - Astra Zeneca
  - Baxalta
  - Baxter
  - Bayer
  - Boehringer Ingelheim
  - Bristol-Myers Squibb
  - Celgene
  - Eisai
  - Janssen
  - Merck
  - MSD
  - Novartis
  - Pfizer
  - Roche
  - Sanofi
  - Sobi
  - Takeda UK

1 This list contains the names given by respondents identifying themselves as Pharmaceutical Companies. Not all supplied their names.
o Nine professional and industry bodies, including:
  • Association of the British Pharmaceutical Industry
  • British Association of Urological Surgeons
  • British In Vitro Diagnostics Association
  • British Oncology Pharmacy Association
  • The Ethical Medicines Industry Group (EMIG)
  • Royal College of Radiologists
  • Royal College of Physicians
  • Royal College of Surgeons
  • UK BioIndustry Association

o 29 responses from the patient and voluntary groups\(^2\), including:
  • Action on Smoking and Health
  • Bloodwise
  • Cancer Research UK
  • Beating Bowel Cancer
  • Breast Cancer Care
  • Breast Cancer Now
  • The Blood Cancer Alliance
  • Cancer52
  • CLL Support Association
  • Genetic Alliance UK
  • Leukaemia CARE
  • Lymphoma Association
  • Myeloma UK
  • Ovarian Cancer Action
  • Pancreatic Cancer UK
  • Prostate Cancer UK and Tackle
  • Rarer Cancers Foundation
  • Target Ovarian Cancer

o NHS organisations:
  • Nine NHS acute trusts
  • Two NHS community organisations

o Two trade unions

o Other organisations and individuals, which include:
  • All Party Parliamentary Group on Pancreatic Cancer
  • All Party Parliamentary Group on Cancer
  • Brain Tumour Research
  • Clinical Commissioning Groups and other NHS organisations
  • London Cancer
  • Members of Parliament
  • NHS England
  • Public Health England

o Three educational establishments

\(^2\) This list contains the names given by respondents identifying themselves as patient and voluntary groups. Not all supplied their names.
‘Sunlight’ provision/conflict of interest disclosures

Respondents were asked whether they had received any payments, grants or other funding from the pharmaceutical industry in the last three years.

Overall, 34% of respondents declared they had received payments from drug companies.

The highest percentage of respondents affirming that they had received such payments were patient and voluntary organisations, 81% of whom said they received drug company funding.
4. Analysis of responses to the questionnaire by question

Question 1: Do you agree with the proposal that the CDF should become a ‘managed access’ fund for new cancer drugs, with clear entry and exit criteria?

61 per cent of respondents agreed with the proposal, with 27% saying they were unsure, the majority of whom wanted clarification and transparency on the entry and exit criteria.

Patients and the public

61.5% of patients agreed with the proposal. In support, they said it was common sense and addressed inequity. They described the approach as evidence-based which they said would address inequity and be less likely to fund ineffective treatment. Several people commented that it should include diseases other than cancer.

I think it is appropriate to have clear criteria by which drugs are assessed and that data on their effectiveness is collected throughout their use.

Female patient, aged 35-54

Members of the public also agreed (73%); of the rest, most were unsure. Concern was expressed about a one-size-fits-all approach and not treating cases on an individual basis. There was also an anxiety that it would be more bureaucratic.

I am strongly in favour of an evidence based approach to the introduction of new medicines/technologies/procedures.

Member of the public, male, aged over 55

Only three people disagreed from the two groups. There was a view that this would need wider reformation of NICE.

Organisations

Pharmaceutical companies and industry bodies were mainly unsure about this proposal (53%) rather than agreeing or disagreeing, wanting more detail of how it would work in practice.
In principle, [...] agrees with the concept of a ‘managed access’ fund and the need for clear entry and exit criteria; however, we are concerned about the proposed criteria as set out in the consultation … Specifically, [...] does not agree with the entry criteria whereby only patients for whom data needs to be collected will have treatment funded out of the CDF and other patients ‘above this number will be paid for by the company’, nor with the strict exit criteria with an arbitrary two-year timeframe in which to collect data.

**Pharmaceutical company**

Respondents from patient and voluntary groups were also unsure (53%).

We agree with the principle of a managed access fund … We also agree that any new medicines access scheme should aim to have clear entry and exit criteria… Whilst we welcome the principle of providing access to new treatments whilst awaiting further data and a final appraisal decision, we remain concerned over the lack of details on how NICE will operate when assessing medicines for routine commissioning …

**Patient/voluntary organisation**

NHS organisations were supportive with nearly 74% of respondents agreeing with the proposal.

This seems to provide a system which would be transparent and clear to manufacturers but also to patients and clinicians who currently have some difficulty understanding why some drugs are taken off the list. It also provides some reassurance for patients with other life-threatening conditions for whom no equivalent to the CDF exists.

**NHS organisation**

**Healthcare professionals**

Most healthcare professionals agreed with the proposal (76%); this included 80% of doctors who responded to this question. The main reasons for agreement were beliefs that the current system did not work well, was unfair or undermined the role of NICE.

I am satisfied that this will allow early and timely use of new agents, while monitoring their benefits and cost effectiveness

**Female doctor, NHS acute trust**

Some people agreed because they felt a new system could have a positive impact on the collection of data. Others agreed because they felt cancer drugs which had little or no proven benefit should not be funded.

Of those that disagreed, concerns raised were that a drugs fund should not be restricted to cancer treatments and that a CDF undermines NICE processes.

Those who felt unsure stated a range of reasons. Some felt unsure about what the new proposal would entail, and what the entry and exit criteria would be. Again, many did not support a fund specifically for cancer patients.
Question 2: Do you agree with the proposal that all new cancer drugs and significant new licensed cancer indications will be referred to NICE for appraisal?

67% of respondents agreed with the proposal. However, there were concerns about the impact on NICE and its workload arising from implementation of this proposal.

Patients and the public

58% of patients and 73% of members of the public agreed with this proposal, stating that they felt that NICE committees have the expertise to do this. There was also some concern about the speed at which NICE could do this and whether it would add bureaucracy.

*NICE is there to govern quality*

Male patient, aged over 55

However, 38% of patient respondents disagreed, stating that they felt that NICE would not be able to cope and would take too long. There was also concern that NICE was financially-driven and did not have a good track record in funding new drugs and/or innovative treatments.

*NICE does not have a good track record for the funding of new drugs/innovative treatments.*

Female patient, aged over 55
Organisations

38% of pharmaceutical companies and industry bodies agreed and 16% disagreed with the remainder saying they were unsure.

[...] supports in principle the proposal that all new cancer drugs and indications be referred to NICE for appraisal but only if significant NICE reform takes place to create a broader value assessment for cancer medicines. It is clear through an analysis of the drugs currently in the CDF, that the existing NICE evaluation framework is not fit for purpose vis-a-vis cancer drugs in general and a fair process needs to be established for medicines for rarer cancers specifically.

Pharmaceutical company

There was strong support from NHS organisations (67%) for the proposal, while patient and voluntary organisations were split between agreeing and being unsure (42% and 45% respectively).

We agree that there should be a single body responsible for assessing new cancer drugs, and that NICE is the most appropriate body to be able to do this. However NICE needs the resources so that decisions are made in a timely manner. Until now the CDF has provided a stop-gap, but it will be a better system if NICE can publish their 1st appraisal in a timely manner. We need to be assured that NICE have the capacity to be able to do this.

NHS acute trust

We support a system for the evaluation and commissioning of medicines and services which would allow each to be assessed on its own merits by balancing the benefit it offers to patients against the cost and then funded accordingly ... However, we are concerned that there has been no indication that the capacity of NICE will be increased to handle this increased number of cancer medicine appraisals.

Patient/voluntary organisation

Healthcare professionals

The majority of healthcare professionals agreed with this proposal (88%).

Yes, we agree with this process. It is essential that all new drugs or new indications should go to NICE for appraisal and final approval ... However it is essential that this process will be carried out in a reasonable time frame and not significantly delay the access.

Male doctor, health advisory group, aged 35-54

However, some people highlighted that this would have an impact on the workload of NICE, and wanted assurance that this would be managed. Others referred to timescales, and had concerns they would be too long.

A small number of people disagreed or were unsure; mostly this was due to concerns over the ability of NICE to take on the extra work. There were also some concerns raised in relation to 'off-label' cancer drugs, and that they needed to be included in this process (in particular for rare cancers).
Question 3: Do you agree with the proposal that the NICE Technology Appraisal Process, appropriately modified, will be used to evaluate all new licensed cancer drugs and significant licence extensions for existing drugs?

Over 60% agreed with the proposal, with the highest level of approval coming from healthcare professionals. Those most likely to disagree were pharmaceutical companies and patient and voluntary organisation organisations.

Patients and the public

54% of patients agreed with the proposal. There was some concern about the capacity of NICE, the speed of the process and whether the evaluation board would include cancer specialists.

As long as this does not have a negative impact on the availability of treatments or the quality.

Male patient, over 55

I am surprised that all drugs aren't already evaluated by some regulatory body already.

Female patient, aged over 55

However, 27% disagreed. They felt the process was too slow.

When you have cancer, you just want to be given the opportunity to try any suitable available process.

Male patient, over 55

There was also some concern about whether this would be suitable for appraising patients with rarer cancers.

19% were unsure. Again they felt the process needed to be quick as well as transparent and consistent. Some respondents also felt they did not have enough information or knowledge to give a view on this question.
Organisations

While 41% of pharmaceutical companies agreed with the proposal, there was support from the professional bodies with none disagreeing with the proposal (only two of the 10 who responded were unsure).

*We agree with this proposal and feel that it builds on 15 years of the technology appraisal process used by NICE which is much more robust than creating a parallel system just for cancer.*

**Professional body**

*Whilst we agree that the modified NICE appraisal process should be used to evaluate all new licensed cancer drugs, the modifications suggested do not fundamentally alter the appraisal process and they are often unclear.*

**Pharmaceutical company**

Patient and voluntary organisations were equally split between disagreeing and not being sure (41% each), with 19% agreeing.

*There needs to be a quicker and more transparent way of appraising and assessing new cancer drugs but as stated above, the criteria goes against what we need to see happening for less common cancers. We are aware of the disproportionate funding through the CDF between common and less common cancers.*

**Patient/voluntary organisation**

*Our support for NICE appraising all cancer drugs is contingent on NICE being reformed to an extent where we feel new treatments for rare cancers and cancers of unmet need will receive a better chance of being recommended for commissioning.*

**Patient/voluntary organisation**

NHS organisations were supportive with 82% agreeing with the proposal.

*There needs to be a single assessment process, using a standard health economic model. NICE has been around for many years and has developed expertise and skills in this field.*

**NHS acute trust**

Healthcare professionals

Most healthcare professionals agreed with this proposal (83%).

*The process is not perfect but it has stood the test of time and is clear.*

**Female doctor, NHS acute, aged 35-54**

Like patients and the public, there were some who wanted further assurances about the process, in particular that it would not take too long.

*… needs to be a much faster process than currently, and has to have much more specific criteria about when it can be used and what can be used before and very importantly, as this is not currently looked at, later lines of treatment.*

**Female pharmacist, NHS acute, aged 35-54**
A small number of people were unsure. Again, some of the concern was about the process taking too long and the capacity of NICE. Others felt unsure about the terminology and implications of ‘appropriate modification’ and ‘significant licence extensions’.

*Makes sense to have a single process, however there needs to be consideration of how the process will manage multiple products with same indication, launched in a sequential manner…The existing multi technology appraisal route takes significantly longer than other options, so how will this be managed to fit time frame. Concerned that NICE has the capacity to deal with the volume of applications in a timely manner without reducing the responsiveness for non cancer TAs and other publications.*

Male pharmacist, NHS acute, aged 35-54

A small number of people (5) disagreed. Again, the main reason was concern about the time this process would take.
Question 4: Do you agree with the proposal that a new category of NICE recommendations for cancer drugs is introduced, meaning that the outcome of the NICE Technology Appraisal Committee’s evaluation would be a set of recommendations falling into one of the following three categories:

i. Recommended for routine use;
ii. Recommended for use within the Cancer Drugs Fund;
iii. Not recommended.

65% of respondents agreed with the proposal, but 22% said they were unsure (of those, pharmaceutical companies and industry bodies were the most unsure).

Patients and the public

59% of patients and 77% of members of the public agreed with the proposal. One person described it as the most important part of the proposal. Another said the cost and benefit needed to be weighed against the overall constraints of the NHS. The importance of streamlining systems and having clear criteria was stressed.

*In theory, this looks sound. However, there needs to be clarification on what specific feedback the CDF requires while the companies have time to submit evidence. Where will patients be involved in the appraisal?*

**Female patient, aged over 55**

*This seems to be a fairer way of assigning categories however the costs of these drugs and the potential benefit does need to be balanced against overall constraints that exist in the NHS.*

**Member of the public, male, aged over 55**

Of those disagreeing, the view was expressed that this would undercut NICE’s bargaining power because it would allow drug companies to maintain anti-competitive prices. Another respondent said that if a drug was deemed cost-effective then it should be approved and if not, then it should not.
Organisations

38% of pharmaceutical companies and industry bodies which responded supported this proposal, with 47% unsure.

... is supportive of the proposals' aim to resolve uncertainty but more specificity is required to guide appraisal committees in their decision making around the parameters of uncertainty that need to be considered and broadened. What level of uncertainty would be acceptable? How would the Committee determine whether the uncertainty has the potential to be resolved within additional evidence? What timeframes for data generation would be considered acceptable?

Pharmaceutical company

69% of patient and voluntary organisations agreed with this proposal, with only 6% disagreeing.

We agree with this proposal. This proposal could allow greater flexibility as promising treatments that have insufficient evidence to gain a positive NICE recommendation have the opportunity to remain on the CDF whilst additional data are collected on their effectiveness. However ...there is a need for greater transparency and patient involvement in the IFR process so that patients are able to understand the basis on which decisions are made.

Patient/voluntary organisation

Similarly NHS organisations showed agreement, with 74% agreeing with the proposal, with 17% unsure.

Healthcare professionals

Most healthcare professionals agreed with this proposal (69%). There were some provisos, largely around what criteria would be used in the decision to assign one category or another. 18% of respondents were unsure, mainly because they felt that this option feels 'half-hearted' and they had concerns around data collection, evaluation and the criteria used.

This categorisation looks reasonable but it has to be clear what drives such a judgement.

Male doctor, health advisory group, aged 35–54

13% of healthcare professionals disagreed, mainly because they felt that cancer should not be treated differently, and/or there should not be a Cancer Drugs Fund. Some of those who disagreed suggested that they would agree, if changes were made.
Question 5: Do you agree with the proposal that “patient population of 7000 or less within the accumulated population of patients described in the marketing authorisation” be removed from the criteria for the higher cost effectiveness threshold to apply?

Patients and the public

Around 46% of patients and 38% of members of the public agreed with the proposal, saying this was ‘overdue’ and ‘statistical common sense’ and that everyone should have the same access to treatment, regardless of the type of cancer or its rarity.

The same proportion – about 43% – was unsure for both groups. This was primarily because they felt the question was not clear.

Of those that disagreed, most did not give a reason but one person said the proposal seemed to be based on numbers rather than clinical need or efficacy. Another said more generous access to drugs should be given to those with a rare condition.

Organisations

85% of pharmaceutical companies and industry bodies agreed with this proposal. 16% stated they were unsure, mainly because of a lack of clarity around the question.

81% of patient and voluntary organisations also agreed with the proposal, with 13% saying they were unsure.

74% of NHS organisations agreed with the proposal, with only one organisation who disagreed with the proposal.

Healthcare professionals

Just over half of healthcare professionals agreed with this proposal (57%), giving as their main reason that they felt there should not be a cap, and that it was ‘arbitrary’.

Those that disagreed (5%) had various concerns about changes to the criteria, mostly due to the impact on people with rarer cancers.
Of those who selected unsure some were unclear why that criteria was included in the first place. Others felt some sort of limit was needed, or questioned what would replace the current part of the criteria.
Question 6: Do you agree with the proposal for draft NICE cancer drug guidance to be published before a drug receives its marketing authorisation?

Nearly two-thirds agreed with this proposal. However over 60% of pharmaceutical companies and industry bodies disagreed.

Patients and the public

About 58% of patients and 81% of members of the public agreed with this proposal. They said it was common sense and transparent, and would help people to make decisions. Several people caveated this by saying as long as it did not delay the process.

*It needs to be completed and published very swiftly so that unnecessary delays are avoided.*

Member of the public, male, over 55

Eight patients and only one member of the public disagreed with the proposal, because they felt the process would take too long and this would be another hurdle to people receiving life-saving drugs. There was also concern about the implications of approving drugs before they receive marketing authorisation.

Seven were unsure because they did not feel they had sufficient understanding of the effect of this proposal, for example whether it would actually delay treatment.

*Anything which speeds patient access to medicines is positive. I agree with this proposal as long as it does not mean having to produce data early when it is not ready for appraisal and will not be considered as mature enough to meet NICE’s clinical and cost effectiveness ratios. This, rather than improving access, has the potential to deny patients access to very effective new medicines which could save their lives.*

Male patient, aged 35-54
Organisations

61% of pharmaceutical companies and industry bodies disagreed with the proposal, citing issues such as:

- how realistic the proposal was e.g. NICE Technology Appraisal process would need to be reformed and this will not be possible in the timeframe; UK pricing is not set until immediately prior to licensing, so how would NICE undertake assessment of cost effectiveness
- inequity e.g. companies and some products may be penalised if they do not have the resources to submit early
- inefficiencies e.g. as new data becomes available after the original submission this will need to be inputted.

Those that did agree (32%) generally assumed a new NICE process would be put in place.

75% of patient and voluntary organisations agreed with the proposal, with 16% saying they were unsure.

Facilitating earlier access to new, potentially life-saving, drugs is a key strength of the CDF and should continue as part of the new fund.

Patient/voluntary organisation

Healthcare professionals

Over half of healthcare professionals agreed with this proposal (59%). Those who disagreed (23%) were mostly concerned about marketing authorisation happening at the right time, and what would happen if a drug did not then receive marketing authorisation.

What will NICE do if the drug fails to receive marketing authorisation? Simply not recommend it? In that case all the preliminary work will be wasted.

Female doctor, acute trust

Some of those who were unsure (18%) cited pros and cons of this proposal, or gave provisos.

I think the MA should come first but if a drug appears to have solid clear evidence of efficacy then it would be in everyone’s interest for a draft proposal to be released prior to MA.

Female pharmacist, acute trust
Question 7: Do you agree with the process changes that NICE will need to put in place in order for guidance to be issued within 90 days of marketing authorisation, for cancer drugs going through the normal European Medicines Agency licensing process?

Over half the respondents agreed with this proposal, with healthcare professionals and NHS organisations showing the highest level of approval. Over 30% of respondents were unsure.

Patients and the public

50% of patients and 55% of members of the public agreed with the proposal, saying this was common sense and anything that speeded up the process had to be good. One person said 90 days seemed reasonable, however another wanted it to be shorter.

Around 16% disagreed (5 people), because they felt that they should be available at the same time as marketing authorisation was given.

Nearly 35% said they were unsure, with concerns being primarily that 90 days was too long. There was also concern about the ability of NICE to cope and make decisions in a timely manner.

Organisations

Just over half of pharmaceutical companies and industry bodies agreed with the proposal, with 36% being unsure.

Where they were unsure of their support or disagreement, the concerns centred around:

- Inequity e.g. there may be instances where companies with limited resources might not be able to support the NICE process or where a global company’s headquarters has not set a price. Companies wanted to see a process that did not penalise companies that missed submission at earlier times if submission timelines have been agreed with NICE and NHSE.
- Deliverability e.g. whether NICE will be provided with the capacity to achieve the aim.

38% of patient and voluntary organisation organisations agreed, and 59% said they were unsure about this proposal, highlighting their concern over the ability of NICE to deliver.
NHS organisations showed nearly two-thirds support for the proposal, with a quarter being unsure. Two organisations disagreed.

**Healthcare professionals**

Most healthcare professionals agreed with this process change, though some expressed concern over the impact on NICE and its ability to put the changes in place within 90 days.

*Early guidance is essential and hence the process needs to change to enable such guidance to be produced. The proposed changes seem sensible on terms of achieving the output of the early guidance.*

**NHS manager, acute trust**

Those who disagreed (7) were generally concerned about the process being rushed, and some asked for flexibility in the time allowed.

Those who were unsure generally felt they needed more information or more detail, or assurances around the decision-making process.
Question 8: Do you agree with the proposal that all drugs that receive a draft NICE recommendation for routine use, or for conditional use within the CDF, receive interim funding from the point of marketing authorisation until the final appraisal decision, normally within 90 days of marketing authorisation?

Two-thirds of respondents agreed with this proposal with a high level of support across all categories of respondents, except for NHS organisations where 44% agreed.

**Patients and the public**

These respondents showed the highest level of agreement in response to this particular question, with 77% of patients and 69% of members of the public agreeing. Where a reason was given, it was that it was important to give access to drug treatment as quickly as possible.

11% and 23% respectively disagreed and several suggested that these drugs could be made available prior to the final appraisal decision but funded by the pharmaceutical company or industry, which would have access to the research data.

Nine percent were unsure, but seemed to think that 90 days was a reasonable length of time.

> Whilst it is important to get decisions made quickly, it would be unfortunate if a drug that was given interim funding was later refused. Therefore, a wait of maximum 90 days does not seem unreasonable in order to get things right.

**Male patient, over 55**
Organisations

77% of pharmaceutical companies and industry bodies agreed with this proposal, and patient and voluntary organisation organisations showed the greatest support with 90% agreeing. Nobody from these two categories disagreed with the proposal.

We support earlier access to treatment that interim funding would provide for drugs that receive a draft recommendation for routine or conditional use.

Patient/voluntary organisation

... supports this concept to ensure that NHSE patients receive access to innovative cancer treatments as soon as they are available.

Pharmaceutical company

44% of NHS organisations agreed and 39% disagreed. Of those that disagreed, concerns raised were about how funding would work during the period.

This would result in churning of drugs between a number of different short-term funding streams which would be very difficult to manage in an operational setting. This would be very challenging for both providers and NHS England.

NHS acute trust

Healthcare professionals

The majority of healthcare professionals agreed with this proposal (66%).

Those who agreed generally felt the proposal was ‘reasonable’. There were some caveats, and one person wanted to know what happens if the manufacturer does not agree to data collection:

The requirement for this needs to be dependent on the receipt of data into the SACT dataset to support this. There does not appear to be an incentive or penalty for supplying the data (or not) to SACT at the moment…

Pharmacist, NHS acute trust

Those who were unsure or disagreed cited a range of reasons, including: difficulties for CCGs and trusts handling complex budgets, and that stopping treatment once it has started would be difficult. Others felt drugs should not be funded on an interim basis and that cancer drugs should not be treated differently to other drugs.
Question 9: What are your views on the alternative scenario set out at paragraph 38, to provide interim funding for drugs from the point of marketing authorisation if a NICE draft recommendation has not yet been produced, given that this would imply lower funding for other drugs in the CDF that have actually been assessed by NICE as worthwhile for CDF funding?

Patients and the public

Generally respondents in this group did not agree with providing interim funding if this would affect funding for other drugs that had already been assessed as worthwhile.

*It risks funding ineffective treatments, which are a loss to the British taxpayer and should not be entertained, even temporarily.*

Member of the public, male, aged 35-54

One person said this could incentivise manufacturers to drag out appraisals that would be negative.

A number of people expressed concern about NICE’s ability to make decisions in a timely manner and said that resources should be put into this.

*I agree, NICE need more people and work faster!*

Member of the public, female, aged 35-54

The point was made that drugs should be funded if they were already being used in the EU or the US.

Organisations

There was general disagreement with this proposal because of the perceived negative impact on risk, financial arrangements, patient communications and expectations; and a view that sufficient funding and arrangements should be put in place at NICE to avoid the scenario occurring.

*Strongly disagree with this approach. In effect it would mean that neither NICE or NHS England would be able to control the CDF spend and the threshold for funding would be lowered. The careful appraisal which the CDF has had to date and is expected from the main consultation proposals would be redundant.*

*If interim funding is given, then a NICE TA process suggests that a drug is not cost effective and should not be funded – either in routine commissioning or the CDF – then invariably there will be political and other pressure to keep the drug in the system.*

NHS organisation

Pharmaceutical companies were more supportive of the proposal (but not exclusively so) whilst at the same time calling for a flexible CDF budget. For instance:

*If a delay in completing the appraisals is a direct result of inadequate resources at NICE then, NHS England should ensure that additional interim funding is granted. This will ensure that patients can continue on treatment and companies are not penalised financially because of NICE delays.*

Pharmaceutical company
Healthcare professionals

Healthcare professionals offered a range of views on this scenario.

Those who responded positively felt this was fair for various reasons, including the likelihood of there being solid evidence already and for those with rare cancers. One respondent supported it because the point of marketing is to have a clear time point from which some form of access/appraisal is needed.

Many who responded more negatively felt that a NICE recommendation was needed before funding, with more resources given to NICE to issue draft guidance promptly if necessary.

Other comments included:

- Drugs could be funded which are later found not to be cost-effective
- Funding for drugs that have already been approved by NICE should not be impacted by this process
- Concern over starting treatment for a patient and then withdrawing it
- Pharma companies should cover the interim drug cost
- The availability of funding should be clear and transparent and controlled centrally
- There should be a maximum cost for this group of drugs per patient treated
- Depends on the reason the guidance has not been produced
- Drug companies and NICE should co-ordinate marketing and recommendations simultaneously.
Question 10: Do you have any comments on when and how it might be appropriate for the CDF in due course to take account of off-label drugs, and how this might be addressed?

Patients and the public

About half the respondents in this group did not comment or said that they were insufficiently informed to be able to comment. Most of those who commented thought that some consideration should be given to the CDF taking account of off-label drugs.

NICE, whether via CDF or routine use decisions, should be able to consider off-label use where requested by clinicians or commissioners. This would be a valid use of the CDF and would be preferable to not progressing such appraisals, although identifying other sources of research funding - such as through NIHR - would be preferable.

Member of the public, male 35-54

Respondents were keen that there should be some evidence of potential benefit:

NICE is currently not allowed to assess the use of drugs off-label. This has been a real disadvantage for patients who could benefit from the off-label treatment but could not have the advantage of the level of evidence needed to meet NICE standards on efficacy & adverse effects. There would need to be recourse to a body of clinicians who could recommend that a drug has good potential for off-label use, and then put the drug through the NICE appraisal procedure.

Member of the public, female, over 55

Organisations

This question drew a wide range of responses from those respondents who felt that use of off-label drugs is only going to increase in future and they should be treated in the same (or a similar) way as licensed drugs, through the CDF.

existing funding of CDF medicines which are used off-label should continue to be made available but that further consideration of additional off-label treatments should be put on hold prior to the evaluation of all currently licenced cancer medicines being completed. Recognising that off-label usage is important in the oncology treatment setting, and is indeed often a lever to innovation, in the future, NICE and NHSE may wish to consider some off-label medicines being selected for evaluation via, for example, the existing NICE Evidence Summaries for Unlicensed and Off Label Medicines Programme.

Pharmaceutical company

However there was also a belief (primarily of pharmaceutical companies) that, given the capped nature of the fund, off-label drugs should not be CDF funded.

There has been a steady stream of ICDFRs for off-label use of the CDF since its inception. Decisions on clinical exceptionality for these requests have been made by regional expert panels with a response time standard of 10 days. The option of putting ICDFRs through the same IFR process as all non-cancer treatments would mean that requests for cancer drugs would be handled in the same way as all other
treatments, including non-drug treatments for cancer. This is more equitable. However, the response times for ICDFRs and IFRs are discordant.

**NHS organisation**

**Healthcare professionals**

Healthcare professionals offered a range of views on this scenario.

Many responded positively. Some felt this would ensure rare cancers get treatment. Some felt NICE needed to be involved. Suggestions for how this could work included:

- Clinicians could submit suggestions for indications to be considered and have some sort of prioritisation/voting system
- NICE could commission trials or systematic observational data collection during the period of interim funding, to reduce uncertainty for unlicensed drugs.
- When a ‘clinical’ body of experience has been built up (using Individual Funding Request) the CDF could then act to collect data over a 24 month period to enable NICE to determine whether a benefit is actually being achieved.
- Create a ‘Rarer Cancers Group’ within the CDF to evaluate requests for funding of off-label uses of drugs.

Some gave the caveat that there needs to be basic levels of evidence that a drug has some action in a disease.

Others responded more negatively or had concerns. Some felt it would be too complicated. Others felt a separate process was needed, such as assessment by NICE, or by a small panel.

Some said the Cancer Drugs Fund should not be involved at all. Others suggested that off-label decisions should continue to be made as they are now.
Question 11: Do you agree with the proposal to fix the CDF annual budget allocation and apply investment control mechanisms within the fixed budget as set out in this consultation document?

Respondents were fairly equivocal about this proposal, with a high degree of uncertainty across most groups.

Patients and the public

27% of patients and 46% of members of the public agreed with this proposal. 42% of patients and 31% of members of the public disagreed.

Of those that agreed with the proposal, respondents stated there must be limits placed on the fund.

*I think that this is necessary for the fund to operate effectively. My only concern is that it does not impede cancer treatment deemed necessary by the clinician for their patients.*

**Member of the public, male, over 55**

For those expressing their disagreement, respondents thought that it was a mistake to fix the amount in the fund because it should be based on the needs of the population.

*The drugs should be available on the basis of clinical need and evidence based efficacy only.*

**Member of the public, male, over 55**

Those who were not sure stated that they could see both sides, but were concerned about patient care:

*I do agree that the budget needs fixing and that there is a contingency; however, there has to be flexibility in how drugs are assessed within the fund with greater emphasis being given to expertise of consultants' knowledge of their patients.*

**Female patient, over 55**
Organisations

22 out of the 23 pharmaceutical companies that responded to this question disagreed with this proposal with one responding as ‘unsure’. There was a high degree of uncertainty across most groups. However ‘NHS’ aligned bodies were generally in favour of fixing the budget (although some NHS Trusts questioned how the system would practically work).

Disagreement from pharmaceutical companies centred around:

- Calendar funding restrictions e.g. penalisation of products brought to market in a busy year or towards the end of the year when budget has run out.
- The financial risk to pharmaceutical companies
- The likelihood that this might mean companies view the UK as too challenging an environment in which to launch a product.

rather than a complete payback by the company, this rebate should be weighted and based on the difference in price based on an agreement of the incremental c-e ratio compared to BSC, as some value may have been gained for some patients (observed in registries and trials). Ultimately some benefit for patients must exist for the treatment otherwise there would be no grounds for granting a license in the first place.

Pharmaceutical company

NHS and other organisations were concerned about how technically the process would work

The system that is proposed in this consultation appears very complicated, and will be complex for pharmacy departments to administer. Perhaps a better system is for NHSE to be responsible for paying the manufacturers directly, depending on which particular scheme the patient is receiving the drug. As long as the patient has been registered appropriately, there is only 1 organisation having to deal directly with the manufacturer, which will be far simpler.

NHS acute trust

The principles are sound as the budget needs to be managed, but the mechanism for these needs to be clarified. How can NHS England/CDF freeze what it pays to manufacturers if Trusts have already paid manufacturer? How will the invoicing be managed, experience has shown that invoicing old cancer drug fund is complex and needs regular local scrutiny. There are problems with reclaiming VAT and use of third party dispensing. There are risks with use of PAS schemes which may not realise expected benefits and are difficult to manage and track.

NHS acute trust

Healthcare professionals

Over half of all healthcare professionals agreed and of those, many cited the need to remain within an allocated budget and to ensure it is spent wisely.

This has to happen. It is unfair that patients with cancer get special treatment over other NHS patients.

Doctor, NHS acute trust

However some felt it could be difficult to maintain, and felt there was a risk of overspend.
Many of those who disagreed or felt unsure had concerns over a fixed budget and how control mechanisms would work in practice.
Question 12: Do you consider that the investment control arrangements suggested are appropriate for achieving transparency, equity of access, fair treatment for manufacturers and operational effectiveness, while also containing the budget? Are there any alternative mechanisms which you consider would be more effective in achieving those aims?

Patients and the public

About half the respondents in this group did not comment or said they did not know. Almost a quarter explicitly expressed support.

Of the small number of people who disagreed, this was on the grounds that cost should not be a factor.

There was support for removing any decisions from the political arena. There was also support for ensuring transparency with suggestions that companies needed to be transparent about development costs and proposed return on investment and that information from all trials would need to be published before approval could be given.

Organisations

Overall, organisations felt they needed to understand the operational detail. There was some belief that the proposals were an improvement on the current system. But 74% of pharmaceutical companies and industry bodies disagreed with the proposal, while appreciating that it is not viable to have a limitless fund. They cited in particular the unknown variable of the number of potential cancer medicine launches in any one year.

Healthcare professionals

52% of healthcare professionals agreed with the proposal, with some feeling the investment control arrangements were appropriate. Others felt they were not, for various reasons such as a perception that it over complicates the control mechanism.

Alternative mechanisms included:

- Offer funding for a fixed number of cycles of treatment then apply for extension of treatment funding
- Use NICE, and their standard appraisal procedures
- Rigorous audit of clinical progress of cases accepted for CDF funding
- Price cap arrangements as per current PPRS
- Manufacturers to supply CDF drugs to be supplied to Trusts at zero cost, under a managed access scheme, with tracking patients
- The NHS receives shares in the marketing company in response to an agreement and invests profits into prevention e.g. smoking cessation
- Value based pricing should be employed based on QALY
- Negotiation with companies for drugs that are out of the boundaries set by either budget or NICE, could be provided in a discount price to make them financially friendly for the organisation. Also, if drugs are used for more (new) indications, the logical process should be to force companies to reduce the price (as the market will be bigger).

There were also a number of comments about the need for transparency. One respondent felt the arrangements would undermine the subsequent NICE process. Another felt it was inappropriate to consult on these matters, and the cost/benefit should be decided by NICE.
Question 13: Are there any other issues that you regard as important considerations in designing the future arrangements for the CDF?

Patients and the public

Most respondents in this group raised other issues. Several people stressed the importance of ensuring that decisions were evidence-based and would meet the population’s needs. The importance of engaging more widely with the public and patients was also mentioned by a number of people, as was the importance of handling data properly and ensuring IT systems could communicate with each other.

Other issues raised were:

- The need for an appeals process
- Ensuring there were systems to evaluate clinical and cost effectiveness
- Providing more clarity about the relationship between the NHS, NICE, the CDF and the government
- That rarer cancers should not be ignored
- The fund should be widened to include conditions other than cancer.

Organisations

Respondents from organisations felt there was a need to look at:

- Impact on NHS trusts e.g invoicing
- Evidence gathering and data collection issues e.g. the funding of this
- Patient information about how the system works
- Ethical issues e.g. how the fund could be broadened to include all innovative medicines
- Transition arrangements and reviews of drugs previously removed from the CDF
- Timing of any changes
- Changes to the NICE technology appraisal process to assess the impact of proposed CDF changes
- How the CDF could consider a more holistic view rather than just cost-effectiveness
- The recruitment and resourcing of the CDF Investment Group and NICE Technology Appraisal Committee and patient involvement
- Alignment with the Accelerated Access Review (AAR)
- Quality of, and interrelationship with the SACT dataset and with the IFR process
- The consultation process e.g. the lack of a patient friendly guide.

Some pharmaceutical companies said they did not support the proposal that the CDF should only fund the minimum number of patients required to generate the data needed for further NICE review, and for companies to pay for all other NHS patients.

Healthcare professionals

Key issues stated by healthcare professionals included:

- The high-profile of the CDF and some cancer treatments; ‘it seems that those who shout loudest will be listened to’. Patient expectations need to be managed better
- The process for dealing with rare and ultra-rare cancers needs to be better
- More onus needed on clinician to provide information on effectiveness of drugs used within CDF
- Appropriate realistic reference data is needed for end of life care that can be applied systematically across all appraisals.
- The approval of drugs for the CDF for a period of 24 months only may not be sufficient to generate new data. We need to specify what type of data is acceptable and provide tools to have the data available.
- Rather than just seeking support for applications, perhaps there should be arguments against applications as part of the process.
- Declarations of all negative data/trials associated with the product, as well as positive.
- It should be easy to access the fund; simple on-line applications and rapid decisions.
Question 14: Do you agree that, on balance, the new CDF arrangements are preferable to existing arrangements, given the current pressures the CDF is facing?

On balance, respondents do agree that the new CDF arrangements are preferable to existing arrangements. However, nearly a quarter said they were unsure, citing lack of detail and unease over future financial sustainability and system bureaucracy.

Patients and the public

Respondents in this group were split about whether the new arrangements would be better than existing arrangements, with no majority opinion: 35% agreed they would be better, 30% disagreed with the remained unsure.

In agreeing, respondents felt that the proposed system would be more sustainable and less political. It would deal with current inequity within the system.

> It seems to me that the current mechanism consists of an extra fund for drugs that have essentially a poor cost/benefit ratio and are not approved by NICE for general use but are then simply funded from another source which is also not (and never can be) bottomless.

Member of the public, male, over 55

Reasons for disagreeing included that this would be returning to the pre-CDF system and that it would discriminate against some cancers.

Those who were unsure thought there would be positive and negative impacts.

> Bringing down costs is good, making new drugs available is good, limiting the application of those drugs by budget is not.

Patient, male, over 55
**Organisations**

Pharmaceutical companies and industry bodies also showed a split across the three options, with 30% agreeing, 36% disagreeing and the remainder unsure.

> Whilst this is likely to create a few short-term problems in the transition, it is the right approach to address the long-term affordability of cancer care.

**Professional body**

Of those patient and voluntary organisations that disagreed (37%), some felt that there was not enough detail in the proposal; others felt that key enablers were not in place e.g. reform of NICE.

**Healthcare professionals**

77% of healthcare professionals agreed that the new CDF arrangements are preferable to the current ones.

> The existing system is not satisfactory, and is also not sufficiently transparent. Taking drugs off the CDF has been fraught because of the lack of clear, robust criteria. This proposal should be a significant improvement.

**Pharmacist, NHS acute trust**

Those who disagreed (9%) expressed a range of concerns including; the new arrangements will mean fewer available treatments; a more holistic approach is needed, including spending money on surgery and radiotherapy; there are risks around the flow of data from providers; there is a lack of mention of PASLU, IFRs and managing combinations of new expensive drugs. Others felt more clarity was needed in various areas, such as who will set criteria for use of drugs.

Most of the people who were unsure felt it was too early to answer this question, or had concerns about the existence of the CDF.
Appendix A – Demographic information

The demographic information below relates to individuals who completed the questionnaire, as those who sent in letters or emails did not give us these details about themselves. Percentages are given after the actual numbers. Where these do not total 108 (100%), the remainder are those who did not respond or preferred not to say.

Gender of respondent

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<tr>
<td>Male</td>
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Age of respondent

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<td>35-54</td>
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### Ethnic group

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### Person with disability

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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.

The Board is asked to consider whether it is content with the transition arrangements as presented in this paper.

Professor Carole Longson  
Director, Centre for Health Technology Evaluation  
March 2016
Introduction

1. This paper provides an update on the work NICE is doing to support the transition from the current to the new Cancer Drugs Fund (CDF).

Existing CDF drugs

2. The Board will be aware that only limited reference was made in the joint NHS England and NICE consultation document to the transition arrangements for moving from the current to a new CDF, other than suggesting that the process of appraising drugs currently in the CDF in line with the new criteria will be completed during the course of 2016-17.

3. In order for NICE to be able to appraise what was a substantial number of drug-indication pairs on the CDF, with limited time to do it, preparatory arrangements were put in place during consultation.

4. Three groups of products were identified for the transition arrangements:

   - Group 1 – drugs currently in the CDF for which NICE has published guidance or will have published guidance by 31 March 2016 (15 drug-indication pairs);
   - Group 2 – drugs currently in the CDF and being appraised by NICE, for which evidence has already been received but where the appraisal will not be completed by 31 March 2016 (9 drug-indication pairs);
   - Group 3 – drugs currently in the CDF which are not yet part of the NICE appraisal process (13 drug-indication pairs).

5. NICE wrote to all the companies holding marketing authorisations for products in the three categories in December 2015, seeking in particular an expression of interest for providing an evidence submission for drug-indication pairs in Group 1, as these had already been appraised. Companies with drug-indication pairs in Group 2 were informed that their products would continue to be appraised in accordance with the timelines already communicated, but that a further Committee meeting would be scheduled after April 2016 to allow for consideration of the CDF proposals for NICE’s methods, where appropriate. Those companies with marketing authorisations for Group 3 drug-indication pairs were informed that these will have to be subject to Ministerial referral.

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1 Some drugs are in the CDF with a number of licenses; each of them is described as a ‘drug-indication pair’.
and, that when referred, NICE would endeavour to conclude the appraisals by the end of 2017.

6. The NICE Board approved a shortened process for re-consideration of the group 1 drug-indication pairs in its January meeting, and this was subsequently been shared with stakeholders for a two-week consultation. The response received was generally supportive, with some key issues raised:

- New clinical evidence should be considered (and appeals allowed on any new evidence considered);
- Revision or update of scope may be necessary (to accommodate new comparators);
- Need to share the model used by the Evidence Review Groups in their exploratory analyses in the original appraisal;
- Involvement of patient and clinical organisations is necessary (including at the committee meeting);
- Need to add a commissioning expert to the committee meeting.

7. In meetings held with individual companies on 9 February 2016, the first three issues have been discussed for individual topics and solutions acceptable to both NICE and companies have been found. Where this involves changes to the scope, other stakeholders will be involved in consultation on those scopes.

8. The re-consideration process will be amended to accommodate the concern raised about involvement of patient and clinical organisations. The sentence included in the consultation version – ‘No statements from non-company consultees are to be sought’ – will be replaced by: ‘Statements from non-company consultees will be requested’.

9. No change is needed to accommodate the concern about involvement of commissioning experts, as the process document already indicates that they will be invited; ‘Clinical experts, patient experts and NHS commissioning experts will be invited to attend the Appraisal Committee meeting’.

Cancer drugs not on the CDF

10. From 1 April NICE will apply the process and methods as presented in the November 2015 proposals for the new CDF operating model to drug-indication pairs not on the CDF.
11. Until 1 July 2016, when the new CDF operating model goes fully live, no recommendations for use within the CDF will be actioned. Neither will interim funding be provided for drug-indication with positive NICE recommendations (recommended or recommended for use in the CDF) before 1 July 2016.

Next steps

12. It is proposed NICE takes the following actions:

- Publish the amendments to the Technology Appraisal processes and methods, as presented in appendix B of the ‘consultation on proposals for the new CDF operating model from 1\textsuperscript{st} April 2016’ paper (published 19 November 2015), on the NICE website on 1 April 2016;

- Publish the final re-consideration process for the transition of existing CDF drug-indication pairs in Group 1 on the NICE website on 1 April 2016.

Decisions for the Board

13. The Board is asked to consider whether it is content with the transition arrangements as presented in this paper.

Professor Carole Longson
Director, Centre for Health Technology Evaluation
March 2016
Regulations under the Equality Act require NICE to publish equality objectives at least every four years. The current objectives were first agreed by the Board in 2012 and therefore require review. This paper presents two new equality objectives together with their rationale. The proposed first objective is consistent with the Board’s discussion of the annual equality report in September 2015. The second objective is consistent with, and supports the delivery of, the workforce strategy that has been approved by the Board.

The Board is asked to agree the following equality objectives for the period 2016 to 2020:

- To increase the proportion of advisory body position applications that are from individuals who describe themselves as from black, Asian and minority ethnic groups.

- To increase the number of staff from black, Asian and minority ethnic groups in senior management roles across the organisation.

Ben Bennett
Director, Business Planning and Resources
March 2016
Introduction and summary

1. The Equality Act 2010 places obligations on NICE as a public authority as part of the Public Sector Equality Duty (PSED).

2. The PSED’s general duty requires public authorities, in the exercise of their functions, to have due regard to the need to:
   - eliminate discrimination, harassment and victimisation and other conduct prohibited by the Equality Act 2010,
   - advance equality of opportunity between people from different groups,
   - foster good relations between people from different groups.

3. A number of specific duties, set out in secondary legislation to accompany the Act, provide a framework to help public bodies meet the general duty. Under the specific duties, NICE must:
   - set and publish equality objectives, at least every four years; and
   - publish information to show compliance with the equality duty, at least annually. This must include information relating to employees and information relating to people who are affected by the organisation’s policies and practices.

4. The NICE annual equality report, most recently considered by the Board in September 2015, met the second specific duty. This paper presents the proposed objectives for 2016-2020 to meet the first specific duty to increase the:
   - proportion of advisory body position applications that are from individuals who describe themselves as from black, Asian and minority ethnic groups,
   - number of staff from black, Asian and minority ethnic groups in management roles across the organisation (defined for the purposes of this document as A&C Grade 7 and above.

5. The paper summarises the legal background and guidance on how equality objectives should be framed. It then presents the proposed objectives and their accompanying rationale, together with an indication of how progress will be overseen.
Background

6. The regulations state there should be one or more objectives, and these must be specific and measurable\(^1\).

7. In guidance to public bodies, the Equality and Human Rights Commission (EHRC) highlight proportionality is a key principle underpinning the public sector equality duty. A proportionate approach should be taken when setting equality objectives, with the number of objectives and their level of ambition varying according to the size and role of the organisation. The EHRC note that objectives may be revised or set more regularly than every four years.

8. The EHRC highlight that good objectives should be explicit about:
   - the policy, function or practice they relate to,
   - the people that are affected,
   - the outcome they seek to achieve,
   - why they have been selected,
   - how success will be measured (e.g. by how much or how many).

9. In March 2012, the NICE Board agreed the following equality objectives:
   - Equality objective 1
     *To evaluate the most appropriate forms of advisory body participation by people with disabilities to ensure NICE meets its responsibilities under equality legislation.*
   - Equality objective 2
     *To explain more clearly to prospective employees and members of advisory bodies why we collect data on age, disability, race, religion or belief, sex, and sexual orientation (protected characteristics under equality legislation), to better inform their decisions on whether or not to declare this information in our monitoring forms.*

10. In April 2013 the Board reconfirmed these objectives following NICE’s establishment as a Non Departmental Public Body (NDPB).

11. The annual equality reports have outlined the actions taken in response to these objectives. For example, a research project was commissioned to consider the extent to which the dynamics, workings and composition of NICE’s advisory bodies enable account to be taken of the perspectives of disabled people. Guidance for committee members has been revised and we have changed how committee members’ support needs are identified so that the necessary arrangements can be made. For the second objective, we

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\(^1\) The Equality Act 2010 (Specific Duties) Regulation 2011.

more clearly explain why we are asking for equalities information, and how it will be used (i.e. it will be anonymised, held securely, and not seen by the recruiting panel), in order to encourage applicants to provide this information.

**Equality objectives 2016 to 2020**

12. The EHRC guidance states that objectives should be designed to achieve improvements in service delivery or the way an organisation employs staff. In line with this, the first proposed objective relates to the way NICE develops its key output (guidance), whilst the second relates to NICE as an employer. The objectives are inter-linked given the centrality of our staff to service delivery. The sections below explain the rationale for the two new proposed objectives set out in paragraph 4 above.

**Equality Objective 1: Guidance production – NICE’s central function**

13. NICE’s overarching function is to produce guidance. The annual equality reports provide an analysis of data on the number and type of equality issues considered by advisory bodies that year and the extent to which such consideration had an impact on recommendations. The purpose of the analysis is to give assurance that advisory bodies are having the necessary ‘due regard’ to equality issues. The data used cannot be the basis of an equality objective, as the rates at which equality issues will be identified and influence recommendations is significantly affected by the topics of the guidance under development.

14. NICE guidance is developed by independent advisory bodies made up of health and social care professionals, service commissioners and providers, academic experts, people who use health and care services and their carers and representatives. There are certain capabilities that members of advisory bodies must have in order to contribute effectively to a committee’s work, but in most cases the range of technical expertise and professional and user experience required varies according to guidance topic.

15. In relation to NICE’s equality duties there are two separate, though related, considerations when recruiting to advisory bodies:

- We need members from a range of backgrounds to help us have ‘due regard’ to equality duties in deciding on recommendations.
- We need diversity of membership so that advisory bodies are representative of the population and provide a wider range of viewpoints and experiences to inform guidance generally and improve its quality.

16. Analysis of the information published in our latest annual equality report shows that broadly similar proportions of people sharing protected characteristics were appointed to the advisory bodies as applied, which could indicate our recruitment processes are not discriminatory. However, the report indicated that compared to the overall population, there is
underrepresentation of people who describe themselves as from black and Asian ethnic groups.\(^2\)

<table>
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<th>Asian/Asian British</th>
<th>Black/African/ Caribbean/ Black British</th>
<th>Other Ethnic Groups</th>
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<td>7.5</td>
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</table>

Figures shown are percentages

17. In line with the Board discussion in September 2015 of the latest equality report, the proposed objective in this regard is therefore to:

- Increase the proportion of advisory body position applications that are from individuals who describe themselves as from black, Asian and minority ethnic (BAME) groups.

Equality Objective 2: NICE workforce

18. Our staff are central to the successful delivery of NICE’s functions. A diverse workforce supports the delivery of the general equality duty and enables us to draw upon the widest pool of talent.

19. We are using the NHS Equality Delivery System (EDS) and the Workforce Race Equality Standard (WRES) to help us identify areas of current good practice at NICE as well as areas where we need to improve.

20. From a self-assessment using the EDS and WRES tools we have identified that we need to increase:

- take-up of mandatory equality and diversity training,
- availability and access to development opportunities staff from minority groups,
- number of staff from BAME backgrounds in senior management roles.

21. We have already started to put mechanisms in place to improve compliance with attendance at mandatory equality and diversity training and so our specific objective focuses on increasing the number of BAME staff in

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\(^2\) England and Wales figures are from the 2011 census; NICE figures are taken from the Picker survey reported in the 2015 equality report. 1.7% of the respondents to the Picker survey did not wish to disclose their ethnicity.
management roles through targeted development programmes and resourcing strategies.

22. We recognise that the diversity of the workforce in management roles does not fully reflect the diversity of the UK population. The majority of staff at NICE from BAME backgrounds occupy junior roles (Agenda for Change Bands 4 &5) and until now we have had no clear strategy for recruiting and developing talent into more senior roles. The proposed objective in this regard is therefore:

- to increase the number of staff from BAME groups in senior management roles across the organisation

Next steps

23. Following agreement by the Board, action plans will be developed to implement the objectives. A cross-Institute equality and diversity group will be established to assist in delivery of these objectives.

24. The action plan for the first objective will draw on the discussions and suggestions at the 2015 equality forum, which were outlined in the annual equality report. These include the way posts are advertised, developing links with voluntary and professional organisations, and making the information provided to applicants about NICE encouraging and welcoming to BAME applicants. Progress will be reported through the information in the annual equality report on the characteristics of applicants to the advisory bodies.

25. The action plan for the second objective will include engaging with management development programmes specifically designed for BAME staff such as the Reach programme run by NHS Blood and Transplant. We will also consider what actions we can take to widen the reach of our recruitment in management positions as they become available and we will work with the DH to adopt similar approaches to the recruitment to non-executive roles.

26. Progress will be tracked as part of the workforce strategy and the information provided in the annual equality report.

Ben Bennett
Director, Business Planning and Resources
March 2016
The Triennial Review of NICE reported stakeholder comments on NICE’s advisory committees and in light of these recommended NICE should ensure ‘that the arrangements for operating and quality controlling the work of the independent advisory committees are robust and transparent’ and should publish these arrangements where feasible.

This report sets out a response to these comments. Having considered this, the Board is asked to consider whether any further action is required to address the review’s recommendation.

The Board is asked to note the issues raised in the Triennial Review and consider whether the arrangements for operating and quality controlling the work of NICE’s advisory bodies and committees are sufficiently robust and transparent, or whether further action is required to either strengthen or publicise these arrangements.

Andrew Dillon
Chief Executive
March 2016
1. The Triennial Review of NICE considered the operation of the Institute’s advisory committees:

   **NICE’s governance of its expert committees**

   7.33 NICE runs a number of advisory committees and working groups made up of health, social care and other professionals and practitioners, patients, service users, carers and members of the public and technical experts. These committees are independent and work in collaboration with NICE to develop quality standards, guidelines and guidance to ensure expert input. NICE provides a secretariat function to these groups to ensure they are running in accordance with its methods and processes. (Page 63)

   7.34 Stakeholders expressed some concerns with the governance of these groups and committees: [...]

2. This led to a recommendation that

   *in order to ensure effective governance of the organisation, including its independent advisory committees, NICE should 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.*

3. The areas of concern outlined in the report are presented in the table below, together with details of relevant arrangements in place at NICE which mitigate these issues. Following consideration of this information, the Board is asked to consider whether the arrangements for operating and quality controlling the work of NICE’s advisory bodies and committees are sufficiently robust and transparent, or whether further action is required to strengthen or publicise these arrangements.
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<th>Area of concern</th>
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<tr>
<td><strong>Transparency</strong></td>
<td>Stakeholder criticised the lack of transparency in recruiting members and chairs of the committees.</td>
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<td></td>
<td>Appointments to the advisory bodies / committees are undertaken in accordance with a written policy, which is available on NICE’s website. The policy states that appointments should attempt to match the Code of Practice of the Commissioner for Public Appointments as far as reasonable and practical. The policy confirms that in line with this Code, openness is one of the overriding principles for appointments. Information about the requirements of the post and the selection process must be publicly available, and appointments must be advertised publicly in a way that is designed to attract a strong and diverse field of suitable candidates. Feedback on the outcome of the recruitment process is available to unsuccessful applicants as part of the process. The Terms of Reference and Standing Orders for the various committees provide further information on the composition of the committees.</td>
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<tr>
<td>Despite NICE’s extensive work in engaging patients and the public (for example, through its Public Involvement Programme) stakeholders expressed a lack of clarity on how patients could be included on panels and, when rejected, why patients were not</td>
<td>As per comments above. The policy also applies to lay member recruitment. Each committee has a minimum of 2 lay members (who may be, for example, patients, carers, people who use services, or employees of voluntary and community sector organisations). Committee vacancies are advertised on the NICE website and are drawn to the attention of lay stakeholder organisations.</td>
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<td>successful in meeting the criteria.</td>
<td>Anyone with relevant experience can apply.</td>
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<td>Applicants complete an application form and are assessed against criteria from a role description and person specification. Members of the Public Involvement Programme team can support lay applicants.</td>
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<td>Applications for lay membership of committees are shortlisted for interview against the person specification and role description. The selection panel will then interview shortlisted candidates by telephone. Feedback on the outcome of the recruitment process is available to unsuccessful applicants as part of the process.</td>
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<td>The guides for the production of NICE guidance also include information on the arrangements for inviting lay people for specific business (for example section 3.6 of the Guide to the processes of technology appraisal).</td>
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<td>A point repeated more than once was that possible conflicts of interests were not handled transparently – for example, panel members, who may be submitting their research to the group or committee may also have the role of deciding which research is eligible for inclusion.</td>
<td>NICE’s policy on Conflicts of Interest outlines the arrangements to ensure that interests are declared and handled appropriately. The policy, which was approved by the Board and is available on NICE’s website, states that interests must be declared on appointment, annually, and prior to committee / body meetings.</td>
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<td>Authoring or co-authoring a document submitted as evidence to the matter under the committee’s / body’s discussion is classified as a specific personal non-financial interest; under the policy the interest of the individual committee member would then be assessed on a case by case basis and this would be recorded in the minutes.</td>
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<td>The policy states that Chairs of advisory committees are in a special position in relation to the work of their committee and so may not have any specific financial or non-financial personal, non-personal or family interests.</td>
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<td>The guides for the production of NICE guidance also outline the requirements regarding the declaration of interests. For example, the guidelines manual which is followed by each guideline programme, states:</td>
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<td><strong>3.6 Code of conduct and declaration of interests</strong></td>
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<tr>
<td><strong>Declaring interests</strong></td>
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<td>All Committee members and anyone who has direct input into the guideline (including the Developer, the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE’s code of practice for declaring and dealing with conflicts of interest. For Committee members, this happens on application for Committee membership. Any relevant interests, or changes to interests, should also be declared publicly at</td>
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<td>the start of each Committee meeting. Before each meeting, any potential conflicts of interest are considered by the Committee Chair and a senior member of the Developer's team. Any decisions to exclude a person from all or part of a meeting should be documented. Any changes to a member's declaration of interests should be recorded in the minutes of the meeting. Declarations of interests are published with the final guideline.</td>
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| It was not always clear how decisions were arrived at. | Each advisory body / committee has clear standing orders and terms of reference, which are based on a standard template across NICE. These include a statement on the arrangements for voting. The guidelines manual (Chapter 9 - Developing and wording recommendations and writing the guideline) indicates that the information included in the guideline should include:  
  - **considerations** – how the Committee developed the recommendations with links between the evidence and the recommendations |
<p>| | The publishing team are currently working with guideline programmes to construct a unified template for linking evidence to recommendations. This framework will ensure that Developers focus on information that guideline users need, and includes a summary of the rationale behind each recommendation. This work will increase the consistency of the |</p>
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<td>documentation of decision making across guidelines, and make it more visible.</td>
<td>Section 3.7 of the Guide to the processes of technology appraisal provides the detail of the process used for the appraisal of the evidence. It describes the role of the various participants in the discussion, including the Committee Lead Team, patient, clinical and commissioning experts, and the company representatives. All this is part of the deliberative process used for decision making. The committee is guided in the appraisal by the NICE Social Value Judgements and the Guide to the Methods of Technology Appraisal. The latter details the technical considerations to be given by the committee to the case for clinical and cost effectiveness as presented to it, using a comprehensive 'Reference Case' (chapters 1 to 5), and including expectations for the evidence to be received. The final chapter of the Guide to the Methods of Technology Appraisal (6) describes the structured-decision making framework that it used by the Appraisal Committees to appraise the evidence and to formulate the recommendations. Specific consideration is given to the appraisal of ‘comparators’, ‘clinical effectiveness and health-related factors’, ‘cost effectiveness’, and ‘non-health factors’, and the chapter concludes with statements about the decision itself, and the link with research recommendations. The output of the Committee’s deliberation is either a document for consultation or for appeal consideration. The Guide to the</td>
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<td>processes of technology appraisal describes in detail what these documents contain (3.7.23 and 3.7.37), including how the committee deals with comments received in consultation.</td>
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The quality standards process guide provides details of how committees decide on the content of quality standards as follows:

*Areas prioritised for quality statements describing enhanced practice should:*

- *be areas of care where there is evidence or committee consensus that there is variation in the delivery of care (in particular aspects of care or services that are not widely provided and/or not considered to be standard practice, but that are feasible to provide)*
- *focus on key requirements for high-quality care or service provision that are expected to contribute to improving the experience of care or services as well as their safety and effectiveness*
- *be measurable and therefore suitable for development as quality measures.*
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<tr>
<td>Consistency</td>
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<td>Stakeholders felt a lack of consistency in the governance of groups and committees is leading to variations in quality, for example: differing decisions on similar medicines due to the different processes adopted.</td>
<td>In order to meet the demand for timely guidance to be developed for health technologies, and in particular medicines, NICE uses four(^1) Appraisal Committees that meet on consecutive weeks of the month, 11 months per year. It is inevitable that some differences in style and approach will exist between bodies, even when working, as they do, to the same methods and processes. These differences should not, though result in materially different outcomes. Notwithstanding the need for flexibility in the scheduling of topics, NICE tries as best it can to allocate topics to the individual committees on the basis of its experience with similar appraisals to help reduce the risk of this occurring. The Guide to the Methods of Technology Appraisal includes a comprehensive description of the reference case to be used for the assessment of clinical and cost effectiveness evidence as received by NICE. It also describes in detail what is expected of the appraisal of the evidence by the committee, and in particular how the committee is to engage in ‘structured decision making’ for key aspects of the case for recommending the technology for NHS funding.</td>
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\(^1\) A fifth committee is likely to be established to reconsider drugs currently funded through the Cancer Drugs Fund that have previously been subject to a NICE appraisal

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National Institute for Health and Care Excellence

Triennial Review Recommendation: Governance of NICE’s Independent Advisory Committees

Date: 16 March 2016

Ref: 16/029
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<td>The application of the methods by the committee is subject to public consultation and subsequently to the consideration of appeal. The grounds for appeal are described in the 2013 Regulations; NICE has failed to act fairly, or has exceeded its powers, or the recommendation is unreasonable in the light of the evidence submitted to NICE. The latter ground is a key vehicle for stakeholders to express their concerns about consistency of the recommendations.</td>
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<td>NICE’s Guidance Executive, which consists of the Senior Management Team, provides further oversight as it receives the recommendations from each of the committees with a detailed report from the NICE team describing they key issues that have been encountered in the appraisal. NICE provides support for regular meetings of Chairs and Vice-chairs of the four appraisal committees in which experiences are shared, and where key areas of potential risk of inconsistency between committees are addressed. The Programme Director attends all committee meetings.</td>
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<td>For guideline committees, the process, methods and economics working groups continue to provide cross-programme fora for discussion of implementation issues associated with the guidelines manual. This includes both process issues, for example around micro processes and the agreement of operational procedures, discussions around consistency of the application</td>
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### Area of concern

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<td>of methods, and consistency of the approach to quality assurance.</td>
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<td>Similarly, a quarterly meeting of the chairs of the four Quality Standard Advisory Committees, discusses issues of consistency. An internal group, comprising members of the quality standards team, reviews each product at various stages during development to ensure similar providing a shared governance approach and ensuring consistency. Again, NICE’s Guidance Executive provides oversight and quality assurance.</td>
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Feedback from workshops and interviews suggested that the approach to NICE’s governance of each committee or group was dependent on the NICE member of staff responsible for the group. (See also earlier, related comments.) Consistency within each programme is assured by performance management of individuals, and discussion of issues at senior team meetings.

### Accountability

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<td>NICE needs to strike a balance, carefully, between securing the independence of its advisory committees and holding them to account for their application of our published methods and processes. They must follow those methods and processes, respond appropriately to the reasoned arguments put to them and deal with the outcome of appeals against their proposed guidance. Beyond that, we and our stakeholders must accept the outcome of their deliberations even though may sometimes be uncomfortable to do so.</td>
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This paper sets out success criteria for the Institute’s external engagement activities delivered by the field team for 2016-17. The paper outlines:-

- Priority audiences
- Aims of engagement
- Approaches to delivering engagement
- Success criteria and process measures against which success will be evaluated

The Board is asked to approve the success criteria and process measures.

Professor Gillian Leng  
Director, Health and Social Care  
March 2016
Introduction

1. The objective of the field team is to ensure that NICE is recognised across health, public health and social care as the primary source of high-quality, evidence-based guidance, advice and standards, and that these are routinely incorporated into practice.

2. In 2015-16, the field team moved away from purely activity based targets in order to demonstrate the impact of engagement to outcome based criteria. This paper continues this process and proposes a combination of success criteria and process measures to evaluate the team’s activities in 2016/17.

3. The success criteria are aligned with priorities contained in the NHS planning guidance 2016/17 - 20/21 and the Five Year Forward View, especially with respect to new care models, primary care and sustainability and transformation plans (STPs). As a flexible resource the field team will adapt its approach to engagement to respond to developments in national policy, changes in local context and the identification of new needs of both national partners and local health and social care economies.

4. Engagement with local authority social care commissioners and social care providers will form a significant part of the field team’s activities in 2016/17. The key objectives are to raise awareness and embed guidance and quality standards at local level. This is in line with recommendations 7 and 9 of the Triennial Review, which recommend that NICE increase its engagement with social care stakeholders and NICE’s own ambition that this audience become major users of guidelines and quality standards.

5. The field team will engage with Public Health England’s (PHE) local teams to support the prevention and health and wellbeing priorities contained in the NHS planning guidance and to support in practice the principles of joint working agreed by NICE and PHE. The field team will work with PHE to support the uptake of NICE guidelines and quality standards by local authorities.

6. In addition to engaging with these prioritised audiences, the field team will continue to work with other partner organisations, responding flexibly to new opportunities. This will include, providing on request tailored packages of resources and support, facilitation of workshops, engagement with local networks and contributions to conferences.
7. As part of the planning process, the field team have identified and liaised with a range of centres, directorates and teams within NICE to request their support where necessary and to ensure that work programmes are appropriately aligned. Collaboration will be key to the delivery of the success criteria and the field team will continue to work closely with colleagues across NICE.

8. A new six monthly report looking at the impact from a range of NICE’s activities, including external engagement, will be developed and presented to the Board from July 2016. The field team will contribute to the report which will replace the field team’s existing annual and six monthly reports.
## External engagement success criteria 2016-17

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<tr>
<th>Target group</th>
<th>Aim of NICE engagement</th>
<th>Delivery approach</th>
<th>Process measure and success criteria</th>
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<tr>
<td>Sustainability and Transformation Footprints</td>
<td>- To support local and national organisations in delivering the objectives of the NHS shared planning guidance, helping to ensure that sustainability and transformation plans (STPs) are informed by relevant NICE guidance and quality standards, especially in the areas of obesity, diabetes, mental health, cancer, learning disabilities and prevention&lt;br&gt;&lt;br&gt;- To ensure that NICE remains up to date on national developments and aware of opportunities to promote uptake of guidance and quality standards</td>
<td>- National:- membership of the national STP Design and Delivery Group&lt;br&gt;- Regional:- contribution to the design and delivery of the STP regional development days&lt;br&gt;- Local:- identifying opportunities for local engagement as a result of regional development days</td>
<td>- Process measure:- contribution to design and delivery of the STP regional development days&lt;br&gt;- Success criteria:-20 examples of working with STP footprints to embed the use of NICE guidelines and quality standards in local plans</td>
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<td>Vanguards, new care models, National Association of Primary Care (NAPC) Rapid Test Sites and GP Federations</td>
<td>• To support the delivery of NHS shared planning guidance at national level by establishing an effective working relationship with NHS England’s New Care Models Team, identifying how NICE guidance and quality standards support the success of the vanguard programme  &lt;br&gt; • To support local vanguard sites and the National Association of Primary Care Rapid Test Sites in delivering their objectives  &lt;br&gt; • To develop intelligence on the development of GP Federations to support future engagement programmes</td>
<td>• National: establish an effective working relationship with NHS England New Care Models Team and the National Association of Primary Care  &lt;br&gt; • Local: identify key contacts and leaders, and build an effective working relationship with each vanguard site and NAPC Rapid Test Site and GP Federations</td>
<td>• <strong>Process measure:</strong> engagement with 52 (80%) of NHS England vanguard sites and NAPC Rapid Test Sites  &lt;br&gt; • <strong>Success criteria:</strong> an example recorded from each vanguard and Rapid Test Site engaged with outlining their current use of NICE guidance, quality standards or indicators  &lt;br&gt; • <strong>Success criteria:</strong> initial engagement with 30 GP Federations and intelligence obtained from each on their use, or planned use, of NICE guidance, quality standards or indicators</td>
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| Public Health England       | • To support the NHS shared planning guidance ‘must dos’ with respect to public health and prevention  
• To support at regional and local level the principles of joint working agreed between NICE and Public Health England                                                                                       | • Regional and local: to work with PHE regional and local teams to jointly support uptake of NICE recommendations, in particular using the PHE and field team contacts to support uptake in local government                                      | • **Process measure:** minimum of one collaborative project between NICE and PHE established with each of the 9 PHE centres  
• **Success criteria:** 40 examples of NICE public health related guidelines or quality standards being used to inform local authority health and wellbeing policies or commissioning arrangements |
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| **Local authority social care commissioners** | • To promote the uptake of NICE guidelines and quality standards by local authority commissioners of social care in line with the recommendations of the Triennial Review and Institute’s own ambition of ensuring that that the social care sector is a major user of NICE produce  
• To encourage and support the use locally of NICE guidelines and quality standards by local authority commissioners of social care | • Local: a targeted programme of visits to individual directors of social care  
• Regional: engagement with regional bodies and workshops with regional networks as requested  
• Promoting current and forthcoming social care guidance and quality standards including the ‘transition’ guidelines, domestic violence, excess winter deaths, home care and social care needs of people with multiple long term conditions | • **Process measure:** engagement with 120 (80%) of local authority social care commissioners  
• **Success criteria:** for all local authorities visited, a practice example outlining how they are implementing, or have challenges with recommendations from either, the NICE guideline on transition between inpatient hospital settings and community or care homes settings for adults with social care needs or, transition from children’s to adults services |
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<td>Social care provider networks</td>
<td>• To promote the uptake of NICE guidelines and quality standards by providers of social care in line with NICE’s ambition of ensuring that the social care sector is a major user of NICE produce  &lt;br&gt; • To build on the engagement programme delivered in 2015/16 to encourage and support the use locally of NICE guidelines and quality standards by providers of social care.</td>
<td>• Regional:- delivery of workshops to regional and county social care associations on the practical use of NICE guidance and quality standards to support providers and their staff to improve quality of care for service users</td>
<td>• <strong>Process measure:-</strong> engagement with 10 county/regional social care provider networks  &lt;br&gt; • <strong>Success criteria:-</strong> for all networks visited, a practice example outlining how they are implementing, or have issues, with recommendations from the NICE guideline on transition between inpatient hospital settings and community or care homes settings for adults with social care needs</td>
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| NHS acute and specialist trusts | • To support a systematic approach to the use of guidelines and quality standards to help address the requirements of the NHS planning guidance to make improvements in quality and reduce avoidable mortality rate  
• To support the systematic use of cost saving guidance and related resources | • Local: a targeted visit programme delivered to medical directors and/or chief nurses of NHS trusts and NHS foundation trusts  
• Regional: identifying and establishing links with local/regional offices of NHS Improvement | • **Process measure:** engagement with 120 (80%) of acute and specialist trusts engaged with during 2016/17  
• **Success criteria:** for all trusts visited, a practice example outlining how they are using (or reasons for not using) NICE guidelines, quality standards and associated resources to deliver value for patients and demonstrate improvements in quality |
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| NHS mental health trusts         | • To support local organisations to achieve the requirements of the NHS shared planning guidance, and the recommendations of the mental health taskforce report, in making measurable progress in improving parity of esteem for mental health  
• To assess whether a ‘virtual’ approach is an effective means of engaging with this target group and if so, how it might be used to engage with other audiences | • Virtual: engagement will be designed flexibly in the form of a webinar. The focus will be on encouraging discussion around the implementation of guidelines and quality standards, and measurement of uptake, which can support the delivery of services which increase parity of esteem between physical and mental health services | • **Process measure:** an assessment of the cost effectiveness of the webinar  
• **Success criteria:** an evaluation of the webinar from the attendees’ perspective |

Date: 16 March 2016
Ref: 16/030
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE AND PUBLIC HEALTH ENGLAND: PARTNERSHIP AGREEMENT AND PRINCIPLES FOR JOINT WORKING

The Board is asked to:

- Note the Partnership Agreement and associated principles for joint working between NICE and Public Health England (PHE)
- Consider the implications of implementing the principles.

Professor Gillian Leng
Director, Health and Social Care
March 2016
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE and Public Health England: Partnership Agreement and Principles for Joint Working

Introduction

1. NICE and Public Health England (PHE) share the common purpose of using evidence to enable the NHS and Local Government to deliver better services that improve and protect the public’s health.

Purpose

2. This Partnership Agreement recognises the individual responsibilities of NICE and PHE in delivering improvements in population health and sets out principles for working in partnership to align common interests and further support the public health system.

3. The Agreement has been reviewed and agreed with PHE.

Recommendations for Board

4. The Board is asked to

- Note the Partnership Agreement and associated principles for joint working between NICE and PHE
- Consider the implications of implementing the principles.

Professor Gillian Leng
Director, Health & Social Care
March 2016
PARTNERSHIP AGREEMENT BETWEEN

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

AND

PUBLIC HEALTH ENGLAND

APRIL 2016
OBJECTIVE

1. This document sets out the nature of the partnership between the National Institute for Health and Care Excellence (NICE) and Public Health England (PHE). It is not intended to imply a legal commitment and is not intended to create or result in any legally binding rights or obligations; its purpose is to define the joint agreement between the two organisations and to indicate an agreed line of action.

CONTEXT

2. NICE and PHE share the common purpose of using evidence to enable the National Health Service (NHS) and Local Government to deliver better services that improve and protect the public’s health.

3. Some functions are unique to one organisation, such as PHE providing advice to Ministers and running systems for emergency preparedness, and NICE having a formal remit to issue quality standards. In areas relating to the provision of evidence for public health, however, the functions are less distinct.

4. The ‘public task’ of NICE means the mandatory functions that NICE is under a legal duty to perform as set out in the Health and Social Care Act 2012. Activities within the public task include:
   
   • The provision of quality standards in relation to the provision of NHS services, public health and social care in England
   • The provision of advice, guidance, providing information and making recommendations about any matter concerning or connecting with the provision of NHS services, public health services and social care services in England.

5. PHE’s Remit Letter says that PHE is tasked with:
   
   • providing evidence-based advice on which the Government will provide the national policy response
   • supporting local government in identifying its priorities for improving the health and well-being of local populations
   • acting as NHS England’s public health advisor helping to ensure that the NHS secures the maximum health gain from its resources.

6. There are no formal, statutory requirements for NICE and PHE to work together. Joint working is important, however, in terms of efficient use of resources and for communicating alignment of purpose to the wider system, demonstrating that we do work together to deliver improvements in the public’s health.
PURPOSE

7. The partnership between PHE and NICE is a key aspect of helping the public health system to deliver improvements in population health. It makes a vital contribution to the work of the Five Year Forward View especially, but not only, the Prevention Board and local prevention plans. The work also supports Sector Led Improvement work by local authorities, especially as the funding stream moves from the public health grant into the business rate retention system.

PRINCIPLES

8. Three principles of complementarity, singularity and inclusivity have been agreed between NICE and PHE:

- **Complementarity** – functions and programmes are aligned and supportive. For example, NICE provides guidance to local practitioners, and support for local implementation can be provided via the PHE Centres and links with local Government.

- **Singularity** - no duplication of activity. This means there should be no duplication of:
  - Advice or guidance to the same audience on the same topic
  - Evidence synthesis or reviewing activity, even when not designed directly for a public audience
  - Resources for display through online web portals or via mobile applications.

- **Inclusivity** – seeking to include each other where relevant, and to share outputs. This will include joint badging by PHE of NICE guidance in relevant public health topic areas, and the potential for mutual endorsement of relevant products.

PRACTICAL ACTIONS

9. A number of practical actions will need to be put in place to take forward these principles. These actions will include agreements on key issues, such as product names, and ongoing processes that facilitate joint working and communications.

Defining evidence-based products

10. A common set of terms has been agreed to describe the key evidence-based outputs of both organisations, thus ensuring complementarity. This is particularly important in relation to potentially overlapping areas, such as evidence summaries and guidance. A proposed approach for key terms is given in appendix 1, highlighting that the terminology used for the outputs needs to be linked to the methodology for their
production. This list of products is not designed to be comprehensive, but to include those areas where we both have outputs. Where appropriate, it relates to the public health taxonomy agreed by PHE and NICE for classifying externally produced material for display via various web portals.

Regular engagement on topic areas of common interest

11. Regular engagement will support all three principles, and generally help facilitate ongoing communications. A number of regular forums have been established to take this forward in the future:

- A Points of Engagement Meeting, to act as an umbrella meeting between NICE, PHE and DH
- Thematic Group meetings, in areas such as environmental health and tobacco control, and economics
- Assessment of mobile health applications, under the umbrella of the National Information Board
- Taxonomy group to cover joint working on online evidence.

Processes to underpin routine work in related areas

12. To ensure adherence to all three principles, it is important that the processes used to develop core products clearly indicate the ways in which there is joint engagement. This is likely to be important for, as a minimum: guidance products; return on investment tools; and online information services. The joint process may include how:

- Topics are approved for product development to ensure both parties are sighted on future work plans, thus helping to avoid duplication
- The scope of any relevant work and audiences are agreed. NICE guidance is not aimed at policy makers unless specifically requested, but in other areas audiences are more flexible
- There is ongoing engagement during product development
- Quality assurance is carried out, especially where formal sign off is required for joint badging.
- Communications planning operates between the two organisations.

Commissioning work

13. Both organisations should consider whether commissioning work from each other will avoid duplication, and take advantage of existing skills, experience and reputation. This may be work that already relates to the organisational remits of NICE and PHE, underpinned by this Partnership Agreement, or be specific requests from PHE to NICE to develop guidance in a particular area. More formal commissions representing new work may require a more formal contract.
Communications and implementation support

14. In general, the NICE and PHE communications teams need clear consistent messages that present the different roles and responsibilities of NICE and PHE to a range of audiences, including Ministers.

15. The NICE implementation function needs to work with PHE to jointly support uptake of NICE recommendations, in particular using the local PHE teams and their links to local government.

ARRANGEMENTS FOR THE PRINCIPLES

15. These principles will be effective from 01st April 2016 and will be reviewed annually.

Signed by, for and on behalf of the National Institute for Health and Care Excellence, 1st Floor, 10 Spring Gardens, London, SW1A 2BU

Name:
Signature:
Position:
Date:

Signed by, for and on behalf of Public Health England, Wellington House, 133-155 Waterloo Road, London, SE1 BUG

Name:
Signature:
Position:
Date:
**CONTACT POINTS**

**For NICE**

<table>
<thead>
<tr>
<th>Name</th>
<th>Gillian Leng</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office Address</td>
<td>10 Spring Gardens, London, SW1A 2BU</td>
</tr>
<tr>
<td>Telephone Number</td>
<td>020 7045 2061</td>
</tr>
<tr>
<td>E-mail Address</td>
<td><a href="mailto:Gillian.leng@nice.org.uk">Gillian.leng@nice.org.uk</a></td>
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**For PHE**

<table>
<thead>
<tr>
<th>Name</th>
<th>Richard Gleave</th>
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<tbody>
<tr>
<td>Office Address</td>
<td>Wellington House, 133-155 Waterloo Road, London, SE1 8UG</td>
</tr>
<tr>
<td>Telephone Number</td>
<td>07767 352270</td>
</tr>
<tr>
<td>E-mail Address</td>
<td><a href="mailto:Richard.gleave@phe.gov.uk">Richard.gleave@phe.gov.uk</a></td>
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</table>
APPENDIX 1: PRODUCT DEFINITION

These product definitions help ensure NICE and PHE adhere to the principles set out above, and provide greater clarity for external audiences and end users.

<table>
<thead>
<tr>
<th>Product</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Standards</td>
<td>Standards are agreed levels of practice or service that are intended to set thresholds, either as minimum levels of practice or more stretching requirements for higher levels of practice or service. Standards may fulfil a variety of functions, such as forming part of an inspection process or setting out professional requirements. All producers of standards should make clear to users the role a standard fills and its status.</td>
</tr>
<tr>
<td>Guidelines</td>
<td>Guidelines are sets of statements or recommendations intended to guide decisions. They do not set mandatory requirements. The methods and rigour by which guidelines are developed are crucial if they are to be trusted sources for the public and practitioners. Guidelines should be systematically developed, based on the best available published research evidence and be clear, precise and easy to follow. The NICE accreditation programme assesses the processes followed by other guideline producers against international standards (AGREE), so users can recognise if guidelines are of the highest quality. Guideline production requires an independent advisory group to assess and interpret the evidence. NICE has a number of Public Health Advisory Committees to fulfil this function. The closest activity in PHE relates to the Joint Committee on Vaccination and Immunisation (JCVI) and the UK National Screening Committee (UKNSC), although the general process that these committees follow has not been assessed against guideline criteria.</td>
</tr>
<tr>
<td>Evidence summaries</td>
<td>Evidence summaries are a critical assessment of the current evidence, without providing recommendations for practice. Evidence summaries are most useful for providing decision-makers, either local or national, with a critical assessment of the current evidence. This should be a complete, comprehensive and objective assessment of the relevant evidence, without interpretation of what that means in practice. PHE is undertaking further work to clarify the different models of evidence summary that it is uses to deliver specific requests, including systematic reviews, rapid reviews and evidence reviews.</td>
</tr>
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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

REVISIONS TO THE NICE STANDING ORDERS, STANDING FINANCIAL INSTRUCTIONS AND RESERVATION OF POWERS TO THE BOARD AND SCHEME OF DELEGATION

NICE is required to review its Standing Financial Instructions, Standing Orders, and Reservation of Powers to the Board and Scheme of Delegation annually. Following this review, a number of relatively minor updates are proposed. These are summarised in this report for the Board’s approval. The full documents are available on request.

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

Ben Bennett
Director, Business Planning and Resources
March 2016
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

REVISIONS TO THE NICE STANDING ORDERS, STANDING FINANCIAL INSTRUCTIONS AND RESERVATION OF POWERS TO THE BOARD AND SCHEME OF DELEGATION

Introduction

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

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

Changes made to the documents

3. Changes have been made throughout the three documents to:

   • Clarify the references to the committees (and whether the text refers to the Board committees or other committees in place at NICE such as the advisory bodies)
   • Ensure the text is clear as to whether it is referring to the Board or to NICE overall (the Institute)
   • Ensure references within and between the documents are consistent, both in terms of the consistency of the content and the numbering of the paragraphs
   • Update the value of the EU tender limit.

4. In addition, the following amendments have been made to the specific documents:

   Standing Orders (SOs)

5. The reference to the Board minutes being signed has been deleted as the current wording does not reflect established practice at NICE.

   Reservation of Powers to the Board and Scheme of Delegation

6. The following matter reserved to the Board – ‘the appointment and dismissal of committees’ – has been amended to ‘the establishment and dissolution of Board committees’ to clarify that the Board’s role is to establish / appoint the committee as an entity rather than appoint the individual members of these committees.
Standing Financial Instructions

7. The section on the role of the Audit and Risk Committee has been updated to reflect its current terms of reference.

8. Clarification has been added that the use of capital budgets to finance running costs (revenue expenditure) requires approval from the Department of Health in addition to the Chief Executive.

9. Terminology through the document has been updated, for example on budget transfers, and reference to PayPal accounts and corporate credit cards has been added to the relevant sections.
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  
March 2016
Centre for Health Technology Evaluation

This report provides the Board with a narrative progress report on the main business plan objectives the Centre for Health Technology Evaluation for April 2015 – February 2016. It also highlights other significant activities undertaken during this period and recent developments within the Centre that may be of interest to the Board.

Business Plan Objectives April 2015 – February 2016

Technology Appraisals Programme

1. Based on the latest information on the regulatory status of relevant medicines, the technology appraisal programme has achieved the business plan target of publishing 45 pieces of final guidance. By 31 March 2016, the programme will have published 48 pieces of final guidance. 20 topics were cancer topics, and 28 topics non cancer topics.

2. The technology appraisals team have worked in partnership with NHS England to develop new proposals for the management of the CDF from July 2016 onwards. Details of the operation of the new CDF arrangements have been presented to the Board previously and feedback from the recent consultation on the proposals is presented in a separate paper to the Board at this meeting.

Patient Access Scheme Liaison Unit

3. The patient access scheme liaison unit has exceeded its target of producing 12 pieces of advice to Ministers and is currently anticipated to provide advice on 36 patient access schemes by the end of this business year.

Medical Technologies Evaluation Programme

4. Between April 2015 and February 2016, the Medical Technologies Advisory Committee (MTAC) considered Briefing Notes on 21 newly-notified technologies. Of these, 5 were selected and routed for medical technologies guidance and 6 for diagnostics guidance. A further 4 notifications had, after additional work undertaken by the programme team, sufficient information to progress to committee and 1 notification did not meet the programme’s eligibility criteria.

5. Based on MTAC’s past selection and routing decisions, 8 medical technology guidance documents were expected to be published during 2015/16. Four topics have needed to be rescheduled and are now planned to publish in 2016/17:

- one topic is delayed because the company has not yet made an evidence submission
- one topic was rescheduled pending availability of key UK clinical effectiveness study findings. Guidance development is now planned to start in May 2016 for planned publication in March 2017.

- one topic was rescheduled to allow alignment with the planned partial update to clinical guideline 65: inadvertent perioperative hypothermia. Consultation on the draft recommendations is planned for May 2016 for anticipated publication in September 2016.

- one topic was paused due to the need for alignment with the update to clinical guideline 95: chest pain of recent onset. It is planned that the committee will reconsider its current provisional recommendations together with relevant new information in May 2016.

- Another topic, selected and routed for medical technologies guidance, was subject to regulatory status change and the company was acquired. Guidance development on this topic has not been initiated. The new sponsor company is engaged with the programme and has provided details of the regulatory strategy being pursued, and the likely timescales.

6. The programme is forecast to publish 36 medtech innovation briefings (MIB) compared with a business plan target of 40. More topics than expected (12/48) had to be delayed or stopped for reasons outside NICE’s control, for example, products withdrawn from UK market. The team aims to mitigate the impact of this by monitoring topics and restarting where possible; and some of the delayed topics will publish early in 16/17.

7. In January 2016, the medical technologies programme published the 50th MIB, on the Bladderscan portable ultrasound scanner for measuring bladder volume.

8. With the help of NICE’s Audience Research Team, the programme has recently undertaken a survey of MIB users. The majority of users find the MIBs useful and use them to inform clinical and commissioning decisions. The respondents also gave feedback on the usefulness of different sections of the MIBs. This feedback is now being used by the team to make the output more concise and focussed on the content of greatest value.

9. The MIB team has begun the process of reviewing its published guidance. The review consideration process has commenced on 6 topics with a further 2 topics planned to commence before the end of March 2016.

10. Between April 2015 and February 2016, the MTEP research facilitation function, which helps companies identify and commission researchers to generate evidence to address guidance recommendations for further research, has worked on 13 projects. Overall, the work has included:
Completion of feasibility studies to inform potential research on 3 guidance topics;
- Ongoing oversight of projects involving pragmatic trials on patients for 5 guidance topics;
- Development of project specifications and protocol generation for 2 recent guidance topics;
- Initial scoping work on 2 further new guidance topics.

The programme encourages publication of research facilitation outputs. Over the past 5 years, the publication output of the MTEP research facilitation work stream will amount to over 50 publications including high-quality peer-reviewed journals and the Pubmed bookshelf.

11. The programme team has carried out 112 product-focussed company engagement meetings to identify potential new topics for guidance production or a MIB. Senior members of the programme carried out 28 national and international speaking engagements or conference presentations, providing further opportunities for engagement with the life sciences and digital technology industries, NHS networks and academic and professional groups.

12. The Programme Director has been invited to speak about our experience with medical technology and diagnostic evaluation at key international meetings and conferences in the last year including a keynote plenary session at the major pharmaco-economics conference, ISPOR, joining 3 panels at the HTA International conference, and joining the UK Office for Life Sciences delegation at the US medical technologies conference, Advamed.

**Interventional Procedures Programme**

13. The interventional procedures programme is on target and expected to publish 34 pieces of guidance.

14. The programme team has also delivered a substantial update to the programme manual which will improve the way in which the programme relates to, and interacts with, the medical devices industry. The update implementation plan is now underway, with the team initiating changes and process efficiencies as soon as possible.

**Diagnostics Assessment Programme**

15. The diagnostics assessment programme has published 6 pieces of guidance this business year and this completes the publication of diagnostics guidance for 2015/16. A second consultation was initiated for the PlGF-based testing to help diagnose suspected pre-eclampsia topic. This resulted in the anticipated earliest guidance publication date moving from 9 March 2016 to 11 May 2016.

16. Given the intense life science and healthcare system interest in diagnostics, the programme has significantly increased external engagement activities during 2015/16. This has resulted in an increased awareness of NICE’s diagnostics capability and expertise and has provided the opportunity for
NICE to participate in key policy discussions and influence the development of national policy. Interactions have included:

- Regular formal dialogue with the Chief and Deputy Chief Scientific Officer for NHS England, resulting in a proposal to initiate a NHS England/NICE diagnostics liaison group
- Membership of the NHS England Personalised Medicine Strategy Board
- Membership of the NIHR Diagnostics Evidence Cooperatives methodology group
- Participation in the NHS England Specialised Services group that introduced changes to the funding mechanism for molecular genetic tests associated with a companion drug or chemotherapy treatment
- Dialogue with the Prime Minister Review on Antimicrobial Resistance and advice on the economic assessment of diagnostics to inform antimicrobials prescribing and identification of resistance
- Routine engagement with diagnostics related professional bodies resulting in the identification of diagnostics assessment of topics of high clinical interest e.g. Molecular testing for Lynch syndrome in people with colorectal cancer

Highly Specialised Technologies Programme

17. The HST program has published 1 piece of guidance this business year and has run 4 scoping workshops. Each topic being evaluated in HST has resulted in 3 committee meetings. The need for extensive interaction and dialogue is due to the intense liaison required with relevant stakeholders during both value assessment and when developing value for money access proposals for medicines for very rare diseases.

18. For a number of current topics, the highly specialised technologies programme has been in discussions with NHS England, companies and stakeholders to produce managed access agreements. The agreements are intended to facilitate affordable access to the technology and capture data for a future evaluation.

19. The HST Associate Director has been invited to present at 3 conferences to outline the NICE HST evaluation process. Feedback from very rare diseases patient organisations at these meetings has been very positive with respect to the open and transparent communication style by NICE.

Observational Data Unit

20. The Observational Data Unit, commissioned and funded by NHS England, is working on 6 Commissioning through Evaluation projects: 3 involve implantable cardiac devices, 2 involve novel radiotherapy techniques and 1 involves dorsal surgery on children with spasticity.

21. These projects are complex and require collecting and submitting patient-level data to modified existing, or newly created, datasets for analysis by our external assessment centres. This gives rise to a number of practical, methodological and ethical challenges, particularly the need to collect high
quality data and meet standards of information governance, data protection and research governance in real world settings. This involves a great deal of quality control and oversight. The experience of coordinating these Commissioning Through Evaluation projects will be helpful to NICE as we develop our processes for supporting the managed access of innovative technologies into the NHS.

**NICE Scientific Advice**

22. NICE Scientific Advice anticipates full recovery of all programme and overhead costs and is expected to exceed its annual business targets.

23. By the end of February 2016, NICE Scientific Advice will have completed 42 advice projects since the beginning of the financial year, hosted 3 educational seminars and attended 38 external events whilst also working on the development of the novel Medtech Early Technical Assessment (META) Tool.

**Science Policy and Research Programme**

24. The SP&R programme is continuing its work on two IMI funded projects – “GetReal”, a pan-European consortium of medicines regulators, HTA bodies, pharmaceutical companies, patients and other stakeholders to explore the role of real-world evidence (RWE) for informing decision making, both during drug development and in subsequent assessment by regulators and HTA bodies; and “ADAPT-SMART” which provides an opportunity to design new collaborative approaches to the development of medicines through what is known as ‘Medicines Adaptive Pathways to Patients (MAPPs). There are 4 members of NICE staff funded by the IMI grant to deliver our work on these two projects.

25. The team is currently exploring the potential of participating in a number of EU funded research projects, including IMI and Horizon 2020.

26. The team has commissioned four projects through its Research Support Unit (RSU); including work to map the social care research funding landscapes and a project exploring the way in which diverse real-world data sources in clinical, health and social care can support NICE guidance production.

27. The SP&R team has led a programme with guidance producing teams to identify “key priority” research recommendations for fast-tracking through NIHR identification and prioritisation processes. This arrangement was introduced in January 2015 following negotiations with the NIHR, which put in place closer cooperation between NICE and NIHR during guidance production. This provision is proving very beneficial; priority research recommendations flagged from advisory bodies using the new process has resulted in five topics being considered or accelerated through NIHR. In addition, there has also been an increase in requests from committee Chairs and Centre Directors for NIHR advice.
28. The Citizens Council meeting held in November 2015 considered the ethical and practical issues in the use of anonymised information derived from personal care records as part of the evaluation of treatments and delivery of care; the report of the meeting will be presented to the Board in May following a period of public consultation. The Citizens Council continues to attract international interest, with requests to speak & engage with organisations including the National Health Insurance Service (NHIS) in South Korea and the Netherlands institute for health services research (NIVEL); a representative from the Centre for Drug Evaluation in Taiwan observed the November 2015 meeting following a Citizens Council presentation to a delegation that visited NICE earlier in 2015.

**Cancer Drugs Fund**

29. Consultation on the new Cancer Drugs Fund (CDF) proposals is now closed. A CDF transition board, with representatives from NHS England and NICE, has been established to oversee the transition to the new CDF arrangements.

30. Meanwhile we are proceeding with the re-consideration of drugs currently funded by the CDF in order to meet the review timelines set out in the CDF consultation document. A rapid reconsideration process is being used and additional Technology Appraisal Committee meetings are being scheduled throughout the 2016-17 business year to accommodate the increased workload.

31. Companies have interacted positively with us during the reconsideration process. Meetings have been held with 8 companies covering 13 drugs, and we envisage publishing updated NICE guidance on the majority of these topics within 2016/17.

**The Office for Market Access (OMA)**

32. 188 enquiries have been received since OMA launched in October 2015. A third of these have been from medical technology & diagnostic companies, a third from pharmaceutical companies and third have been general enquiries about the role of OMA within the life sciences landscape. The team have also held 22 introductory meetings with companies. Rate cards for fee for service activities have been developed and we are in discussions with several companies regarding fee for service projects. OMA staff are also participating in speaking engagements, recovering costs through speaker fees in many cases.

33. OMA has published procedures explaining how NICE supports the Early Access to Medicines Scheme (EAMS) run by the Medicines and Healthcare products Regulatory Agency. EAMS provides an opportunity for important drugs that address high unmet medical need to be used in UK clinical practice in parallel with the later stages of the European regulatory review process. It is anticipated that medicines with a positive EAMS opinion could be made available to patients 12-18 months before formal marketing authorisation.
34. The team is working with two companies on pilots of ‘safe harbour’ discussions. We anticipate that this process will offer meaningful assistance to companies through NICE brokering multi-stakeholder, non-binding discussions with NHS England, clinical commissioning groups, patient groups and regulators in a facilitative environment that allows identification, and exploration, of potential market access issues and their solutions.

**Topic Selection**

35. During the 2015/16 business year (up to end of February 2016), the Topic Selection team have considered 281 topics for either the Technology Appraisal or Highly Specialised Technologies programme.

**General Centre activities**

36. Between April 2015 and February 2016, 42 members of staff attended 37 training courses or conferences as part of their personal development plans.

37. Fifteen committee members were recruited to 8 committees within the Centre. This also included two new committee Chairs for MTAC and IPAC following the departure of Professor Bruce Campbell.

38. Between February and December 2015, Nina Pinwill, CHTE Associate Director was seconded to the Office for Life Sciences to work on the Accelerated Access review. As a Senior Policy Lead, Nina led the development and engagement on how horizon scanning could be enhanced to help support NHS forward planning and align life science product development closer to health system priorities. Nina also worked on plans for the proposed National Innovation Partnership, the forum for arm’s length bodies, including NICE, to work together to support faster patient access to transformative technologies.

39. Between April 2015 and February 2016, the CHTE Equality Expert Group held 6 meetings. In total, the group has considered 20 requests for real time advice from Centre staff working on guidance production on equality issues.
Key indicators

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

Figure 1. Programme activity April 2015 - February 2016

<table>
<thead>
<tr>
<th>Ref</th>
<th>Programme</th>
<th>Unit of output</th>
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<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>
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<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>
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The Centre for Clinical Practice (CCP) develops and maintains a portfolio of high quality, timely, evidence based and 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. These guidelines form the principal source for Quality Standards.

The Centre for Clinical Practice also includes the NICE Medicines and Prescribing Programme, which provides 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 and supports commissioned work for NHS England.

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

The Board is asked to review the progress report.

Professor Mark Baker  
Director, Centre for Clinical Practice  
March 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 and 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, 33 have been published up to the end of February. The 33 publications are listed in Appendix A.

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 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, 31 have been published up to the end of February 2016, including 7 ad hoc or exceptional reviews. These were due to challenges to decisions or as a result of identified safety issues being raised. The 31 publications are listed in Appendix B.

8. Thirteen surveillance reviews are in progress and a further 5 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.
starting in February 2016. Two surveillance reviews have been sub-contracted using CCP underspend. The 4 and 8 year full reviews have been prioritised for delivery this year.

9. We continue to evaluate and streamline these methods and processes to deliver an efficient programme. We have recently reviewed some of our microprocesses to shorten the time taken to conduct surveillance reviews with the aim of increasing planned outputs.

10. Work is ongoing to develop a process to allow a rapid response to anticipated new research.

11. Following publication of the diabetes suite of guidelines we are developing a process in collaboration with Evidence Information Services to conduct continuous searching and surveillance across the suite of diabetes guidelines. This will inform the work of the standing specialist diabetes committee being set up in the CGUT programme.

12. We have developed a reference panel and database of topic experts for CCP activities. Recruitment to the panel of former GDG members is progressing. Application forms have been sent to all those who responded positively to the invites and over 50% of completed application forms have been received to date. A gap analysis of specialist areas required will be carried out and wider recruitment to the panel is scheduled based on that analysis.

**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. These committees will focus on more generalist topics.

- Recruitment is currently underway for a chair for Committee A following the recent resignation of the existing postholder. Recruitment for a number of new core member posts for Committees A and B is also in progress.

- Committee C will focus on updates of specialist guidelines. Recruitment for a number of core standing members and condition specific standing members for Committee C is also currently underway.

- 23 topics in total have now been referred to the programme for updating of which 14 have published to date. Seven topics have been published this year.
New Contracts

14. The Centre for Clinical Practice has awarded two new contracts for the development of clinical guidelines and a new contract for the Technical Support Unit this year. Progress to date is as follows:

- Following an EU wide tendering process, the contracts for developing guidelines, were been awarded to the Royal College of Physicians (RCP) London and the Royal College of Obstetricians & Gynaecologists (RCOG).
- The contract negotiations with the RCOG and RCP are complete. Both contracts are agreed and have been signed by all parties. The new contracts will come into effect on 1st April 2016.
- The Statement of Transfer has been agreed and signed by the current host organisations, RCOG, RCPsych and the Velindre NHS Trust.
- A Transition contract with the RCOG has been agreed and awaiting signatories.
- We have agreed with the RCOG to manage the implementation of the new centre in a phased approach to reduce the risk of high staff turnover which could lead to a break to business continuity. This includes maintaining a small satellite office in Cardiff for a period of up to one year. This will allow time for relocation where staff wish, and to enable staff to test out new ways of working (home-based) or seek alternative local employment in a timely manner.
- The NICE steering group meets monthly to oversee governance and risk management and to ensure business continuity. The RCOG have in place a project board and operational groups, including representation from all members of the new centre.
- The contract with the University of Bristol, for the Technical Support Unit has been agreed, continuing our collaboration. The new contract will commence on the 1 April 2016.

15. 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 3 review meetings with contractors are underway. Estimated year-end financial positions are being monitored and actioned.
ITEM 13

- The current end of year position is predicted to report an underspend of approx. £140k, representing an underspend of 1% of the annual budget. We have commissioned two additional guidelines in year, Chest pain (update) and Heavy menstrual bleeding (update), as well as 2 surveillance reviews, utilising underspend.

- £600,000 of CCP underspend, that had accumulated from the Safe Staffing budget, has been transferred to NICE reserves resulting in a more accurate financial position for the directorate.

16. 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. This group will meet to discuss methods to address the challenges in developing service guidance.

- The service guidance, acute medical emergencies, is helping to populate six quality standards, namely; 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.

- We are collaborating with economists and operational researchers at MONITOR and NHS England to discuss their economic and modelling work on accident and emergencies services 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 Acute Medical Emergencies service guidance.

- We continue to contract the Technical Support Unit (TSU) to provide specialist technical and methodological advice for guideline-specific issues and ongoing training and development sessions for staff in the Centre for Clinical Practice, National Collaborating Centres and members of Guideline committees.

- We have maintained involvement with the international Grading of Recommendations Assessment Development and Evaluation (GRADE)
working group. Two members of staff will be attending the annual GRADE working group meeting in May 2016.

- The Centre’s proposal to the GRADE Guidance Group to co-lead with University College London, a UK GRADE Network has been accepted. The Network includes partners from the Scottish Intercollegiate Guideline Network (SIGN), Cochrane UK and BMJ Evidence amongst others. A launch meeting is being planned for quarter 1, 2016/17.

- We continue to attract interest from students and researchers seeking short-term placements to gain experience in clinical guideline development. We have agreed with the European Respiratory Society to host, with the Cochrane Collaboration, 2 research fellows for 3 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 Datasets was held in February 2016.

- We continue to promote the advance of methodological and process innovation in guideline development. Our approach to updating guidelines will form a plenary session at the 2016 Guidelines International Network conference.

**Medicines and Prescribing Programme (MPP)**

17. The purpose of the Medicines and Prescribing Programme (formerly the Medicines and Prescribing Centre) 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:

18. To publish 30 Evidence Summaries, including New Medicines, Unlicensed/off-label medicines and one Medicine and prescribing briefing. Of the 30 planned topics, 20 have been published up to the end of February 2016.

19. 12 Evidence summaries new medicines have been published and are listed in Appendix C.

20. 6 Evidence summaries unlicensed or off-label medicines have been published and are listed in Appendix C.
21. 2 rapid Evidence summaries unlicensed or off-label medicines were commissioned by NHSE, have been published and are listed in Appendix C.

22. The MPP reduced the total number of planned evidence summaries for 2015/16 in Q2/3 to release adviser capacity to support the guideline, surveillance and endorsement programmes. As a result 5 of the 6 evidence summary slots scheduled for publication in February were removed and 1 was rescheduled to publish in March 2016. MPP will publish 25 evidence summaries against a target of 30 for 2015/16.

23. To publish 2 Medicines Practice Guidelines. Of the 2 planned topics, 1 has been published up to the end of February and is listed in Appendix C.

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

BNF Print and Distribution

25. As reported in the previous quarter, the September editions of BNF and BNFC contained factual errors, some of which were rated as high risk by UK National Medicines Information. Some NHS Trusts have reported withholding or manually correcting the books. Consequently, after receiving advice from UKMi, NPPG and NPSA, the BNF Publisher will issue stickers which highlight the errors and direct users to the digital formats where they have been corrected. The stickers will be distributed across the UK to all recipients of print BNF and BNFC along with instructions from the BNF Publisher.

BNF Online

26. A steering group comprising representatives from NICE, the BNF Publisher, HSCIC, NHS BSA, DoH, Pharmaceutical Advisors Group and the Devolved Administrations has been established to develop an NHS owned information standard to replace the legacy BNF hierarchy, which is currently used in information systems across the NHS. The group will also focus on supporting transition to the new information standard, which will eventually be mandated.

27. The new BNF platforms on NICE Evidence are ready for Alpha release. NICE MPP staff and Associates will be provide expert feedback on the prototype sites, which are due for public release in April 2016.

BNF Apps

28. The BNF Publisher’s new app delivery has been delayed until April 2016. It is planned for release in June 2016 pending NICE approval. Transition planning is already underway via liaison with the BNF Publisher, NICE Communications and IM&T.
Cross Institute Work

Guidance Development Project (GDP)

29. 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:

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

31. NICE is in final stage 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. Initial training has taken place to enable to tool to be trialled across NICE programmes. Work will be undertaken over the next few months to provide an integrated solution to improve the efficiency of the document supply process.

32. The transformation of NICE guidance involves breaking down NICE content into elements that can discovered outside the document in which they were created. The first project in the knowledge base stream, creating a new searchable dataset of quality statements, is progressing well. Planning to extend the knowledge base to guidance recommendations is underway.

Recent developments

Access and Waiting Times - working in Partnership with NHSE

33. The Access and Waiting Times work programme has transferred to the Health and Social Care Directorate.

Contextualisation of clinical guidelines for non-UK settings

34. 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. 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.

35. Following an oral presentation showcasing this work was presented at the Guidelines International Network (GIN) conference in October 2015, we have received International interest. We are currently in discussion with guideline
developers from other countries such as Saudi Arabia and Ireland. In March, staff members will be meeting with the Clinical Effectiveness Unit Team at the Department of Health, Ireland.

**Medicines and Prescribing Programme (MPP)**

36. 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 were implemented during November and December 2015.

**Associates and associate recruitment**

37. The associates network operates in a wide range of settings to influence medicines and prescribing strategy. 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 commissioning services.

38. 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 (including 2 on sabbatical, 2 on maternity leave) in England, Wales, Northern Ireland, Guernsey and Jersey. Most are pharmacists but there are also 3 nurses, a hospital physician, and general practitioner.

**Associate development**

39. 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.

**Associate and NICE work programmes**

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

**Presentations**

41. 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 was developed in January (in collaboration with the associates), and launched at the final 2015-16 training day in February.

42. As part of the weekly medicines awareness service the MPP produces Medicines evidence commentaries (MECs). Medicines evidence commentaries help to contextualise important new evidence on medicines and prescribing, highlighting areas that could signal a change in clinical practice. It is expected to meet the target of 40 MECs this year.

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

44. 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, guidelines and endorsement programmes by providing structured but flexible advice around medicines. Formal arrangements will be agreed and fully implemented during 2016/17.

45. 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**

46. To date the MPP have assessed 11 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**

47. 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. The implementation tool will publish in June 2016.

**Rapid evidence summaries**

48. NHS England has accepted 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.
49. The programme will displace existing ESUOM slots, and is expecting to begin formally from 1 April 2016.

Professor Mark Baker
Director, Centre for Clinical Practice
March 2016
Key indicators

CCP Activity Summary

Clinical Guidelines Activity Summary

Published clinical guidelines

Cumulative Clinical Guideline Publications 2015/16

-5 0 5 10 15 20 25 30 35 40
April May June July Aug Sept Oct Nov Dec Jan Feb March

Cumulative Surveillance Review Publications 2015/16

-20 0 10 20 30 40 50
April May June July Aug Sept Oct Nov Dec Jan Feb March
Medicines Prescribing Programme Activity Summary

Published Evidence Summaries

Cumulative Evidence Summaries Publications 2015/16

-10 -5 0 5 10 15 20 25 30 35
April May June July Aug Sept Oct Nov Dec Jan Feb March

Planned
Actual
Variance
Appendix A

Clinical Guidelines Publications (April 2015 – February 2016)

- 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 (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 dying adults in the last days of life (NG31)
- Tuberculosis - clinical diagnosis and management of tuberculosis, and measures for its prevention and control, incorporating PH37 Tuberculosis - Hard to reach Groups (update) (NG33)
- Myeloma: diagnosis and management (NG35)
- Cancer of the upper aerodigestive tract: assessment and management in people aged 16 and over (NG36)
- Complex fractures: Assessment and management of complex fractures (NG37)
- Fractures: Diagnosis, management and follow up of fractures (NG38)
- Major trauma: assessment and management of airway, breathing and ventilation, circulation, haemorrhage and temperature control (NG39)
- Major trauma services: service delivery for major trauma (NG40)
- Spinal injury assessment: assessment and imaging, and early management for spinal injury (spinal column or spinal cord injury) (NG41)
- Attention deficit hyperactivity disorder (standing committee update) (CG72)
- Motor neurone disease: Assessment and management of motor neurone disease (NG42)
Appendix B

Surveillance Reviews Publications (April 2015 – February 2016)

Two year reviews:
- Antisocial behaviour and conduct disorders in children and young people (CG158)
- Crohn’s disease (CG152)
- Falls (CG161)
- 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)
- Varicose veins in the legs (CG168)

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)
- Colorectal cancer (CG131)
- 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)
Twelve year reviews
- Improving outcomes in colorectal cancer (CSG5)

Exceptional reviews
- Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) (CG53)
- Diagnosis and management of CFS/ME in adults and children (CG53)
- Surgical management of otitis media with effusion in children (CG60)
- Caesarean section (CG132)
- Alcohol use disorders: diagnosis and management of physical complications (CG100)
- Prostate cancer: diagnosis and management (CG175)
- Depression in children and young people: Identification and management in primary, community and secondary care (CG28)
Appendix C

Medicines Prescribing Programme Publications (April 2015 – February 2016)

Evidence summaries new medicines:

- 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
- ESNM 68: Inflammatory lesions of papulopustular rosacea: ivermectin 10 mg/g cream

Evidence summaries unlicensed or off-label medicines:

- 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

Rapid Evidence summaries unlicensed or off-label medicines:
• ESUOM 49: C3 glomerulopathy in the native kidney: eculizumab
• ESUOM 50: Hormone-sensitive metastatic prostate cancer: docetaxel

Medicines Practice Guidelines:
• Antimicrobial Stewardship (AMS) (NG15)
The Communications Directorate at NICE is made up of a number of teams:

- Enquiry handling
- Audience Insights
- Internal communications
- Website
- External relations 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
Director, Communications
March 2016
Communication directorate’s plans for 2015-16

1. This paper covers the period between 1 January and 29 February 2016. 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>
</thead>
<tbody>
<tr>
<td>NICE’s offer: Communicate the narrative about NICE’s role (USP) within the health and social care system</td>
</tr>
</tbody>
</table>

Media relations

Safety in the sunlight

3. New guidance weighing up the risks and benefits of sunlight exposure was widely covered. The recommendations ranged from focusing on developing effective local and national educational campaigns, to advice for healthcare professionals in identifying those people most at-risk from over or under exposure to the sun.

The guidance received extensive national and local media attention with two tabloid front pages and local radio stations across the country discussing the guidance throughout the day.

Gill Leng was interviewed for BBC breakfast and Good Morning Britain. Eugene Healy, committee member spoke to the Times and the Mail. A storify is available here.
Nivolumab

4. The positive appraisal of nivolumab was widely covered in the nationals.

   The FT, Daily Mail, Telegraph, Metro reported the decision.

   The Sun (left) had the punchiest headline.

Tuberculosis

5. The update of NICE guidance for the prevention and treatment of TB in England was covered well by press in London – where TB is a particular problem. The update combined both clinical and public health recommendations focusing on active case finding in those communities most at-risk, rapid diagnosis and extending the age at which latent TB should be treated (35 years to 65 years of age).

   The deputy Chair of the guideline committee spoke to BBC London radio and evening news. We also published two short films we’d made to anchor the public health and clinical aspects of this work.

   We won the support of the Mayor of London’s TB ambassador, Emma Thompson, who raised the profile of the guideline at a photoshoot at UCLH’s Find and Treat TB van on the day of publication. A storify is available here.

Indicator menu consultation

6. Within the 22 draft indicators for the QOF/CCGOIS menu, there were two that focused on BMI recording and weight management.

   These were the two the majority of the press focused on.

   We received national press coverage (including the front page of the Sun) about the proposed incentives for GPs to better manage their overweight patients.

   We had hoped to focus on the range of draft indicators aiming to improve the diagnosis and management of atrial fibrillation – which is a leading cause of stroke.

   This was picked up by the academic and medical press. A storify is available here.
Asthma

7. We took the opportunity to move on a story that led the Telegraph on new research about asthma which included reference to the draft asthma guideline which is currently in development.

We worked with James Meikle at the Guardian to focus on the current pilots on quality improvement and disinvestment activity.

Team changes

8. Our new head of media, Rebecca Smith has joined the team. A former medical editor at the Daily Telegraph and Evening Standard, Rebecca will work on broadening our offer to the media. She’ll be supported by 2 other new members of the team – Patricia Regis and Oliver Michelson.

Coverage

9. We have streamlined the way we analyse coverage to reduce the volume of data but retained enough to ensure that that we know we are reaching our target audiences effectively and appropriately.

<table>
<thead>
<tr>
<th>Tone</th>
<th>January (258)</th>
<th>February (308)</th>
<th>Total (566)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>66%</td>
<td>78%</td>
<td>71%</td>
</tr>
<tr>
<td>Neutral</td>
<td>31%</td>
<td>16%</td>
<td>25%</td>
</tr>
<tr>
<td>Negative</td>
<td>3%</td>
<td>6%</td>
<td>4%</td>
</tr>
</tbody>
</table>

External events and speaking engagements

10. We also supported speaking engagements for SMT, Board members and other NICE colleagues at almost 30 events, including:

- **Psychological Therapies in the NHS – 4 February 2016, London**: David Haslam spoke about defending quality so the vulnerable don’t lose out.
- **Collaboration for Action on Fuel Poverty – 23 February 2016, Manchester**: GDG member, David Sloan discussed the health impacts of living in a cold home - the evidence base and NICE guidance and recommendations.
• **Antibiotic Guardian London – 24 February 2016:** Jacqueline Sneddon, member of antimicrobial resistance guideline committee spoke about changing behaviour to reduce drug resistant infections.

**Enquiry handling**

11. From 1 January to 29 February the enquiry handling team responded to 2045 enquiries.

12. The popular areas of enquiry were clinical guidelines products (23%), technology appraisals (11%), OpenAthens (7%) and PharmaScan (4%). 7% 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%.

13. Following publication of the draft scope for supportive and palliative care in adults (update), the team handled a large volume of enquiries from people who were concerned that complementary therapies were to be removed from the scope of the updated guideline. The team received a number of enquires on the risk stratification recommendations made within diabetic footcare guideline and managed the process which led to changes being made to the recommendations. Challenges to the evidence base for NICE’s guideline on prophylaxis against infective endocarditis were responded to following the publication of an article in the British Dental Journal, and a small number of enquiries were received challenging the impartiality of a topic expert involved in the development of the sunlight exposure guideline.

14. The enquiry team responded to 16 Freedom of Information requests. These included several requests for information about contracts managed and software procured by IT, a request for a copy of any impact assessments carried out by NICE relating to the consultation on the Cancer Drugs Fund and a request for information about how much NICE paid to the Newspaper Licensing Agency for media licenses in the last financial year.
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

15. We got off to a busy start to the year, with 50 topics published in January and February, including 23 CHTE items and 12 NICE guidelines. The guidelines included the suite of 5 guidelines on trauma. The editorial team worked closely with the developers to ensure consistency and high quality across the 5 trauma topics.

16. The new TB guideline, published in January 2016, updated and replaced NICE guideline CG117 and incorporated and adapted a public health guideline (PH37) published March 2012. With over 300 recommendations covering such a wide range of areas, this guideline was another challenge for both the editorial and digital publishing teams to make the information as easy to navigate and accessible as possible.

17. We are currently working on 2 guidelines for people with learning disabilities. These are in development, and we prepared specially written and designed slides for committee meetings to explain the role of the editors and what makes a good recommendation. We had very good feedback from the committee chair, the programme manager and the committee members who have learning disabilities. The editors will need to make sure all of the information we give throughout the whole process is understandable by the whole committee, including the members with learning disabilities. One of the editors is currently writing an easy read version of our information for the public to explain the forthcoming guideline on mental health problems in people with learning disabilities.

18. The editorial team has completed an update of the NICE style guide and set up a Writing and style hub on NICE Space. Before we started on the update, we asked colleagues across NICE about how they used the style guide and how it could be improved. We used the feedback to develop a guide that is grouped on themes, rather than an A to Z of topics. This has made it much shorter, because information no longer needs to be duplicated. And we've added bold formatting so that it's easier to find the relevant information at a glance. The NICE style guide is available on the website.

19. The writing and style hub brings together all the publishing team’s advice onto one page: the style guide, information on templates and formatting, Word
workshops, Writing for NICE, and an Ask an editor blog for questions and suggestions.

**NICE Pathways**

20. In January and February, we:

- Published 6 new pathways
- Fully updated 3 pathways
- Updated 37 pathways to take account of new guidance (for example, adding new health technology guidance)
- Updated a further 62 pathways to add related pathway links or as maintenance updates.

21. The digital publishing team developed a pathway pulling together the recommendations from all 5 trauma guidelines as well as other relevant guidance, to help users access all of our guidance on the topic in one easy-to-use format. The updated TB pathway also gave a clear visual presentation of an extensive guideline.

**Guidance transformation project**

22. The Publishing team is involved in most of the workstreams to transform the way NICE develops guidance.

23. The publishing and audience insights team are carrying out a user research project to find out more about what users want from our guidance, in particular our recommendations.

24. The digital publishing team have continued to work with digital services on the quality standards knowledge base project. They are currently discussing with the digital services team both the quality assurance of the content before the launch, and how to ensure the system works well enough to support the knowledge base as a fully live service after launch.

**NICE website**

25. The graphs below contain a standard at-a-glance view of website and Pathways statistics and data for January 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
26. The new website homepage went live in January 2016. Positive feedback included, ‘I think the new design is very clear and the colours aid that clarity’; ‘very nice, clear, easy to navigate layout’; ‘great update with easy to access headings’. Analytics have shown the new homepage is performing better than the previous version. In particular we have seen significant improvements in users accessing the homepage through their mobile or tablet.

27. Work is underway to create a new stakeholder registration form for the website to make it quicker and easier for stakeholders to register their interest in guidance development. The new form will resolve some of the issues identified from enquiry feedback and usability tests.

28. Work has started to review and refresh the ‘About NICE’ section of the website. Content will be updated and streamlined to make it easier for users to find the information they need and support the promotion of key messages. New content will be published from the end of March.

29. The guidance pages on the website are the responsibility of the digital publishing team. In January and February they prepared and digitally published 101 documents. Developments on the guidance pages in the past 2 months included:

- The ‘your responsibility’ text is visible on all guidelines, technology appraisals, and highly specialised technologies guidance as requested by SMT.
- The guidance list pages now have a last updated date to alert audiences when a topic has been updated. This change was made in response to user feedback. The last updated date will soon be visible on individual guidance pages.
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

**Audience and user research**

30. Work is continuing with the Reputation Institute on the Cabinet Office-sponsored pilot stakeholder reputation survey. A project plan has been prepared for review and advice from the Reputation Institute and we are aiming to carry out the research in April 2016.

31. The Audience Insight team conducted an online survey on the involvement of patients and the public in the development of our guidance. Just under 700 responses were received. The results indicated strong support for the current involvement activities for patients and the public whilst also highlighting potential gaps to further enhance the process.

32. We also reported internally on insight work regarding the use of our savings and productivity collection and ‘do not dos’ in particular. Further work will be carried out to validate the findings and inform an ongoing communications strategy for the collection.

33. A pilot research project with GPs was carried out in January with Manchester CCG. The results are currently being reviewed and a decision will be taken on the viability of rolling it out across a larger geographical area.

Objective 4

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

34. NICE Space beat strong competition to win ‘most engaging intranet’ at the Sorce intranet awards. The award recognises the work carried out by internal communications to create a truly interactive and engaging intranet which is highly valued by staff.

35. During January the internal communications team led staff engagement for Healthy Work Week. We used a range of different media from articles and blogs to videos and tweets to promote activities and key messages on the 5 ways to wellbeing. The Healthy Work Week articles on NICE Space were popular with over 1,150 views in total. Our video featuring staff talking about how they connected to the 5 ways to wellbeing was shown at the All Staff Meeting in February. For the first time, we promoted our internal staff activities through
external social media channels. Conversations on #healthyworkweek included posts and retweets from Fitbit UK, Manchester Art Gallery, Casserole Club and the University of Salford’s Student Nurses.

36. In January we published the staff magazine, NICEtimes. Features included an interview with George Freeman MP, an update on Greater Manchester Devolution and quick guide to proposed changes to the Cancer Drugs Fund.

37. To raise awareness of new guidance we worked with the press team to run a homepage poll on sun exposure and featured the subsequent press coverage in a news article.

38. Other topics we covered in our internal communications included improvements planned for NICE Space, the new e-learning system, and information governance training.

39. We also published a number of blogs including the popular David’s diary from David Haslam, and non-executives Rosie Benneyworth and Rona McCandlish.

### Objective 5

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

40. 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.
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
March 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 February 2016, 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.
   - In response to user requests, continuous improvement work has been delivered to the Evidence Search service including a date feature and a help sheet on advanced searching. More developments are in progress and due to deliver soon. This includes some new Information Types filters which have undergone user testing during this period.

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 (CCP) 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.
   - Following a review of pilot processes, a process has now been agreed to provide information support to the Health and Social Care Directorate’s surveillance activity. Work on the first 5 topics has begun.
The Information Resources team continues to co-sponsor and provide stakeholder input to the Evidence Management digital project.

4. 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. In addition to developing the requirements of the minimum viable product, substantial improvements are being made to user experience. A minimum viable product will be available for testing from early March, with a view to releasing the new service in Q1 of 2016/17 as scheduled. Plans are being drawn up to promote the new service and early discussions have begun with Health Education England (HEE) for them to provide some e-learning modules on HDAS.

- 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 March 2016. This is later than anticipated however the product is expected to include more content on initial release.

- 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. An extension of the Evidence Management Project is currently underway to identify, or develop, a system to underpin the document supply service.
  
  - 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
ITEM 15

has been well received and can be found at http://ld.nice.org.uk/q6. Work is continuing to Quality Assure content, develop the user presentation and integrate the solution into the NICE Website. Further work is planned to develop the ability to highlight recent changes to Quality Standards.

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 off the end of March 2016, the following activity had taken place:

- In total, 31 continuous improvement change requests were completed in January and February 2015/16 and 51 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. A new tool has now been implemented 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 has been completed and the contract is currently being agreed. This will enable the migration of the services to a new platform, currently targeted to be substantially completed by 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. This will now be considered alongside work required on NICE stakeholder management databases and project work will be prioritised accordingly by the relevant service groups.

**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 in NHS England to explain and support the re-use of NICE content in the development of nhs.uk. With this endeavour in mind, the Digital Services Team are working with HSCIC and other ALBs to review the overlaps, synergies and gaps in the content created by ALBs and to agree an overarching Content Strategy. This will enable the rationalisation, joining up and re-using content across ALBs.

- 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 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 has 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. Recent collaborative activity included NICE attending a clinical workshop in February 2016 to coach HEE colleagues on how to get the most out of the NICE website and NICE granting HEE a test syndication licence for NICE guidance, CKS and Evidence Search. The Memorandum of Understanding with HEE is being revised and updated accordingly.

- A fourth meeting was held with the NIHR Dissemination Centre to explore opportunities for joint working. As their products are now ingested into Evidence Search the meeting focussed on the evidence summary products of both organisations, how the Dissemination Centre can support NICE’s surveillance activities and cross promotion of each organisation’s products.

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’. The NIB programme has received substantial funding from the Comprehensive Spending Review. In February 2016, NICE attended a series of planning workshops organised by HSCIC and NHS England to produce integrated business cases. 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
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:

- A NICE Evidence Evaluation Centre was 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. The report was delivered in February 2016 and is being assessed so that contact can be made with those major system providers that have been identified. In addition, further detailed discussions took place with 6 suppliers to evaluate the technical implications and standards that NICE needs to be aware of to ensure that its content continues to be relevant and usable to the major system providers to the NHS and Social Care system. This insight will be used to inform the continued development of NICE’s Content Strategy;

- A full licence has been granted to St George’s NHS Foundation Trust to facilitate the creation of a localised database to support internally the dissemination of NICE guidance and to evaluate implementation;

- Discussions are ongoing with a provider of virtual doctor/patient consultations and the use of NICE content as part of this process. There is the possibility that this would be rolled out in both the UK and Eire.

10. As of the end of February 2016, there had been 109 expressions of interest to access content via the NICE syndication service. Out of these expressions of interest, 15 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 7 current test licences (allowing the applicant to test the feasibility of developing a product). Licences have been issued to a further 7 organisations following approval which are being followed up (signature pending). This includes full licences for Public Health England, St Georges NHS Hospital Trust and MGP Ltd.

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 started in January 2016 covering all vacant roles across the Digital Services teams. This was accompanied by a ‘Working for NICE’ information on the website and other advertising and social media prompts. Offers towards three new permanent posts will be made in March 2016.

• 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 now complete and migration to the new service is expected to be substantially under way by the end 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. 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.

14. In addition, the Evidence Resources leadership team has been working with the SMT and the Institute’s HR and finance teams to agree its savings targets over the next 4 years and develop implementation plans. As part of this work, the Directorate has taken a leadership role in identifying and assessment commercial revenue generation opportunities arising from the use and adaptation of NICE content by third party organisations, nationally and internationally. This work will contribute to the development of the NICE’s commercial strategy in FY16/17.

Selected activity indicators – Two months 1st January 2016 to 29th February 2016

**NICE Evidence Services: statistics**

15. 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.
Evidence Search

461,979 visits
74% meaningful interactions
20% return within 10 days
BNF
- 404,370 visits
- 33% meaningful interactions
- 28% return within 10 days

BNFc
- 58,507 visits
- 33% meaningful interactions
- 34% return within 10 days

CKS
- 331,690 visits
- 52% meaningful interactions
- 51% return within 10 days

HDAS
- 34,254 visits
- 77% meaningful interactions
- 48% return within 10 days

eBooks
- 332 visits
- 51% meaningful interactions
- 18% return within 10 days

Journals
- 18,652 visits
- 74% meaningful interactions
- 50% return within 10 days

DUETS
- 3,410 visits
- 84% meaningful interactions
- 12% return within 10 days
**NICE Apps: statistics**

16. The reporting for NICE Apps follows the same new performance reporting model. Downloads are now omitted from this report.

<table>
<thead>
<tr>
<th></th>
<th>Visits</th>
<th>Meaningful Interactions</th>
<th>Return within 10 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BNF</strong></td>
<td>428,272</td>
<td>81%</td>
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<td><strong>BNFc</strong></td>
<td>88,495</td>
<td>76%</td>
<td>82%</td>
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<tr>
<td><strong>Guidance</strong></td>
<td>42,456</td>
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</table>
**Information Services: activity levels**

17. The activities undertaken by guidance Information Services (gIS) to support teams across NICE are summarised in the graph below.

![Graph of gIS core activity Jan - Feb 2016](image-url)
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 since January 2016 alongside key programme indicators.

The Board is asked to review the progress report.

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

1. The following sections, by programme, provide the Board with an overview of achievement against the business plan objectives from April 2015 to February 2016.

Public Health and Social Care Centre

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:

- Four social care guidelines as planned for 2015/16:
  - Home care: Delivering personal care and practical support to older people living in their own homes
  - Older people with social care needs and multiple long-term conditions
  - Transition between inpatient hospital settings and community or care home settings for adults with social care needs
  - Transition from children’s to adults’ services for young people using health or social care services

- Five out of 7 public health guidelines including the publication of sunlight exposure: risks and benefits in February 2016, which received extensive television, radio and newspaper coverage. The remaining 2 guidelines are scheduled for publication in March.

- Four out of the 6 surveillance review decisions scheduled for public health guidelines, with the remaining 2 reviews being scheduled for Guidance Executive in March.

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. Overall progress against deliverables during 2015/16 includes:

- Hosting 24 student champion training events to date, more than the predicted target of 15 events for the year.
• Identifying 43 examples of Local Authority public health teams using NICE public health related quality standards in their contracts between April 2015 and January 2016.

• Identifying 77 examples of Health and Wellbeing Boards using NICE guidance, advice and quality standards to improve population health during the same period.

• Identifying 85 Clinical Commissioning Groups (CCGs) 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 - 191 trusts have been identified as using quality standards to improve clinical services between April and January.

• Achieving 100% 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 384 applications for 72 vacancies across 46 guideline and standing committees. Of these:
  – Seventy four places were offered, slightly more than anticipated because of the exceptional quality of applications
  – A further 30 lay people were invited to join the Quality Standards, Public Health, Diagnostics and Guidelines Update Committees as specialist members
  – 108 people gave testimony to the Technology Appraisals and Highly Specialised Technologies Committees as patient experts.

• In addition, the following training events were provided:
  – Five training sessions for guideline committee members
  – Two masterclasses for North West HealthWatches
  – One ‘Introduction to NICE’ masterclass
- Three 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:

- Thirty four of the planned 36 quality standards for 2015/16, including publication of the first update to a quality standard (Chronic Obstructive Pulmonary Disease) in February 2016. A further 3 quality standards are scheduled for publication in March.

- Eleven of the 12 final accreditation decision reports, with 1 report pending and the final report expected to be published before the end of Quarter 4.

- Fifteen endorsement decisions, with continued and growing interest in the programme. A plan to promote the programme is being developed with the Communications team and work is being undertaken to explore options for income generation.

- The following additional outputs: 7 quality and productivity case studies; 5 Cochrane reviews that highlight ineffective interventions; and 50 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 15 adoption scoping reports for guidance teams to advise them of the likely barriers to adoption and completing 69 '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 7 'Insights from the NHS' adoption support resources for selected technology appraisals (TAs), 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. 1471 new data points have been identified in 2015/16. 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 the content and improve the presentation of the scorecard. This has included detailed analytical work estimating uptake of NICE appraised medicines

- Developing a new quality standards service improvement template which was 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

- Conducting 41 implementation need analyses for long guidelines, enabling publication of 20 shared learning case studies, assessing and publishing endorsement statements for 7 resources developed by other organisations and producing 12 implementation chapters within long guidelines.

### Notable recent developments

#### Economic and Methodological Unit

7. An Economic and Methodological Unit (EMU) has been commissioned to support the development of guidelines in public health and social care. After a tender process during which 3 bids were submitted, York Health Economics Consortium (YHEC) has subsequently been awarded the contract. YHEC has experience in developing economic models and reviews for NICE public health guidelines, and their core team will include the Centre for Health Economics (CHE) at the University of York, who will lead the methodological work. The contract is due to start in April.

#### Involvement of people with learning disabilities

8. The first two Guideline Committees for the service guidance for People with learning disabilities and behaviour that challenges were held in February, including two members with learning disabilities. This is the first time that people with learning disabilities have been involved as Guideline Committee members.
9. The Committees ran smoothly with all members describing the process as fully inclusive. The NICE presentation that was given at the Committee by the social care team was highlighted by Committee members as setting the standard for positive accessibility.

Alignment of NICE Quality Standards with national audit

10. A review of 102 quality standards has been undertaken to identify the current and potential usage of QS measures in HQIP commissioned national audits at an individual measure by measure level. 114 additional measures have been identified from quality standards, which could be used in future national audits.

11. The detail of linkages between standards and audits will be published on the NICE website. We are also liaising with HQIP to improve future alignment between the specification process of national audits and NICE measures.

Indicator development

12. Consultation on potential new indicators for the NICE Indicator menu took place during February. This was the first time a full suite of indicators for a variety of purposes has been consulted on, following a single consultation process.

13. The new indicators attracted substantial media attention and focussed on some of the key priorities in the Five Year Forward View including:

- Prevention: obesity and the identification and management of atrial fibrillation
- Mental health and learning disabilities: physical health checks and non-elective admissions and readmissions to secondary care.

14. NICE is also involved in a number of national work streams focussed on metrics and indicators. These include the development of the Clinical Commissioning Group Improvement and Assessment Framework and the My NHS GP Practice Metrics, where 10 key metrics will be published for every practice in April 2016.

Public involvement review

15. The review of NICE’s public involvement support for guidance development continues. A short survey ran in January 2016 and a meeting with stakeholders was held on 26 January.

16. Nearly 700 people responded to the survey, the majority of whom identified themselves as patients, carers or members of the public. The survey asked a combination of qualitative and quantitative questions various aspects of public
involvement at different stages of guidance development. We also asked respondents to let us know their suggestions for ways in which we could ensure we were capturing people’s experiences of care, and where they felt there were gaps in our current involvement work.

17. In order to properly assess and incorporate the findings of the survey and the views of the stakeholders, proposals and considerations on the future shape of public involvement at NICE will be presented at the May public Board meeting, rather than in March as originally planned.
Key programme indicators

18. 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 February

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### LA and NHS visits

![Graph showing LA and NHS visits over time](chart)

*Data not available for February

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### Examples of Local Authorities using NICE outputs

![Bar chart showing examples of NICE outputs](chart)

*Data not available for February
Public Involvement Programme

Lay member recruitment summary - April 2015-February 2016

<table>
<thead>
<tr>
<th></th>
<th>GDGs</th>
<th>Specialist members</th>
<th>Standing committees</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of vacancies</td>
<td>40</td>
<td>29</td>
<td>3</td>
<td>72</td>
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<td>No. of successful applicants</td>
<td>42</td>
<td>29</td>
<td>3</td>
<td>74</td>
</tr>
<tr>
<td>No. of applications</td>
<td>214</td>
<td>145</td>
<td>25</td>
<td>384</td>
</tr>
</tbody>
</table>

Quality Programme

Quality Standards

Cumulative published vs Cumulative plan
Accreditation reports

Adoption and Impact Programme

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.
Uncollocated minutes of the meeting held on 27 January 2016 in London

Present
Jonathan Tross, Non Executive Director (Chair)
Linda Seymour, Non Executive Director
Rona McCandlish, Non Executive Director

In attendance
Ben Bennett, Business Planning and Resources Director
Andrew Dillon, Chief Executive
Natalie Sargent, Head of Financial Accounting, Finance
Barney Wilkinson, Associate Director, Procurement & IT
Catherine Wilkinson, Associate Director of Finance & Estates
Felicia Wright, NAO
Karen Finlayson, PwC
David Coombs, Associate Director, Corporate Office
Julian Lewis, Governance Manager

APOLOGIES FOR ABSENCE
Bill Mumford, Non Executive Director, David Hunter, Non Executive Director

DECLARATIONS OF INTEREST
1. There were no declarations of interest.

MINUTES OF THE LAST MEETING
2. The Committee noted that it is the last meeting Rona McCandlish is attending as committee member and expressed their appreciation for the help and support provided by Rona over the years.

3. Action log: The progress detailed in the action log was noted.
   - Points 141 and 149 are to be rolled into one action point with Chris Carson scheduled to attend the April meeting.
   - Lorraine Howard-Jones is to attend the April meeting in relation to point
150.

- Point 153 was clarified: Is the ARC doing all it should?
- Barney Wilkinson gave a verbal response to point 155: the first software was over-written when we were trying to download the new software. The first software therefore no longer worked when the download failed.

4. The minutes were agreed as a correct record with the exception that Andrew Dillon’s attendance had been omitted.

RISK MANAGEMENT

Assurance Framework and Risk Register

5. The committee had an open discussion about the risks and issues, with Andrew Dillon adding that he has yet to discuss his ideas with the senior management team, but anticipate that it would be taken to the February Board Strategy meeting.

6. Generally, the level of anxiety has declined. Relationships with national agencies and key business links have been established, and they now understand NICE’s business. With the passage of time those risks are becoming more day-to-day business.

7. Visibility and impact remains a key risk. Given NICE’s limited resources and the squeeze on the public sector, and especially on Local Authority finances, attending to NICE’s offerings are not likely to be high on anyone’s agenda. There needs to be alignment between what we do and the system’s expectations. NICE is being pulled in two directions - responding to NHS constraints with calls for less ‘do more’ guidance at the same time as pressures for Accelerated Access to introduce new approaches - which means NICE guidance satisfies neither perspective.

8. Integrating the management of the guidance programmes could lead to a loss of focus/quality in specific areas. There is also risk in that a common approach could devalue the gold standard, devaluing the offer of quality and engagement, and that NICE’s traction becomes less. This then lead to the question whether there is a risk that NICE will go back to what it was in the beginning, to drugs appraisals. It was acknowledged that the system will have changes every 5-10 years, and what NICE does may change but it will always offer value.

9. Risks around losing focus and impact of effective implementation and public engagement are currently under review. NICE’s impact through public involvement in guideline production is assessed by looking at the evidence to see if it works. The Implementation team has conducted interviews with the NEDS, for evidence that the team have been effective in their role. The committee noted that impact and influence is very important and that NICE aims to drive this (rather than following government lead), and have people use NICE’s outputs.
10. NICE need to consider the strategic period of its risk register. If it is to 2020 which is the end of the spending review, then NICE need to consider what the health and social care landscape would look like then. The Board has had good discussions about what NICE should look like, following a reduction in its funding. However there are risks and assumptions about what can and should be done. There is once again a need for alignment between what we do and the system’s expectations. Funding risks still prevail - further funding squeeze threatens NICE’s broad option aim. Further, competing and losing out to Guidance producing competitors remains a risk. It is worth noting though that NICE have already taken action to ensure a balanced budget for 16/17.

11. The following risks around the workforce were discussed: maintaining range of activity with fewer resources squeezes capacity and potentially impacts quality; senior management capacity and continuity; reduction in staff may lead to loss of skills, and loss of morale of those remaining. At a time of significant challenge the current low risk rating may therefore be too confident.

12. The Triennial Review has specified actions that NICE should do. Some of which carry significant risks, e.g. the commercialisation of some of NICE’s products, and the impact associated with changes to NICE International.

13. The pressure to generate income risks diverting senior management time and focus, while at the same time introducing and maybe even requiring a different value set and ethos. This might well change NICE’s overall standing and reputation over time in ways that may be difficult to discern or predict.

14. NICE’s Digital Strategy could face the risk of being undermined by duplication of effort by others, or face lack of sponsorship for our external evidence offer.

15. The committee noted on reflection on the whole set of risks is that they are most or all interrelated, and reflect a complex system that is becoming more complex. It was acknowledged that this version of the risk register is being developed and would be further revised and presented to the Board for sign off.

Action: BB

INTERNAL AUDIT

Financial Management


17. The Committee extended its congratulations to Ben Bennett and his team on
the positive report and note that the team are implementing the recommendations.

IT General Controls

18. Karen Finlayson presented the report, adding that the audit was around access controls, and the recommendations centre around more robust processes.

19. Barney Wilkinson confirmed that there is a working group (lead by HR) currently designing a process to notify a host of departments for all staff starting, moving or leaving, which will address the recommendations. The committee noted that action is in hand.

Risk Management

20. Karen Finlayson presented the report, highlighting that Risk Owners do not appear to record and mitigate risks consistently at present, and that stronger processes are required.

21. Julian Lewis noted that teams use the risk register in different ways and that updates were not always consistent with the template process. He advised that the risk management policy will be amended to reflect the comments of internal audit to assist in a more consistent approach to recording risks. The committee noted that the report was on the strong side of moderate and also noted that the follow through to divisional risk registers was good.

Progress report and Audit Plan

22. Karen Finlayson confirmed that they are on track to deliver the audit plan by the end of March. Karen added that the Board Effectiveness review will be completed in time for the June ARC meeting.

Estates

23. Karen Finlayson presented the advisory report. Much of the report relates to the history of NICE’s staff levels and office accommodations. Karen highlighted that the purpose of the report is to inform the committee if the strategy is going in the right direction, in line with the DH estates strategy.

24. Ben Bennett added that NICE does not have a formal Estates Strategy which is updated regularly, which may be what other organisations do. NICE is pulled in all different directions by DH and Treasury with changing metrics introduced regularly, yet NICE has achieved the right strategic position nonetheless. He confirmed that he surplus capacity has now been sub-let, and the next challenge is around the Manchester lease which ends in 2017.

25. The committee noted that they have been well engaged through the years, through the Board, that NICE’s accommodations are being actively managed, and resources are being put to best use. It acknowledged that there are culture challenges with hot-desking and home-working.
WHISTLEBLOWING report

26. Ben Bennett confirmed that there have been no incidents to report.

27. The committee briefly discussed whether the lack of incidents is due to strength or staff not knowing how to report incidents. It concluded that staff should be made aware of process and that lack of incidents should not make NICE complacent.

INTERNAL AUDIT ARRANGEMENTS

28. The committee discussed the status quo without officers present. After the officers were invited back and some further discussion, it was confirmed that NICE will be using DH as internal auditors from 16/17, with the option to obtain external resource as required. The committee requested that a draft plan for 16/17 be drawn up for the April meeting.

Action: BB

CONTRACT WAIVERS

Waivers report

29. Barney Wilkinson presented the report, adding that the market had been tested indirectly. The Committee noted that NICE have had validation that competitive prices are being charged.

USE OF SEAL

30. The committee noted the report.

INFORMATION GOVERNANCE

31. Julian Lewis presented the paper, highlighting the main information governance risks. These included the development of ‘future state’ systems, with guidance information being managed on both network drives and future state systems. In addition HSCIC have asked for further assurance on the controls for the management of their data.

32. The Committee noted that satisfactory governance is in place. NICE haven’t had any Serious Untoward Incidents, and where information governance incidents have occurred, these have been reported to the ARC with appropriate responses from management. The committee noted the need to ensure NICE addresses the issues raised by the HSCIC whilst maintaining a proportionate approach to general information governance controls at NICE.
ANY OTHER BUSINESS

33. There was no other business.

PRIVATE DISCUSSION

34. As normal the Committee briefly reviewed progress with auditors without officers present.

Future meeting dates

20 April 2016
15 June 2016
13 October 2016