# PUBLIC BOARD MEETING

There will be a Public Board Meeting on the 18 May 2016 at 1.45pm in the Deafblind UK Conference Centre, The National Centre for Deafblindness, Cygnet Road, Hampton, Peterborough PE7 8FD

## AGENDA

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<th>Item Number</th>
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<tr>
<td>16/040</td>
<td><strong>Apologies for Absence</strong></td>
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<td>To receive apologies for absence</td>
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<td>16/041</td>
<td><strong>Declarations of Interests</strong></td>
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<td>To record any conflicts of interest</td>
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<td>16/042</td>
<td><strong>Minutes of the Board Meeting</strong></td>
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<td>To approve the minutes of the meeting held on 16 March 2016</td>
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<td>16/043</td>
<td><strong>Matters Arising</strong></td>
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<td>To consider matters arising from the minutes of the last Meeting</td>
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<td>16/044</td>
<td><strong>Chief Executive’s Report</strong></td>
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<td>To receive the Chief Executive’s report</td>
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<td><em>Andrew Dillon, Chief Executive</em></td>
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<td>16/045</td>
<td><strong>Finance and Workforce Report</strong></td>
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<td>To receive a report on NICE’s financial position to the end of March 2016 and an update on the workforce strategy</td>
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<td><em>Ben Bennett, Director, Business Planning and Resources</em></td>
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<td>16/046</td>
<td><strong>Public Involvement Programme 2015</strong></td>
<td>(Item 4)</td>
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<td>To receive the annual report</td>
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<td><em>Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate</em></td>
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<td>16/047</td>
<td><strong>Abbreviated Technology Appraisal Proposal</strong></td>
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<td>To consider the proposals</td>
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<td><em>Professor Carole Longson, Director, Centre for Health Technology Evaluation</em></td>
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<td>16/048</td>
<td><strong>Citizens Council</strong></td>
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<td>To consider the report from the Citizen’s Council meeting</td>
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<td><em>Professor Carole Longson, Director, Centre for Health Technology Evaluation</em></td>
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16/049 **Audit and Risk Committee Annual Report 2015-16**  
To receive the annual report from the Committee  
*Jonathan Tross, Chair, Audit and Risk Committee*

16/050 **Director’s Report for Consideration**  
*Evidence Resources Directorate*  
*Alexia Tonnel, Director, Evidence Resources Directorate*

16/051 **Directors’ Reports for Information**  
*Centre for Clinical Practice*  
*Centre for Health Technology Evaluation*  
*Communications Directorate*  
*Health & Social Care Directorate*

16/055 **Committee minutes**  
To receive the unconfirmed minutes of the Audit and Risk Committee held on 20 April 2016

16/056 **Any Other Business**  
To consider any other business of an urgent nature

**Date of the Next Meeting**  
To note the next Public Board meeting will be held on  
**Wednesday 20 July 2016** in the Education Centre, Conquest Hospital, The Ridge,  
Saint Leonards-on-sea, East Sussex TN37 7RD
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
- Dr Rosie Benneyworth
- Professor David Hunter
- Tim Irish
- Professor Finbarr Martin
- Professor Rona McCandlish
- Andy McKeon
- Bill Mumford
- Linda Seymour
- Jonathan Tross

**Executive Directors**

- Sir Andrew Dillon
- Professor Gillian Leng
- Ben Bennett
- Professor Carole Longson

**Directors in attendance**

- Jane Gizbert
- Alexia Tonnel

**In attendance**

- David Coombs
- Christine Carson

**16/019 APOLOGIES FOR ABSENCE**

1. Apologies were received from Professor Mark Baker who was represented by Christine Carson.
16/020 CONFLICTS OF INTEREST

2. None.

16/021 MINUTES OF THE LAST MEETING

3. The minutes of the meeting held on 20 January 2016 were agreed as a correct record subject to the amendment of paragraph 32 to clarify that the implementation of the proposals for the reconsideration of drugs currently funded through the Cancer Drugs Fund (CDF) was subject to the outcome of the public consultation on the changes to the CDF.

16/022 MATTERS ARISING

4. The Board reviewed the actions arising from the Board meeting held on 20 January 2016. It was noted that:

- The NICE website will be updated shortly to include both the revised presentation of the quality standards and the mapping of the NICE quality standards to the Care Quality Commission’s (CQC) inspection framework.
- Chapter 7 of the guidelines manual has been updated following the Board’s discussion on resource impact considerations, and these amendments are in place for draft guidelines issued for consultation from 1 April 2016.

16/023 CHIEF EXECUTIVE’S REPORT

5. Andrew Dillon presented his report, describing the main programme activities to the end of February 2016 together with a summary of NICE’s financial position to the end of January 2016.

6. Following a question from Bill Mumford regarding NICE’s response to the Triennial Review, Andrew Dillon confirmed that NICE is required to submit a report in July 2016 on progress with the recommendations. This will be presented to the Board prior to submission.

7. David Hunter asked about progress with the ‘RepTrak’ study and the outcomes of the work on decommissioning and disinvestment. Andrew Dillon briefed the Board on the recent event to explore NICE’s support for decommissioning. The event noted the limited scope for ‘quick wins’ beyond implementation of NICE’s existing ‘do not do’ recommendations. The initial work undertaken by NICE on potential savings from reducing inappropriate prescribing of a number of drugs to elderly patients will though be explored further. Jane Gizbert briefly updated the Board on the RepTrak pilot and agreed to provide further information on the timescales for this work.

ACTION: Jane Gizbert
8. The Board received the report.

16/024 FINANCE AND WORKFORCE REPORT

9. Ben Bennett presented the report which outlined the financial position as at 31 January 2016 and provided an update on the workforce strategy. At the end of this period there is an underspend of £3.8m, which is consistent with the position previously reported to the Board. He stated that HM Revenue and Customs (HMRC) has recently challenged NICE’s practice of reclaiming the VAT on journals and evidence resources purchased on behalf of the NHS. NICE has previously been advised by professional VAT advisors that this was allowable under NHS VAT rules and indeed HMRC has not raised it at previous inspections. NICE will be appealing this decision but it will be necessary to make a provision in this year’s accounts of approximately £1.8m, which reduces the year-end projected position to an under spend of £2m. If the appeal is unsuccessful then it will lead to an unplanned cost pressure in future years although most of this will be recovered in the re-charge NICE makes to Health Education England for these services.

10. The Board received the report and noted the impact of the recent HMRC decision.

16/025 BUSINESS PLAN 2016-17

11. Andrew Dillon presented the proposed Business Plan 2016-17 for the Board’s approval. He highlighted that the plan reflects the outcomes of a series of Board discussions and also the priorities for NICE identified by the Department of Health (DH).

12. Andrew Dillon highlighted two further comments from the DH on this final draft of the business plan. Firstly, a suggestion that NICE should seek to recover the costs from the Highly Specialised Technology programme from industry in addition to the proposal to charge industry for the Technology Appraisal programme. Secondly, that the business plan should include an indicator in the ‘speed of production’ section of the balanced scorecard on the timescales for considering products under the Early Access to Medicines (EAMS) scheme.

13. The Board reviewed the business plan and approved the document subject to the amendments to reflect the two points raised by the Department of Health, plus further points raised by the Board including additional reference to national policy initiatives such as the Sustainability and Transformational Plans, the clarification of paragraph 54 and the correction of appendix 4. The Board delegated authority to Andrew Dillon to approve these and any other required amendments.

ACTION: Andrew Dillon
14. The Board noted and welcomed the intention to develop a microsite on NICE’s website for the finalised business plan, similar to that for the annual report. This will include the topics of the NICE guidance that will be published in the year ahead.

15. Given the priority placed on NICE’s support for decommissioning by key stakeholders, the Board requested a mid-year progress report on these activities.

ACTION: Gillian Leng

16/026 CANCER DRUGS FUND

16. Carole Longson presented the report that outlined the relevant themes for NICE from the recent public consultation on the proposed changes to the Cancer Drugs Fund (CDF).

17. Carole Longson summarised the key themes from the consultation and noted that the majority of the responses welcomed NICE’s proposed role in the CDF. Several consultees suggested further amendments to NICE’s methods. However, NHS England has not indicated that it wishes to change the proposals in this area, and therefore NICE is not proposing to amend its methods. Consultees also raised the question of whether NICE will have sufficient capacity to undertake its new role. In relation to this issue, Carole Longson noted that NHS England has approved a business case to fund additional capacity at NICE, and the funding is anticipated shortly.

18. Board members raised a number of questions on the report, in particular on whether NICE will have sufficient capacity in place by September as envisaged in the report. Carole Longson confirmed that recruitment is underway for the additional staff. There are further contingency options available, including utilising staff with the required skills currently employed by NICE and commissioning support from the Decision Support Unit under the existing contract. In response to questions from the Board, Carole Longson clarified that the Standard Operating Procedure to be developed in conjunction with NHS England will include further information on the data collection process and the budgetary control mechanisms in the CDF, which will both be central to the successful implementation of the revised CDF. The Board noted that NHS England has agreed to reconsider the proposals for this latter point in light of the consultation feedback.

19. Following discussion of the report, the Board:
   - Agreed the proposals set out in the report for how NICE will respond to the issues raised in the consultation.
   - Agreed that NICE should engage with NHS England to implement the proposed arrangements for the Cancer Drugs Fund (CDF) from 1 July 2016, subject to the resolution of the matters identified as outstanding in the CDF Standard Operating Procedure.
• Authorised Carole Longson to liaise with NHS England to establish the methods, processes and joint working arrangements in support of the CDF.

**ACTION:** Carole Longson

### 16/027 CANCER DRUGS FUND: UPDATE ON TRANSITION ARRANGEMENTS

20. Carole Longson presented the update on the work being undertaken by NICE to support the transition to the new Cancer Drugs Fund (CDF) following the public consultation discussed under the preceding agenda item. She highlighted the amendments to the process for the reconsideration of the drug indication pairs that are currently in the CDF and for which NICE has published guidance (group 1), in light of the feedback from the short consultation.

21. Andy McKeon noted that the amendments to the process for the group 1 indication pairs could further increase the work-load on NICE. Carole Longson stated that the impact of reviewing new clinical evidence will fall on the Evidence Review Groups, which have indicated ability to undertake this additional activity.

22. The Board noted the paper and supported the work underway as part of the transition to the new Cancer Drugs Fund. The Board thanked Carole Longson and her team, in particular Meindert Boysen and Jennifer Prescott, for their outstanding contributions in this area.

23. A representative from the Association of the British Pharmaceutical Industry (ABPI) stated that the association and its members would be willing to help develop the data collection arrangements that will be included in the Standard Operating Procedure (SOP). She asked for an impact assessment of the new CDF and the transition to the new arrangements is undertaken. Carole Longson stated that she would discuss with NHS England whether to include in the SOP a 12 month review of the changes.

**ACTION:** Carole Longson

### 16/028 NICE EQUALITY OBJECTIVES

24. Ben Bennett presented the proposed equality objectives for NICE for the period 2016 to 2020, which have been developed in line with NICE’s statutory responsibilities.

25. Linda Seymour welcomed the proposal to engage with the Department of Health in order to seek to increase the diversity of the non-executive directors. She also highlighted that the 2015 equality forum suggested NICE produces a statement of its values on equality and diversity, in particular in relation to committee recruitment. Ben Bennett stated that information on this matter is included on the website, but he would review whether it could be developed further.

**ACTION:** Ben Bennett
26. The Board discussed a proposal from Tim Irish that the two objectives should include specific measures for the level of improvement required. Whilst Board members agreed it could be helpful if the objectives included specific targets, it was noted that it is challenging to identify the appropriate benchmark population - for example, whether this should be the English population or the NHS medical and dental workforce.

27. The Board agreed the proposed equality objectives, subject to the following amendment:

- 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 proportion of staff from black, Asian and minority ethnic groups in senior roles (agenda for change band 7 and above) across the organisation.

28. It was agreed that objectives should seek year on year improvements in each of these proportions. Further consideration should be given to more specific targets for measuring performance, and performance should be included in the annual equality reports.

**ACTION:** Ben Bennett

16/029 TRIENNIAL REVIEW RECOMMENDATION: GOVERNANCE OF NICE’S INDEPENDENT ADVISORY COMMITTEES

29. Andrew Dillon presented the paper that set out NICE’s response to the issues raised in the Triennial Review regarding the governance of NICE’s advisory committees. He asked the Board to note the issues raised by stakeholders and reported in the 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.

30. Jonathan Tross stated that he felt the issues reported in the review had been addressed, in particular through the revised Conflicts of Interest Policy. Finbarr Martin agreed that the shift to non-expert chairs following the revised policy has helped address the issues raised but recommended that NICE further publicises this change in practice. He stated that this would help NICE attract applicants for chair positions and also address ongoing perceptions around conflicts of interest.

31. Andy McKeon suggested that the reference to the way in which conflicts of interests were handled by the advisory committees could be made clearer, with a specific reference to the publication of the explanation and handling of conflicts being made available through the minutes, on the Institute’s website.
ACTION: Andrew Dillon

32. The Board noted the issues raised in the Triennial Review and agreed that the arrangements for operating and quality controlling the work of NICE’s advisory bodies and committees are sufficiently robust and transparent. The Board supported further publicising these arrangements.

16/030 ENGAGEMENT SUCCESS CRITERIA

33. Gillian Leng presented the proposed success criteria for NICE’s external engagement activities delivered by the Field Team in 2016-17, which reference a range of high profile national initiatives such as the Sustainability and Transformation Plans and Five Year Forward View vanguards.

34. In response to questions from the Board, Gillian Leng and Chris Connell, Interim Associate Director, Field Team, confirmed that the measures are felt to be deliverable and had been discussed at the Implementation Strategy Group (ISG). David Hunter noted that the non-executive directors were not aware of the meeting, despite previously having been invited to the ISG. Gillian Leng stated that this was an oversight following transfer of the responsibility for the ISG meetings to a different member of staff and she would follow this matter up.

ACTION: Gillian Leng

35. Bill Mumford noted that the measures are segmented into target groups, such as public health. He suggested that it would be helpful to look at NICE’s impact across health and social care. Gillian Leng stated that she would look at whether a suitable example could be identified.

ACTION: Gillian Leng

36. The Board approved the success criteria and the process measures, and noted that progress against these will be included in the six monthly Board reports on impact. Gillian Leng confirmed that these reports will also include feedback gathered by the Field Team, and evidence on NICE’s impact from third party sources such as Care Quality Commission reports.

16/031 NICE AND PUBLIC HEALTH ENGLAND: PARTNERSHIP AGREEMENT AND PRINCIPLES FOR JOINT WORKING

37. Gillian Leng presented the partnership agreement between NICE and Public Health England (PHE). She declared a personal interest in that her spouse is an Executive Director at PHE.

38. The Board noted and welcomed the partnership agreement and the associated principles for joint working. The Board noted though the need to continue to minimise duplication between NICE, PHE and other public health partners.
including the Local Government Association. It was agreed that the Board should be kept updated on partnership working with Public Health England.

**ACTION: Gillian Leng**

**16/032 REVISIONS TO THE NICE STANDING ORDERS, STANDING FINANCIAL INSTRUCTIONS AND RESERVATION OF POWERS TO THE BOARD AND SCHEME OF DELEGATION**

39. The Board agreed the changes subject to the amendment of the proposed revision to the Reservation of Powers to the Board to state 'the establishment and dissolution of committees'.

**ACTION: Ben Bennett**

**16/033 DIRECTOR’S REPORT FOR CONSIDERATION**

40. Carole Longson presented the update from the Centre for Health Technology Evaluation (CHTE). She drew the Board’s attention to key items of note in the report, including the work of the MTEP research facilitation function and the Science Policy and Research (SP&R) programme. The SP&R programme has several funding bids in progress, which if approved, could lead to the programme attracting income of £1m next year.

41. Following a request from Tim Irish, Carole Longson agreed to provide an update on the ‘safe harbour’ pilot to a future meeting.

**ACTION: Carole Longson**

42. The Board received the report and thanked Carole Longson for the work of the Centre.

**16/034-16/037 DIRECTORS’ REPORTS FOR INFORMATION**

43. The Board received the Directors’ Reports.

44. Bill Mumford noted and welcomed the inclusion of members with learning disabilities on a guideline committee for the first time.

**16/038 COMMITTEE MINUTES**

45. The Board received the unconfirmed minutes of the Audit and Risk Committee held on 27 January 2016.
ITEM 1

16/039 ANY OTHER BUSINESS

46. David Haslam noted that this was Rona McCandlish’s last Board meeting. On behalf of the Board he paid tribute to Professor McCandlish’s outstanding contribution as a non-executive director.

NEXT MEETING

47. The next public meeting of the Board will be held at 1.45pm, 18 May 2016, in the Deafblind UK Conference Centre, Cygnet Road, Hampton, Peterborough, PE7 8FD.
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CHIEF EXECUTIVE'S REPORT

This report provides information on the outputs from our main programmes and the financial position for the 12 months to the end of March 2016, and comment on other matters of interest to the Board.

The Board is asked to note the report.

Andrew Dillon
Chief Executive
May 2016
1. This report sets out the performance of the Institute against its business plan objectives and other priorities, for the 12 months ending 31 March 2016. It also reports on guidance published since the last public Board meeting in March and refers to business issues not covered elsewhere on the Board agenda.

Performance

2. The year-end position 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 3. The outturn performance of the main programmes between April 2015 and March 2016 is set out in Graphs 1 and 2, below.

4. The balanced score card, showing the outturn position for each metric and an explanation of the variances, where they have occurred, is set out at Appendix 2.

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

Notes to Graph 1:

a) IP refers to Intervventional 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.

5. Details of the variance against plan are set out at Appendix 4. Guidance quality standards and other advice published since the last Board meeting in March is set out Appendix 5.

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

Graph 2: Advice programmes main outputs: April 2015 to March 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 12)

4. The financial position for the 12 months from April 2015 to the end of March 2016 is an under spend of £0.5m (0.7%) against a budget of £75.7m. 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 March 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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<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. Instead, we have agreed performance metrics for our direct contracts with NHS England, including the Cancer Drugs Fund, we have reviewed and refreshed our impact assessment report and the balanced score card. In addition, our standard reporting metrics to the Board are available to both the Department of Health and to NHS England.</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 2015. 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</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>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>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>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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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.

A GP Advisory Group led by NICE’s chairman has 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. The group has now completed its work.

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 1500 volunteers have joined. The volunteers including GPs, nurses and midwives, and social care and public health have expressed interest in providing their views and
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<td>Feedback on a wide range of NICE products and services. We recently sought the views of the insights community on use and accessibility of NICE products. Feedback received will help inform continuous improvement of the presentation and dissemination of our work.</td>
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<td>Triennial review, business plan</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. We are developing two new products for social care, which we will test with audiences in the autumn.</td>
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<td>DH priority, business plan</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, a full brief and project plan have been prepared and we are working with the Reputation Institute on</td>
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<td><strong>Adoption</strong></td>
<td>Triennial review, business plan</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 organisations in implementation activity.</td>
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<td><strong>DH priority, business plan</strong></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>
<td>A report on our approach to decommissioning advice 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 are taking part in a series of Department of Health ‘deep dives’ to identify what further contribution we might be able to make. As part of this, we are undertaking further work on identifying inappropriate prescribing amongst older people.</td>
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<td><strong>DH priority, business plan</strong></td>
<td>Support the more rapid introduction and diffusion of innovative and cost-effective medicines and technologies.</td>
<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 scheduling of field work.</td>
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<td><strong>Programme</strong></td>
<td><strong>DH priority</strong></td>
<td><strong>Develop plans to better support the medical technologies sector in understanding the needs and priorities of the NHS.</strong></td>
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<td><strong>DH priority</strong></td>
<td><strong>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.</strong></td>
<td><strong>The May and October 2015 innovation scorecards were published as planned, and an updated set of data was published by the HSCIC in 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.</strong></td>
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<td><strong>Programme development</strong></td>
<td><strong>DH priority</strong></td>
<td><strong>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.</strong></td>
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<tr>
<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></td>
</tr>
</tbody>
</table>

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 the long term future of the programme, in June.

| Triennial review, DH priority, business plan | Actively engage with the Accelerated Access Review. |

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 the Board considered at its meeting in January. We are involved in ongoing discussions relating to implementation of the AAR in advance of its expected publication in July.

| DH priority, business plan | Develop proposals to improve awareness and uptake of the advisory services NICE offers to the life sciences industry. |

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.

| DH priority, business plan | Identify opportunities to evaluate digital health technologies and services within NICE’s guidance programmes, where evidence is |

This is being undertaken as part of NICE’s role in supporting the National Information Board to develop a framework for assessing digital
<p>| Business plan | Continue to implement the digital strategy of NICE with emphasis on transforming internal guidance development systems while continuing to maintain and enhance our externally facing digital service. | Implementation of the digital strategy continues under the governance of the 5 Service Groups and SMT. The Digital Services function has recently achieved the highest rating in an internal audit review of NICE's digital strategy. |
| Business plan | Participate in the NHS England review of the management of the Cancer Drugs Fund. | 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 and NICE Boards. Two additional appraisal committee meetings are planned, in May and July, to consider products currently funded through the CDF. We are also now working with NHS England to develop detailed operating procedures for management of CDF, including the budget control |</p>
<table>
<thead>
<tr>
<th><strong>Business plan</strong></th>
<th><strong>Methodology</strong></th>
<th><strong>Partnership</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Redesign and future-proof the clinical guidelines programme.</strong></td>
<td><strong>Integrate and future-proof the clinical guidelines programme.</strong></td>
<td><strong>Work with the Medicines and Healthcare Products Regulatory Agency (MHRA) to review the partnership agreement and arrangements.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>The Partnership Agreement has been reviewed and updated and regular meetings are taking place between the two organisations to identify the current state of the agreement.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>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.</strong></td>
<td><strong>The Partnership Agreement has been reviewed and updated and regular meetings are taking place between the two organisations to identify the current state of the agreement.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>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.</strong></td>
</tr>
<tr>
<td><strong>Consolidate the integration of the methods and processes for the development of guidelines (clinical, public health and social care), and continue to consider improvements.</strong></td>
<td></td>
<td><strong>The Partnership Agreement has been reviewed and updated and regular meetings are taking place between the two organisations to identify the current state of the agreement.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>The tendering process for external contractors to develop clinical guidelines from 1 April 2016 is complete. Plans are in place, within the constraints of current capacity to maintain the currency of all published clinical guidelines.</strong></td>
<td><strong>The Partnership Agreement has been reviewed and updated and regular meetings are taking place between the two organisations to identify the current state of the agreement.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>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, which was completed by March 2016.</strong></td>
<td><strong>The Partnership Agreement has been reviewed and updated and regular meetings are taking place between the two organisations to identify the current state of the agreement.</strong></td>
</tr>
</tbody>
</table>

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National Institute for Health and Care Excellence
Chief Executive’s Report
Date: 18 May 2016
Ref: 16/044
<table>
<thead>
<tr>
<th><strong>ITEM 2</strong></th>
<th><strong>consider publicising both the agreement and steps taken to ensure the principles are put into practice throughout all levels of the organisations.</strong></th>
<th>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 scientific advice have taken place.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Business plan</strong></td>
<td>Explore with CQC how to ensure that NICE quality standards and guidelines complement and reinforce essential standards, building on existing work to map NICE Quality Standards into the CQC inspection work.</td>
<td>A programme of work, to map NICE quality standards to CQC’s inspection framework is well advanced and will continue with support from Clinical Fellows in both organisations. NICE is actively working with CQC to consider how the new CQC strategy should be best aligned with NICE products.</td>
</tr>
<tr>
<td><strong>Business plan</strong></td>
<td>Engage with NHS England in the implementation of their 5 Year Forward View.</td>
<td>NICE is 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. NICE senior managers are involved in a number of the FYFV programme boards, including the new Leadership and Improvement Board.</td>
</tr>
<tr>
<td><strong>Triennial review</strong></td>
<td>Work with NHS England to identify systems and processes, with associated metrics where appropriate, to secure the application of the commitment in the Partnership Agreement between the two organisations to the use of NICE guidance in the centralised and</td>
<td>NICE guidance is already referenced in a range of central and devolved commissioning guidance. We are in discussion with them about extending our support to them in the development of their specialised commissioning policies.</td>
</tr>
<tr>
<td><strong>Triennial review</strong></td>
<td>Work to further enhance relationships with organisations across health and care, clarifying areas where roles and responsibilities could be made clearer to stakeholders.</td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Work is underway to clarify the role of NICE guidance and standards, with involvement of colleagues at the DH, Skills for Care and the RCP. NICE is actively working with PHE to align our work programmes to be mutually supportive, and clear for the end user. As part of its strategy to 2020, NICE will undertake a programme by programme review of the alignment between its outputs and the health and care system they are designed for. This will include ensuring, over time that each set of recommendations has a clear system owner or owners and a commitment from the system to manage the recommendations into practice.</td>
<td></td>
</tr>
<tr>
<td><strong>Financial</strong></td>
<td><strong>Business plan</strong> 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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The Institute is operating within its resource limits. Further information is available elsewhere in this report and in the Finance Report.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Business plan</strong> Plan for a balanced budget for 2016-17, taking account of anticipated significant grant in aid reductions.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The Institute has set a balanced budget for 2016-17.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Triennial review</strong> Explore charging industry for health technology appraisals and medical devices and diagnostics evaluations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>As part of the longer term plans to address the 30% reduction in GIA income this is now being actively pursued. A project, chaired by the Chief Executive and including DH membership has</td>
<td></td>
</tr>
<tr>
<td><strong>ITEM 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td><strong>DH priority, business plan</strong></td>
<td>Explore opportunities for further efficiencies: making transactions digital and considering opportunities for back office efficiencies from synergies within your organisation or closer working with other system players.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Efficiencies continue to be sought from back office functions. Shared services arrangements and investment in IT solutions will continue to be used where they provide value. Co-location with other public bodies has provided an income stream and more efficient use of office accommodation in Manchester. A similar co-location arrangement has now been agreed for the London office which began in April 2016.</td>
<td></td>
</tr>
<tr>
<td><strong>Governance</strong></td>
<td><strong>Triennial review</strong></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></td>
<td></td>
<td>A proposal for the Internal Auditors to undertake this work was considered and approved at the January Board meeting. The assessment is now complete, and the final report and action plan has been considered by the Board.</td>
</tr>
<tr>
<td><strong>Business plan</strong></td>
<td><strong>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.</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All staff receive a set of personal objectives and a personal development plan.</td>
<td></td>
</tr>
<tr>
<td><strong>Triennial review</strong></td>
<td><strong>Ensure that the arrangements for operating and quality controlling the work of NICE’s independent advisory committees are robust</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The Board considered a discussion paper on this at its March meeting.</td>
<td></td>
</tr>
<tr>
<td><strong>DH priority</strong></td>
<td><strong>Promote a culture of continuous improvement within the organisation and uphold the ambition to remain a world-renowned organisation, benchmarking its systems, processes and outcomes against best players internationally, proactively thinking about succession planning and attracting and retaining talent.</strong></td>
<td><strong>All NICE’s methods and processes are reviewed regularly and are subject to public consultation. There is no obvious way of benchmarking our processes for producing guidance with other international organisations, but all NICE programmes are accredited using the NICE independent Accreditation Programme. The Board has considered and approved a workforce strategy.</strong></td>
</tr>
</tbody>
</table>
**Appendix 2: Balanced Scorecard 2015-16: April 2015 – March 2016**

**Delivering services and improvements**

Development and publication of guidance and evidence outputs (as specified in Business Plan)

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Planned Q1 to Q4</th>
<th>Actual Q1 to Q4</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish 7 public health guidelines</td>
<td>Publication within year</td>
<td>75%</td>
<td>7</td>
<td>7</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 34 clinical guidelines, including updates</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>34</td>
<td>33</td>
<td>97%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 2 medicine practice guidelines</td>
<td>Publication within year</td>
<td>75%</td>
<td>2</td>
<td>2</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 8 local government public health briefings</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>8</td>
<td>1</td>
<td>13%</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
This programme has been discontinued.

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Planned Q1 to Q4</th>
<th>Actual Q1 to Q4</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish 45 technology appraisals guidance</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>45</td>
<td>47</td>
<td>104%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 34 interventional procedures</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>34</td>
<td>34</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 7 diagnostics guidance</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>7</td>
<td>6</td>
<td>86%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 3 highly specialised technologies guidance</td>
<td>Publication within stated quarter</td>
<td>100%</td>
<td>3</td>
<td>1</td>
<td>33%</td>
<td>Red</td>
</tr>
</tbody>
</table>

**Notes:**
2 topics are delayed:
- Ataluren for treating Duchenne muscular dystrophy caused by a nonsense mutation in the dystrophin gene [ID 428]
- Eliglustat for treating type 1 Gaucher disease [ID709]

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Planned Q1 to Q4</th>
<th>Actual Q1 to Q4</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish 8 medical technologies guidance</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>8</td>
<td>4</td>
<td>50%</td>
<td>Amber</td>
</tr>
</tbody>
</table>
Notes:
4 topics are delayed (see main report for explanation).
- Heartflow FFRct for the estimation of fractional flow reserve from coronary CT angiography
- Microthane implants for breast reconstruction or breast augmentation
- Endocuff for endoscopic investigation of patients with suspected colonic pathology
- The HumiGard surgical humidification system

<table>
<thead>
<tr>
<th>Activity</th>
<th>Target Date</th>
<th>Status</th>
<th>Achievement</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish 40 medtech innovation briefings (MIBs)</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>40</td>
<td>35</td>
</tr>
<tr>
<td>Submit advice to Ministers on 12 Patient Access Schemes</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>12</td>
<td>36</td>
</tr>
<tr>
<td>Publish 45 Clinical Guideline Surveillance Updates</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>45</td>
<td>32</td>
</tr>
</tbody>
</table>

Notes:
13 evidence updates were delayed due largely to the implementation of a new process and a delay in recruitment of new staff. Publication is expected in 2016-17.
## Provision of support products for the effective implementation of guidance

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Planned Q1 to Q4</th>
<th>Actual Q1 to Q4</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide 12 adoption scoping reports to NICE scoping meetings</td>
<td>Publication within year</td>
<td>100%</td>
<td>12</td>
<td>16</td>
<td>133%</td>
<td>Green</td>
</tr>
<tr>
<td>Conduct a minimum of 30 first adoption engagements</td>
<td>Publication within year</td>
<td>100%</td>
<td>30</td>
<td>87</td>
<td>290%</td>
<td>Green</td>
</tr>
<tr>
<td>Complete a minimum of 6 adoption support products</td>
<td>Publication within year</td>
<td>75%</td>
<td>6</td>
<td>7</td>
<td>117%</td>
<td>Green</td>
</tr>
<tr>
<td>Deliver 15 Student Champion training events</td>
<td>Publication within year</td>
<td>80%</td>
<td>15</td>
<td>24</td>
<td>160%</td>
<td>Green</td>
</tr>
</tbody>
</table>

## Development and publication of evidence awareness services

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Planned Q1 to Q4</th>
<th>Actual Q1 to Q4</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish 12 monthly evidence alerts via Eyes of Evidence</td>
<td>Publication within stated quarter</td>
<td>100%</td>
<td>12</td>
<td>21</td>
<td>175%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 5 new Clinical Knowledge Summaries topics</td>
<td>Publication within stated quarter</td>
<td>80%</td>
<td>5</td>
<td>7</td>
<td>140%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 12 monthly updates of the BNF and BNF C content</td>
<td>Publication within stated quarter</td>
<td>80%</td>
<td>12</td>
<td>30</td>
<td>250%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish a regular medicine awareness service</td>
<td>Publishing to regular weekly and daily (working day) schedule</td>
<td>90%</td>
<td>260</td>
<td>260</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 16 Medicines optimisation key therapeutic topics</td>
<td>Publication within stated quarter</td>
<td>80%</td>
<td>16</td>
<td>16</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 40 medicines evidence commentaries</td>
<td>Publishing within stated quarter</td>
<td>80%</td>
<td>40</td>
<td>40</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td>Deliver 5 education and publishing within stated quarter</td>
<td>Publishing within stated quarter</td>
<td>80%</td>
<td>5</td>
<td>5</td>
<td>100%</td>
<td>Green</td>
</tr>
</tbody>
</table>
**Investing in the organisation**

Delivering programmes and activities on budget

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Planned Q1 to Q4</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective management of financial resources</td>
<td>Revenue spend</td>
<td>To operate within budget</td>
<td>Annual budget for 2015-16 was £63.1m</td>
<td>Net spend for 2015-16 was £62.5m (Net underspend £543,000)</td>
<td>Green</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>
<td>To break even or better</td>
<td>Net Income and expenditure was a surplus of £27,000 at 31 March 2016</td>
<td>Green</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>
<td>Annual budget for NICE International was £50,000</td>
<td>Net income and expenditure was £45,000 at 31 March 2016, a surplus of £5,000</td>
<td>Green</td>
</tr>
<tr>
<td>Produce the annual report and accounts within the statutory timeframe</td>
<td>Publications</td>
<td>100%</td>
<td>To be laid before Parliament Summer Recess</td>
<td>100% (Laid before Parliament on)</td>
<td>Green</td>
</tr>
</tbody>
</table>
Maintaining and developing a skilled and motivated workforce

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management of recruitment</td>
<td>Proportion of posts appointed to within 4 months of first advertisement</td>
<td>80%</td>
<td>100%</td>
<td>Green</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>
<td>100%</td>
<td>Green</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>
<td>91%</td>
<td>Green</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>
<td>74%</td>
<td>Amber</td>
</tr>
</tbody>
</table>

Note:
The reduction, of a single percentage point, is unlikely to represent a significant shift in staff attitudes to their employer.

Staff involvement
Hold monthly staff meetings

Sustainable development

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recycled waste</td>
<td>% of total waste recycled</td>
<td>50%</td>
<td>100%</td>
<td>Green</td>
</tr>
</tbody>
</table>

Improving stakeholder satisfaction

| Outputs                          | Measure                                              | Target | Cumulative performance | RAG   |
|----------------------------------|                                                     |        |                        |       |
| Improved satisfaction            | Complaints fully responded to in 20 working days     | 80%    | 94%                    | Green |
| Improved satisfaction            | Enquiries fully responded to in 18 working days      | 90%    | 96%                    | Green |
| Improved satisfaction            | Number of Freedom of Information requests           | 100%   | 97%                    | Amber |
responded to within 20 working days

Notes:
In Q3, two requests required legal advice and additional time to consider the public interest test.

<table>
<thead>
<tr>
<th>Improved satisfaction</th>
<th>PQs contribution provided within requested timeframe</th>
<th>90%</th>
<th>86%</th>
<th>Amber</th>
</tr>
</thead>
</table>

Notes:
In 2015-16, 5 PQs (out of a total 51) were not responded to within the agreed timescale due to the short notice of the requests.

<table>
<thead>
<tr>
<th>Improved satisfaction</th>
<th>DPA requests responded to within 40 calendar days</th>
<th>100%</th>
<th>100%</th>
<th>Green</th>
</tr>
</thead>
</table>

| Ensuring stakeholders have access to our websites as the main communication channel | Percentage of planned availability, not including scheduled out of hours maintenance | 98% | 100% | Green |

### Outputs

#### Measure

<table>
<thead>
<tr>
<th>Interest in opportunities for lay people (patients, carers, service users, community members etc) to sit on our advisory reflected by ratio of applications to positions</th>
<th>Target</th>
<th>Planned Q1 to Q4</th>
<th>Actual Q1 to Q4</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 to 1 (or greater) each quarter</td>
<td>100%</td>
<td>2 to 1</td>
<td>5.8 to 1</td>
<td>100%</td>
<td>Green</td>
</tr>
</tbody>
</table>

Maintaining and developing recognition of the role of NICE

#### Outputs

<table>
<thead>
<tr>
<th>Understanding user requirements</th>
<th>Web analytics performance monitoring report delivered monthly to each digital Service Group</th>
<th>Annual target</th>
<th>Planned Q1 to Q4</th>
<th>Actual Q1 to Q4</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>60%</td>
<td>96</td>
<td>96</td>
<td>100%</td>
<td>Green</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Understanding user requirements | Evidence of adherence to the Government Digital Services development standards of | 50% | 100 | 865 | 865% | Green |
### Understanding user requirements

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence of adherence to the Government Digital Services development standards of engaging in user needs analysis: Number of users tested per month on average</td>
<td>10</td>
<td>8</td>
<td>80%</td>
</tr>
<tr>
<td>Evidence of adherence to the Government Digital Services development standards of engaging in user needs analysis: Number of focus groups or lab testing sessions per year</td>
<td>10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Notes:
The business need regarding user testing in this quarter was focussed on individual user testing rather than group sessions.

### Examples of CCGs working with NICE quality standards identified

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% of CCGs inform quality improvement in primary care providers based on at least 1 piece of NICE guidance or use of a quality standard.</td>
<td>100%</td>
<td>106</td>
<td>107</td>
</tr>
</tbody>
</table>

### Examples of Trusts working with NICE quality standards identified

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>80% of Trusts are using quality standards to improve clinical services</td>
<td>100%</td>
<td>208</td>
<td>221</td>
</tr>
</tbody>
</table>

### Ensure ongoing awareness of NICE equality strategy and implementation across all programmes

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Produce an annual Equality report</td>
<td>100%</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

### Outputs

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of positive coverage of NICE in the media resulting from active programme of media relations</td>
<td>80%</td>
<td>75%</td>
<td>Amber</td>
</tr>
</tbody>
</table>

### Notes:
The increase in neutral and negative coverage within 2015-16 was related to the suspension of the safe staffing programme and the ongoing debate about the impact of the new Cancer Drug Fund.
Change and Business Improvement: Improving the way we work

Improving efficiency and speed of outputs

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Annual target</th>
<th>Cumulative performance</th>
<th>RAG</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>
<td>84%</td>
<td>Amber</td>
</tr>
</tbody>
</table>

Notes:
In 2015-16, 4 topics have been delayed by the timing of the referral, meaning that marketing authorisation had been received by the time topics were referred.
- Leukemia (chronic lymphocytic, previously treated) idelalisib
- Daclatasvir for treating chronic Hepatitis C
- Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma after chemotherapy
- Leukaemia (chronic lymphocytic, previously treated) – idelalisib

Speed of production           | % of multiple technology appraisals from invitation to participate to ACD in 41 weeks, or where no ACD produced to FAD in 44 weeks | 85%           | 43%                    | Amber |

Notes:
In 2015-16, 4 topics were delayed.
- Ankylosing spondylitis and axial spondyloarthritis – TNF inhibitors (inc review of TA143 & TA233). Release of ACD was delayed due to General Election purdah. An appeal has been lodged against this topic which will lead to further delay
- Rheumatoid arthritis – adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, abatacept and tocilizumab: following a consultation with consultees and commentators on the executable economic model for this appraisal NICE agreed that further work on HAQ score progression was required. The Decision Support Unit was commissioned to take on this additional work. An appeal has been lodged against this topic which will lead to further delay.
- Kidney transplantation (adults) – immunosuppressive therapy (review of TA85)
and
Kidney transplantation (children, adolescents) – immunosuppressive regimens (review of TA99): due to the size and complexity of these appraisals the Assessment Group requested further time to prepare the reviews of the clinical and cost effectiveness of the technologies. This request was considered and as a consequence the first committee meeting for these topics was rescheduled.
<table>
<thead>
<tr>
<th>Speed of production</th>
<th>% of Appeal Panel decisions received within 3 weeks of the hearing</th>
<th>80%</th>
<th>100%</th>
<th>Green</th>
</tr>
</thead>
</table>

**RAG Status - Key**

- **Green** = Greater than or equal to annual target
- **Amber** = Between 50% and less than annual target
- **Red** = Less than 50%
### Appendix 3: Extracts from the Directors’ reports

<table>
<thead>
<tr>
<th>Director</th>
<th>Featured section</th>
<th>Section/ reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health and social care</strong></td>
<td>Choosing Wisely is an initiative established by the Academy of Medical Royal Colleges (AoMRC) to avoid wasteful or unnecessary medical tests, treatments and procedures. In April 2016, NICE submitted 5 ‘do not do’ recommendations to the Choosing Wisely initiative, spanning different physical and mental health conditions. These recommendations were chosen from those included in Quality Standards, and then assessed on the basis of the population affected, the applicability of shared decision making, the cost of the practice being recommended and the potential for significant cost saving. AoMRC is scheduled to implement Choosing Wisely during 2016.</td>
<td>Section/para 12</td>
</tr>
<tr>
<td><strong>Clinical practice</strong></td>
<td>We have developed a reference panel and database of topic experts for CCP activities and have recruited over 198 topic experts so far from the previous GDG membership. 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 is scheduled to begin in April based on that analysis. This panel of experts will help us speed up the process of finding expert advice for the surveillance programme and in recruiting topic experts to the standing committees.</td>
<td>Section/para 11</td>
</tr>
<tr>
<td><strong>Technology evaluation</strong></td>
<td>The Science Policy and Research programme is continuing its work on two IMI (Innovate Medicines Initiative: an EU funded project to speed up the development of better and safer medicines) funded projects – “GetReal”, a pan-European consortium of medicines regulators, health technology assessment bodies, pharmaceutical companies, patients and other stakeholders to explore the role of real-world evidence for informing decision making; and “ADAPT-SMART” which is exploring the design of 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 grants to deliver our work. The team is exploring the potential of participating in a range of EU funded research projects, including IMI and Horizon 2020 (an EU Research and Innovation programme with nearly €80 billion of funding between 2014 to 2020). Currently, NICE is an active partner on three IMI research project funding submissions.</td>
<td>Section/para 13</td>
</tr>
<tr>
<td><strong>Evidence resources</strong></td>
<td>The NICE Digital Services team has attended regular showcases of the nhs.uk new platform for healthcare transactions and met with the development team in NHS England</td>
<td>Section/para 7, bullet 2</td>
</tr>
</tbody>
</table>
to explain and support the re-use of NICE content in the development of nhs.uk. With this
demand in mind, the NICE Digital Services team is 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.

| Communications | A press conference in September 2015 launched our guideline for the social care sector to promote high-quality home care services for older people. 11 journalists from key outlets including BBC, Sky, Daily Mail and Daily Telegraph attended. The guideline was reported widely across national and regional media. It ran all day, including in the evening news programmes. All of the pieces were positive. This was echoed on Twitter, where reaction was also extremely positive. There was also widespread coverage for our key audiences through trade media including Community Care, the Local Government Chronicle and in local and regional newspapers and broadcasts. | Section/para 8 |
| Finance and workforce | Formal notification of funding for 2016-17 was received on the 21 April 2016. The Department of Health confirmed that administration (£49.4m) and programme (£8.7m) revenue funding which matches the NICE 2016-17 business plan totalling £58.1m (£62.0m funding in 2015-16). The capital allocation requirement of £0.5m has also been confirmed | Section/para: 23 |
## Appendix 4: Guidance development: variation against plan April 2015 – March 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 to enable local pilots of the FeNO diagnostic test. 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>No variation against plan 2015-16</td>
<td></td>
</tr>
<tr>
<td><strong>Medical technologies</strong></td>
<td>4 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>Microthane implants for breast reconstruction or breast augmentation – Delayed due to company not completing submission. Publication date to be confirmed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Endocuff for endoscopic investigation of patients with suspected colonic pathology - Delayed awaiting pivotal clinical trial data. Due to publish Q4 2016-17 (March 2017).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The HumiGard surgical humidification system - Delayed awaiting parallel development with the clinical guideline update to CG65. Due to publish Q2 2016-17 (September 2016).</td>
</tr>
<tr>
<td><strong>Public Health</strong></td>
<td>No variation against plan 2015-16</td>
<td></td>
</tr>
<tr>
<td><strong>Quality Standards</strong></td>
<td>2 additional quality standards published</td>
<td>Anaphylaxis and food allergy published as two separate quality standards in March 2016 (Q4 2015-16).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Preventing unintentional injury published as one quality standard titled in January 2016 (Q4 2015-16) although it was referred as two quality standards: preventing unintentional injury and prevention in homes.</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>1 topic delayed</td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The Triage PIGF test, Elecsys immunoassay sFlt-1/PIGF ratio, DELFIA Xpress PIGF 1-2-3 test and BRAHMS sFlt-1 Kryptor / PIGF plus Kryptor PE ratio to aid the assessment of suspected pre-eclampsia – The second Diagnostics Consultation Document (DCD) was released after the committee meeting in December 2015. The third committee meeting was held in February 2016. Publication now scheduled for Q1 2016-17 (May 2016).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Technology Appraisals</th>
<th>6 topics delayed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ovarian cancer (advanced - relapsed disease only) topotecan, pegylated liposomal doxorubicin hydrochloride and paclitaxel – delayed due to appeal being upheld. The appraisal will now be referred back to the committee. Due to publish Q1 2016/17 (April 2016).</td>
</tr>
</tbody>
</table>

|                      | Systemic lupus erythematosus (active seropositive) – belimumab – Following discussions between NICE and external parties the release of the Final Appraisal Determination was delayed. Publication is now to be confirmed. |

|                      | Prostate cancer (advanced hormone dependent) – degarelix depot – The company submitted additional evidence to this appraisal, which was reviewed by the ERG. The additional evidence and the ERG review were considered by the committee at the meeting held on 4 November 2015. Following discussions between NICE and external parties the release of a document has been delayed. The anticipated publication date is to be confirmed. |

|                      | Dupuytren’s contracture – collagenase clostridium histolyticum (1st line) – An appeal hearing was held on 30 November 2015 and the outcome discussed at NICE’s Guidance Executive in early 2016. Further internal discussion is required before we are able to release the outcome of the appeal. The anticipated publication date is to be confirmed. |

|                      | 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 ERG exploratory scenarios that were fundamental to decision making. Further details will follow once they are available. Publication date to be confirmed. |

|                      | Primary hypercholesterolaemia (heterozygous, familial and non familial) and mixed dyslipidaemia – evolocumab - Following the release of a second ACD the anticipated publication date is now Q1 2016-17 (June 2016). |

|                      | Cangrelor for reducing atherothrombotic events in people undergoing percutaneous coronary intervention or awaiting surgery requiring interruption of |

<p>| 8 additional topics published in 2015-16, that | |</p>
<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>were not planned for this financial year</strong></td>
<td>anti-platelet therapy – Published in Q2 (July 2015) as a terminated appraisal.</td>
</tr>
<tr>
<td>Bevacizumab for treating relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer (terminated appraisal) – Published in Q2 (August 2015) as a terminated appraisal.</td>
<td></td>
</tr>
<tr>
<td>Pancreatic cancer (previously untreated, metastatic) - paclitaxel as albumin-bound nanoparticles (in combination with gemcitabine) – This was a post appeal publication. Following the appeal hearing held on 16 March 2015, the appeal was upheld and the appraisal went to Committee for further discussion. Following the release of a second FAD the guidance was published post appeal in Q3 (October 2015).</td>
<td></td>
</tr>
<tr>
<td>Non-small-cell lung cancer (untreated) - paclitaxel albumin-bound nanoparticles (with carboplatin) - Published in Q3 (October 2015) as a terminated appraisal.</td>
<td></td>
</tr>
<tr>
<td>Breast cancer (HER2 positive) - trastuzumab emtansine - Following the 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>
<td></td>
</tr>
<tr>
<td>Non-small cell lung cancer (second line treatment) erlotinib (TA162) and gefitinib (TA175) - An additional committee meeting was held to reconsider the relevance of the PPRS in the light of NICE's position statement for this appraisal. Published in Q3 (December 2015).</td>
<td></td>
</tr>
<tr>
<td>Eltrombopag for treating severe aplastic anaemia refractory to immunosuppressive therapy – Published in Q4 (January 2016) as a terminated appraisal.</td>
<td></td>
</tr>
<tr>
<td>Melanoma (unresectable or metastatic) – nivolumab - This appraisal went straight to FAD. Originally planned for May 2016 (Q1 2016-17). Published February 2016.</td>
<td></td>
</tr>
<tr>
<td><strong>Highly Specialised Technologies (HST)</strong></td>
<td>2 topics delayed</td>
</tr>
<tr>
<td>Ataluren for treating Duchenne muscular dystrophy caused by a nonsense mutation in the dystrophin gene - Additional information submitted by the company following FED release in December 2015 lead to the topic being referred back to the committee and the appeal stage suspended. Guidance was issued for appeal in April. Publication date to be confirmed.</td>
<td></td>
</tr>
<tr>
<td>Accreditation</td>
<td>No variation against plan 2015-16</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td></td>
<td>Eliglustat for treating type 1 Gaucher disease - The topic is currently suspended following information received from the company to align with the commercial availability of the product in the UK.</td>
</tr>
</tbody>
</table>
**Appendix 5: Guidance published since the last Board meeting in March**

<table>
<thead>
<tr>
<th>Programme</th>
<th>Topic</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Guidelines</td>
<td>None planned</td>
<td></td>
</tr>
<tr>
<td>Interventional procedures</td>
<td>Endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia</td>
<td>Special arrangements</td>
</tr>
<tr>
<td></td>
<td>Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis</td>
<td>Special arrangements</td>
</tr>
<tr>
<td></td>
<td>Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine</td>
<td>Special arrangements</td>
</tr>
<tr>
<td>Medical technologies</td>
<td>Spectra Optia for automatic red blood cell exchange in patients with sickle cell disease</td>
<td>Case for adoption is fully supported</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>No publications</td>
<td></td>
</tr>
<tr>
<td>Public Health</td>
<td>Community engagement: improving health and wellbeing and reducing health inequalities</td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td>Workplace health: management practices</td>
<td>General guidance</td>
</tr>
<tr>
<td>Quality Standards</td>
<td>Medicines optimisation</td>
<td>Markers of good practice</td>
</tr>
<tr>
<td></td>
<td>Food allergy</td>
<td>Markers of good practice</td>
</tr>
<tr>
<td></td>
<td>Anaphylaxis</td>
<td>Markers of good practice</td>
</tr>
<tr>
<td></td>
<td>Preventing excess winter deaths and illness associated with cold homes</td>
<td>Markers of good practice</td>
</tr>
<tr>
<td>Technology Appraisals</td>
<td>Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis</td>
<td>Optimised</td>
</tr>
<tr>
<td>Highly</td>
<td>None planned</td>
<td></td>
</tr>
<tr>
<td>Specialised Technologies (HST)</td>
<td>Scottish Dental Clinical effectiveness programme (SDCEP)</td>
<td>Accredited</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td><strong>Evidence summaries – new medicines</strong></td>
<td>Moderate to severe acute post-operative pain: sufentanil sublingual tablet system</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>Attention deficit hyperactivity disorder in children and young people: guanfacine prolonged-release</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>Prevention of chemotherapy induced nausea and vomiting in adults: netupitant/palonosetron</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td><strong>Evidence summaries – unlicensed/off label medicines</strong></td>
<td>Pulmonary hypertension in neonates: sildenafil</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td><strong>Medtech Innovation Briefings (MIB)</strong></td>
<td>TheraSphere for treating operable and inoperable hepatocellular carcinoma</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>SIR-Spheres for treating inoperable hepatocellular carcinoma</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>TactiCath Quartz catheter for percutaneous radiofrequency ablation in atrial fibrillation</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>ThermoCool SmartTouch catheter for percutaneous radiofrequency ablation in atrial fibrillation</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>Icare rebound tonometer to measure intraocular pressure</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>Mersey Burns for calculating fluid resuscitation volume when managing burns</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>Otovent nasal balloon for otitis media with effusion</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>ClearWay RX for drug delivery to coronary artery thrombotic lesions</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td>Evidence Surveillance Reviews</td>
<td>Summary of best available evidence</td>
<td></td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------------------------------</td>
<td></td>
</tr>
<tr>
<td>Aquilion PRIME CT scanner for imaging coronary artery disease in adults in whom imaging is difficult</td>
<td>Evidence</td>
<td></td>
</tr>
<tr>
<td>Somatom Definition Edge CT scanner for imaging coronary artery disease in adults in whom imaging is difficult</td>
<td>Summary of best available evidence</td>
<td></td>
</tr>
<tr>
<td>The diagnosis and management of lung cancer</td>
<td>Surveillance review decision</td>
<td></td>
</tr>
<tr>
<td>The recognition and initial management of ovarian cancer</td>
<td>Surveillance review decision</td>
<td></td>
</tr>
<tr>
<td>Urinary incontinence: the management of urinary incontinence in women</td>
<td>Surveillance review decision</td>
<td></td>
</tr>
<tr>
<td>Acutely ill patients in hospital: recognition of and response to acute illness in adults in hospital</td>
<td>Surveillance review decision</td>
<td></td>
</tr>
<tr>
<td>Mechanical thrombectomy for large vessel occlusion stroke: improving clinical outcomes and reducing cost</td>
<td>Examples of quality and productivity improvements</td>
<td></td>
</tr>
<tr>
<td>Routine 72–96 hour replacement of peripheral venous catheters</td>
<td>Evidence review</td>
<td></td>
</tr>
</tbody>
</table>
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

FINANCE AND WORKFORCE REPORT

This report gives details of the

- financial position for the year ended 31 March 2016;
- update on funding allocations for 2016-17.

The Board is asked to review the report.

Ben Bennett
Director, Business Planning and Resources Directorate
May 2016
Summary

1. Table 1 summarises the financial position for the financial year ended 31 March 2016. There is a full analysis in Appendix A.

<table>
<thead>
<tr>
<th></th>
<th>Budget £m</th>
<th>Expenditure £m</th>
<th>Income £m</th>
<th>Variance £m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidance &amp; Advice</td>
<td>55.2</td>
<td>55.8</td>
<td>(2.7)</td>
<td>(2.1)</td>
</tr>
<tr>
<td>Corporate</td>
<td>7.8</td>
<td>12.8</td>
<td>(6.6)</td>
<td>(1.6)</td>
</tr>
<tr>
<td>NICE International</td>
<td>0.1</td>
<td>2.3</td>
<td>(2.3)</td>
<td>0.0</td>
</tr>
<tr>
<td>Scientific Advice</td>
<td>0.0</td>
<td>1.1</td>
<td>(1.1)</td>
<td>0.0</td>
</tr>
<tr>
<td>NICE Total</td>
<td>63.1</td>
<td>71.9</td>
<td>(12.6)</td>
<td>(3.7)</td>
</tr>
<tr>
<td>Year End Adjustments</td>
<td>0.0</td>
<td>3.2</td>
<td>0.0</td>
<td>3.2</td>
</tr>
<tr>
<td>NICE Total</td>
<td>63.1</td>
<td>75.2</td>
<td>(12.6)</td>
<td>(0.5)</td>
</tr>
</tbody>
</table>

Table 1: Financial Position at 31 March 2016

2. The under spend of £0.5m against revenue budget was due to vacant posts, unbudgeted income, reducing the spending run rate in anticipation of savings required in future years and year-end adjustments.

3. The total capital spend in 2015-16 was £0.3m, relating to a minor furniture refit in the London office, IT hardware upgrades and new meeting pods in Manchester, resulting in an under spend of £0.2m against budget. Refurbishment work on the toilets in Manchester which was planned for 2015-16 will now start in the 2016-17 financial year.

4. The total Administration and Programme Grant-in-Aid allocation for 2016-17 has now been confirmed by the DH as £58.1m (excluding depreciation of £1m) in line with the business plan. The capital requirement of £0.5m has also been confirmed.
Financial Position as at 31 March 2016

5. Work on the 2015-16 financial accounts and statutory audit is close to completion. The details in this report are based on the accounts pre-audit and are may be subject to change. The next step is for the accounts and annual report to be approved on behalf of the Board at the Audit Committee meeting on 15 June 2016, with the accounts being laid before parliament in July 2016.

6. Table 1 above and Appendix A shows that the net operational expenditure in 2015-16 was £59.3m. This was a £3.7m (5.9%) under spend against budget. Of this,

- £2.1m related to pay under spends arising from vacancies (see below section for further details).

- £0.4m of unbudgeted income mainly made up of £0.1m for HDAS development work from Health Education England and £0.1m for an extra register associated with Commissioning Through Evaluation work (see the other operating income section below for further details). The remainder relates to smaller or irregular income streams such as research grants and publications income.

- There was an under spend of £0.5m for public health evidence reviews in the Public Health and Social Care programme. Several contracts that were in the procurement pipeline during 2015-16 budget setting did not go out to tender because the new in-house process was activated more rapidly than expected, resulting in the under spend.

- £0.1m depreciation budget was unutilised due to lower than expected capital spend in 2015-16.

- The remaining £0.6m of the under spend is made up of smaller non-pay under spends across the Institute, mainly arising from new activity not operating at capacity for the full-year and the knock-on effect of vacant posts.

- The above operational under spends are offset by two significant liabilities that have been included in the 2015-16 annual accounts. Firstly, a provision of £1.5m was made in relation to potential redundancy costs of staff affected by future management of change (£1.2m) and the current NCC transition (£0.3m). Secondly, an accrual for £1.7m was made at year end for a backdated VAT liability following a recent HMRC inspection relating to online journals and databases procured by NICE on behalf of the NHS.
• This brings the total net expenditure to £62.5m resulting in an under spend for the year of £0.5m against the total budget of £63.1m.

Pay

7. Total pay costs for 2015-16 were £34.0m. This is inclusive of salaries, employer’s pension and national insurance contributions and expenses paid through payroll. It also includes agency of £2.6m (£3.5m in 2014-15) and other temporary staff costs of £0.2m (£0.2m in 2014-15). Total pay costs were £2.1m (5.8%) under spent during 2015-16 due to vacancies across the Institute.

8. The number of staff directly employed during 2015-16 rose from 577 wte in April 2015 to 597 wte in March 2016, an increase of 3.5% Some of this increase is due to new programmes in place (for example the new Office for Market Access team) and expansion of existing programmes such as Scientific Advice, with the remainder mainly relating to recruiting to long-standing vacancies such as those in IM&T, which were previously filled by agency and contractor staff. Some of this increase has been offset by NICE standing down its work programme on developing guidance on safe staffing levels in June 2015 (11 wte).

9. At 31st March 2016, there were 46 wte vacancies against a budgeted headcount of 643 wte. Of these, 28 posts were covered by agency (26 posts) or seconded staff (2 posts). Figure 1 below shows a summary of the staff on payroll (excluding agency and seconded staff) during March 2016 – further detail on staff in post is shown in Appendix B.
**Figure 1:** Chart showing number of employees (wte) in post compared to budget (wte) for each directorate during March 2016 *(see also Appendix B)*

---

**Non-Pay and other operating income**

10. Total non-pay expenditure was £41.1m and other operating income (i.e. income other than DH revenue allocation) was £12.6m, giving a net non-pay and income total of £28.5m (see Appendix A).

11. Figure 2 below shows a breakdown of the non-pay expenditure. The most significant category of expenditure (£10.8m) is that payable to the 4 National Collaborating Centre’s that help develop clinical guidelines, the NCC for Social Care to help produce social care guidelines and quality standards and the NCC for Mental Health for work on Access and Waiting Times.
Figure 2: Breakdown of Non-Pay expenditure during 2015-16

<table>
<thead>
<tr>
<th>Non-Pay Expenditure description</th>
<th>Non-pay spend 2015-16 £m</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Collaborating Centres, including the new NCC for Social Care</td>
<td>10.8</td>
<td>26%</td>
</tr>
<tr>
<td>BNF (digital and print)</td>
<td>4.8</td>
<td>12%</td>
</tr>
<tr>
<td>Digital content (journals and databases) and access management (Athens) on NICE and Evidence Search website</td>
<td>4.2</td>
<td>10%</td>
</tr>
<tr>
<td>Rent, Service Charges, Business Rates and other facilities costs</td>
<td>3.8</td>
<td>9%</td>
</tr>
<tr>
<td>Medical Technology External Assessment Centres</td>
<td>2.8</td>
<td>7%</td>
</tr>
<tr>
<td>Other non pay costs</td>
<td>2.5</td>
<td>6%</td>
</tr>
<tr>
<td>Travel and subsistence costs for staff and non-staff</td>
<td>2.4</td>
<td>6%</td>
</tr>
<tr>
<td>IT and Telecoms infrastructure, hardware, software and hosting costs</td>
<td>1.8</td>
<td>4%</td>
</tr>
<tr>
<td>VAT Liability Provision</td>
<td>1.7</td>
<td>4%</td>
</tr>
<tr>
<td>Redundancy Provisions</td>
<td>1.3</td>
<td>3%</td>
</tr>
<tr>
<td>NICE International partner sub-contracts</td>
<td>1.2</td>
<td>3%</td>
</tr>
<tr>
<td>Committee members chair costs, honorariums, lay member reimbursements and expenses</td>
<td>1.1</td>
<td>3%</td>
</tr>
<tr>
<td>Depreciation and other non-cash transactions</td>
<td>0.9</td>
<td>2%</td>
</tr>
<tr>
<td>Technical / Decision / Research support contracts with universities</td>
<td>0.8</td>
<td>2%</td>
</tr>
<tr>
<td>Public Health external contracts for fieldwork, evidence reviews and economic modelling</td>
<td>0.6</td>
<td>1%</td>
</tr>
<tr>
<td>Education and Training</td>
<td>0.4</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Total Non-pay costs 2015-16</strong></td>
<td><strong>41.1</strong></td>
<td></td>
</tr>
</tbody>
</table>

12. The cost of purchasing and distributing the BNF on behalf of the NHS was £4.8m and spending on accommodation and facilities was £3.8m.

13. The NICE Evidence search and services website provides access to clinical knowledge summaries, advanced search functionality and several journals and databases for use by NHS employees (for example the BMJ). The total cost of this content (and access and identity management infrastructure (Open Athens) is £4.2m, although much of this content is funded through an MOU with Health Education England.

**Other operating income**

14. A summary of the £12.6m other operating income received is shown in figure 3 below.
Figure 3: Breakdown of other operating income received during 2015-16

<table>
<thead>
<tr>
<th>Income sources 2015/16</th>
<th>£m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Devolved Administrations</td>
<td>2.1</td>
</tr>
<tr>
<td>Health Education England</td>
<td>3.7</td>
</tr>
<tr>
<td>NHS England</td>
<td>2.5</td>
</tr>
<tr>
<td>NICE International</td>
<td>2.3</td>
</tr>
<tr>
<td>Scientific Advice</td>
<td>1.1</td>
</tr>
<tr>
<td>Research grants</td>
<td>0.3</td>
</tr>
<tr>
<td>Other Income</td>
<td>0.6</td>
</tr>
<tr>
<td><strong>Total other operating income</strong></td>
<td><strong>12.6</strong></td>
</tr>
</tbody>
</table>

15. The devolved administrations (Wales, Scotland and Northern Ireland) contributed £2.1m towards the cost of developing NICE guidance and procuring the BNF. The amounts payable by each country is dependent on the NICE products used in those countries and factors such as the relative size of the populations. Decisions relating to the usage and application of NICE products are made within each country.

16. NICE also received income from other NDPBs whose parent is the Department of Health. NHS England funding has risen to include £1.4m to pay for Access and Waiting Times Standards as well as continuing to issue £0.5m funding for the MedTech Innovation Briefings, and a further £0.6m funding provided to establish the Observational Data Unit (ODU) to support the Commissioning Through Evaluation (CTE) programme.

17. NICE International were close to break even in 2015-16 generating receipts of £2.3m (£2.8m in 2014-15) with a significant amount of the receipts relating to several major multi-year projects with funding from Bill and Melinda Gates, Rockefeller and the Department for International Development. This income was offset by costs (pay and non-pay) of £2.3m. There is a non-exchequer cash-backed reserve carried forward of £0.4m from surplus generated in previous financial years.

18. Scientific Advice income totalled £1.09m in 2015-16. Costs were £1.06m; therefore it made a small surplus of £0.03m (£0.03m in 2014-15). The team expanded during 2015-16 in order to better cope with demand – the increased capacity is expected to increase the total income generated in future years.

19. The small surplus generated by Scientific Advice will be carried forward in (non-exchequer) cash-backed reserves.
20. A further £0.6m was received from other sources, including £0.3 from research grants for projects such as the IMI GetReal project and EUNetHTA. The remaining income is from secondment and other recharges, publications income and UK Pharmascan partner funding.

**Capital Expenditure**

21. The capital budget during 2015-16 was £0.5 million. Of this, £0.3 million was spent, relating to a minor furniture refit in the London office (£0.1m), IT hardware upgrades and new meeting pods in Manchester (£0.1m). Refurbishment work on the toilets in Manchester which was planned for 2015-16 will now start in the 2016-17 financial year.

22. The remaining capital expenditure related to upgrading power and data cables in the both the London and Manchester offices.

**2015-16 Funding allocation**

23. Formal notification of funding for 2016-17 was received on the 21 April 16. The Department of Health confirmed that administration (£49.4m) and programme (£8.7m) revenue funding which matches the NICE 2016-17 business plan totalling £58.1m (£62.0m funding in 2015-16). The capital allocation requirement of £0.5m has also been confirmed.

**Other information**

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

**Figure 4: Better Payment Practice Code performance statistics**

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>£000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total non-NHS bills paid 2015/16</td>
<td>4,172</td>
<td>39,766</td>
</tr>
<tr>
<td>Total non-NHS bills paid within target</td>
<td>3,820</td>
<td>36,100</td>
</tr>
<tr>
<td>Percentage of non-NHS bills paid within target</td>
<td>91.6%</td>
<td>90.8%</td>
</tr>
<tr>
<td>Total NHS bills paid 2015/16</td>
<td>194</td>
<td>3,363</td>
</tr>
<tr>
<td>Total NHS bills paid within target</td>
<td>176</td>
<td>3,246</td>
</tr>
<tr>
<td>Percentage of NHS bills paid within target</td>
<td>90.7%</td>
<td>96.5%</td>
</tr>
</tbody>
</table>
## Appendix A – Summary of full year outturn as at 31 March 2016

### Year end position as at 31 March 2016

<table>
<thead>
<tr>
<th>Centre / Directorate</th>
<th>Year End Position</th>
<th>Budget £000s</th>
<th>Expenditure £000s</th>
<th>Variance £000s</th>
<th>Variance %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Centre for Clinical Practice</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>5,574</td>
<td>5,449</td>
<td>(124)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>13,389</td>
<td>13,657</td>
<td>268</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>(654)</td>
<td>(769)</td>
<td>(115)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>18,309</td>
<td>18,337</td>
<td>29</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td><strong>Centre for Health Technology Evaluation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>6,340</td>
<td>6,167</td>
<td>(173)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>4,958</td>
<td>4,893</td>
<td>(65)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>(285)</td>
<td>(296)</td>
<td>(11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>11,013</td>
<td>10,764</td>
<td>(249)</td>
<td>(2%)</td>
<td></td>
</tr>
<tr>
<td><strong>Health and Social Care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>9,274</td>
<td>8,501</td>
<td>(773)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>3,886</td>
<td>4,811</td>
<td>925</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>(10)</td>
<td>(1,475)</td>
<td>(1,465)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>13,150</td>
<td>11,837</td>
<td>(1,313)</td>
<td>(10%)</td>
<td></td>
</tr>
<tr>
<td><strong>Evidence Resources</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>6,745</td>
<td>6,450</td>
<td>(296)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>6,054</td>
<td>5,892</td>
<td>(162)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>(45)</td>
<td>(172)</td>
<td>(127)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>12,755</td>
<td>12,170</td>
<td>(585)</td>
<td>(5%)</td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal Guidance and Advice</strong></td>
<td>55,227</td>
<td>53,108</td>
<td>(2,119)</td>
<td>(4%)</td>
<td></td>
</tr>
<tr>
<td><strong>Communications</strong></td>
<td>3,768</td>
<td>3,590</td>
<td>(177)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>454</td>
<td>402</td>
<td>(52)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>4,221</td>
<td>3,992</td>
<td>(229)</td>
<td>(5%)</td>
<td></td>
</tr>
<tr>
<td><strong>Business Planning and Resources</strong></td>
<td>2,430</td>
<td>2,503</td>
<td>72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>5,765</td>
<td>5,760</td>
<td>(5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>0</td>
<td>(8)</td>
<td>(8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>8,195</td>
<td>8,254</td>
<td>59</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Centre / Directorate</td>
<td>Year End Position</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Budget £000s</td>
<td>Expenditure £000s</td>
<td>Variance £000s</td>
<td>Variance %</td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>(6,772)</td>
<td>(6,975)</td>
<td>(202)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>(6,772)</td>
<td>(6,975)</td>
<td>(202)</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>Depreciation / Capital Adjustments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>1,000</td>
<td>909</td>
<td>(91)</td>
<td>(9%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1,000</td>
<td>909</td>
<td>(91)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reserves</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>696</td>
<td>0</td>
<td>(696)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>460</td>
<td>0</td>
<td>(460)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1,156</td>
<td>0</td>
<td>(1,156)</td>
<td>(100%)</td>
<td></td>
</tr>
<tr>
<td>NICE Operational Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>34,827</td>
<td>32,660</td>
<td>(2,167)</td>
<td>(6%)</td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>35,966</td>
<td>36,323</td>
<td>357</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>(7,766)</td>
<td>(9,695)</td>
<td>(1,929)</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>63,027</td>
<td>59,288</td>
<td>(3,739)</td>
<td>(6%)</td>
<td></td>
</tr>
<tr>
<td>Year End Adjustments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vat Liability</td>
<td>n/a</td>
<td>1,685</td>
<td>1,685</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provisions arising</td>
<td>n/a</td>
<td>1,542</td>
<td>1,542</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>n/a</td>
<td>3,227</td>
<td>3,227</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>63,027</td>
<td>62,515</td>
<td>(512)</td>
<td>(1%)</td>
<td></td>
</tr>
<tr>
<td>NICE International</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>673</td>
<td>679</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>1,916</td>
<td>1,628</td>
<td>(288)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>(2,540)</td>
<td>(2,263)</td>
<td>276</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>45</td>
<td>(5)</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Scientific Advice</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>643</td>
<td>692</td>
<td>49</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non pay</td>
<td>266</td>
<td>373</td>
<td>107</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>(909)</td>
<td>(1,092)</td>
<td>(183)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>(27)</td>
<td>(27)</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>NICE Grand Total</td>
<td>63,077</td>
<td>62,532</td>
<td>(545)</td>
<td>(1%)</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** These are figures as at 03 May 2016 and are subject to change following the audit of the 2015-16 annual accounts.
Appendix B – Analysis of whole time equivalents in post and vacancies during March 2016

The below table shows the total budgeted headcount for each directorate for the March 2016 pay period compared to the number of staff in post.

The total number of vacancies (46 wte) is further analysed to show how teams are managing these vacant posts. Some are covered by agency staff and contractors, with a couple of posts being covered through secondments from other organisations.

There were 18 unfilled posts during March 2016. Most of the vacancies are due to natural staff turnover and the gap between leavers and new starters. There are also recruitment controls in place to mitigate redundancies arising from the ongoing 2020 group which means that there are currently few posts being filled by external applicants causing a knock on effect of internal recruitment.

BPR are showing to be in excess of budgeted wte. This is due to restructures earlier in the year not being reflected in the 2015-16 budgets. BPR have also been trialling the use of undergraduate placement students and apprentices to cover substantive posts, creating an increase in headcount whilst remaining within the financial budget envelope.

The number of agency staff within Evidence Resources takes the headcount slightly (1wte) above budget. This is because some of the IM&T contractors are not covering substantive posts, but are brought in on a flexible basis to contribute to short-term projects. However, there is budget cover for this and overall the directorate has under spent against its pay budget.

<table>
<thead>
<tr>
<th>Permanently employed staff</th>
<th>Vacant posts covered by</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2015-16 Budget wte</strong></td>
<td><strong>Agency staff March 2016</strong></td>
</tr>
<tr>
<td>Employees on payroll March 2016</td>
<td>164</td>
</tr>
<tr>
<td>Health &amp; Social Care</td>
<td></td>
</tr>
<tr>
<td>Health Technology Evaluation</td>
<td>113</td>
</tr>
<tr>
<td>Clinical Practice</td>
<td>101</td>
</tr>
<tr>
<td>Evidence Resources</td>
<td>113</td>
</tr>
<tr>
<td>Communications</td>
<td>79</td>
</tr>
<tr>
<td>Business, Planning &amp; Resources</td>
<td>49</td>
</tr>
<tr>
<td>NICE International</td>
<td>10</td>
</tr>
<tr>
<td>Scientific Advice</td>
<td>14</td>
</tr>
<tr>
<td><strong>Total wte</strong></td>
<td><strong>643</strong></td>
</tr>
<tr>
<td><strong>Vacant posts covered by</strong></td>
<td><strong>26</strong></td>
</tr>
</tbody>
</table>
Appendix C – Workforce Strategy Update at 21 April 2016

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

### Transformational change

- **Enabling change**
- **Business and workforce planning**

Workforce Planning and Change Management guidance has now been launched and is being used across the institute. This guidance supports a revised Organisational Change Policy which is now in place. This guidance will help managers plan and manage change effectively in the future.

Change and workforce planning tools have been developed to support this work and will be further developed into interactive training programmes once NICE’s Learning Management System has launched. This work also feeds into the use of the “NICE Manager” core competencies.

### Resourcing

- **Recruitment**
- **Retention**
- **Innovation**

A review continues in order to assess NICE’s approach to recruitment to improve and advance current recruitment practices as well as to inform potential new and innovative ways of recruiting in the future. Working closely with our outsourced recruitment administration provider, we have planned a number of enhancements to the service which will greatly improve the experience of managers and candidates and result in a more efficient recruitment process.

As part of the Government initiative to increase the number of apprenticeships Department of Health has set an interim target that requires its ALBs to ensure that apprentices form 2.3% of its workforce by March 2017. For NICE this equates to 15 apprentices. We currently employ 5 apprentices across both Manchester and London and are out to advert for 2 more posts and are working closely with Directorates to form plans to increase our apprenticeship numbers to achieve this target.

### Maximising potential
The NICE Manager core competencies have been developed and training and support is being provided to help managers assess themselves and their staff against these competencies. This will help us better understand and plan our development programmes, improve management interventions and will feed in to other workforce strategy work-streams such as talent management, succession plan and resourcing.

An electronic Learning Management System (LMS) has been procured and is currently being built for NICE. This will enable us to better deliver and manage training and development resources, identify and assess individual and organisational learning needs and track progress. Additionally it will provide a full e-appraisal recording solution which will be trialled in a number of teams commencing in May 2016.

A programme of work to implement talent management and succession planning has recently been approved and will commence roll out in May 2016 for Senior Managers, Programme Directors and Associate Directors. This staff group will be used as a pilot with the programme of talent management rolling out to all staff groups over the next two years. NICE continues to be actively engaged with other ALB’s and the Department of Health in the development of senior talent pipelines and succession planning tools. A new cohort of the DH Aspiring Directors programme has launched and NICE has put forward 3 candidates.

Pay and Reward

- Total reward
- Pay review

Non-pay benefits continue to be investigated with a view to increasing the offerings available for staff. These will be promoted in new innovative ways for employees, to improve engagement (and attraction of new staff to NICE).

Culture

- Engaged workforce
- Inclusive workforce
- Wellbeing at work

The staff survey 2015 action plan continues to be worked through, with development and implementation of a number of initiatives. The staff survey for 2016 will be launched this month.

The mentoring scheme now has 42 register mentors and 40
mentees. The scheme has received very positive feedback and is currently being reviewed.

The Health and Wellbeing Strategy group meet regularly to continue to support employee wellbeing at work, and to meet our obligations in line with NICE Guidance.
ITEM 4

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

PUBLIC INVOLVEMENT PROGRAMME 2015

The Board is asked to receive the Public Involvement Programme’s 2015 annual report and approve it for further publication.

Professor Gillian Leng
Director, Health and Social Care Directorate
May 2016
Public Involvement Programme Annual Report 2015

Introduction

1. As part of the Public Involvement Programme’s 2015-16 objectives, we agreed to build on last year’s work and produce an annual report for the NICE Board. The Programme’s second annual report, describing our activities during the 2015 calendar year, is presented here.

Considerations for Board

2. The Board is asked to receive the Public Involvement Programme’s 2015 annual report, and approve it for further publication

Professor Gillian Leng
Director, Health and Social Care Directorate
May 2016
Public Involvement Programme Annual Report 2015
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Public Involvement Programme Annual Report – 2015

Executive Summary

1. This report describes the work of NICE’s Public Involvement Programme (PIP), and our contribution to supporting the development and implementation of NICE guidance, advice and quality standards during 2015.

2. It should be noted that the information in this report only covers the work of the Public Involvement Programme and not public involvement activities run by other NICE teams such as the holding of Committee meetings in public\(^1\), and the work of the Citizens Council\(^2\).

Expanding and changing workload

3. The team has worked hard to build knowledge and relationships in new fields of work and with new stakeholder communities. We have worked directly and collaboratively with local Healthwatch networks, and have been encouraging the wider voluntary and community sector in supporting NICE guidance for their constituencies.

4. We continue to facilitate the identification and recruitment of, and support for, NICE’s committee lay members, consistently attracting a wide range of applicants. We provide advice and support to the internal teams and our collaborative partners, and continue to build on our national and international profile. We have developed our involvement approaches in newer areas of work such as the Scientific Advice Programme to ensure routine and meaningful participation from patients at the earliest opportunity.

Increasing profile of public involvement, and experiences of care

5. NICE’s public involvement work sits in a wider context of an increasing profile for patient and public involvement and engagement across the health, public health and social care fields. Public involvement was also a significant workstream in the Accelerated Access Review.

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\(^1\) [www.nice.org.uk/get-involved/meetings-in-public](http://www.nice.org.uk/get-involved/meetings-in-public)

\(^2\) [www.nice.org.uk/get-involved/citizens-council](http://www.nice.org.uk/get-involved/citizens-council)
6. There is also an increasing research agenda in this area. As part of the overall review of NICE’s public involvement work we have worked with one of NICE’s clinical fellows to undertake a literature review of best practice in public involvement to ensure our future approaches are as evidence-based as the rest of NICE’s work.

7. As part of contributing to raising the profile of patient and public involvement, PIP has produced a guide\(^3\) to how we find, support and train the lay people who work with us. This was approved by the Board at the March 2015 meeting.

**Planning for the future**

8. We are playing an increasingly active role in supporting NICE’s engagement with wider policy initiatives such as shared decision-making, and are exploring NICE’s potential future role in this work.

9. Ever mindful of the need to deliver efficient services in a time of resource constraints, PIP has been examining its overall involvement approaches as a way of ensuring the greatest value can be achieved within the most effective framework. Further details of this work are included below and proposals for the future of public involvement at NICE will be presented to NICE’s Board in July 2016.

\(^3\) [www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Public-involvement-programme/PIP-process-guide-apr-2015.pdf](http://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Public-involvement-programme/PIP-process-guide-apr-2015.pdf)
Introduction

10. NICE is committed to involving patients, carers, people who use health and care services and the public in the development of its guidance and other products. The aim of lay involvement in NICE’s work is to ensure all our guidance products are informed by this unique perspective. As a result of this contribution, NICE guidance and standards have a greater focus and relevance for the people most directly affected by NICE recommendations.

11. NICE’s approach to public involvement is based on the principle that the contributions of lay people, and organisations representing their interests, are integral to developing NICE guidance, advice and quality standards, and supporting their implementation.

It was a very enjoyable experience. I felt fully included in the discussions and that the opinions of the lay members were treated with respect and incorporated in the final guidance, which I am proud to have been a part of.

Lay member

12. Lay contributors to NICE’s work have equal status to health and social care practitioners and other professional contributors. This applies at an individual level for members or expert contributors to NICE Committees, and for stakeholder organisations, including those run by or for users of services.

13. On NICE Committees, lay members’ perspectives have equal value to those of professional and practitioner members when considering the evidence. The views of all members of a NICE Committee are given equal weight during discussions about the interpretation of the evidence, and lay members bring a unique perspective. The objective consideration of the evidence, combined with the diverse perspectives of the Committee members, ensures that no one ‘voice’ is able to dominate when drawing up the recommendations.

14. Involving lay people is integral to NICE’s approach to developing guidance, quality standards and other products. NICE’s methods and processes for involving lay people are based on the best available evidence, and on extensive practical experience. NICE has adopted a flexible model of involvement that allows us to develop different approaches for new areas of NICE work. This flexibility allows for the most effective lay input.
15. This is the second Annual Report from NICE’s Public Involvement Programme a centralised team at NICE that develops and supports the organisation’s public involvement activities.

**The Public Involvement Programme**

16. PIP works across all of NICE’s programmes to ensure that there are opportunities for lay people (and the organisations that support them) to participate meaningfully in NICE’s activities, and that those opportunities are appropriately supported. At any one time PIP provides support to between 250 and 300 individual lay committee members.

17. PIP’s work is supported and guided by NICE’s Board-level [policy and principles](#).

18. Specific PIP areas of work covered in this annual report include:

- Reviewing NICE’s public involvement approaches
- Support for new programmes
- Recruitment and identification of lay committee members and expert witnesses
- Training
- Raising awareness among NICE staff and other professionals
- Contribution to NICE process and methods reviews
- Implementation support and local outreach

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Before I started working with NICE on a guideline development group I was in awe of doctors, nurses, and specialists, especially where they have a title such as Professor. Through the five years that I have been involved with these processes I have become much more confident in talking to people like this as equals’. ‘(Being involved in a committee) increased my confidence and enabled me to talk openly about my health problem about which I had previously been very reticent. This has helped me in negotiations with my GP.

*Lay member*

If you decide to be a NICE patient expert, don’t be frightened to ask questions, just remember to push the button on the mic

*Patient expert*
• International work  
• NICE annual conference  
• Speaking engagements  
• Patients Involved in NICE (PIN)  
• Working with the voluntary and community sector  
• Support for NICE’s equality programme  
• New products  
• Research and evaluation  
• Review of patient participation  
• Other notable achievements

Team Resource

19. PIP has a split of team members between NICE’s London and Manchester offices, as detailed in the organogram in Appendix 1. This year there have been changes to our staffing model, including employing job share workers to allow for more flexibility with the team.

20. 2015 sees the second year of a specific project management role within the team. The support team headed up by the Project Manager continue to develop PIP’s internal systems, and have allowed capacity for exploring new initiatives within PIP, such as development of a bespoke public involvement planning system, a review of current lay member training and recommendations for future training and support, detailed analysis of lay member exit surveys and appropriate action planning in response to survey comments, development of a social media presence, and, in liaison with the communications and web teams at NICE, strategic planning around communications.

21. PIP has been funded by NHS England on a short term basis to develop a feasibility plan for updating a suite of patient decision support tools. One of PIP’s Public Involvement Advisers has been seconded into a Senior Management post to deliver this work by the end of the 2015-16 financial year, working in collaboration with the Person Centred Care team at NHS England.

22. One of our Public Involvement Adviser roles is now a job share post, with the two job share partners working 3 days per week each, based in the London office. This is a first for PIP, and has introduced greater flexibility in the team as both job share partners agreed to work full time on a temporary basis to cover a short-term PIP vacancy.
Reviewing NICE’s public involvement approaches

Background and aims

23. During 2015 PIP initiated a review of NICE’s overall approach to involving patients and the public in the development of guidance and standards. This was triggered by three key issues:

- the findings from a review of the literature on best practice in public involvement
- recommendation 8 from the report of the Triennial Review of NICE\(^5\) which stated “NICE should 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.”
- concerns expressed by some Board members about the continuing capacity of PIP team to deliver a ‘gold standard’ public involvement service.

24. The review will set out the aims for public involvement at NICE and the principles underpinning those aims. It will describe the evidence-base for best practice in public involvement in guidance and standards development processes, and will make recommendations for change, including activities that should be continued, stopped, initiated or reconfigured.

Process and methods

25. The project has been led by PIP and is overseen by an Oversight Group chaired by the NICE Deputy Chief Executive. Membership of the group includes members of PIP, representatives of NICE’s guidance and standards development teams, an academic with a specialist research interest in public involvement, and two of NICE’s committee lay members.

26. The project has drawn from a variety of information sources including the above literature review and interviews with key individuals. The Oversight Group met in November 2015 and initial project concepts were presented to the NICE Board strategy meeting in December 2015.

Literature review

27. The literature review was conducted by one of NICE’s Keogh Clinical Fellows in collaboration with PIP and the NICE Information Services team. In order to increase the specificity of the search the focus of the review concentrated on patient and public involvement guideline standards and indicators development, and health technology assessment.

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28. The review identified a parallel rise in the currency of evidence-based medicine and public involvement concepts in international health policy. Five key themes emerged from the findings as important to the success of public involvement:

- the rationale for involvement, and how involvement is evaluated
- the integration of scientific and experiential paradigms
- clarity about the purpose of recruitment i.e. diversity of views, issues of ‘representation’, patient vs citizen views
- methodological models of involvement and the role of social media
- stages of involvement

29. The review indicated areas for NICE to consider in relation to improving its public involvement processes and methods including:

- widening reviews of evidence to take account of people’s preferences and experiences of care
- providing clearer instructions on how stakeholder organisations can submit data and intelligence to inform guidance and standards development
- adapting guidance presentation to highlight preference sensitive decision points
- closing feedback loops allowing lay participants to feed back about their experiences of working with NICE and for NICE to feed back how their contributions have been taken into account.

**Next steps**

30. PIP will continue its information gathering during the early part of 2016 through a public survey and a stakeholder meeting. Draft proposals will be considered by the Oversight Group and the NICE Senior Management Team. The summary of the overall findings and proposals for any changes will be brought to the July 2016 public Board meeting.

31. Following consideration by the Board the proposals will be subject to a 12 week public consultation. Final recommendations and an implementation plan will be brought to the January 2017 public Board meeting with a view to initiating formal changes at the beginning of the 2017-18 financial year.

**Support for new programmes of work**

32. PIP and NICE’s Scientific Advice Programme have included individual patient experts in 7 pieces of Scientific Advice in 2015. The teams are working together to review the process to see what can be learnt to improve patient involvement for next year.
33. We have begun negotiations with the newly established Office for Market Access about the potential role for patient and voluntary and community sector organisations to support this work. We are also supporting the start-up work for the proposed programme of Commissioning Support Documents to support NHS England’s commissioning policy decisions.

**Recruitment and identification of lay Committee members and expert witnesses**

34. Lay members and expert witnesses are recruited or identified in 3 different ways, all of which are administered and supported by PIP:

- Open advertising and recruitment.
- Targeted identification through expressions of interest.
- Nomination: self-nomination, nomination by committee members or via voluntary and community sector organisations.

35. During 2015, PIP helped to recruit 91 new lay members to our committees and working groups, from 514 applications. In addition we identified 33 lay expert committee members (known as specialist members or topic expert members) to sit on a variety of committees. We also helped to identify 81 expert witnesses to give testimony to our committees.

36. As part of NICE’s efficiency measures the size of some standing committees has reduced and this process is ongoing. In 2015 the size of the Technology Appraisals Committees reduced by a third which reduced the number of lay members proportionately from 3 to 2 per committee. Similarly the Clinical Guidelines Updates Standing Committees are reducing from 2 core lay members to 1, whilst retaining 1 topic expert lay member for each guideline topic under consideration. In contrast, on topic specific guideline committees, 2 or 3 lay members per committee remains the norm, with a consistently higher number of lay members (typically 4) recruited for social care topics. NB: 2 lay members are the minimum for any committee within NICE.

37. It will be important to monitor any change in the effectiveness of lay input to committees as a result of the reduction in lay membership and also the tendency to have just 1 lay member contributing topic expertise in the case of some standing committees.

> I felt it was a very valuable and worthwhile experience. I enjoyed it very much and felt it an honour to be chosen to work with such a dedicated group of professionals.

*Lay member*
Figure 1: number of lay members and expert witnesses recruited or identified between January and December 2015

Training

I really enjoyed the training today and feel a lot more confident about my role in the process.

Guideline Committee training attendee

38. PIP delivers training days across the year to key audiences. We run inductions and follow up workshops for lay members involved in developing guidelines. We also offer a series of masterclasses, aimed at voluntary and community sector organisations, who are interested in learning more about NICE to help them better understand how the organisation works, and the role they can play.

39. As a part of a new initiative in 2015, and in partnership with NICE’s Field Team, we ran two training workshops with the North West Healthwatch Network which is made up 27 local Healthwatches across the North West. These workshops resulted in the development of a toolkit to support and enable local Healthwatches to use NICE guidance and recommendations effectively across the broad remit of their work.
40. During 2015, we ran 7 lay member training sessions, attended by 82 people. These sessions were a mixture of 4 induction sessions and 3 follow-up workshops for lay members of guideline committees (GCs),

41. We ran 2 masterclasses for voluntary and community support organisations attended by 52 people. In November we piloted a new format for Masterclasses working with a much larger group, as there was a high uptake of Masterclass places from organisations. In the past Masterclass places have been restricted to 20, however, we decided to trial working with a bigger group of 34 attendees and redeveloped the agenda to include more interactive group work. The feedback was very positive and this new format allowed for wider peer networking and engagement for those in attendance.

**Evaluation**

42. All those attending training and masterclasses are asked to complete evaluation forms. This allows PIP to regularly review these sessions to ensure they are high quality and suitable for the task, and to make any improvements as needed. On average, all PIP training sessions and masterclasses in 2015 were rated as ‘good’.

43. Overwhelmingly, lay members report that they value the opportunity the training days give to meet other lay members who are on different stages of their NICE journey, to share experiences and get peer support. They also appreciate the time and space to learn more about NICE procedures such as research methodologies and health and social care economics, as this information helps them to understand the remit of NICE, and how all the different areas of work link together to support guidance development. It also gives lay members a greater understanding of their role and how it fits into the wider processes of guidance development.

44. Masterclass attendees reported that they had gained a much better understanding of NICE as a result of attending. Many stated that the masterclasses highlighted the breadth of evidence that NICE takes into account, and importantly, how their organisations can work with and support NICE. There was praise for the presentations and materials that could be taken away to share with colleagues and cascade the learning. Attendees were asked for suggestions for future workshops that will enable PIP to continue to develop masterclasses that meet the needs of our stakeholders.
Figure 2: number of people who attended PIP training sessions in 2015

45. Below are sample responses from evaluation forms when asked what went particularly well at the training session or masterclass:

Excellent group – useful to share experiences

Very relevant. Feeling much more confident about my role now

Really concise and good opportunities to interact with others and varied exercises.

Health economics presentation particularly clear

Timing was really helpful, being before first GC meeting

I feel I have learnt a lot about NICE and this has encouraged me to learn more and understand it fully. I thought this was a good introduction to NICE

Very good – mixed media and ways of learning. Well thought out teaching/learning. Sessions good length

46. Below are sample responses from evaluation forms when asked for suggestions for improvement:

The presentation of how to get involved was very complex, it is complex material but possibly there is a way of presenting it in a more engaging way?

NICE dictionary!? Something to help remind us what things mean
Maybe a tiny bit more help on practical side for some e.g. what we should be commenting on and what topics

More group work

Timing. Some of it would have been helpful before GDG meetings 1&2.

More networking time please

Raising awareness among NICE staff and other professionals

47. PIP raises awareness among staff, committee members and other professionals on the value of patient and public involvement and how to make it work in practice. In 2015, in addition to the day-to-day advice we offer to NICE teams and collaborating centres, we have also:

- worked with NICE committee chairs including contributing to 3 training days for new chairs of clinical and social care guideline committees.
- contributed to good practice guides for guideline committee members and chairs. These guides are sent to committee chairs and members on recruitment.
- given presentations in numerous induction meetings for new NICE committees.
- contributed to a learning day for student champions.
- provided inductions for new staff in NICE and our collaborating centres.

Contribution to process and methods reviews

48. PIP has continued to provide advice to support the implementation of Developing NICE guidelines - the manual\(^6\), which provides a unified approach to developing clinical, public health and social care guidelines. PIP is represented on the project’s methods and process working groups. We have contributed to a range of supporting documentation and templates for use by those involved in guideline development. We have also drafted a new chapter on the guideline development methods which will facilitate the identification of preference-sensitive decision points and support shared decision making between the person using services and the practitioner.

49. Members of PIP team sit on steering and working groups for updates of other methods and process guides. In 2015 work continued on developing the updated Interventional Procedures Manual including amendments to the patient

\(^6\) [https://www.nice.org.uk/article/PMG20/chapter/1-Introduction-and-overview](https://www.nice.org.uk/article/PMG20/chapter/1-Introduction-and-overview)
commentary process so that commentary from patients can be considered at the second committee meeting if it was not available for the first.

50. PIP has also commented on other guides, as appropriate.

**Implementation support and local outreach**

51. Encouraging and advising voluntary and community sector organisations how to support the use of NICE guidance and standards remains a central dimension of PIP’s work. During 2015 we continued our ongoing work to help develop the Information for the Public versions of our guidance, which include contact details for voluntary and community sector organisations, to provide readers with information about what NICE has recommended and signpost them to additional sources of support.

52. This year, we relaunched our policy which covers PIP’s role in identifying the voluntary and community sector organisations to include in our Information for the public (IFP) versions of our guidance. The first significant change was to remove the need to seek permission from an organisation every time we want to include their details in a relevant IFP, where they are happy to agree to this proposal. This has streamlined the process both in terms of PIP’s workload, but also helps to reduce the volume of emails that organisations receive from NICE.

53. Finally, the new policy also now enables us to include the details of those organisations which do not have a telephone helpline in our IFPs. This is important because some organisations are not able to offer this kind of service but do still have lots of useful information and resources for members of the public available on their websites.

54. In 2015 we continued to support individuals and voluntary and community sector organisations to be proactive in supporting the use of NICE guidance and standards. Support included:

- producing factsheets outlining the ways that voluntary and community sector organisations can help to put NICE guidelines into practice, which are distributed to key organisations for each guideline produced.
- reviewing the content of workshops for lay members of guideline development groups has brought new content focusing on what individuals and voluntary and community sector organisations can do to support the use of NICE guidelines.

55. PIP continues to produce a monthly bulletin for the local Healthwatch networks and patient and public involvement leads working locally.
56. In partnership with NICE’s Field Team, during 2015 PIP ran two training workshops with the North West Healthwatch Network to develop a support toolkit for local Healthwatches on using NICE guidance and standards (see paragraph 29). Our particular thanks to Annie Coppel from the Field Team for her collaboration and support on this project. The toolkit is in Appendix 3.

**Examples of support for implementation**

57. The JDRF[7] have published their examples of practice in line with NICE guidance on the Local Practice Collection[8] in 2015 in the form of a type 1 diabetes pregnancy toolkit[9]. The toolkit is an accessible and easy-to-read information resource for women with type 1 diabetes planning a pregnancy. The resource covers preconception planning and takes the patient through to delivery, describing what healthcare to expect during each trimester and at delivery. The resource follows the recommendations made in the latest NICE guidelines (NG3) to ensure it complements the information provided at clinic/hospital appointments.

58. More generally, voluntary and community sector organisations have formal agreements with NICE to support the use of NICE quality standards. PIP work with the team developing quality standards, to identify and encourage key voluntary and community sector organisations to take action to support use of the quality standards.

**Supporting shared decision making**

59. PIP has played a key role in supporting and taking forward work around shared decision making. In July PIP and Keogh Clinical Fellow Aoife Molloy held a meeting of key national and international stakeholders in the field of shared decision making. The group, known as the Shared Decision Making Collaborative developed and agreed a statement outlining a commitment to taking forward shared decision making and identifying key areas for development.

60. Following the meeting PIP was commissioned by NHS England to develop methods and processes for updating existing patient decision aids and to progress other activities identified by the Collaborative around NICE’s role in supporting shared decision making; the quality assurance of patient decision aids; and working with external partners to embed shared decision making in undergraduate, postgraduate and continuing professional development (CPD) curricula for healthcare professionals.

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International work

61. **Health Technology Assessment International (HTAi).** The Public Involvement Programme is a member of the HTAi Patient/Citizen Involvement Interest Sub-Group\(^\text{10}\) (PCISG) of the HTAi Board. We sit as a member of the PCISG steering group, as well as co-chair of the PCISG working group on Patient Involvement and Education. In 2015 we participated in a number of activities at the HTAi annual conference in Oslo. These activities included:

- co-facilitating a workshop to bring together the experiences and challenges of using HTAi PCISG resources such as the patient organisation submission template for medicines’ HTA
- taking part in a panel session discussing the HTAi Values and Quality Standards for Patient & Citizen Involvement in HTA and reporting on NICE’s work towards achieving these.
- presenting on evaluating patient involvement in medical technologies guidance at NICE.
- presenting on whether patient commentary for NICE’s interventional procedures guidance meets the needs of decision makers and patients.

62. The Public Involvement Programme also attended the annual meeting of the PCISG working group in Ottawa, Canada and we are currently working with PCISG colleagues to develop a patient organisation evidence submission template for diagnostics guidance.

63. We are also part of the HTAi PCISG working group scoping the development of the HTAi Roadmap. The Roadmap will identify opportunities for patient engagement in the HTA process. It will signpost existing resources to help patients and patient organisations engage in HTAs as well as identify gaps where resources need to be developed.

64. **Guidelines International Network (GIN).** PIP is a steering group member of GIN Public\(^\text{11}\) working group, which promotes good practice on involving patients and the public in developing and implementing guidelines. In 2015 we contributed to the updating and expansion of the GIN Public Toolkit\(^\text{12}\), including writing a new chapter on involving people who face barriers to participation and peer reviewing other new and revised chapters. In October 2015 we also participated in a number of activities at the GIN annual conference in Amsterdam. These activities included:

\(^{10}\) [www.htai.org/interest-groups/patient-and-citizen-involvement.html](http://www.htai.org/interest-groups/patient-and-citizen-involvement.html)

\(^{11}\) [http://www.g-i-n.net/working-groups/gin-public](http://www.g-i-n.net/working-groups/gin-public)

\(^{12}\) [http://www.g-i-n.net/working-groups/gin-public/toolkit](http://www.g-i-n.net/working-groups/gin-public/toolkit)
• facilitating a NICE pre-conference workshop on patient and public involvement in guidelines and giving presentations on the topic
• chairing a conference session on patient involvement and shared decision making in guidelines
• presenting on ‘involving people facing barriers to participation’ in a conference workshop to launch the updated GIN Public Toolkit
• giving an oral presentation on involving young people in guideline development

65. **European Patient Academy on Therapeutic Innovation (EUPATI).** PIP sits on the Project Advisory Board for EUPATI\(^{13}\), which is a patient-centred team of 30 organisations, led by the European Patients' Forum, with partners from patient organisations, universities, not-for-profit organisations and experts in patient and public engagement, along with many European pharmaceutical companies. EUPATI provides scientifically reliable, objective, comprehensive information to patients on the research and development process of medicines. EUPATI provides educational resources (online and face-to-face) to increase patients’ capacity to be effective advocates and advisors in clinical trials, with regulatory authorities and on ethics committees. PIP has presented at the face to face training for the first tranche of students to go through the course and at the national launch events in England and Ireland.

**NICE Annual Conference**

66. PIP has worked closely with the Communications team and the NICE conference organisers to support patient and public involvement opportunities at the NICE conference.

67. Patient and public involvement, and the experiences of people who use services and their carers, was a theme that ran throughout the NICE Conference. Speakers included patient, carer and lay committee members, and members of voluntary and community organisations who have worked with NICE. The speakers were able to offer their perspectives on the importance of involving people who use services, and their carers, in the development of guidance and the impact that has. Also discussed was the support that voluntary and community organisations can offer to promote the implementation of NICE guidance and bring about changes in services.

68. As in previous years, in 2015 we ran a bursary scheme to support the attendance of voluntary and community sector organisations, by offering delegate passes to the conference, the cost of which was met by NICE. PIP received 68 applications for a conference bursary and 20 delegates from voluntary and community sector

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\(^{13}\) [www.patientsacademy.eu/index.php/en/]
organisations were able to benefit from the scheme. Our evaluation report highlights the value that delegates placed on being able to attend:

“The different parts of NICE and the breadth of work undertaken. The sessions where charities and voluntary organisations were represented show how charities are working with the NHS to benefit patients”

“Really important to have these places for people other than professionals. It was very interesting and I learnt a lot. Just to thank you for the opportunity to attend. I really appreciated this opportunity and hope NICE continue to offer this.”

Speaking engagements

During 2015, PIP gave 18 speaking engagements at a local, regional, national and international level. These included the Health Technology Assessment International (HTAi) annual conference in Oslo in June, the Guidelines International Network (G-I-N) annual conference in Amsterdam in October, the National Cancer Patient Conference in March, and two Healthwatch events; ‘Giving Healthwatch NICE Teeth’ and ‘Healthwatch Warrington Medicines Management’.

Patients Involved in NICE (PIN)

PIP works collaboratively with Patients Involved in NICE (PIN)\(^\text{14}\). PIN describes itself as: “a coalition of over 80 patient organisations and is committed to enabling patient groups to engage productively with NICE. Independent from NICE and the pharmaceutical industry, they use their combined knowledge, experience and direct contact with patients from a wide range of conditions, to ensure NICE puts patients, carers, and patient groups at the centre of all of its work. They act as a critical friend and a respected and equal partner in developing and shaping aspects of NICE’s work. They provide a forum for enabling patient groups to engage with NICE.”

During 2015 PIN has restructured its governance. It has moved from formal Chair and Vice Chair supported by an Executive Group to an Executive Group formed of 6 members of PIN who are elected by their members for a 2 year term on a rolling basis (3 a year). Members of the Executive Group share consultations, communications and the agenda development and chairing of the quarterly meetings between them. We wish those members of the PIN Executive who have stepped down this year, Lorna Lord, Nick Bason, Lee Marriott-Dowding, every success in the future. The Executive Group currently comprises:

- Farhana Ali, Rare Disease UK
- Heather Bird, Diabetes UK

\(^\text{14}\) [www.nice.org.uk/about/nice-communities/public-involvement/pin](http://www.nice.org.uk/about/nice-communities/public-involvement/pin)
- Hannah Winter, Prostate Cancer UK
- Ben Moody, Juvenile Diabetes Research Foundation

72. There are currently two vacancies, which the Executive Group will hope to fill before the end of this term of office.

73. PIN met 4 times during 2015 in February, May, August and November; the dates for 2016 meetings and the PIN mailbox address are available on the NICE website\textsuperscript{15}. Topics and speakers from the 2015 meetings are shown in table 2.

**Figure 2: topics and speakers from the Patients Involved in NICE (PIN) meetings in 2015**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Development Groups (GDG)</td>
<td>Professor Mark Baker, Director for the Centre for Clinical Practice, NICE</td>
</tr>
<tr>
<td>Politics of Health</td>
<td>Tom Mludzinski, ComRes</td>
</tr>
<tr>
<td>Overview of HTA process</td>
<td>NICE PIP team</td>
</tr>
<tr>
<td>Patient experience of HTA process</td>
<td>Hannah Winter, Prostate Cancer UK</td>
</tr>
<tr>
<td>BMJ Patient Partnership Strategy and What Your Patient is Thinking Series</td>
<td>Ros Snow, BMJ</td>
</tr>
<tr>
<td>Interventional Procedures process and methods guide</td>
<td>Sally Compton, Programme Manager, Interventional Procedures, NICE</td>
</tr>
<tr>
<td>NICE Shared Decision Making</td>
<td>Dr Aoife Malloy, NICE Fellow</td>
</tr>
<tr>
<td>Genetic Alliance UK: Update on HST Patient Charter</td>
<td>Dr Louisa Petchey</td>
</tr>
<tr>
<td>Social Care Quality Standard Development</td>
<td>Nick Baillie, Associate Director: Quality Standards</td>
</tr>
<tr>
<td>Office for Market Access</td>
<td>Carla Deakin/Fay McCracken</td>
</tr>
<tr>
<td>Accelerated Access Review</td>
<td>Zoe Molyneux, Office of Life Sciences</td>
</tr>
<tr>
<td>National Programme for Patient Safety</td>
<td>Phil Duncan, NHS Improving Quality</td>
</tr>
<tr>
<td>ABPI proposals for HTA reform</td>
<td>Paul Catchpole, Director of Value &amp; Access, ABPI</td>
</tr>
<tr>
<td></td>
<td>Tim Windle, Public Affairs Manager, ABPI</td>
</tr>
</tbody>
</table>

\textsuperscript{15} https://www.nice.org.uk/About/NICE-communities/Public-involvement/PIN
How NICE communicates guidance to the public: a publishing team overview

Patient organisation case study: JDRF example

Accelerated Access Review

Fellows and Scholars scheme

<table>
<thead>
<tr>
<th>How NICE communicates guidance to the public: a publishing team overview</th>
<th>Alison Wray, Editorial Adviser, NICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient organisation case study: JDRF example</td>
<td>Ben Moody, Senior Public Affairs Manager, JDRF</td>
</tr>
<tr>
<td>Accelerated Access Review</td>
<td>Nilum Patel, Senior Policy Lead, Accelerated Access Review</td>
</tr>
<tr>
<td>Fellows and Scholars scheme</td>
<td>Lucy Scarle, Fellows and Scholars scheme lead, NICE</td>
</tr>
</tbody>
</table>

Working with the patient, and voluntary and community sector

74. As part of our routine business we identified a wide range of patient and voluntary and community sector groups to register as stakeholders and consultees, and supported them in their interactions with NICE. We also conducted 20 outreach visits with 19 patient and voluntary sector groups. These groups are listed in Appendix 2. This year the core focus was on equalities, particularly BME and faith organisations. Meetings were arranged with the Equalities National Council, Medical Information for Ethnic Minorities (MIEM), the South Asian Health Foundation, and the Black Health Agency. Further effort will be made to connect with faith organisations in 2016.

Support for NICE’s equality programme

75. The Public Involvement Programme contributed to the NICE annual equality report for 2014/15 by providing a detailed report of equality monitoring data from lay applicants to NICE advisory bodies. We have also contributed to a review of the corporate equalities monitoring form with the aim of improving data collection.

76. We continue to support the implementation of research recommendations arising from NICE’s equality objective 1, which is “to evaluate the most appropriate forms of advisory body participation by people with disabilities to ensure NICE meets its responsibilities under equality legislation”. This has included providing advice to guidance development teams on supporting disabled members of advisory bodies.

77. We are working with colleagues to develop NICE’s approach and capacity to support the involvement of people with learning disabilities, including participation on guideline committees.

78. We have continued to develop the public involvement pages on our website liaising with the web team, and running a series of workshops to identify ‘user stories’ – to find out what patients and the public coming to the website want to know. There are plans to produce videos of lay member experiences and interviews with committee chairs discussing the importance of lay involvement in
guideline development. We are also exploring different avenues of online engagement such as social media, online learning resources and online forums.

New products

79. PIP has supported the development of 4 patient decision aids\(^\text{16, 17}\) during 2015, providing advice and assistance to colleagues in the Medicines and Prescribing Programme and collaborators at Dartmouth College in the USA.

80. PIP has supported the development of a toolkit ‘Giving Healthwatch NICE teeth’ in partnership with the NICE Field Team and the North West Healthwatch Network. The toolkit aims to support and enable local healthwatches to utilise NICE guidelines and recommendations through a series of ‘I’ statements along with examples and case studies of best practices.

Research and evaluation

81. PIP is a member of INVOLVE’s Advisory Group\(^\text{18}\), which shares knowledge and experience of public involvement in research, and informs policy and practice in this area.

82. PIP is a member of NICE’s Internal Research Advisory Group, to ensure public involvement is appropriately considered within NICE’s methodology research agenda and associated projects. Review of patient participation in the technology appraisals process

83. In January 2013 the Health Select Committee Eighth Report\(^\text{19}\) stated that ‘it is important for the credibility of NICE and for the decisions that it makes that the patient voice is effectively and openly represented in all its work’. In response to this, NICE’s Market and Audience Intelligence team was jointly sponsored by the Technology Appraisals team and PIP to explore and understand patient experts’ and organisations’ perceptions of engagement in the technology appraisal (TA) process, and specifically identify any barriers to engagement.

84. In order to prioritise the 5 key recommendations (more targeted NICE wide communication; clarifying the role of patient groups and experts; more direction on what is expected from patient participation; creating a feedback loop on patient participation; and explaining in lay terms how the NICE committee uses the principles of cost effectiveness in its decision making) an action plan has been developed and will start to be implemented in 2016.

\(^{16}\) [www.nice.org.uk/guidance/ng28/resources](http://www.nice.org.uk/guidance/ng28/resources)

\(^{17}\) [www.nice.org.uk/guidance/ng14/resources/option-grids-250598413](http://www.nice.org.uk/guidance/ng14/resources/option-grids-250598413)

\(^{18}\) [www.invo.org.uk](http://www.invo.org.uk)

\(^{19}\) [www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/782/78202.htm](http://www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/782/78202.htm)
Feedback from Exit Surveys

It was a huge privilege for me to be a part of this process - to have a voice and help to shape the guideline.

Lay member

85. PIP uses an online exit survey to enable lay people who have worked with NICE to provide feedback on their experiences. The survey is tailored to lay members depending on their type of membership. Feedback from lay members is used to develop and improve the support PIP provides, and to improve lay members' wider experience of working with NICE, with suggested new initiatives and areas for improvement implemented as appropriate.

86. Survey results are collected and analysed on a quarterly basis, and the findings are discussed at PIP team meetings to identify recommendations for improvement. PIP then develops an action plan, and works with internal teams across NICE, along with relevant external stakeholders, to make improvements. The exit survey itself is reviewed every 6 months to ensure it remains accessible and fit for purpose.

87. For the reporting period January–December 2015, 47 exit surveys were returned; some of the results are presented in figures 3–6. Please note that these figures represent the actual numbers of returned surveys. 111 survey invitations were sent out, so the response rate across the year is 40%. This is a significant improvement on 2014’s response rate which was 25%.

What is working well?

88. Overall, responses were very positive with a high number of respondents stating that they have enjoyed being on committees and that they felt supported, included, involved and valued. Many recognised the importance of their contributions, and that they were made to feel welcome in committee meetings.

89. Many lay members felt that the experience of being on committees and working with NICE has improved their knowledge, confidence and self-esteem, and in several cases has led to voluntary or paid work. There was praise for the competency of the chairs, for the organisation of meetings and the clarity of information, which was provided in a timely fashion. Overall, lay members felt proud to be able to contribute to NICE’s work.

What needs improvement?

90. There was dissatisfaction with the expenses system, with one lay member finding the system 'very difficult to navigate'. The physical challenge of carrying large
amounts of printed information to and from meetings was mentioned and that could cause particular difficulties for lay members with disabilities. Another potential barrier to contribution was the process and fast flow of the meetings. There were real challenges for some lay members around accessibility of venues and travel and accommodation.

I would happily recommend to anyone to become a part of the work of NICE. Contributions can really have a positive impact.

Lay member

Figure 3: overall experience of being a lay member on a NICE group or committee January–December 2015

![Bar chart showing lay member's experience]

- Excellent: 19
- Good: 21
- Adequate: 5
- Poor: 2
- Very Poor: 0
Figure 4: ease of contribution to the work of the group or committee January–December 2015

![Pie chart showing ease of contribution]

Figure 5: effectiveness of contribution to the work of the group or committee January–December 2015

![Bar chart showing effectiveness of contribution]
Other notable achievements

91. We have continued to work on increasing the patient group attendance at Technology Appraisals scoping workshops and this year we have identified and supported the highest number of patient group attendance in any year to date. There were 91 (49% increase since last year) patient group attendees who participated in 53 (49% increase since last year) technology appraisal scoping workshops. The workshops were grouped into 5 batches across the year.

92. Of 34 Interventional Procedures topics in 2015, 28 topics (82%) were suitable for patient commentary. We gained agreement from 31 practicing centres to send out questionnaires for 18 topics. Patients for 16 topics returned questionnaires. Overall, of the 596 questionnaires sent 235 were returned (an increase of 16% return rate from last year). Patient commentary summaries were written by PIP lead for 10 of the 18 topics; summaries are written when 10 or more questionnaires are returned.
Appendix 1 – Public Involvement Programme Staffing Structure – December 2015
(L = London; M = Manchester; FT = Full-time; PT = Part-time)

Victoria Thomas (L, FT)
Head of Public Involvement

Lizzie Thomas (L, FT)
Senior Public Involvement Adviser
On Maternity Leave until Summer 2016

Heidi Livingstone (L, FT)
Senior Public Involvement Adviser
Maternity cover until July 2015

Laura Norburn (M, FT)
Senior Manager – Shared Decision Making (to April 2016)

Jane Coad (L, FT)
Senior Public Involvement Adviser

Victoria Thomas (L, FT)
Public Involvement Adviser

Simran Chawla (L, PT)
Public Involvement Adviser

Juliet Kenny (L, PT)
Public Involvement Advisor
Start date: 27/11/14

Erin Whittingham (M, FT)
Public Involvement Adviser

Jessica Fielding (M, FT)
Public Involvement Adviser

Emma Chambers (L, PT)
Public Involvement Adviser
On Maternity Leave until Spring 2016

Laura Norburn (M, FT)
Public Involvement Adviser
(on secondment to April 2016)

Chloe Kastoryano (L, FT)
Public Involvement Adviser
Maternity cover until Summer 2016

Lydia Shears (M, FT)
Administrant (on secondment to April 2016)

Sally Taylor (M, FT)
Coordinator

Lydia Shears (M FT)
Coordinator

Anika Emery (M, FT)
Project Manager

Sally Taylor (M, FT)
Coordinator

Lydia Shears (M, FT)
Administrator (on secondment to April 2016)
Appendix 2 – Meetings with and visits to patient and voluntary sector groups 2015

Black Health Agency
Breast Cancer Now
Brittle Bone Society
Cancer 52
Child Growth Foundation
Climb
Equalities National Council
Genetic Alliance UK
Lesbian and Gay Foundation
MIEM (Medical Information for Ethnic Minorities)
MS Society
Netmums
North West People in Research Forum
Sarcoma UK
Scope
South Asian Health Foundation
User Voice
Vision 2020
Appendix 3 - Giving Healthwatch NICE Teeth toolkit
Giving Healthwatch NICE Teeth

A guide for local Healthwatch organisations:
How to use resources from the National Institute for Health and Care Excellence (NICE)
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How this guide came to be

A note from Sir Bill Taylor,
Healthwatch Blackburn with Darwen Chair

As a North West Network we have co-developed this guide which can be used by every local Healthwatch across the country. We envisage this guide will enable and support local Healthwatch to incorporate National Institute for Health and Care Excellence (NICE) evidence-based practice into our work, and increase our confidence when challenging local services.

This guide came about as at Healthwatch Blackburn with Darwen we have an imaginative and creative approach to problem solving and service development. I guess that’s truly getting more for less. Like others, our Board thrives on individual commitment, vision and stamina. Our small staff team is both hard working and talented, working hard and productively with key partners to improve the local services.

Healthwatch Blackburn with Darwen first met with NICE to explore how we could improve our work locally. At the meeting we found kindred spirits in terms of developing the best possible quality of service for local citizens. We further saw opportunities to develop the collaboration between NICE and ourselves to create a North West Healthwatch approach.

Our approach with NICE was quite honestly because we wanted to better utilise resources produced by NICE to ensure our work uses their tried and tested national guidance and standards. We’ve already benefitted locally by incorporating NICE guidelines into reports and seen our local Hospital Trust develop action plans for improvements based on our recommendations supported by NICE guidelines.

This document is in itself yet another example of our far sighted perception of the benefits of joint working and sharing good practice as a network. We hope that the benefits of the guide is that it will strengthen our positive impact on local provision with hard, sought in the field, evidence.

Sir Bill Taylor
Healthwatch Blackburn with Darwen Chair
NICE and Healthwatch

Since their inception local Healthwatch organisations are having a positive impact in carrying out statutory functions and improving local provision.

As a statutory body it’s vital to ensure the work completed by local Healthwatch is done to a high standard.

While local Healthwatch is commissioned and structured differently around the country, and each will have its own local priorities, there are many local Healthwatch functions that NICE resources can support.

The resources produced by NICE can help local Healthwatch in a number of ways, including:

**Issues Raised**
Understanding the guidance and quality standards for best practice developed by NICE can support Local Healthwatch establish whether their local services are providing adequate care.

**Recommendations**
Recommendations to providers and commissioners must be achievable and realistic. Using NICE resources, such as their guidance and quality standards for health and social care, can ensure recommendations are based on the current evidence of what is effective and good value care.

**Engagement**
Knowing what the recommendations are for best practice/care can help a local Healthwatch develop relevant questions and research techniques.

Within this document Local Healthwatch in the North West have identified functions which can be enhanced by NICE resources, and provided hints and tips, and case studies of best practice.

- Enter and View Visits
- Obtaining the views and experiences of the public
- Providing information to the public
- Promoting and supporting the involvement of the public in commissioning, provisions, and scrutiny of services
- Healthwatch role on the Health and Wellbeing Board
- Recommending investigations or special reviews
What is NICE?

NICE is the National Institute for Health and Care Excellence. It is an independent public body that provides national guidance and advice to improve the quality and productivity of healthcare, public health and social care in England.

What does NICE do?

NICE develops national guidance, standards and information on safe, effective and value for money practice; helping to improve outcomes for people using health and care services, and aiming to reduce variation and inequalities.

What is NICE guidance?

NICE guidance contains recommendations on safe, effective and value for money practice based on the best available evidence. They provide an objective and authoritative summary of the research and evidence, and an assessment of the effectiveness and cost-effectiveness of health and social care interventions. Guidance aims to promote both individualised care and integrated care, and cover a range of topics, including:

- Preventing and managing specific conditions
- Improving health
- Managing medicines in different settings
- Providing social care and support to adults and children
- Planning broader services and interventions to improve the health of communities.

Many guidance recommendations are for individual health and social care practitioners, who should use them in their work in conjunction with their professional judgement and discussion with people using services.

Some recommendations are for local authorities, commissioners and managers - and cover planning, commissioning and improving services; others are for service providers, schools, and local and national organisations and partnerships in the public, private and voluntary sectors.

Guidance recommendations are also useful for people who use health and social care services (including people who purchase their own social care), their families and carers, and organisations representing their interests.

See [www.nice.org.uk/guidance](http://www.nice.org.uk/guidance)

NICE products and resources can be used by the NHS, local authorities, employers, voluntary groups and anyone else involved in commissioning or providing healthcare, public health or social care services.
What are NICE Quality Standards?

NICE quality standards provide short and clear descriptions of high-priority areas for quality improvement in a defined care or service area. They have 2 main components:

1) quality statements: typically 5-8 statements, detailing a concept or requirement for high-quality care or service provision.
2) quality measures: for each statement in order to assess the quality of care or service provision specified in the statement.

Each quality statement is accompanied by a description of its implications for different audiences e.g. service providers, health, public health and social care practitioners, commissioners, and people using services and carers.

Quality standards consider all areas of care, from public health to healthcare and social care. Evidence relating to effectiveness and cost effectiveness, people’s experience of using services, safety issues, equality and cost impact are considered during development.

See [www.nice.org.uk/qualitystandards](http://www.nice.org.uk/qualitystandards)

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**NICE quality standards enable:**

1. Health, public health and social care practitioners to make decisions about care based on the latest evidence and best practice.
2. People receiving health and social care services, their families and carers and the public to find information about the quality of services and care they should expect from their health and social care provider.
3. Service providers to quickly and easily examine the performance of their organisation and assess improvement in standards of care they provide.
4. Commissioners to be confident that the services they are purchasing are high quality and cost effective and focused on driving up quality.

What are NICE Pathways?

NICE Pathways visually present everything NICE has recommended on a particular topic - providing quick and easy access to the full range of NICE guidance, quality standards and implementation support tools.

They offer an easy-to-use, intuitive way of accessing recommendations and resources from NICE about health, public health and social care.

See [http://pathways.nice.org.uk](http://pathways.nice.org.uk)
Using NICE resources to support local Healthwatch

As previously noted, there are many local Healthwatch functions that resources produced by NICE are able to support.

Below are some examples of how your local Healthwatch can use them. These examples were gathered from local Healthwatch in the North West through two engagement events hosted by the North West Network in partnership with NICE.

1. Enter and View visits

- I can use and promote Information for the Public (lay version of NICE guidelines) at events / consultation meetings to help patients make individual choices and the right choice for them.

- I can use a NICE guideline and its associated quality standard to develop questionnaires and build assessment tools.

- I can use a NICE guideline and its associated quality standard to identify recommendations to help services improve.

- I can read relevant NICE guidelines prior to enter and view visits so that I am better informed on that topic.

- I can use NICE guidelines and shared learning examples to help us to focus our quarterly/ yearly planning for particular topics that we will work on for that period.

- I can brief the Healthwatch Chair on agenda topics related to relevant NICE guidelines to present information at the board meetings to build on knowledge we provide.

- I can share our learning and experience with others through the NICE Local Practice Case Studies [www.nice.org.uk/sharedlearning](http://www.nice.org.uk/sharedlearning)

- I can investigate and review enter and view visit training for staff / team using NICE guidance to support impact of our work.
Hints and Tips:

- Use the NICE Quality Standard for the topic you are interested in - turn the quality statements or the description of what they mean for different audiences into questions. Use these in the questionnaire for your service review.
  - For example, quality statement 5 (understanding treatment options) in the quality standard on patient experience in adult NHS services (QS15) states that patients are helped by healthcare professionals to understand the relevant treatment options, including the benefits, risks and potential consequences of care. If you were assessing whether a service delivers a good experience for patients you could ask patients the question “have healthcare professionals supported you to understand the relevant treatment options, including the benefits, risks and potential consequences of care?”
- Share learning and prevent duplication of effort by working with other local Healthwatch organisations to keep each other informed on enter and view programme themes and how resources produced by NICE were used to support that work.

Case example 1:

Healthwatch Blackburn with Darwen (BwD) incorporated NICE guidelines during their Enter and View visit to their local Emergency Department. Whilst developing recommendations for service improvement Healthwatch BwD reviewed NICE clinical guidance to support recommendations. In one of the findings Healthwatch BwD referred to NICE clinical guideline 138: “Give the patient information, and the support they need to make use of the information, in order to promote their active participation in care and self-management”. This supported their recommendation of ensuring all patients have a clear understanding of their care pathway before leaving, resulting in an improvement plan being developed by the Hospital Trust.

Case example 2:

Healthwatch Cheshire West representatives and staff have used NICE guidelines in a number of areas. Information from NICE about infection control has been used to research and inform if something is being done correctly. The information has also formed additional reading following specific Infection Control training which many of the representatives have completed.

One NICE document in particular, “Using Quality Standards to Improve Care Homes for Older People”, is referred to in their Enter and View training package and used for research.
2. Obtain the views and experiences of the public

- I can look at the NICE website to see what NICE has produced. The guidelines and quality standards can support our work plan themes and help establish whether local services are using these in practice.

- I can use the NICE guideline on community engagement to help communicate what good engagement looks like.

- I can use NICE guidelines to form questions around what ‘good looks like’ in order to benchmark public views and their first-hand experience.

- I can use specific NICE guidelines to help build evidence-based objectives for project work to gather the public’s view and experience of a service or care.

- I can ensure that the lay versions of NICE guidance ‘Information for the Public’ are accessible to members of the public, and can signpost to them during conversations.

- I can use NICE guidelines to direct our thinking and inform our starting point for conversations.

- I can use NICE guidance to cross reference with what the public ‘should’ be getting from health, public health and care services to empower and inform them.

- I can provide training on, and share information about, NICE resources with our Healthwatch staff, engagement workers and volunteers so they can draw on them when engaging with members of the public.

- I can use the NICE quality standards on patient experience in adult NHS services (QS15) and service user experience in adult mental health services (QS14) as a framework to understand patient and service user experience.

- I can use NICE guidance and shared learning examples to help us focus on the yearly/quarterly planning for particular topics that we will work on for that period. I will also share learning from this with other Healthwatch organisations.

Hints and Tips

- NICE produces versions of all its guidance for patients, carers and members of the public. They are called Information for the Public - click on the ‘information for the public’ tab on the guidance pages.

- Use the audience descriptors for patients/service users from relevant quality standards to understand the quality of care being provided by local services.
Case example 1:

Healthwatch Blackburn with Darwen engaged with refugees and asylum seekers as part of their #personfirst programme, which aims to engage with seldom heard residents and enabling them to share their experience and concerns. One of the main findings from engagement with this group of residents was that communication barriers between residents and healthcare professionals resulted in heightened anxieties, and not being able to understand their condition or medicines they were prescribed. Healthwatch used the NICE clinical guideline 138 Patient experience in adult NHS services to support the recommendation that “General Practitioners should ensure asylum seekers and refugees understand their care pathway. GPs should review their appointment time to ensure residents are able to fully understand the care they will require, and have enough time to ask questions.”

Case Example 2:

Healthwatch Salford has been working with children and young people to gather views and experiences of emotional wellbeing and mental health services. In the priority setting exercise, local people said that children and young people needed to have more of a say on mental health and emotional wellbeing services. Healthwatch Salford worked with a group of young people (carers, service users, people from hard to reach groups and those involved with the Youth Council) to design a questionnaire, an engagement tool and a lesson plan to gather views of children and young people on these services. The young people were involved in promoting the work, supported by Healthwatch Salford staff. The response was phenomenal. Around 400 responses were received.

The public health team worked with Healthwatch Salford using a range of NICE guidance on young people’s mental health services to inform the analysis of the responses.

This was then developed into a report in partnership with the young people and presented back to leaders in the city. The information in the report helped to shape the transition plan around Children and Adolescent Mental Health Services and the local review around services for people aged 0-25 years. By using NICE Guidance, the recommendations in the report were guaranteed to be evidenced based from a clinical perspective, whilst also respecting and responding to the needs and wishes of local young people.

“Using the NICE guidance helped us to look at the recommendations for services and to map the responses. It provided a structure for the themes identified from the information we gathered and helped us to back up our recommendations with best practice and guidance.”

Clare Mayo
Chief Officer
Healthwatch Salford
Case example 3:

Healthwatch Salford Engagement Officers search through the NICE Pathways to find any that are relevant to the services we are working with. NICE Pathways are then used to understand more about the way in which the services work, along with helping us to understand what the patient might expect when being referred to a service.

The NICE Pathways can then be used to help build questions around the parts of a patient’s pathway. This helps them to think about the different parts of a service that people will experience and to structure our questions around this. Using NICE resources in this way helps people to think about their journey and helps them stay on track when they are interviewing them. We also use the information from NICE to help us to structure our case studies in a clear and logical manner.

Case example 4:

Healthwatch Blackpool developed a set of 30 questions based on NICE Quality Standard 14: service user experience in adult mental health services to collect the views and experiences of mental health service users and those who haven’t accessed mental health services but live with a mental health condition. They ran a series of focus groups to test the questions before publishing an on-line survey which was promoted on their website, through social media platforms and directly with mental health services. In addition they visited a number of groups and spoke directly with people who have a mental health conditions.
3. Provide information to the public

- I can look at guidance so that we are more familiar with what is available and what it says.

- I can make the public aware that NICE produces *Information for the Public* versions of NICE guidance to help them understand their condition and what NICE recommends.

- I can include important message from a NICE guideline on our website or in materials we produce for members of the public, patients, service users and carers.

- I can share / direct people to the NICE website.

- I can link to the NICE website from our website so that our web users can access NICE content more readily; and I can put a clear, accessible description of how people can benefit from NICE.

- I can use and promote NICE Pathways to help members of the public understand what tests, treatment options and care they can expect, and to empower them to ask the right questions of professionals providing care to them. I can print off the relevant pathway to provide a reminder of that information. This helps with signposting enquiries.

- I can add a brief overview of NICE’s role to the information we share with the public in order to inform and educate people about NICE and how people can get involved and use the guidance.

- I can share information from the NICE Public Involvement Programme newsletter for Healthwatch with my networks and members of the public so they are aware of opportunities to get involved with NICE, and of the guidance published recently. Email pip@nice.org.uk to be added to the newsletter mailing list.

- I can signpost people who have ‘lived the experience’ who are interested in joining a NICE committee.

- I can share information with other organisations / voluntary sectors / CVS so they are also aware of recently published guidance and opportunities to get involved with NICE.

- I can use social media to retweet opportunities for people to get involved with NICE through Healthwatch or patient representative organisations.

- I can increase my knowledge on NICE guidance and other NICE resources to ensure patients, carers, public member receive a better experience and service.
Hints and Tips:

- Add some information to the Healthwatch website (see example wording below) on how the public can ‘get involved with a NICE working group or committee’; listing the current opportunities with closing dates for application.

  Every piece of NICE guidance and every quality standard is developed by an independent committee of people that includes those who provide, commission and use health and social care services. NICE also run consultations, to allow individuals and organisations to contribute to the development of their recommendations. There are opportunities for opportunities for patients, service users, carers and lay people to join a NICE committee or working group.

- The following text can be used or modified to put on local Healthwatch websites or in newsletters to help explain to the public what NICE is about.

  NICE stands for National Institute for Health and Care Excellence. It is an independent national organisation that works to make care and treatment better for people using health, public health and social care services.

  NICE looks at the evidence for different ways of working and different types of treatment and care. Based on this evidence, NICE makes recommendations for health and social care workers so that people get the best possible care. These recommendations can be about a wide range of topics including medicines, surgical procedures, medical devices, promoting wellbeing and preventing ill health, care for people with a range of illnesses and conditions, and care provided by social services. NICE also helps the people who organise, plan and buy services (commissioners) to measure how well services are doing. Local people can use the information from NICE to check if they are getting a good service and the best care. If you are having problems getting a particular medicine treatment or investigation, NICE may have made recommendations that can help you. See their website at [www.nice.org.uk](http://www.nice.org.uk)
Case example 1:

Healthwatch Cheshire West use guidance from the NICE website to inform responses to individuals who have made signposting enquiries. Two enquiries of note include the availability of drugs for treating Multiple Sclerosis and patients’ rights in relation to obtaining a particular breast cancer treatment.

Further use of NICE guidelines have been made in other signposting activities. For example supporting research into a complaint being made about the quality of care someone should expect to receive. One such example is where Healthwatch Cheshire West was asked for help regarding a hip replacement operation that had gone wrong. The patient’s wife was supported by Healthwatch in making a formal complaint.

NICE guidelines, in terms of best practice, had been used for research and quoted in the initial letter of complaint to the hospital to directly support her case.
4. Promote and support public involvement in commissioning, provision and scrutiny of services

- I can use NICE guidance and quality standards to bring commissioners, stakeholders and the public together, to understand what good quality care and services look like and to raise questions about local quality provision and commissioning.

- I can use NICE guidance and quality standards to build frameworks / guides to support change in practice to reduce the gaps in service quality.

- I can use NICE Pathways to understand whether what is being commissioned or provided takes account of what NICE recommends is best practice and value for money.

- I can incorporate NICE guidelines and quality standards into developing the audit / baseline assessment tools to identify what should be expected from a service i.e. ‘what good looks like’.

- I can support the public to feed into the development of national guidance by providing or signposting to the relevant information on how to get involved with NICE.

- I can promote NICE resources at every opportunity locally - at schools, colleges and Healthwatch member forums to increase the understanding as to how NICE resources can support them in their discussions and interactions with health and care professionals.

- I can train Healthwatch staff to empower and involve the public in their own decision making using NICE guidance recommendations.

- I can signpost individuals to the NICE website to gather information to make individual choices.

- I can use NICE guidance to help the public ask the reason for a chosen treatment / service rather than just accepting, that is, empower them to question.

- I can increase my knowledge on NICE guidance and other NICE resources to ensure patients, carers, public member receive a better experience and service.
Hints and Tips:

✓ The NICE Public Involvement Programme has lots of information about involving patients and the public. Check out the NICE website for more information: www.nice.org.uk/about/nice-communities/public-involvement

Case example 1:

Healthwatch Rochdale received concerns from local residents regarding the removal of a Diabetic Retinopathy Screening (DRS) service from one location following a serious incident.

The service is now based at 6 sites, but concerns were raised around accessibility to and from the fixed based sites. Furthermore, there was no public consultation for the relocation of the site.

Healthwatch Rochdale facilitated a Question Time event with the NHS England Greater Manchester Area Team and local residents. Using NICE guidance documents they ensured the public consultation process was effective in supporting all aspects of the community.

Healthwatch Rochdale also highlighted the NICE guidance on Community Engagement when NHS England set up a subcommittee for the future service. The NICE guidance documents helped empower Healthwatch Rochdale with knowledge on how to tackle a number of issues which they were confronted with.

Case example 2:

Healthwatch Cheshire West representatives used the NICE guideline on medicines optimisation prior to and after scrutiny of services to inform a detailed study on the discharge process at the Countess of Chester Hospital.

This was a detailed study by two representatives who made three structured visits looking at different aspects of the process, and where the pharmacy service was scrutinised in detail over a morning period. This provided information for one of three reports published - other reports covered the discharge lounge itself and integrated and complex discharges.
Case example 3:

Healthwatch Manchester have used NICE resources to support a local resident who was in severe chronic pain. Healthwatch were contacted by this resident regarding his GP’s refusal to refer him for pain (denervation) treatment earlier than the usual 12 month cycle. He wished to make a complaint about his GP for this reason. After checking the NICE guidance regarding this treatment and seeing no reason why it couldn’t be brought forward, Healthwatch Manchester wrote to the pain specialist whose prompt response to Healthwatch Manchester and the resident enabled his immediate treatment. The resident didn’t pursue the complaint with his GP.

Case example 4:

Healthwatch Cumbria (HWC) used NICE guidelines in the formation of a report on the provision of cancer services in the county and as a reference point in a response to a county wide Children and Adolescent Mental Health Services (CAMHS) survey. In the first case the NICE guidelines provided a tangible timeline for the diagnosis, treatment and care pathways to which HWC statistical responses could be measured. This helped form the basis of a number of recommendations that HWC made to the Clinical Commissioning Group reflecting the current state of Cumbria’s cancer care services.

HWC response to the CAMHS survey was strengthened by referencing NICE guidelines as they enabled us to highlight specific areas of the services that were not performing to the standards expected. This enabled us to produce a robust, focussed response to the survey and recommend areas for improvement with achievable targets.
5. Role on Health and Wellbeing Boards

- I can use NICE guidance to inform discussions about the commissioning and quality of local services with Health and Wellbeing Boards / commissioners / providers / appropriate providing bodies.

- I can support public health teams when they use NICE guidelines to provide evidence of good practice.

- I can check and challenge joint health and wellbeing strategies and action plans, commissioning decisions, strategic plans are evidence-based, that is, draw on relevant NICE guidance and quality standards.

- I can question when the Board seeks to take decisions that contradict what the evidence recommends is best practice or the most cost-effective intervention.

- I can help to make sure that NICE guidance recommendations are included in plans to improve the quality of health and social care.

- I can work with patient and carer organisations to help interpret how a NICE guideline should be adapted to our local area and population.

“The local Healthwatch role on the Health and Wellbeing Board is really important - this is where you can hold all organisations in the local health economy to account. It is important to know whether they have used NICE guidance and quality standards to support local commissioning decisions and local service provision. If they are using them locally then we have assurance that we are only buying and providing the most effective care and support for our local population and using our local resources wisely.”

Mike Lappin - Healthwatch Stockport
6. Recommend investigations or special reviews

- I can use NICE quality standards for in-depth review / enter and view visits to understand whether there are areas of quality for concern that need further investigation.

- I can use NICE guidance and quality standards when looking at service user complaints to understand whether local care may have fallen short of expected standards.

- I can use NICE guidance and quality standards to back up our findings when we report and escalate issues to the appropriate bodies, for example care quality commission, local safeguarding team, clinical commissioning group.

- I can conduct surveys to find out whether NICE guidelines are being followed, and using the findings to push for improvements.
Keep up to date with the latest from NICE

Subscribe online at www.nice.org/newsletter to:

**NICE News**
A monthly newsletter containing information about new guidance, quality standards and implementation resources launched each month.

**Social Care Stakeholder Update**
A monthly email bulletin detailing social care related activities at NICE.

**Public Involvement Programme bulletin**
A monthly email detailing the latest opportunities to get involved with NICE’s work by commenting on consultations or applying to become a committee member. The bulletin also contains a notice board where Healthwatch organisations can promote opportunities they may have for the public or other organisations working with patients and the public to get involved in. Email pip@nice.org.uk to be added to the mailing list.

Search a unique index of authoritative, evidence-based health, public health and social care information from hundreds of trustworthy and accredited sources. www.evidence.nhs.uk

Download our free NICE Guidance app to have offline access to all NICE’s guidance products while on the move. Use it to browse, search, and bookmark individual sections of guidance. Receive automatic updates and new guidance as soon as it is published on the NICE website. www.nice.org.uk/apps

@NICEcomms

www.nice.org.uk
Sharing success nationally

NICE can help promote nationally the success and impact of local Healthwatch using resources produced by NICE to support improved care. It can do this through feature articles on its website and in its Public Involvement Programme bulletin.

Through its Local Practice Collection, NICE is also interested to receive and share good practice examples of how local Healthwatch has supported local implementation of NICE guidance and quality standards. Make a submission at www.nice.org.uk/sharedlearning

Get Involved with NICE
www.nice.org.uk/getinvolved

NICE wants people to be involved, keeping open lines of communication and telling them what matters to you, your organisation or your community. There are many ways that individuals and organisations can get involved in NICE’s work.

Click on the pink headings below to find out more.

Register as a stakeholder:
Healthwatch can register as a stakeholder to help develop a guideline or a quality standard - feeding in the views of their local population and commenting on draft documents.

Comment on a consultation: All guidelines and quality standards are open for consultation during their development. Registered stakeholders can comment on our recommendations.

Talk to NICE: Have a question or comment? Contact us by telephone or email.

Join a committee: NICE committees and working groups are made up of health, social care and other professionals and practitioners, patients, service users, carers and members of the public and technical experts. Healthwatch can direct individuals who wish to work with NICE as a lay member to join a committee.

Come to a meeting: Advisory committee meetings, technology appraisal appeal hearings, public board meetings and some of our other meetings are open to the public and press. Come along and see how we work.

Find out about Citizens Council:
Made up of members of the public, our panel debates the overarching moral and ethical issues around our work.

Be an ambassador: Join our growing network of professionals working in health, public health and social care. Help us to share our work.
Local Healthwatch pledges

Use this section to capture how your Healthwatch intends to use any of the ideas in this guide during this financial year.

Healthwatch .............................................. commits to:

1.

2.

3.

4.

5. To share our experiences and learning from using NICE resources with other Healthwatch organisations via our networks

6. To celebrate our experiences, learning and successes nationally by submitting a case study to the NICE Local Practice Collection www.nice.org.uk/sharedlearning .

Signed:
(Chair / Chief Executive)

Dated:
Contributing Organisations

This guide was developed by local Healthwatch organisations in the North West with support from the National Institute for Health and Care Excellence.

For further information about this guide, please contact:

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NICE: nice@nice.org.uk
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

ABBREVIATED TECHNOLOGY APPRAISAL PROPOSAL

The Board is asked to consider the proposal for development of a new process to appraise health technologies that provide similar or greater health benefits at a similar or lower cost than technologies already recommended in NICE guidance for the same indication, and to approve the accompanying process and methods statements for public consultation.

Professor Carole Longson
Director, Centre for Health Technology Evaluation
May 2016
Overview

1. The aim of the abbreviated technology appraisal (ATA) process is to provide a less resource-intensive process for appraising technologies that provide similar or greater health benefits compared with those already recommended in NICE guidance for the same indication, at a similar or lower cost – for example, new drugs within an established therapeutic class of treatments (such as a new TNF-alpha inhibitor or a new factor Xa-inhibiting oral anticoagulant). It is expected to allow NICE to appraise some new technologies efficiently, supporting patients and clinicians in accessing a broader range of treatment options. By adopting a practical and pragmatic approach, technologies can be appraised efficiently while minimising unnecessary analysis and assessment.

2. The ATA process is an adaptation of the STA process. It broadly follows the same steps as an STA, but with shortened timelines for the company submission and evidence review group (ERG) review; a summary of the differences between ATA and STA can be found in appendix 4. Recommendations developed through ATA will be subject to appeal, and will carry a funding direction.

3. The methods of ATA are also adapted from STA, drawing on relevant aspects of the methods used in the medical technologies evaluation programme (MTEP); a summary of the differences between ATA and STA can be found in appendix 4. The methods have been refined to focus on particular aspects of clinical effectiveness and to reduce unnecessary economic analyses.

4. ATA offers a number of advantages for NICE, ERGs, appraisal committees and companies, including: shorter evidence submissions, reduced time to critique and summarise the evidence for committee, shorter committee discussions, and shorter guidance documents. This will increase some capacity in NICE technical and project teams and for the appraisal committees and ERGs, while minimising the burden on companies.

5. The challenges in introducing an ATA process include the need to balance a pragmatic and resource-saving process with academic rigour, selecting and
scheduling topics as ATA based on incomplete information, and the small risk that the evidence collected for an ATA may be insufficient for decision-making in some cases. An additional risk is that companies may not be enthusiastic to follow this process, or that they consider that it advantages companies that develop second- or third-in-class technologies over more innovative products. The risks associated with introducing this process are summarised in Appendix 3.

Proposal for ATA

Selecting topics for appraisal through ATA

6. Technologies may be eligible for appraisal through the ATA process if they meet the following criteria:

- It is expected to provide similar or greater health benefits, compared with an established, NICE-recommended treatment for the same indication
- It is expected to have a similar or lower cost, compared with this comparator
- It will be compared with 1 or more technologies already recommended in published NICE guidance for the same indication.

NICE will select technologies for appraisal through ATA if the technology can be reasonably expected to meet these criteria, and if it is confident that the ATA process is an appropriate route to establish the clinical and cost effectiveness of the technology.

7. When possible, technologies will be identified for appraisal through the ATA process during the topic selection and scoping processes. The topic selection and scoping processes will, in general, be the same as the equivalent processes for STA – that is, topics will be identified from a variety of sources, after which NICE will develop a draft scope, seek the views of consultees and commentators through a scope consultation, before finalising the scope and seeking referral by the Department of Health. A decision on whether to follow the ATA process will ideally be made after the scope consultation, by a group including representatives from NICE, the Department of Health, NHS England and the appraisal committees (the ‘Decision Point 4’ or ‘DP4’ meeting). This decision will take into account information from the company and key
stakeholders, including any case made by the company as to whether it supports its technology following the ATA process. In addition, to maximise opportunities to route to the ATA process, the process includes the option to change to ATA at a later stage: if the company considers that its technology is suitable for the ATA process after DP4, it can advise NICE before the start of the appraisal, and NICE will consider whether the topic fulfils the ATA selection criteria and whether it is logistically possible to change process.

8. To allow maximum flexibility, it is proposed that referrals from the Department of Health will not specify which appraisal process will be used (that is, the topics will be referred as ‘technology appraisals’ and not specifically ATA, STA or MTA), with the final decision on the type of appraisal resting with NICE. The wording of the remit for ATA topics will be then be same as for STAs and MTAs. This will be explored with the Department of Health before consultation.
**Overview of the ATA process:**

- **Week 0**: Invitations to participate sent to consultees and commentators; company invited to submit evidence.
- **Week 6**: NICE receives evidence submission from company and sends to the ERG. Consultees and commentators receive company submission (executive summary) and are invited to submit responses.
- **Week 7.5**: ERG submits clarification questions to NICE.
- **Week 8**: Company receives clarification question from NICE.
- **Week 9**: Company submits clarification response to NICE.
- **Week 10**: Consultee and commentator statements received.
- **Week 12**: ERG submits report to NICE.
- **Week 13**: Factual error check of ERG report by company.
- **Week 14**: Committee papers sent to attendees.
- **Week 15**: Committee meeting.
- **Week 16 onwards**: Consultation (if required), guidance development and appeal, as in STA process.

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**Appraisal process and methods**

**Date:** 18 May 2016

**Ref:** 16/047
9. The ATA process will broadly follow the same steps as STA (including scoping, evidence submission, evidence review, appraisal, opportunity for appeal, and publication), modified for efficiency and to reflect the specific needs of ATA as follows:

- The analytical burden for both companies and ERGs will be reduced compared with STA; the timelines for the company submission and ERG critique are reduced from 8 weeks to 6 weeks each to allow for flexibility.

- After the first appraisal committee meeting, a final appraisal determination (FAD) will be produced if the technology is recommended. An appraisal consultation document (ACD) will be produced only if the committee does not recommend the technology or limits its use more than the marketing authorisation or than published NICE recommendations for the comparator.

- Patient access schemes will only be considered when approved by the Department of Health by the company submission deadline, or as part of a rapid review of guidance produced through an ATA; it is impossible to accept a patient access scheme during an ATA.

- NICE is not intending to provide tools to support the local implementation of ATA guidance, and no budget impact information will be requested in the submission.

- An additional ‘engagement’ step is included in the ATA process, starting at the same time as the ERG review of the company submission. Consultees will be sent a redacted executive summary from the company submission and asked to provide their opinion on the clinical and resource similarities of the technology in clinical practice. Comparator companies will have the opportunity to comment on factual inaccuracies related to their own product.

10. The clinical evidence to be considered will be broadly similar to that in an STA, including a full systematic review to identify all relevant studies and, where necessary, indirect comparisons. Committees will make pragmatic decisions based on all available evidence, taking into account factors such as evidence supporting similarity, non-inferiority or equivalence in the key outcome(s) on which the clinical and cost-effectiveness of the comparator were based, absence of evidence for non-equivalence, how clinically meaningful any
apparent differences in specific outcomes may be, and clinical or biological plausibility (see section 3.1 of the methods guide for ATA [appendix 2]).

11. The approach to appraising the costs of investing in a technology through the ATA process will be through a cost-comparison analysis. This compares the costs and resource use associated with the intervention with that of the comparators. The effects of the intervention and comparator on health outcomes are captured in the clinical effectiveness evidence, and are not estimated in an economic model (see section 3.1 of the methods guide for ATA [appendix 2]); a key difference from the STA process is that QALYs are not needed to assess the benefit of the technology. The appraisal committee will then consider the results of the cost-comparison analysis in light of this clinical effectiveness evidence, to establish whether the technology represents an appropriate use of NHS resources.

12. When recommending a technology that has been appraised through the ATA process, committees will be encouraged to recommend that, if 2 or more clinically similar treatments that are recommended by NICE are suitable, treatment should normally start with the lowest cost option.

**Issues for information and discussion**

*Benefits of ATA*

13. It is anticipated that ATA will provide advantages for NICE, ERGs, appraisal committees and companies. The key advantage of the ATA process for NICE is the opportunity it provides to meet an expected increase in demand by offering another option for guidance development that requires fewer resources than an STA. It is expected that less time will be needed for the NICE technical team, project team and appraisal committee at each step: the estimated resource requirements per topic (compared with an STA) are summarised in table 1. It will also reduce the overall duration of appraisals, although this is not the main priority for the ATA process – the proposed timelines allow timely guidance to be produced while maximising efficiency and flexibility in scheduling.
Table 1: Anticipated resource requirements per topic for ATA

<table>
<thead>
<tr>
<th></th>
<th>Anticipated resources required compared with STA</th>
</tr>
</thead>
<tbody>
<tr>
<td>NICE</td>
<td></td>
</tr>
<tr>
<td>Technology appraisals technical team</td>
<td>75%</td>
</tr>
<tr>
<td>Technology appraisals project team</td>
<td>75%</td>
</tr>
<tr>
<td>Editors</td>
<td>50%</td>
</tr>
<tr>
<td>Implementation team</td>
<td>0 (no implementation tools required)</td>
</tr>
<tr>
<td>ERG</td>
<td>From discussions with NETSCC and ERGs:</td>
</tr>
<tr>
<td></td>
<td>approximately 40–50%, to be confirmed</td>
</tr>
<tr>
<td>Committee</td>
<td>30–50%</td>
</tr>
</tbody>
</table>

14. It is acknowledged that the precise resource savings for companies, ERGs and NICE through the ATA process are currently uncertain. It is also difficult to predict how many topics will be eligible for ATA.

Risks

15. It is anticipated that introducing the ATA process will be associated with limited risks, and that these risks can be effectively mitigated. The key risks associated with introducing an ATA process are summarised in appendix 3.

16. There remains a risk that some companies may be reluctant to follow the ATA process. In addition, some stakeholders may perceive that ATA is a less-intensive appraisal process and therefore unfairly advantages less-innovative products (such as second- or third-in-class technologies or small additions to the treatments for conditions which already have several effective options), rather than encouraging more novel treatments that target important areas of unmet need. However, it is important to note that technologies appraised through the ATA process will not gain an advantage in the timing of market access (because the guidance will be published within 6 months of the marketing authorisation, as in STA), and the decision-making process within ATA is no more or less rigorous than an STA. Consequently, although companies gain a small advantage in terms of analytical burden with an ATA, this is unlikely to outweigh the commercial advantages of being the first product to the market.
Identifying suitable topics

17. Identifying suitable topics will be crucial for the success of the ATA process. In particular, the key challenge will be that the information available at the topic selection and scoping stages is likely to be limited (for example, if clinical trials have not completed and pricing strategies are not yet known), and it is not practical to independently assess large amounts of information in detail before the appraisal starts.

- Although the ATA process is expected to need fewer resources than an STA, if a topic were selected for the ATA process inappropriately, it may become delayed and need additional resources. This situation is not expected to happen frequently. The risks are reduced by the broad, flexible eligibility criteria defined in the process guide, and by exercising careful judgement on a case-by-case basis. In the early days of the ATA process, it may be appropriate to select topics cautiously (for example the first ATA topics could be limited to those in which there are 2 or more comparators that have been recommended in published technology appraisal guidance, or the intervention is in the same therapeutic class as its comparators). The broad eligibility criteria allow for this cautious approach, while also enabling the process to be expanded to include more topics in the future if appropriate (without the need to amend the process).

- Candidate topics will be identified by the NICE topic selection and technical teams, taking into account factors such as the characteristics of the technology, an initial review of completed and ongoing studies, existing NICE guidance and any input from the company and stakeholders during scope development and consultation. Where possible, in line with the STA and MTA processes, a decision on whether to follow the ATA process will be made at the DP4 meeting, taking into account feedback from the company and key stakeholders.

- In particular, it will be crucial to consult with the company and stakeholders on the suitability of the ATA process for individual products. It is recommended that the company’s agreement is obtained before the final decision is made, if possible (rather than enforcing the ATA process) to minimise the risk of non-submission, inappropriate submission or appeal. However, the final decision
rests with NICE; the decision will be communicated to companies, consultees and commentators (without reference to any specific commercially sensitive information).

- As much as possible, topic selection for the ATA process will also take into account whether the technology is expected to have a similar or lower cost to at least 1 of the comparators. This may be challenging if the technology’s price has not been agreed or if one or more comparators has a confidential patient access scheme. By including cost in the eligibility criteria, the risk of selecting inappropriate topics will be reduced – for example, by avoiding technologies that companies position as more effective than the comparator to justify a higher price. The company will be asked to include the expected resource impact on the NHS (if known) in its case for inclusion in the ATA process during the scope consultation. If the price of the technology is not known, and so the resource impact on the NHS cannot be estimated, NICE will seek assurance of the company’s expected positioning of the technology. The decision whether to follow the ATA or STA process may then be made based on the balance of risk for NICE.

- In addition, the process is able to accommodate later requests to route the topics to ATA, to maximise opportunities to benefit from this process. If a company with a product scheduled for an STA becomes aware that the technology is likely to have similar efficacy with a similar or lower cost to the comparator(s), it can make a request to follow the ATA process at any time before the start of the appraisal. NICE will then consider whether the technology meets the ATA criteria and whether it is possible for the appraisal to convert to the ATA process.

- The current proposal specifies that technologies will normally have at least 1 comparator that has been recommended in published technology appraisal guidance for the same indication. This minimises risks by increasing the likelihood that the treatment pathway will be well established and the key issues will have been discussed previously. It is likely, particularly in the early days of the process, that all ATA appraisals will have a comparator that is recommended in a NICE technology appraisal. However, the process is flexible enough that technologies with comparators recommended in other
guidance (NICE or other nationally recognised clinical guidelines) can be included in the future (if that guidance is sufficiently complete and robust).

- There is likely to be some uncertainty about the appropriateness of the ATA process when the comparator has an 'optimised' recommendation from NICE. It is proposed that if the company wishes to make a case only for the same recommendation as for the comparator, ATA would be suitable. Otherwise, an STA would be more appropriate. In cases when the company makes its case within the comparator recommendation, and the technology is recommended in that context, the guidance may proceed straight to FAD (without consultation). In all other cases, an optimised recommendation for the technology through the ATA process would lead to an ACD being prepared.

Process

18. An additional engagement step has been included in the ATA process, at the same time as the ERG review, to ensure consultees and commentators other than the company and the ERG are provided with the opportunity to state their view on whether the technology provides similar or greater health benefits at similar or lower costs to the comparator. This step replaces consultee and commentator submissions at the time of the invitation to participate, and is focused primarily on the clinical similarity of the technology with the comparators.

- It is proposed that as part of this engagement step, companies that have comparator technologies will be invited to state whether there are any factual inaccuracies in the evidence presented on the comparator technologies (that is, their own technologies), or whether they know of any additional evidence for the comparator that has emerged since the publication of the NICE guidance on that technology. This is necessary to ensure the committee has an accurate and comprehensive picture of all views.

- The ATA working group considered that early engagement (at the invitation to participate stage, as in the STA and MTA processes) would not be particularly helpful as the consultees and commentators may be limited in how much additional information they can provide for the committee without information about the case being made by the company. It considered that it would be
more appropriate for the engagement step to coincide with the ERG’s review of the company submission.

19. With the agreement of the chairs of the appraisal committees, it is proposed that clinical experts, patient experts, non-company consultees and commentators will not normally be invited to take part in the appraisal committee meeting discussion. Although expert attendees could help the committee address specific uncertainties in some circumstances, this is not expected to be necessary for most topics in the ATA process; a substantial amount of time would be saved (for NICE, the committee and the experts) if experts were not invited routinely. It is acknowledged that there is a small risk that some uncertainties may be more difficult to address. However, this risk is minimised by actively seeking experts’ views throughout the scoping and engagement processes and carefully tailoring the submission templates to capture the key information required.

20. The proposed ATA process is aligned to the STA process at the time of writing, including the nature of pre-meeting briefing documents, committee meeting preparation and guidance documents. If any changes to the STA process are agreed as part of the strategic review, these changes can be included in the ATA process too, and further efficiencies could be realised.

Methods

21. The appraisal of clinical effectiveness aims to establish whether the technology provides similar or greater health benefits to the comparator. It is not possible or appropriate to establish a single, robust definition of clinical similarity, non-inferiority or equivalence that would apply to all topics. Rather, a list of factors that could be considered is identified in the methods addendum; this list is not exhaustive, and committees will have the flexibility to take into account these factors and others depending on the specifics of the appraisal topic. See section 3.1 of the methods guide for ATA (appendix 2) for more details. This approach strikes a balance between a complete and rigorous appraisal of the evidence and a pragmatic, practical and resource-saving process.

22. Similarly, the proposed cost-comparison analysis is a balance between efficiency and completeness. Although a full cost–utility analysis might provide
the most robust evaluation of cost effectiveness, for technologies that are clinically similar to existing treatments it is sufficient to compare costs only. This is expected to substantially reduce the analytical burden for companies, NICE, ERGs and committees. The analysis will capture only relevant differences in resource requirements and costs – as a minimum, the acquisition costs, with other costs such as drug administration, healthcare appointments and treatment of adverse events considered only if relevant. It is noted that substantial differences between technologies in costs that directly relate to health outcomes (such as adverse events) are unlikely to be consistent with a conclusion that the new drug and the comparator provide similar health benefits. Uncertainty will be explored through univariate sensitivity analyses and scenario analyses, and probabilistic sensitivity analyses will not be undertaken. See sections 2.4–2.7 and 3.2 of the methods guide for ATA (appendix 2) for more details.

23. The cost-comparison analysis will include the acquisition cost of the technologies, with other costs (such as drug administration or monitoring) included only if there are relevant, meaningful differences. In this way, committees will have the flexibility to consider aspects beyond the acquisition cost if appropriate. For example, if the new technology has a higher acquisition cost but less frequent administration than the comparator, the committee can consider if any additional purchasing cost is offset by savings elsewhere. It will be important to ensure that, if relevant, costs relating to health outcomes (such as for managing adverse events) are included in the analysis.

Implementing ATA

24. After approval by the NICE Board, there will be a consultation with key stakeholders on the processes and methods of ATA. This consultation will last 12 weeks and will include selected organisations representing industry, professional groups and patient groups, as well as NHS England and the Department of Health. After this consultation completes, the final processes and methods will be presented to the NICE Board, and the ATA process will be implemented for appropriate topics.
Recommendations for the Board

The Board is asked to:

- Approve the process and methods statement, presented in the addenda to this paper, for 12 week public consultation

Authors of paper

- Elisabeth George, associate director, technology appraisals
- Meindert Boysen, programme director, CHTE
- With input from Ian Watson (technical analyst), Zoe Charles (technical adviser) and Ellie Donegan (technical adviser), on behalf of the other contributors to the proposal (see appendix 5)

SMT Member

- Professor Carole Longson, Executive director, CHTE
Appendix 1:

**Abbreviated technology appraisal: process addendum**

1 **Introduction**

1.1 This document provides an overview of the process of the NICE abbreviated technology appraisal (ATA) process. It builds on the general processes outlined in NICE’s *guide to the processes of technology appraisal* (2014). This document should be read alongside the guide.

1.2 This document does not describe the methods used to develop guidance. Information on the methods of doing an ATA is in appendix 2 to this document.

1.3 The aims of the ATA process are:

- To allow NICE to meet an expected increase in demand for technology appraisal guidance by providing a robust but less resource-intensive process for appraising technologies compared with the single technology appraisal (STA) and multiple technology appraisal (MTA) processes.

- To appraise technologies that provide similar or greater health benefits compared with existing NICE-recommended technologies, at a similar or lower cost.

1.4 Technologies appraised through the ATA process are subject to the funding requirements outlined in the guide to the processes of technology appraisal (see section 1).

2 **Selection of technologies**

2.1 The topic selection process and prioritisation of technologies for the ATA process will, in general, follow the selection process outlined in NICE’s guide to the processes of technology appraisal (see section 2).

2.2 Technologies can be appraised through the ATA process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with that have been previously recommended in NICE guidance (normally technology appraisal guidance) for the same indication. NICE will select technologies for appraisal through ATA if the technology can be reasonably...
expected to meet these criteria, and if it is confident that the ATA process is an appropriate route to establish the clinical and cost effectiveness of the technology.

3 Developing the scope

3.1 Technologies that are being considered for appraisal through the ATA process will, in general, follow the scoping process outlined in NICE’s guide to the processes of technology appraisal (see section 2).

3.2 When an ATA is proposed, the company is invited to make a case as to whether it supports its technology following the ATA process. This case should take into account the clinical evidence and likely costs of the technology, including any relevant patient access schemes for the intervention and comparator(s).

3.3 Consultees and commentators are invited to comment during the scope consultation on whether the technology is suitable for the ATA process.

4 The appraisal process

4.1 The ATA process consists of 4 phases: evidence submission, evidence review, engagement with non-company consultees and commentators, and appraisal (figure 1). The evidence submission, review and appraisal phases follow the STA process as described in NICE’s guide to the processes of technology appraisal (see section 3), except for the steps detailed below. The ATA process also includes the opportunity for appeal, consistent with the STA and MTA processes.
Figure 1 Overview of the ATA process

- **Week 0**: Invitations to participate sent to consultees and commentators; company invited to submit evidence

- **Week 6**: NICE receives evidence submission from company and sends to the ERG; Consultees and commentators receive company submission (executive summary) and are invited to submit responses

- **Week 7.5**: ERG submits clarification questions to NICE

- **Week 8**: Company receives clarification question from NICE

- **Week 9**: Company submits clarification response to NICE

- **Week 10**: Consultee and commentator statements received

- **Week 12**: ERG submits report to NICE

- **Week 13**: Factual error check of ERG report by company

- **Week 14**: Committee papers sent to attendees

- **Week 15**: Committee meeting

- **Week 16 onwards**: Consultation (if required), guidance development and appeal, as in STA process
Evidence submission from the company

4.2 NICE invites the company to provide an evidence submission using a detailed ATA template. The deadline for receipt of the evidence submission is at least 6 weeks from invitation. After receiving this, NICE sends it to the evidence review group (ERG) for review.

Evidence review

4.3 The ERG prepares a report on the clinical and cost evidence in line with relevant sections of NICE’s guide to the methods of technology appraisal. The deadline for receipt of the report is at least 6 weeks after the ERG receives the company submission.

4.4 The ERG must submit any requests for clarification within 1.5 weeks of receiving the company submission. NICE then sends the clarification requests to the company, and the company has 5 working days to respond.

Engagement with non-company consultees and commentators

4.5 NICE invites non-company consultees and commentators to comment on whether the technology under consideration provides similar health benefits at a similar cost to the comparator(s) specified in the scope. Companies that have comparator technologies are also invited at this stage to state whether there are any factual inaccuracies in the evidence presented on the comparator technologies (that is, their own technologies), or whether they know of any additional evidence for the comparator that has emerged since the publication of the NICE guidance on that technology. After the company’s evidence submission is received, all non-company consultees and commentators will be sent the executive summary of the submission and a template in which to provide their comments. They will have at least 15 working days to provide their response to NICE.

4.6 Clinical experts, patient experts, non-company consultees and commentators will not normally be invited to take part in the appraisal committee meeting discussion. In exceptional circumstances, the committee chair and NICE may agree to invite clinical or patient experts to the meeting to help address specific uncertainties.
**Appraisal**

**Appraisal committee meeting to develop the recommendations**

4.7 When the appraisal committee meets it may develop an appraisal consultation document (ACD) or a final appraisal determination (FAD). The committee will be able to make a range of recommendations:

- **Recommended as an option**: a FAD will be produced.

- **Not recommended** or the **recommendation limits the use** of the technology more than the marketing authorisation or than published NICE recommendations for comparator technologies: an ACD will be produced, and a second appraisal committee meeting will be held.

4.8 In exceptional circumstances, the committee may identify such substantial uncertainties in the evidence that it is not able to recommend the technology without further information. If this happens, the committee will request additional information and analyses from the company and discuss these at a subsequent appraisal committee meeting.

5 **Appeals**

5.1 Guidance produced through the ATA process includes the option for appeal. The principles and processes for appeals will be the same as those for STAs and MTAs, as outlined in the guide to the processes of technology appraisal (see section 4).

6 **Patient access schemes and flexible pricing**

6.1 The principles and requirements for patient access schemes for ATAs will be the same as those for STAs and MTAs, as outlined in the guide to the processes of technology appraisal (see section 5).

7 **Reviews**

7.1 The review of guidance produced through the ATA process will, in general, follow the same principles and requirements for STAs as outlined in the guide to the processes of technology appraisal (see section 6). This includes the option for rapid review if a new patient access scheme is agreed within 16 weeks of
7.2 If guidance for a technology used as a comparator in an ATA is reviewed, the ATA guidance will be reviewed at the same time.

8 Tools and resources

8.1 NICE will not provide tools to support the local implementation of its ATA guidance. Therefore, resource impact tools or statements will not normally be published. This is because technologies appraised through the ATA process are not expected to cause substantial increases in resource use in the NHS.
Appendix 2:

**Abbreviated technology appraisal: methods addendum**

1 **Introduction**

1.1 This document provides an overview of the methods used in the National Institute for Health and Care Excellence (NICE) abbreviated technology appraisal (ATA) process. It shares and builds on the general methodological concepts outlined in NICE’s guide to the methods of technology appraisal (2013) for the single technology appraisal (STA) and multiple technology appraisal (MTA) processes. This document should be read alongside the guide.

1.2 This document does not describe the processes used to develop guidance. Information on the process of doing an ATA is in appendix 1 to this document.

2 **Clinical effectiveness and cost-comparison analysis**

2.1 The methods for the appraisal of technologies suitable for ATA, in general, follow the existing NICE reference case (as described in NICE’s guide to the methods of technology appraisal, section 5), except for the economic evaluation: the preferred form of economic evaluation is a cost-comparison analysis (see section 2.4–2.6), a cost–utility analysis is not required. Other aspects of the NICE reference case that apply solely to the cost–utility analysis (for example, modelling of quality-adjusted life years [QALYs] and discounting of health effects) are therefore not applicable to ATA and may be disregarded.

2.2 The guiding principles for the clinical evidence base, and the types of evidence considered relevant for the ATA programme, are outlined in NICE’s guide to the methods of technology appraisal (see sections 3.2, 3.3 and 5.2). The evidence requirements of clinical effectiveness for the ATA process are the same as those defined for the STA and MTA processes, through the outcomes defined in the scope for the appraisal.

2.3 A systematic review of published, relevant evidence on the cost effectiveness of the technology is not needed. However, possible data sources used for parameters in the cost-comparison analysis (such as acquisition or monitoring costs) should be identified systematically to avoid selection bias in the choice of
sources, taking into account any relevant considerations in recent published NICE guidance for the same indication.

2.4 In ATA, a cost-comparison analysis is the preferred form of economic evaluation. This is a simple analysis of the costs and resource use associated with the intervention compared with that of the comparators. The effects of the intervention and comparator on health outcomes are captured in the clinical effectiveness evidence, and are not included in the cost-comparison analysis.

2.5 The cost-comparison analysis should capture the relevant cost differences between the intervention and comparator(s), over a time horizon that is long enough to reflect all important differences between the technologies being compared. As a minimum, this must include the acquisition costs of the technologies. If other relevant differences in costs or resource use are identified, these may also be included – for example, drug administration, monitoring and healthcare appointments. If there are relevant differences in health outcomes that affect resource use (for example, managing adverse events), these may be included in the cost-comparison analysis; however, it is noted that substantial differences between technologies in costs that directly relate to health outcomes (such as adverse events) are unlikely to be consistent with a conclusion that the intervention and comparator provide similar health benefits, and any such cost differences must be clearly justified. It is expected that a lifetime time horizon will not normally be necessary in the ATA process. Whenever possible and appropriate, cost data and data sources should be consistent with any corresponding data and sources that were considered appropriate in recent published NICE guidance for the same indication.

2.6 When a technology has a patient access scheme that has been agreed with the Department of Health or when there is a nationally available price reduction (for example, through contracts negotiated by the NHS Commercial Medicines Unit), these should be included in the base-case analysis to best reflect the prices relevant to the NHS.

**Exploring uncertainty**

2.7 Appropriate methods of exploring uncertainty will, in general, include the use of clinically relevant scenario analyses and univariate sensitivity analyses to identify
parameters that may have a substantial impact on the cost-comparison results. A probabilistic analysis is not needed for the cost-comparison analysis.

**Impact on the NHS**

2.8 Technologies appraised through the ATA process are not expected to cause substantial increases in resource use in the NHS. Information on the net impact of the implementation of the health technology on the NHS (and personal and social services, when appropriate) is therefore not needed in an ATA.

### 3 Structured decision-making

**Appraisal of the evidence**

**Structured decision-making: clinical effectiveness**

3.1 The appraisal committee’s judgements on clinical effectiveness in an ATA take account of the following factors:

- The nature and quality of the evidence derived from:
  - the company submission
  - the review of the company submission by the evidence review group
  - the views expressed by non-company consultees and commentators during the engagement phase including experience of the technology in clinical practice and the patient’s perspective on the benefits and adverse outcomes associated with the technology.

- Evidence of whether the new technology provides similar or greater health benefits, compared with the comparator, taking into account all relevant outcomes (including both clinical effectiveness outcomes and adverse effects), for example:
  - evidence that the clinical effectiveness of the intervention is the same or greater than the comparator
  - absence of evidence indicating that the intervention is less effective than the comparator
  - evidence of whether any apparent differences in effectiveness are clinically meaningful
  - evidence on the clinical or biological plausibility of similarities or differences in health benefits
whether there is sufficient certainty that the technology produces similar or significantly greater clinical benefits.

- Uncertainty generated by the evidence.
- Consideration of both the evidence submitted for licensing and that relating to effectiveness in clinical practice.
- The possible differential benefits or adverse outcomes in different groups of patients.
- The position of the technology in the overall pathway of care and the alternative treatments that are established in clinical practice.

**Structured decision-making: cost-comparison analysis**

3.2 In an ATA the appraisal committee will consider the cost-comparison analysis of the intervention relative to its comparators. The committee’s judgements on the cost-comparison analysis are likely to be influenced by the following factors:

- The robustness and appropriateness of the approach to cost comparison. In particular, the committee considers carefully whether the analysis reflects the decision problem.
- The uncertainties around the assumptions on which the analysis is based and the results from relevant cost comparison scenarios and univariate sensitivity analyses.
- The possible differential costs in different groups of patients.
- The committee’s preferred analysis, taking into account all of the cost comparison evidence submitted.
- The likelihood of decision error and its consequences.

**Decision-making**

3.3 The appraisal committee’s main considerations when making its decisions are:

- Health benefits to patients: whether the technology provides similar or greater health benefits to patients, compared with technologies recommended by NICE for the same indication, measured by relevant outcomes.
• Cost to the NHS: whether the impact of the technology is likely to result in similar or reduced overall costs to the NHS compared with technologies recommended by NICE for the same indication.

3.4 The appraisal committee makes its recommendations based on the clinical and economic evidence, informed by contributions from the company, the evidence review group, patient and professional organisations, comparator companies and other consultees and commentators. The appraisal committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to form the basis of robust recommendations. If there are any uncertainties the appraisal committee makes informed judgements and describes its uncertainties in the ‘committee discussion’ section of the guidance.

Table 1: Committee recommendations

<table>
<thead>
<tr>
<th>Decision</th>
<th>Type of recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology provides similar or greater benefits at a similar or lower cost than the comparator(s)</td>
<td>‘Recommended as an option’</td>
</tr>
<tr>
<td>Technology provides less health benefit at a similar or greater cost or Technology provides similar health benefits at a greater cost</td>
<td>‘Not recommended’</td>
</tr>
</tbody>
</table>

3.5 Consultation takes place only if the appraisal committee does not recommend use of the technology, the recommendation limits the use of the technology more than the marketing authorisation or than published NICE recommendations for comparator technologies. This may happen if the technology provides similar health benefits at a similar or lower cost to the comparator only in a subgroup of the population.

3.6 In exceptional circumstances, the committee may identify such substantial uncertainties in the evidence that it is not able to recommend the technology without further information. If this happens, the committee will request additional information and analyses from the company.
### Appendix 3: Risk assessment

<table>
<thead>
<tr>
<th>Risk</th>
<th>Mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection of the ATA process for individual topics may be based on limited information – inappropriately selected topics may be delayed and require additional resources.</td>
<td>The proposal defines broad, flexible selection criteria; the decision to follow the ATA process will be made on a case-by-case basis, using as much information as possible and taking into account information from companies and key stakeholders (including any case made by the company and, if known, the price of the technology). In addition, the process is able to accommodate requests to route topics to ATA at several stages, to maximise flexibility.</td>
</tr>
<tr>
<td>Companies may not be enthusiastic to follow the process in some cases.</td>
<td>There will be a consultation with key stakeholders to maximise engagement with the process and identify any concerns. For individual topics, careful negotiation with the company during the topic selection and scoping stages will maximise the likelihood that the company understands the most appropriate appraisal process for its product.</td>
</tr>
<tr>
<td>Stakeholders may perceive that ATA is a less-intensive appraisal process and therefore unfairly advantages less-innovative products.</td>
<td>Technologies appraised through the ATA process will not gain an advantage in the timing of market access (because the guidance will be published within 6 months of the marketing authorisation, as in STA), and the decision-making process within ATA is no more or less rigorous than an STA. Consequently, the benefits of the ATA process for some technologies are unlikely to outweigh the commercial advantages of being the first product to the market.</td>
</tr>
<tr>
<td>Clinical experts, patient experts, non-company consultees and commentators will not normally be invited to take part in the appraisal committee meeting discussion – some uncertainties may be more difficult to address.</td>
<td>Experts’ views will be actively sought throughout the scoping and engagement processes, and the submission templates will be carefully tailored to capture the key information required.</td>
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Appendix 4: Comparison of ATA and STA

STA

Scoping and topic selection
Topics identified from a variety of sources
NICE develops draft scope, consults and finalises scope
Referral sought from Department of Health
Topics eligible for ATA if they meet criteria

Evidence submission and review
Invitation to participate
8 weeks
Company and consultee submissions
- Clinical effectiveness
- Cost effectiveness: cost–utility
8 weeks
ERG review
21 weeks
Factual error check

Appraisal committee meeting: structured decision-making
Appraisal of clinical effectiveness evidence
- full range of evidence
Appraisal of cost effectiveness evidence
- cost–utility analysis and the incremental cost-effectiveness (cost per QALY)

Consultation, subsequent committee meetings and appeal
As described in the STA process guide, if required

ATA

Scoping and topic selection

Evidence submission and review
Invitation to participate
6 weeks
Company submission
- Clinical effectiveness evidence
- Cost effectiveness: cost-comparison
15 weeks
ERG review
3–6 weeks
Engagement with non-company consultees
Factual error check

Appraisal committee meeting: structured decision-making
Appraisal of clinical effectiveness evidence
- full range of evidence, including evidence for similarity vs comparator
Appraisal of cost-comparison analysis – relative costs of intervention and comparator

Consultation, subsequent committee meetings and appeal
As described in the STA process guide, if required
Appendix 5: Contributors to proposal

ATA working group:

- Jane Adam – Chair of committee A and chair champion for ATA
- Martyn Burke, technical analyst
- Zoe Charles, technical adviser – working group lead
- Bernice Dillon, technical adviser (medical technologies evaluation programme)
- Ellie Donegan, technical adviser – working group lead
- Lori Farrar, project manager
- Elisabeth George, associate director
- Caroline Hall, technical analyst
- Cathryn Hall, project manager
- Jasdeep Hayre, technical analyst
- Bijal Joshi, project manager
- Vicky Kelly, technical analyst
- Liga Kremere, administrator
- Jeremy Powell, project manager – process lead
- Jenniffer Prescott, associate director
- Sheryl Warttig, technical adviser (medical technologies evaluation programme)
- Ian Watson, technical analyst – methods lead

ERG representatives who contributed to the proposal development:

- Eva Kaltenthaler, Abdullah Pandor and Matt Stevenson; School of Health and Related Research (ScHARR), University of Sheffield
- James Mason and Norman Waugh; Warwick Evidence
- Nerys Woolacott; Centre for Reviews and Dissemination and the Centre for Health Economics, York
ITEM 6

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CITIZENS COUNCIL

The Board is asked to:

- receive the 2015 Citizens Council meeting report and note the public comments received
- approve the report to be published on the NICE website.

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

1. This paper submits the 2015 Citizens Council meeting report, together with public comments received, for consideration by the NICE Board ahead of publication on the NICE website.

About the Citizens Council

2. The Citizens Council is a panel of 30 members of the public. It provides NICE with a public perspective on challenging social and moral issues that NICE has to take into account when producing guidance.

3. The Citizens Council does not develop guidance, nor does it input directly into individual pieces of guidance that NICE produces.

4. The Citizens Council is managed by the Science Policy and Research programme with input from other directorates, particularly the Public Involvement Programme. The Council operates through a two-day meeting, held approximately once per year. Each two-day meeting focuses on a single topic, put to the Citizens Council in the form of a question.

5. As the purpose of the Council is to explore moral and social issues, the topic question does not seek views on a particular NICE decision or product but rather asks, in more general terms, about the social values and principles that NICE should consider when conducting its business.

The 2015 Citizens Council meeting report

6. The Citizens Council met in November 2015 to consider the question: “What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care?”

7. This important topic has direct relevance to guidance production, in circumstances where evidence is limited but where there is potential to develop recommendations that enhance the efficiency and effectiveness of care. Randomised controlled trials (RCTs) are considered the gold standard for establishing causal relation between a particular treatment, therapy or action and outcome, and for measuring the size of the treatment effect (efficacy). Whilst most NICE programmes indicate that data from RCTs is preferred, there are occasions where other types of data are required; for instance for extrapolating outcomes over a long time horizon, or when there is a need to confirm that the trial results apply to the ‘real life’ population for which the intervention is being considered. There are also circumstances when RCTs are not possible or no
data are available, for example in the social care sector or in the case of treatments for very rare conditions where patient numbers are low.

8. Collecting data on how well things work in real world settings could provide evidence that reduces uncertainty about effectiveness, providing data are analysed appropriately and care is taken to minimise biases. Such analyses remain methodologically challenging. NICE is engaged in a number of activities to establish best scientific practice for how and when this kind of evidence should be used for evaluating treatments or interventions, either alongside or instead of evidence from traditional RCTs. However, there are also a number of ethical and practical issues that need to be considered when using information derived from personal care records, including questions to do with privacy and consent, issues about the benefits of patients and service users contributing information for the good of society as a whole, and considerations about how all of this impacts on access to care.

9. Consideration of these issues is important for shaping future systems for collecting and using information direct from care records, but also relevant for mechanisms that NICE is already using to gather real world data, such as disease registers. NICE’s Research Governance Policy and Information Governance Policy cover these activities.

10. The overall aim of the 2015 meeting question was to develop a better understanding of such ethical and practical issues, and the underlying attitudes that exist in relation to them. In order to respond to the topic question, the aims of the meeting were to:

- consider the strengths and limitations of using information from personal care records for evaluating treatments;
- identify and explore the ethical issues which would need to be considered in order to collect and use information from personal care records;
- consider which circumstances, if any, it would be reasonable to make access to a treatment within an evaluation scheme only possible for those patients or service users who consent for their data to be used;
- examine how to approach reconciling a social duty for the greater good and individual rights to privacy in the context of evaluation schemes.

11. A report of the meeting (Appendix 1) was prepared by an independent report writer and reviewed by Citizens Council members.

Public comments received

12. The draft report was made available for public comment between 24 February and 9 March 2016. Key stakeholders were invited to respond, including colleagues from the National Information Board (NIB), the Health and Social Care Information Centre (HSCIC), the Office of the National Data Guardian (NDG) and
Dame Fiona Caldicott. The questions we asked during the public comment period were:

- Do you have any comments about the difference in attitudes towards data collection within health and social care contexts, compared with data collection in other ‘every day’ contexts?

- Do you have any comments about the difference in attitudes towards pharmaceutical companies compared with non-profit organisations?

- Do you have any further comments on ethical and practical requirements for collecting and using information from personal care records?

- What do you think about the Council’s conclusions around allowing access to care not yet fully approved only to those willing to share their data?

- What do you think about the Council’s discussions about reconciling ideas of social duty for the greater good and individual rights to privacy?

- Do you have any general comments you would like to make?

13. We received two responses, which are included in Appendix 2. One response was from Dame Fiona Caldicott and one from an academic researcher. The two respondents were generally supportive of the report and felt its conclusions were in line with other work in this area. Particular noteworthy comments were:

- In relation to the Council’s conclusions around allowing access to care not yet fully approved only to those willing to share their data: the importance of being explicit that this is in the context of ‘early’ access only, to ensure safety monitoring, and not care more generally. The importance of this distinction is illustrated in both responses received.

- For each project NICE should:
  i. demonstrate a clear public benefit to the collection of the data
  ii. ensure that data security and consent is robust
  iii. be fully transparent over the arrangements in place to share, analyse and communicate the data.

- The importance of ensuring NICE’s understanding and use of terminology such as ‘anonymisation’ is consistent with others. Dame Fiona notes that the Information Commissioners Office (ICO) is the official regulator on this subject and that reference to the ICO’s Anonymisation Code of Practice would be helpful to achieve consistency.

- Dame Fiona noted that the reports’ conclusions align and add to the work being done by the office of the National Data Guardian.
Next steps

14. Following Board approval, the final report will be published on the Citizens Council pages of the NICE website.

15. NICE will consider whether any updates to relevant policies are required to reflect the Citizens Council output contained in this report.

Recommendations/Considerations for Board

16. The Board is asked to:

- receive the 2015 Citizens Council meeting report and note the public comments received
- approve the report to be published on the NICE website

Professor Carole Longson
Director, Centre for Health Technology Evaluation
May 2016
What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and delivery of care?”

NICE Citizens Council
Meeting report: 10-11 November 2015
**Foreword**

Once again, the Citizens Council has approached the meeting question with enthusiasm, this year examining the range of ethical and practical issues that relate to using data derived from personal care records for research and the evaluation of care interventions.

The use of personal care records is controversial and has been subject to much national debate. From NICE’s perspective, we are looking to collect information with the consent of patients and service users to resolve uncertainties about the effects of interventions in order to produce national guidance. Whilst this approach is conceptually straightforward and is being explored as part of the Accelerated Access Review and refresh of the Cancer Drugs Fund it presents a number of challenges. Work is ongoing to address the methodological challenges; for example, it is difficult to identify cause and effect if sicker patients are given new drugs because they haven’t responded to the older ones, or if patients are taking other medications.

The starting point for this Council meeting was therefore not whether care information should be aggregated and analysed, as this is a governmental policy, but what ethical and practical issues need to be considered when arrangements are put in place to collect data for analysis. In particular, we wanted to explore the Council’s attitudes and beliefs underpinning issues of privacy and consent, the benefits of patients and service users contributing information for the good of society as a whole, and how all of this impacts on access to care.

This report from the 2015 Citizens Council meeting provides some interesting insight and highlights the complex and sometimes conflicting attitudes that exist. The Council’s discussions reveal different attitudes depending on the context in which information is collected. There was a clear disconnect between members’ concerns about the personal information that is collected by retail loyalty cards and internet browsing, which by default companies are permitted to sell-on, and that which is compiled in a health or care setting. Many of the Council’s conclusions suggest that although they would be happy to contribute their own information, their concerns centred around the sufficiency and transparency of the control procedures in place when information is collected automatically by the system. The reasons for this dichotomy are not clear and could be explored further in order to more fully understand the underlying values guiding views on this.

As to be expected, Council members were concerned about the security and robustness of the data collection and analysis processes. They were particularly concerned about the raw data, however anonymised, being given or sold onto third parties who could then profit from it. The raw data were seen to be the ‘crown jewels’; in one Council member’s words “Once you’ve given your data, you can’t get it back.” There was less concern about the results of any requested analyses being made available. There was also limited awareness about how information from care records is currently used; many thought such data was already pulled together and analysed routinely by the health and care systems to improve care.
The biggest challenge, particularly when researching new interventions of uncertain benefits, is ensuring all patients can be safely monitored and the data collated as efficiently as possible. This would lead us to make data provision a condition of access. On this issue, the Council identified that factors such as how many people want to access the treatment and the type of organisation running the research would need to be considered.

There was an apparent tension between the ‘social duty’ to provide information, particularly given the interventions are being publically-funded, and the individual rights to privacy. Most council members felt that in a publically-funded system the ‘greater good’ should prevail as it would benefit all users. Freedom of choice should however be maintained which could be taken account of when choosing whether or not to receive that intervention.

The Council’s discussion highlighted the need for NICE to be very clear about what its role is, whether that is as a receiver of analyses derived from care records, or receiver of data themselves. In either case NICE has a responsibility to ensure all necessary governance mechanisms are in place, either directly or through collaborators who provide analyses to NICE. It is also important to determine where the actual data should lie. For example, could a system be set up that allows data to be collected and held in one location, with specific analyses to be undertaken on request? Above all, this report of the 2015 Citizens Council meeting demonstrates that it is essential that any national plans take the public views into account.

Going forward, the Council’s discussions and conclusions will not only feed into the development of methods and processes for NICE programmes, alongside scientific findings relating to the use of observational and real world data, but will also support the development of the NICE Observational Data Unit that supports NHS England’s Commissioning through Evaluation work. Furthermore, this report contributes to broader debate within the health and social care system.

Thank you to the Citizens Council members who attended the two-day meeting to dissect and debate the question we set for them.

Sarah Garner
Associate Director
Science Policy and Research, NICE
Executive summary

Individual privacy, confidentiality of personal information, data protection, transparency, the public benefit of research and good scientific practice ensuring the accuracy and validity of research findings are key ethical concerns, according to the NICE Citizens Council, when it comes to the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care.

Complete transparency on how information from personal data will be used and who it will be shared with, effective informed consent procedures and strategies to ensure complete anonymisation of personal data, data security and research governance are needed if NICE uses information derived from personal care records for its work in the future.

These were the main conclusions and recommendations from the 2015 meeting of the NICE Citizens Council, a panel of 25 members of the public that provides NICE with a public perspective on challenging social and moral issues that the Institute takes into account when producing guidance. The Council met to discuss and answer the question:

What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care?

This question was asked to explore the use of information from care records as part of the evaluation and research of new treatments and approaches to delivering care. This is an important topic of direct relevance to producing guidance in circumstances where research from more traditional sources, such as randomised controlled trials, is limited or absent, such as for new treatments to treat rare conditions, and to provide information on ‘real world’ populations.

The Council explored the question by thinking about the benefits and concerns in the collection and use of anonymised personal data in everyday situations and then in health and social care, before identifying ethical issues from the perspective of the care user/service user, the care provider, the research organisation and society as a whole. They considered whether there are circumstances when access to interventions being researched in care should be limited to patients consenting to share their data and finally weighed up how sharing personal care data for health and social care research fitted within the values of a social duty for the greater good and an individual’s right to privacy.

At the end of the meeting just over half of the members of the Council said they would have no concerns about NICE using anonymised data derived from personal care records. The remainder had concerns about the use of such data, including its use by NICE. These concerns related to use of data from personal care records generally, regardless of the organisation using it for research.
They centred on transparency about how data is used and how it might be used in the future; the potential for data to be sold on to other organisations and used for profit and for purposes other than research; ensuring research is conducted according to good scientific practice and data is used to benefit society; and data security.

To ensure people fully understand use of data from personal care records for research the Council suggested that NICE should hold open days and provide information resources designed to ensure people understand what data is being used for, precisely how it will be used and providing reassurance that personal care data will not be passed on or sold to other organisations. Consent procedures should be audited and an ombudsman should oversee the governance of the use of personal care information for research. The Council recommended that appropriate systems and good working practices should be put in place to ensure a consistent approach to research planning, data capture and analysis.

**Key outcomes from the meeting**

**The strengths and limitations of using information from personal care records for evaluating treatments**

The Council considered a main strength of this approach may include better research outcomes because the effects of the intervention being tested are monitored by each patient or service user’s regular care provider, who has greater knowledge of their individual circumstances. Other strengths included greater convenience and potentially lower cost to the patient; better continuity of care; and data being collected from a more representative population. Limitations identified were lack of time and research expertise among GPs and other care staff; risk of human error and lack of accuracy in data collection and entry; concern about security of data transfer and security; and concerns about the efficacy and safety of the intervention being researched.

**The ethical issues that would need to be considered in order to collect and use information from personal care records**

- **Confidentiality, privacy and data security** were identified as key ethical concerns, with questions around whether data from personalised care records can ever really be anonymised and who might have access to data.
- **Transparency** was considered a very important issue and that patients/service users should be informed about exactly what is being done with their data, what else might be done with their data, and what might happen in the future.
- **The public benefit of research** was identified an important ethical concern. The Council considered it essential to focus on research that makes the best use of resources and ensure that research is open to all members of society, with no discrimination.
- **Good scientific practice** was also considered an ethical issue, with concern about the accuracy and validity of research design and data analysis. The Council felt that research that does not produce any useful findings because it is not scientifically robust is a waste of time and resources.

Citizens considered there was a difference in the level of concern for these ethical issues, depending on the type of organisation doing research, with potentially more trust that the NHS or an academic group would have greater openness about the aims of research and more focus on research for public benefit than for-profit organisations. Protection and confidentiality of personal data should be a top priority for all types of organisations, the group agreed.

**Circumstances, if any, in which it would be reasonable to allow access to a treatment not yet approved for routine use only to those patients or service users who consent for their data to be used as part of an evaluation scheme**

Members of the Citizens Council were sharply divided on this issue. Some felt there should be no circumstances that would justify opting out of sharing data, mainly because to do so would limit the accuracy and validity of data collected as part of an evaluation scheme, which is of particular importance when monitoring the safety of new interventions. They also considered it only fair that people receiving treatment or care as part of research should provide their data to allow progress in care delivery. However, some felt that access to treatments or care being evaluated should never be restricted only to those consenting to share their data. They considered that this would be taking away people’s freedom of choice and would be coercing people to take part in research in return for receiving treatment, which they felt was not appropriate in a care situation.

**Reconciling a social duty for the greater good and individual rights to privacy**

Citizens Council members considered social duty and the greater good was of much greater importance that individual privacy when it came to the use of data from personal care records for research. There was clear recognition that this was necessary to make advances in health and social care research and for the good of society as a whole. However, there was also a desire to maintain individual freedom of choice, which was also considered a mark of a healthy society.
Introduction and background

What is the Citizens Council and how does it contribute to NICE’s work?

The Citizens Council is a panel of 30 members of the public that provides a public perspective on challenging social and moral issues that NICE needs to take into account when producing guidance. This is achieved through a two-day meeting usually once a year, focusing on answering a question that helps elicit Council members’ views, opinions and concerns about a particular issue that NICE needs to understand in its work. The main findings are used to inform the principles set out in NICE’s Social Value Judgements document and to guide specific areas of NICE’s work.

The question addressed at the 2015 Citizens Council meeting was:

What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care?

This question was asked to explore the use of information from care records as part of the evaluation and research of new treatments and approaches to delivering care. This approach to obtaining information is an important topic of direct relevance to producing guidance in circumstances where there is potential to develop recommendations that can enhance the efficiency and effectiveness of care but where research from more traditional sources, such as randomised controlled trials (RCTs), is limited.

Randomised controlled trials are considered the gold standard for establishing a causal relationship between a particular treatment or action and an outcome and for measuring the size of the treatment effect (efficacy) and assessing side-effects. RCTs that are well designed and carried out provide an accurate answer to the question they are setting out to answer within the group of people who take part (in research terminology, high internal validity) but they may sometimes be limited in the extent to which findings can be generalised to a wider group of people in ‘real world’ practice (external validity).

People in ‘real world’ care may be more varied in their characteristics, such as having a wider age range or more comorbidities, compared to those included in clinical trials. In these circumstances data from sources other than RCTs, such as from observational studies or anonymised data from care records, may provide useful information. However, care must be taken when interpreting outcomes from these types of data because it is less straightforward to minimise potential bias than in RCTs.

Most NICE programmes use evidence from RCTs to evaluate the effectiveness and cost-effectiveness of a treatment or approach to care but there are some situations where other types of data are required, such as extrapolating outcomes over a long period of time (many RCTs are
relatively short in timescale) or where there is a need to confirm that trial results apply to the ‘real life’ population for which a particular treatment or intervention is being considered. There are also circumstances where RCTs are not possible or no data are available or are very limited, for example with social care or for treatments for rare conditions where there are very limited numbers of patients.

Collecting and analysing data on how treatments and care work in real world settings can provide evidence that helps to reduce uncertainty about their effectiveness, as long as findings are analysed appropriately and care is taken to minimise potential biases. However, there is currently limited consensus about the role of these types of data and NICE, together with other organisations, is working to establish how to make use of these data and in what circumstances such data may and may not be useful.

**How will NICE use outputs from the meeting?**

The meeting enabled Citizens Council members to explore several questions on the use of anonymised data derived from care records that NICE needs to answer for its work. NICE is currently engaged in several activities to establish best scientific practice in the use of observational data and to understand its potential limitations. Deliberations from the meeting will enable developments in NICE methods and processes to take account of citizens’ views and ensure these are integrated with other sources of information.

The ethical and other issues that need to be considered and resolved in order to use observational data to assess the effectiveness of interventions in real life is currently a key issue for the NICE Observational Data Unit and the NHS England Commissioning through Evaluation work that it is supporting. Citizens Council deliberations will inform governance arrangements and NICE’s position in discussions with the numerous stakeholders interested in the use of observational data.

A particularly challenging and timely ethical question in this arena is whether there are any circumstances where it would be reasonable for treatments that are not yet fully approved and are being made available as part of an evaluation scheme to be available only to those patients who consent to their data being collected and analysed. There may be a greater role in the next few years for patient access schemes linked to recommendations contingent on further research to support earlier patient access to medicines addressing currently unmet need. It is essential that citizens’ views are incorporated into adapting decision frameworks to take account of these developments.

Understanding more fully the issues involved in reconciling social duty for the greater good and individual rights to privacy and choice, is an issue of broad importance for NICE and other healthcare system partners. Outputs from discussions on this balance at the Citizens Council meeting will add to the understanding of citizens’ views and support public engagement on the use of real world data in assessing health and social care interventions.
How did the Council explore the question?

The Citizens Council 2015 meeting was organised to guide Council members in a logical way through the different elements and issues underpinning the question being addressed: **What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care?**

Council members started by considering their initial thoughts on the pros and cons of using anonymised data from personal care records. They then thought about the benefits and concerns for the individual and for the organisation in everyday examples of collection and use of anonymised personal data, such as store loyalty cards, before exploring examples in health and social care.

The group identified the ethical issues they felt were associated with use of data from personal care records, from four different perspectives: the care user/service user and his/family, the care provider, the research organisation and society as a whole, before suggesting practical solutions to solve these concerns. The Council then explored the implications of limiting access to interventions being researched in care to only those patients / service users who agree to their share data for research. As a last step they weighed up how sharing personal care data for health and social care research fitted within the values of social duty for the greater good and an individual’s right to privacy.

Discussion encouraged Council members to think why they held the opinions they expressed and what lay behind their conclusions. Throughout the meeting members of the Citizens Council were asked to challenge themselves by asking why they held the views they expressed. Experts in research design and ethics, research participants and researchers involved in using personal care data shared background information, ideas, insights and personal experiences to provide further ‘food for thought’ for Citizens Council members to consider in their deliberations.
Understanding the meeting topic

Setting the scene

Maggie Helliwell, a non-executive director with NICE and previously a GP for 34 years, set the scene for what the Citizens Council members were being asked to consider by tracing how the collection of personal care data has changed since she first started working in general practice in 1981 and the opportunities and challenges offered by growing computerisation of patient records.

“I want to take you back to 1981,” she said, taking Council members back to her surgery when GPs recorded information on each patient’s paper notes. “There were no computers and no mobile phones. The computer was the GP’s brain, where we collected and analysed information about each patient,” she explained, adding that continuity ensured this knowledge built over time.

“Times change. Patients’ paper notes are now on computer. A patient’s record is now continuously updated by GPs, other practice staff and by hospital clinicians,” Dr Helliwell told the meeting. She traced developments in the use of routine care data for research and how this could add to what is provided by randomised controlled trials and the care of the individual patient. “Computerised patient care records provide an incredibly rich data source; a huge tapestry of information for every patient,” she explained.

Recognising that people have concerns about the potential security and use of their data, she explained some of the processes in place for ensuring data is kept confidential, including her role as Caldicott guardian responsible for data governance and protection at her local hospital. Outlining some of the benefits of computerised data to individual patients, she noted that test results can be rapidly shared with clinicians managing their care to inform decision making and multidisciplinary teams, such as those caring for people for cancer, can share information easily and quickly.

NHS England’s care.data project, in which all primary care data would be aggregated across the country and potentially made available to organisations other than those working in research, has changed the situation, Dr Helliwell suggested, adding that people would have to opt out of data sharing. She noted that a survey on this issue revealed a huge spectrum of opinions, ranging from people thinking data were already shared with outside bodies to those with concerns about data security and sharing.

“But we compartmentalise our attitudes to sharing data, using Facebook and Twitter with little thought of what happens to the information they collect,” she challenged, concluding, “Where does that leave us with using care data for research? That is what you must consider over the next two days.”

Introducing the question and its importance to NICE

Professor Sarah Garner, Associate Director for Science Policy and Research, NICE. Professor Garner explained to the Citizens Council why NICE needs to consider the use of anonymised data derived from personal care records in its work and what these data would add to
the current evidence that NICE uses to make its decisions. “We are trying to look at where NICE needs to be in five years’ time. A ‘tsunami’ of data is being created by the NHS and social services. NICE needs to look at what we should do with this information and we are asking you for your advice on this,” she told Council members.

After recapping NICE’s role in providing national guidance and advice to improve use of health and social care, she underlined the fact that all NICE guidance is based on the best evidence available, including expert input and patient and carer involvement. She then introduced the question being addressed by the meeting – What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care? – and defined key terms:

- **Anonymised information**: information that has had all personally identifiable data (such as name, address or full date of birth) removed.
- **Personal care records**: an official record of a person’s health or social care history, such as their patient record held by a GP or a record health by their social care provider.

Detailing how these data are used in research, she explained that anonymised information from many personal care records is gathered together into a separate set of data, which researchers then view without having full access to each individual care record.

Why does this matter to NICE? Professor Garner explained the importance of good quality evidence in reducing uncertainty about well a treatment works and helping to manage risks and noted that evidence is created by collecting and analysing data. In the traditional ‘hierarchy of evidence’ randomised controlled trials (RCTs) are considered the gold standard but, although they have many strengths (careful selection of patients, random allocation to the new treatment being tested or the control and relatively straightforward analysis), there are also limitations, and other types of data can provide necessary supplemental information relevant to how the intervention is used in practice. RCTs are also not possible for testing certain kinds of treatment or interventions, for example surgery.

Is there another way? A lot of data is already recorded as part of routine care providing information on how people use and respond to treatments and interventions in real life. Analysis is more complicated than for RCTs but can be done. Professor Garner gave the Citizens Council members an example to illustrate the difference between using evidence from a randomised controlled trial and from observational data for a new drug to lower blood pressure during pregnancy.
The pros and cons of using data derived from personal care records

Using Professor Garner’s example, the Citizens Council discussed the pros and cons of using data from anonymised personalised care records compared to those for a randomised controlled trial. Working in small groups they considered three different people’s perspectives: the service user; the doctor caring for the patient; and the researcher.

For the service user, Council members focussed particularly on the burden to the individual, the quality of their care, individual privacy, data security and the validity of the research approaches. Potential disadvantages of taking part in an RCT included time, cost (including travel), having to take time off work and the difficulty of travelling in later stages of pregnancy. Potential advantages of taking part in research in usual care included ‘no duplication of effort for the patient,’ with all data being collected at routine visits. Discussion drew on personal experience of attending clinics during pregnancy and some people’s experience of taking part in research studies that were not part of routine care.

In terms of quality of care, council members considered that an RCT might have a more specific focus than that achieved in usual care so a woman’s blood pressure and the treatment she is given may be monitored more carefully. They also thought that any problems might be dealt with more quickly at a research centre and that a woman on a research study might receive better care overall. In contrast, they considered a potential downside of the new drug being tested in usual care was that the doctor would be checking other things in addition to blood pressure. Delegates were also concerned that doctors already have a lot to do, so research would be adding more to what is required in routine care. Another disadvantage was the lack of continuity in care, with patients seeing different doctors each time. There was also concern about whether the efficacy and

Another way to collect data?

Imagine a new drug is being developed to lower blood pressure during pregnancy. Patients taking part in a randomised controlled trial are regularly monitored by researchers. In this case, this could include measuring blood pressure, carrying out urine and blood tests and checking the baby’s heart rate. But research could also be carried out as part of the routine care process, with a woman’s own doctor monitoring these things as part of her usual care.

This would be more efficient, less of a burden for participants and less expensive overall. But there are also drawbacks. This type of observational study may attract only the sickest patients who haven’t responded to the usual treatments, which may potentially skew results. Other factors, such as other medications women are taking, may make it more difficult to interpret the effects of the new treatment and there are more chances of mistakes with entering data. Analysis of results is therefore more difficult than for an RCT, but it is not impossible.
safety of a new drug would be properly monitored in routine care. In contrast, a potential benefit of research in usual care where a patient sees their own doctor regularly is that they will know more about them than an outside researcher.

Regarding confidentiality and security of data, some Council members were concerned about the privacy of taking part in research and whether this would be greater in usual care or within an RCT. One group member questioned whether data collected as part of usual care are “ever truly anonymised”. There was some concern about where data might potentially be transmitted.

There was also some feeling that the quality of findings might be better with an RCT – “because it’s being done properly” – than with research conducted in routine care, where doctors may lack research expertise. However, council members also recognised a disadvantage of an RCT is the limited range of patients that can take part, particularly because “most people have more than one thing wrong with them.” “Trials exclude a lot of people,” one participant noted. There was some concern about the date of birth being removed in anonymised data and whether this might lose information that could be useful in interpreting the effects of the drug being tested.

One group member had found taking part in a research study at a specialist centre very interesting but was disappointed not to have had any feedback on the eventual study findings. She said: “All that time and effort, considering I was so ill, and I have no idea what was found.” This comment underlines the value of ensuring research findings are reported back to participants, regardless of the research design used.

Council members also raised the positive effect of taking part in research in routine care that can potentially benefit other people: “You feel you are making a difference by being involved.” One delegate recalled giving extra blood during her routine pregnancy care as part of a study on Down’s syndrome. “I never noticed it, after talking it through and agreeing to take part. If it can make a difference to other women by identifying Down’s syndrome earlier ... It took no extra time.”

From the perspective of the doctor caring for the patient, Council members focused largely on the quality of patient care and the reliability of research findings. They considered that research conducted as part of routine care could place extra time pressure on doctors and this may result in the quality of patient care being reduced. However, they recognised that the continuity of care achieved through the doctor having greater involvement in the research might also be associated with better quality of patient care. The development of an effective new treatment if an RCT proved positive was considered a further benefit of this approach. However, a potential downside
of an RCT is that important information about the patient collected during the research may not be shared with the patient’s doctor, who would be providing care in the longer term.

In terms of the reliability of research findings, Council members considered that one advantage of research conducted as part of usual care is that a woman’s GP would have greater involvement. However, potential negative factors included the increased workload for GPs and the risk of human error in recording research data.

From the researcher’s perspective, Council members focussed mainly on the reliability, efficiency and cost of research and the security of data. They considered that an RCT offered the benefit of being conducted by experts in the field. Carrying out research using care records could potentially recruit more easily, drawing on the large number of pregnant women in routine care and so could be carried out more quickly and potentially reduce research costs. However, potential disadvantages of research using care records included the impact on doctors’ workload, which may affect the quality of both patient care and the research, and concern about data security.

Summary

Each group then shared their top pros and cons for each research approach from the three different perspectives they had discussed. They generally considered there were more disadvantages than advantages for both types of research approach, particularly from the patient’s perspective. The main themes that emerged in discussion were:

- the burden to the individual in terms of their costs and time, which were considered greater for taking part in a randomised trial than for research using data collected from routine care;

- the quality of care provided to the patient, which Council members thought may be higher in a trial centre than in routine care, although they considered the continuity of care and wider understanding of the patient/service user’s individual circumstances would be better in routine care;

- individual privacy and data security, which the Council identified as important but were unsure of the differences between RCTs and research within routine care in how well these issues are addressed

- the reliability of research findings, with groups considering the accuracy would be greater in an RCT but findings would be more widely applicable in research using care records; and the efficiency/cost of research, with research conducted using data from care records being more efficient and avoiding the duplication of effort that may occur in an RCT where a person still needs to see their GP for aspects of their care other than that being studied in the trial.
Issues in data collection and use - everyday examples

The Citizens Council began to explore the issues associated with the collection and use of anonymised data from individuals by considering three everyday examples of systems that collect personal data:

- Supermarket loyalty cards – Information is collected up-front on: name, address, email, gender, date of birth, and (optionally) on the number in a person’s household, their ages and specific dietary requirements. Data about shopping activity is also collected as the loyalty card and related coupons are used. The terms and conditions note that data will never be shared outside the group of businesses owned by the supermarket, but the company may use and share anonymised information outside the group.

- Healthcare retail loyalty card – This collects similar information to the supermarket loyalty card, including data about shopping activity for health related products. Terms and conditions say details will be shared only with businesses that process loyalty card information on their behalf and with companies owned by the same retail group.

- Price comparison website for home insurance – a website that asks for a wide range of information up-front (postcode, home ownership, value of home contents, previous insurance claims etc) to provide a person with quotation for home insurance.

The aim was to help people to start considering the issues in the collection and use of personal data using examples to which they could immediately relate. “We all give a lot of data away in everyday situations,” explained the meeting facilitator Pete Spriggs. “We are going to think about the pros and cons associated with this before moving on to thinking about this for examples in care situations.”

Concerns for the customer

Council members were generally much more focused on the concerns for the customer in these everyday examples and several groups started their discussions by thinking about these before considering benefits. Concerns sprang to people’s minds more immediately than benefits and the list of concerns was much longer than that for the benefits to either the customer or the organisation. Meeting participants were generally surprised and concerned about the range of personal information that the organisations they discussed were able to collect about individuals.

Council members were particularly concerned about information being shared with other organisations or sold to them without the individual’s knowledge or agreement. Although this was explained in the terms and conditions of the schemes discussed, people were concerned about the wide range of organisations that might gain access to their information, for example The supermarket might share a person’s personal information with its mobile phone and insurance companies. They thought this might lead to being offered unwanted products and services as well
as having wider consequences, such as affecting insurance premiums. In their discussion Council members drew on examples of situations where they realised their information was being shared with other organisations or sold on. For example, one person recounted renewing their car tax online and automatically being asked to join the organ donor registry.

Several people expressed a general concern about loyalty cards collecting potentially personal information without a person consciously giving it. They realised that a customer’s shopping information provided detailed information on what they bought, when and where, their spending capacity and habits and could reveal information about their family structure, diet and lifestyle. One delegate said, “Big Brother is watching you by tracking your purchases.” Another commented, “I stopping using a supermarket loyalty card a few years ago because I thought they had too much information on me.” Information given to an insurance site could be even more revealing about a person’s life and circumstances and may affect their insurance in the future. There was particular concern about how information provided for one purpose, such as food shopping, could be used for another purpose, such as a loan application.

Council members were concerned about the security of their data, including how securely it was stored and transferred and who else may be able to access information collected online, particularly after recent cases of hacking. Some were also concerned about whether an organisation’s employees could access an individual's personal information.

There were questions about how information is anonymised, and what is included in anonymised information when organisations share it with others. The underlying concern was that personal details might be shared much more widely with unforeseen results for the person who had simply signed up to a store loyalty card. There was also concern about whether information held about one person might be inadvertently shared with another if the loyalty card was in joint names. “Could your partner get information, such as on your smoking and drinking behaviour?” one Council member asked.

Several people were concerned about who owned the information that individuals supply to organisations and puzzled why they had to pay a company for supplying a copy of the information the company holds about them. One delegate asked, “Why should you pay when it’s your information?” Council members wondered whether other organisations also charged people for copies of the information they held on them.

Benefits for the customer

Members of the Citizens Council initially found it easier to think of benefits for the customer than the benefits for the organisation.
One of the most useful benefits to the customer was being offered tailored or personalised suggestions for products to buy based on the information they provided and data collected on their shopping habits. This was seen as saving customers time. Another potential benefit was ‘not being bombarded’ with information and offers not relevant to them. Receiving points and discounts with store loyalty cards was one of the more obvious benefits of store loyalty cards to customers.

Price comparison websites for insurance give people options that are personalised to their needs and may save them money. They can be convenient to use, saving people time and also reminding them of renewal dates.

Benefits for the organisation
This was an aspect Council members hasn’t really thought about before, but they quickly identified that such data collection systems provide an important way of targeting customers for particular products and special offers, with the aim of increasing sales. They suggested that a customer’s shopping information provided detailed information on what they bought, when and where, their spending capacity and habits and could reveal information about their diet and lifestyle, which could all help organisations in targeting products to relevant customers. Shopping information can also inform sales statistics, charting trends and planning. Companies can profit from the information they collect by selling it to other parts of their company or outside organisations.

Several people considered that store cards provided ‘good PR’ for companies, suggesting that they are there to help save money and for members to feel part of the organisation, building customer loyalty.

Summary
Greatest concerns lay in the potential for sharing information with other parts of an organisations or selling it on, especially if this results in data being abused, for example using information on purchasing of alcohol or cigarettes to inform insurance premiums or staff having access to information on when a person routinely shops in a store to time a burglary at their home. People were particularly concerned that information they provided for one purpose may be used, without their intention or permission, for another purpose. Council members were concerned about data security and how data is anonymised before being shared or sold on. There was also a question over who owns the data – the individual who supplies it or the organisation that collects it.

Council members were clear on the benefits to the customer of these everyday examples in helping to save them money and receive tailored offers and information, and to organisations where they facilitate customer profiling, potentially increase sales, support planning and build customer

“All of the pros to the companies collecting the data are the cons for us.”
loyalty. However, they considered there were more concerns for the customer than benefits for either the customer or the organisation in the everyday examples of data collection they discussed.

Summing up the balance between the benefits of data collection schemes to organisations against the potential concerns for customers, one Council member commented, “All of the pros to the companies collecting the data are the cons for us.”
Issues in data collection and use – health and social care

Everyday systems collecting personal health information

Having considered the pros and cons of everyday examples of personal data collection, Professor Sarah Garner asked Citizens Council members to think about whether their attitudes towards data collection are different when it concerns health and social care than for other aspects of life. She explained that health related information is already being collected outside the NHS, outlining recent research showing that Google and Facebook are the commonest websites approached by third parties to obtain information provided by people in their searches on Google or in posts they make on Facebook. This can be very revealing, for example a Google search for information about a particular health condition can potentially be traced back to an individual by the IP address unique to their computer or mobile phone number if they search using a smartphone.

She asked Council members: “What is special about health or social care data? Is the important issue who enters the data or who holds the data? And is there something in particular that is special about health and social care records that we need to take into account?”

Examples of data collection in health and social care research

The Citizens Council then moved on to consider health and social care scenarios for data collection. The scenarios varied in terms of who was collecting the data, how it was collected, the purpose of the research and the type of health or social care need to which the research related. The aim was to tease out whether there was anything different about the collection and use of data in health and social care situations, and, if so, what these were and any potential benefits and ethical concerns.

1. A company that provides telecare equipment and services to support a person’s safety and independence in their own home, such as reminders to take pills or systems calling for help if they fall, is carrying out research to test the effectiveness of their products in supporting people with social care needs to live more independently. They are collecting anonymised data about when and how the telecare equipment is used and analysing this alongside anonymised information extracted from service users’ care records about how and when they access other social care support.

2. A manufacturer of e-cigarettes is carrying out research to test the impact of e-cigarettes on public health using a password protected online data registry where members of the public can sign up to give fortnightly information on things like: how and when they have used e-cigarettes, other nicotine replacement products or regular cigarettes; their levels of physical activity; levels of alcohol consumption; their general health.

3. A drug company is developing a new drug for the treatment of epilepsy, which has been shown to be safe but the full extent of health benefits and side-effects are not known. Research is
needed to test how well the new drug works before NICE can consider recommending it for use by the NHS. This will involve the drug company giving the new treatment to the NHS to offer to patients as part of their routine care and the NHS will give the company anonymised data from the health records of patients treated with the drug so they can analyse how well it works.

4. A new surgical procedure has been developed for treating a form of cancer that, although not rare, currently has few treatments available and most patients live less than 12 months. The procedure has been shown to be safe but the full extent of the health benefits and side-effects are not known so research is needed before NICE can consider recommending it for routine use by the NHS. This research will involve offering the new procedure to patients as part of their care and using anonymised data derived from their health records to analyse how well the procedure works.

5. A pharmaceutical company wants to better understand a very rare condition before it starts to develop a new treatment. Because there are very few people with the condition (around one in 60,000 people) it is hard to recruit participants for a traditional research study. So, instead, the research will use anonymised data derived from the health records of patients with the rare condition to analyse how it is experienced and managed in real life.

6. The National Survey of Health and Development has collected information from birth to the current date on the health and life circumstances of 5,500 men and women born in March 1946. With study participants now in their late 60s, the survey offers a unique opportunity to explore the long-term biological and social processes of ageing. Participants take part in questionnaires, interviews and cognitive tests and information is also being automatically collected from their records, including hospital admissions, educational qualification, cancer diagnoses, blood samples etc.

Benefits and concerns for the patient or service user and his/her family

Citizens Council members generally found it much more straightforward to see the benefits and concerns of each research scenario from the perspective of the patient or service user and his or her family than from the point of view of the care provider, the researcher or collector of data, or society as a whole.

People drew on their own experiences and those of their family to consider the scenarios and there was some focus initially on the practical benefits and concerns of the interventions being tested in the research studies rather than the ethical concerns. For example, regarding the telecare equipment study, one group member considered that this type of support would be ‘a reassurance to me’ in the care of her mother who has Alzheimer’s disease, including reminding her to take her medication. A couple of people felt that having access to this type of service through taking part in the study would help a person stay in their own home and support their independence. E-cigarettes
could help people to stop smoking and reducing passive smoking, and could also save individuals money they previously spent on cigarettes.

Citizen Council members immediately identified the benefit of taking part in research offering a new therapy or surgical treatment to the patient in improving their health or extending their life, particularly where treatment options are currently limited. In a terminal situation or where there are currently no treatments they felt patients had nothing to lose by taking part in research offering them options and potentially everything to gain, so the benefit of sharing their data outweighed any risk. A benefit for individuals contributing health data to an ongoing survey would be feeling involved in something important, that could potentially help them, their family and others.

When the group considered concerns for the patient/service user they initially focused on the practical issues or risks associated with the intervention being tested in the study, such as whether a telephone reminder to take a tablet would be effective in getting a person to actually take their medication, the fire risk with e-cigarettes or whether their use might become a habit, and potential adverse effects of a new drug or surgical procedure.

Moving on to considering ethical concerns, a major concern was whether the patient/service user would feel comfortable for information to be shared about falls or other incidents, or about their personal habits, such as alcohol consumption or exercise. This was considered very personal information that should not be shared and there was concern that others could potentially use the information to their harm. Data security was a major concern. People were concerned about what was being done with the data collected, who the information was being shared with and where it might potentially go.

There was a tension between concerns that pharmaceutical companies potentially use data ‘for their own ends’ and the recognition that these companies are often necessary for the development of new treatments to meet unmet medical needs. Overall, people considered the benefit for people of having a new treatment outweighed their concerns about sharing data with companies.

One group member raised the issue of the consent process because they were unsure how this would happen for research carried out as part of usual care. There was also concern about what the individual would get from providing their data. “What do I get from this?” asked one participant. The group considering a new treatment for a rare condition were concerned that a patient might contribute to research by sharing their data but might no longer have access to or be able to afford the drug once it was approved and not available as part of a research study. Some Council members were concerned why so much more information was collected in some of the scenarios than seemed necessary to answer the research question.
Reflecting the **shift towards becoming more concerned** about sharing personal data expressed by several people during the meeting, one Council member said, “I’ve completely changed my mind. When I first started [the meeting] I thought ‘yeah’, but now all I can think of is cons.” Another noted, “Once you’ve given your data, you can’t get it back.” The impression was that this was mainly in relation to concerns about data security and who else may have access to a person’s data other than the researcher.

**Benefits and concerns for the care provider**

Council members considered the benefits and concerns for the care provider in very practical terms based on the interventions being researched. Benefits included having **more efficient and improved care and treatment options** for patients. However, care providers might have concerns about whether innovations, such as telecare, resulted in **meaningful improvements for users**. They might also be concerned about the risk of **previously unrecognised side-effects** with drugs being researched in routine care.

Taking part in research as part of providing routine clinical could take up doctors’ **time** and affect careers, either negatively or positively. There were also concerns about the **costs** of a new treatment or intervention and whether the service would be able to afford it.

**Benefits and concerns for the researcher or collector of the data**

Groups quickly identified the potential benefit for researchers of **making money and profiting** from a successful new development resulting from analysis of data collected, for example if e-cigarettes proved beneficial for public health or a new drug was effective. Participants felt that the company collecting data on e-cigarettes could also potentially use the database for **marketing** to target people with specific products and use the information collected during the study for promoting its products.

Organisations gain the benefit of a **valuable database of information** provided free-of-charge by research participants. They may have a **wider range of data** than collected in a randomised trial, which they could use for various purposes. In terms of research methodology, accessing data from care records would provide information on a **broader range of people more representative of the population** than in a randomised trial. Carrying out research using routine data from care records may be **cheaper** than a randomised trial.

A concern for the researcher was whether people were truthful in providing self-reported information, such as for the database on e-cigarettes and other health behaviours, or healthcare providers input data correctly, potentially affecting the **accuracy and quality** of data. “Would you say online how much alcohol you consume, or how much exercise you take?” asked one group member. Another asked, “How truthful are people when they asked to supply information about
habits such as smoking, and how might this affect research?“ There was also concern about how many people would sign up to an online database and how long they would continue to provide information without an incentive. Voluntary research projects may provide skewed data because people taking part may not be representative of the population.

Benefits and concerns for society as a whole

At a society level a major concern was transparency in what is being done with data, who the data collected is being shared with, particularly the risk of it being sold to commercial organisations, and how it is being shared, particularly in terms of how carefully personal details are anonymised. Data security was also considered a major concern. Council members thought it particularly important to ensure protection of vulnerable members of society, such as the older people, by handling their data with added security so it is not used to their detriment or to target them for marketing. There was real scepticism about the security of data. “Nothing is every totally secure,” suggested one group member, noting data leaks recently reported in the media.

Some Council members were concerned that for-profit organisations, such as pharmaceutical companies, might manipulate data to optimise their profits. There was also concerns about the value to society of the research questions that private companies might ask, with one participant questioning whether pharmaceutical companies could delay bringing out a new drug until an old one had ceased to be profitable to them. Some citizens questioned whether research with very expensive drugs in rare conditions might take resources away from treating more common conditions.

The main benefit to society in the care scenarios on data collection was considered to be new knowledge and access to new interventions or treatments being researched and its potential public health impact. For example, group members considered the telecare service, if successful, could help people to remain independent in their own homes and reduce the pressure on social services. E-cigarettes could potentially reduce smoking, and, in turn, passive smoking (particularly for children). Research programmes could free up resources for other patients and care users.

Summary

The main concerns that emerged in common for all health and social care scenarios were transparency about what is being done with the data and who has access to the data, how sharing their data might affect the individual (eg insurance premiums, family members, what may be done with their data in the future), data security and the accuracy and validity of data collected from care records. People could generally see more benefits than concerns for research aiming to

“Nothing is ever totally secure.”

“If people have a rare condition, research will benefit them and others with the condition so we would be happy to allow access to their records for this.”

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find new treatments or interventions for conditions that are life-threatening, where there are currently no effective options or where a condition is too rare for a randomised controlled trial. One delegate commented, “If people have a rare condition, research will benefit them and others with the condition so we would be happy to allow access to their records for this.”

However, there were concerns that even if the research found a treatment or care intervention was effective, it might not continue to be available after the research study has finished if its high cost means it is not cost effective to provide as routine care. This reflected a general concern about the cost to society of innovative treatments and how to fund them.

Is there a difference according to who is collecting the data?

During further discussion, Council members were asked to consider whether there different attitudes towards pharmaceutical or other commercial companies compared to other types of organisation carrying out research using data from personal care records, such as the NHS or academic researchers.

“We feel as a society we are at the mercy of pharmaceutical companies because they usually put profit before people.”

At this point, the Council felt that there was a clear difference. This was due to a fundamental difference in the aims of these organisations, with pharmaceutical companies working to make a profit and operating in a competitive market, while the NHS and academic groups aim to improve people’s health and care.

“Pharmaceutical companies hold a lot of power and the potential for life or death, and make huge profits out of life or death situations,” one person suggested. Another said, “We feel as a society we are at the mercy of pharmaceutical companies because they usually put profit before people.” There was a feeling that pharmaceutical companies had eroded trust in the past and one person asked a question about who oversees pharmaceutical companies. Several Council members considered they felt more positively about use of data from personal care records if a healthcare organisation was using it “to create more health for people”.

“I can see the benefit of using data from care records if organisations are using it to create for health for people.”
**Research ethics and associated practicalities**

**Principles of research ethics**

Dr Harriet Teare, DIRECT Project Officer at the Centre for Health, Law and Emerging Technologies (HeLEX), Nuffield Department of Population Health, University of Oxford.

Dr Teare introduced the Council to why it’s important to consider ethical concerns associated with different research strategies and the different ethical considerations and key principles that may apply. “It’s tempting to think that ethics is really just common sense and about ‘doing the right thing’,“ she said, before explaining that it is more complex in practice and needs to take account of different people’s perspectives.

International codes put the patient’s wellbeing at the centre of any medical situation and Dr Teare explained four key values - autonomy, beneficence, non-maleficence and justice – that underpin decisions about ethics. However, these can conflict in some situations. For example, if an individual patient refuses essential treatment, following this wish (respecting autonomy) may be at the expense of making the patient better (beneficence) or avoiding further harm (non-maleficence). If not treating the patient leads to a worsened condition that is more costly to manage, then this also conflicts with making best use of resources for society as a whole (justice). “To improve treatment means we need to do research,” Dr Teare pointed out, but the Declaration of Helsinki makes it clear that the rights of the individual are even more important. Considering the use of personal health data in research, she suggested that key measures to protect individuals in research aim to ensure privacy, confidentiality, good scientific practice, public benefit and protection of future generations.

Tools used to protect individuals in traditional research include informed consent and right to withdrawal at any point with no personal consequences. However, their use may be more complicated in research using data from personal care records. An individual may give consent to the initial research study but there be uncertainty about how the data might be used in the future. It may also be difficult to withdraw consent at a later date, with the individual unable to check if their data has been deleted. Other issues that may occur with this type of research include incidental findings, which have nothing to do with the research question but may have implications for the individual, and the question of whether anonymised data can be traced back to the individual.

**Ethical issues in the collection and use of data from personal care records**

The Citizens Council moved on next to explore the ethical issues that they felt should be considered in the collection and use of data from personal care records. To do this, the Council built on the concerns identified earlier in the meeting and considered the main ethical issues suggested by Dr
Teare: individual privacy, confidentiality, good scientific practice, ensuring no financial incentives to take part in research, public benefit, and the possible impact on future generations.

Groups considered whether their responses applied only to care situations or only to non-care scenarios before suggesting practical solutions that researchers / collectors of data could put in place to respond to the ethical issues identified.

Confidentiality, privacy and data security were immediately identified as key ethical concerns for the patient/service user, care provider, researcher and society, with questions around whether data from personalised care records can ever really be anonymised and about who might have access to data. People drew on other health-related situations to consider the potential implications of data not being kept confidential, such as sperm donors being traced in the future by offspring. These issues were not considered unique to health and social care situations and Council members considered there was no difference in the need to protect data and keep it confidential depending on who was collecting and using data. Protection and confidentiality of personal data should be a top priority for all types of organisations, the group agreed.

Practical solutions for ensuring confidentiality and data security suggested were better regulation and auditing of data management, for example by the Information Commissioner, and a requirement that all staff should be trained in information governance. Researchers should be accountable for ensuring they use secure IT systems for storing and analysing data and staff involved in data collection and analysis should be vetted. Data management systems and staff training need to be updated regulated in the face of new challenges to data security.

Transparency was considered a very important issue for the patient/service user, including having information on exactly what is being done with their data, what else might be done with their data, and what might happen in the future. There was concern about whether an organisation could keep data forever and whether they might use it for other purposes. Council members considered there was a difference in the type of organisation doing research, with potentially more trust that the NHS or an academic group would have greater openness about the aims of research than for-profit organisations.

Council members suggested that systems should be established to ensure that researchers are transparent from the outset, with informed consent procedures requiring them to tell study participants how their data will be used and who might have access to it (including whether their data may be sold to other organisations), how long data will be kept and what will happen to data once the research study has finished. Explanations should be kept simple to ensure study participants can understand and they should be given written information. Informed consent procedures should include information about what a researcher plans to do with data if they discover incidental findings about a participant’s health and wellbeing. Citizens also suggested that individuals should have access their own data as part of ensuring transparency.
The public benefit of research was identified an important ethical concern, with one Council member commenting, “I don’t mind if research is helping people but if it’s marketing I would decline.” A potential solution that researchers could put in place to ensure public benefit of any research they carry out is patient / service user involvement in the design of research, which Council members considered particularly important if it could potentially affect their health or have wider long-term consequences. Council members felt that researchers must think about the benefits to society of their research, particularly if resources for a study are coming from the public purse. Research studies of greatest benefit to society should be prioritised and this should be discussed transparently with the public. Focusing on research that makes the best use of resources was identified as an important issue and ensuring that research is open to all members of society, with no discrimination.

Good scientific practice was considered a concern for patients/service users, care providers and researchers. Council members considered that researchers have a ‘duty of care’ for optimising accuracy of data and ensuring data are analysed correctly. Appropriate systems and good working practices should be put in place to ensure a consistent approach to research planning, data capture and analysis. Council members were concerned that there should be a complaints process in place for research study participants, overseen by an ombudsman. They felt there was no difference between different types of research organisations in this regard.
Different perspectives on using information from care records

To illustrate what research using anonymised data derived from personal care records might look and feel like in real life, the Council heard from a patient, a service user and a researcher who have each been involved in different research projects.

Patient / service user perspectives

Alan Campbell, a patient with diabetes and participant in research to test a new piece of monitoring equipment.

Alan Campbell, who has had type 1 diabetes for 22 years, told Council members about his experience of taking part in research studies involving the use of data from his personalised care records. He told them why he considers this is beneficial both to him as an individual and to society as a whole.

He is currently participating in a trial funded by Diabetes UK, to test an electronic detector that he wears in his shoes to monitor the pressure under his feet. The technology aims to reduce the risk of pressure ulcers, which can be a particular problem for people with diabetes. He explained that he has diabetic neuropathy, which reduces his ability to sense the pressure under his feet. The electronic detector alerts him via a monitor like a watch around his wrist when the pressure is too high. The research uses data collected from the device together with information from his patient records. This helps him and the study findings will also help others with diabetes. Alan’s view was that if we don’t share data, people won’t get the care and attention they deserve and need, and that data saves lives.

Alan noted that an added benefit for him was that all 11 sets of health records (paper and electronic) previously held on him by his GP clinic and several hospitals were now collected together electronically. He felt it is essential that all clinical records about a patient are pulled together, explaining that in all the different sets of records held previously not one had a complete picture of him. When asked, around 60% of Council members had thought that personalised care data was already linked and shared by different healthcare providers and were surprised that this was not the case in many areas of the country.

Martin Rathfelder, a member of the public and participant in a national UK Biobank study

Martin Rathfelder explained why he is one of the half a million volunteers taking part in the UK Biobank study, hosted by the University of Manchester and supported by the NHS. His view was that sharing your data lets others learn from your experience. All participants have provided blood, urine and saliva samples for analysis, answered questionnaires about their diet and lifestyle and agreed to have their health followed using information from their GP healthcare records. Over the years this will build into a powerful resource that will help researchers to discover why some people develop particular diseases and others do not. He explained that unlike a lot of research, which studies people who are already ill, this study will enable researchers to follow what happens to
people who are currently healthy and what factors may be associated with conditions they develop over time.

**Clinician / care provider perspective**

Dr Sue Collier, Head of Medical Operations with the Salford Lung Study GSK (GlaxoSmithKline), described how the linked-up medical records between GPs and hospitals in Salford are enabling research into a new medicine given as part of usual care to patients with asthma or a type of chronic bronchitis (termed chronic obstructive pulmonary disease, or COPD). Data from their care records is being collected and analyse to assess the benefits and side-effects with the new treatment. The aim is to mix the robustness of a randomised controlled trial with a ‘real world’ approach and learn how we can use patient data in new ways to answer scientific questions, she explained.

A major advantage of this approach is that it can be more inclusive than a randomised trial, by including patients with asthma who smoke and those with chronic bronchitis and an abnormal ECG (which is common because most of these patients smoke) and by being available to patients who are housebound. Linkage of records means that safety monitoring can be performed in real time rather than with a time delay, which occurs in a clinical trial.

Seven thousand patients have been recruited so far, with a very good response rate, which Dr Collier considered had been achieved by individual conversations explaining why the study is being carried out. She noted that a lot of people had previously opted out of sharing their data but opted back in when the study was explained to them.

Professor Garner asked Citizens Council members what they thought about this type of research partnership between a pharmaceutical company and the NHS. One delegate said they had a ‘nagging doubt’ about any research that involved a company potentially making profit at their expense.

**Other views on data sharing**

Professor Garner explained to the Council that there are some extreme views on the use of anonymised data from personal care records and that speakers representing the ‘middle ground’ who would report factually on the relevant issues had been chosen for the meeting. To provide a wider perspective she gave Council members a handout giving examples of views expressed by members of the public through online comments in response to news articles about sharing data from care records under NHS England’s care.data project. Some of the views opposed to data sharing included:

“If pharmaceutical companies want your data, their main interest is likely to be in their profits, not in your health.”
“Has it occurred to you that unless you have personally verified that the GP medical history held about you is accurate then you will be forever be the one-eyed chain smoking, legless dwarf with a liver transplant that it says on your record. Try to get you head round the reality of GP records - before they kill you! Unless the patient checks the record this whole system is pointless."

“Once your data is digital it is distributable. Once it's distributable, it can be commoditised. Once it's commoditised, insurance companies will come sniffing... After that, don't be unemployed, sick or old.”

“Under no circumstance should anyone outside of the NHS be using my health information... insurance companies will be able to charge more because they will know everything about you. In whose world is that ‘the greater good’?”

“I have no issue with the collection of medical data for the purposes of research. However, the major point here is that the data is for sale. The data is for sale to those not only who will better health, but to those who will seek to profit from your ill health. Health is a human right, and it should never be for sale; especially to big pharma.”
Implications on access to care for patients and service users

In the next stage of the meeting the Citizens Council considered the relationship between access to a new treatment or care innovation willingness to share data from personal care records.

Research that allows early access to treatments not yet fully approved

Professor Vikki Entwistle, Professor of Health Services Research and Ethics, Health Services Research Unit at the University of Aberdeen.

Professor Entwistle outlined the standard regulatory process for new medicines before explaining the exceptions underlying ‘early access’ or ‘compassionate use’ schemes. Such schemes allow ‘early’ use of medicines that have not yet been approved for patients with serious conditions and who have limited or no treatment options. There are obvious benefits for these schemes, particularly in providing treatments for people who previously had no or few options. However, there are also concerns, explained Professor Entwistle. In particular, there is a concern about the greater good. “We need medicines to be tested to demonstrate that they are effective and safe before being used by patients. Making exceptions in very rare cases does not compromise this regulation, but offering larger scale ‘exceptional’ access to unapproved medicines could undermine systems designed to ensure the safety of medicines,” she pointed out. It could also discourage manufacturers from running trials and make it hard to withdraw drugs if the research conducted whilst ‘exceptional’ access is allowed shows the treatment to be ineffective.

Collecting data from personal care records for people prescribed a drug on an early access programme can produce additional information on the risks and benefits of the treatment that would otherwise be lost, Professor Entwistle suggested. Experience with a number of initiatives suggests “a large majority of people are willing to offer their data for the common good,” Professor Entwistle reported. But she acknowledged that some people might have concerns about the privacy of their data. She concluded by asking the Citizens Council to consider whether participation in early access schemes should be restricted to those people willing to share their data. Would this be fair? And what kinds of conditions and protections are needed?

Implications on access to care for patients and service users

Members of the Citizens Council considered the practical and ethical issues associated with sharing information from personal care records as part of research and started to think about whether only those willing to share their data should be able to receive early access to care that is not yet routinely available.

Why an individual might not want to share information from their personal care record

Some Council members considered that people might not want to share data from their medical care records because of concerns about what might be done with the data in the future, or because
it might be shared with, or sold on to, other organisations. Others suggested that a person might not want to share information from their care record if they had a particular condition or treatment that they did not want others to know about, for example treatment for drug abuse. Some people commented, based on personal experience, that incorrect information may be in a person’s care record and they would not want this shared.

Commonest concerns about sharing data were similar to those raised previously about the use of personal care record data generally: confidentiality of data (particularly information that could have future repercussions for the individual, such as affecting a person’s insurance or employment), privacy, data security, and transparency. There was concern about a person potentially wanting to change their mind and withdraw during a study. “If you have given your data you can’t take it back,” noted one delegate.

Why it might be important to allow access only to those prepared to share data

Some Council members considered that allowing people to opt out of sharing data might undermine research. One person argued, “If people are not willing to share their information how can we go forward?” “You would end up with no study or not enough data to get a good study,” another added. They considered that medical treatments available today have been made possible only because people have shared their data and research for the future would be put ‘in danger if people don’t share their information’. There was also a concern that research data would be incomplete and vital data may be missed if not everyone treated with a new drug shared their data.

People recognised that an early access scheme is a ‘special case’ so some felt differently about data sharing compared to standard medical care. “If you are being treated with an unlicensed drug, all of your medical information is needed,” one delegate suggested. Meeting participants considered that sharing data for new and unlicensed medicine is essential to ensure safety is carefully monitored, for the individual being treated and for other patients who might wish to receive that treatment in the future.

Reflecting on these discussions, the Council considered the most important reasons for making treatments or interventions not yet fully approved available only to those who are willing to share their data were:

1. Full knowledge of medical history is required before drugs can be prescribed to ensure safety and efficacy (which could be categorised as both benefit to society and personal benefit to the individual patient).

2. If the trial goes wrong the data and information need to be used to prevent harm to others (which can be classified as benefit to society and safety).
3. Safety for everyone because the drug is unlicensed (benefit to society, safety).

4. Helping people in the future (benefit to society).

5. Someone else who is willing to share their data could be missing out (individual benefit).

Other reasons given by the whole Council were: it’s not cost-effective and doesn’t add value if people don’t share their data; to increase medical benefit to the patient (for example, how do you know the drug would suit you if you don’t share data?); if you are going to benefit from trials you should be prepared to share your data; to have continuity of evidence; to ensure no missing vital data such as on side-effects; those unwilling to share their data are no use to the study; to get the best outcomes; commitment of patients; you will end up with no study if you don’t get sufficient data.

In which circumstances, if any, would it be reasonable to allow only people who consent to use of their data to access the treatment or care being evaluated?

Council members worked in small groups to consider this question before sharing areas of agreement and points of disagreement. They were sharply divided on the issue. Some of the groups considered there should be no circumstances that justify opting out of sharing data because this would stifle research. They considered that if people were getting the benefit of a treatment they should be willing to share their data so others could benefit and research knowledge could move forward. “If you won’t share your data, I would say you can’t have the treatment,” said one participant.

However, others felt that access to treatments or care being evaluated should never be restricted only to those consenting to share their data. Illustrating this divergence, one group said, “We all agreed if you decide to take part in research you should agree your data is used for research purposes that would eventually help others,” while another group noted, “One suggestion is that there are no circumstances where someone should not be given access to treatment. The opposing argument is only in special circumstances or in dire need.”

Some people considered that the requirement to share is a matter of fairness and of making most efficient use of available resources. “If there are limited resources for a new drug it should be prescribed firstly to those helping with sharing data,” suggested one group member, with another adding that giving a drug to a person unwilling to share their data may mean that it’s not available for another person who would. It was suggested that it was not cost-effective to give the drug to someone unwilling to share their data.
Others felt that people should be able to say ‘no’ because sharing personal data should be a free choice. “You should be able to say ‘no’ otherwise you are taking people’s rights away. They should be able to say ‘yes’ or ‘no’,“ a Council member suggested.

Council members also considered circumstances where it would be reasonable to allow access to a treatment that was being evaluated in research to those not willing to share data from their personal care records, rather than circumstances where access should be made available only to those sharing their information. These circumstances included: people needing urgent treatment; people who are terminally ill; children; vulnerable adults who can’t give informed consent; people with certain religious beliefs (because they would not want their family to know they were receiving treatment); people with conditions they don’t want others to know about; politicians and other people in the public eye (although one group member pointed out that data is anonymised so no-one would know who it had come from).

Overall, Council members generally felt it would be appropriate to make treatments being researched available only to people willing to share their data where a study was over-subscribed, so treatment should be given to those consenting to provide information, and where sufficient numbers are needed so that a study can be published and to ensure it is comprehensive. One person observed the tension between thinking about this issue as an individual patient and thinking about the benefit to the NHS / society as a whole. The Council went on to explore this further in subsequent discussion considering the public and private interests relating to social duty for the greater good and individual rights to privacy, in the context of sharing information from personal care records.

**Does this depend on the type organisation that data is shared with?**

Some Council members discussed the different types of organisations involved in research and felt that it made a difference whether the data were being collected for use by the NHS (in which case data should be shared) or by a profit-making organisation (where there should be a choice). Professor Garner asked the Citizens Council as a whole to consider this further and asked again about whether they had different views depending on the type of organisation wanting to analyse information from personal records. “Is there a difference between organisations such as NICE and academic groups compared to pharmaceutical companies and device manufacturers? And does it depend on whether organisations are paying for the data?”

The majority of Council members still considered there was a difference in the use of data from personal care records for research by NHS organisations compared to pharmaceutical companies. Themes that emerged at this point in the discussion were: the level of trust in an organisation, what an organisation intends to do with data and whether information is being used with the aim of making a profit or not. People generally considered that organisations such as NICE are trusted more than pharmaceutical companies. However, there was some uncertainty about what NICE
might potentially do with personal care data, with some group members questioning why it needs data if it’s not developing new medicine. This might point to the need for further public education on how NICE uses data in its role of evaluating medicines and interventions for use by the NHS.

However, Council members were now divided on whether for-profit organisations should benefit from the use of data from personal care records. Some considered it was wrong for companies to make money out of information that patients/service users give as part of their NHS care. “If it’s mainly for profit and not for medical benefit, then it’s not right,” suggested one Council member. But others felt this was a not a clear-cut issue, Another Council member argued, “Drug companies are profit making, but they have to be. They are doing studies and doing work to bring new drugs. Without these companies there would be no new drugs so it’s very important they have data.”

There was recognition that organisations such as NICE need good quality data for evaluating medical treatments. “NICE needs full information – the more that is provided by trials, the better you can make decisions,” one participant suggested.

Several areas of concern emerged during this discussion. One issue (which had been raised previously) was the oversight and regulation of pharmaceutical companies. A new concern was what would happen if something goes wrong with a drug being tested by providing access in routine care, including liability issues. Professor Garner explained that this is currently ‘a grey area.’ A Council member said they would be “worried if the onus was put back on the patient even though they might not be aware.”

“NICE needs full information – the more that is provided by trials, the better you can make decisions.”
Social duty for the greater good and individual rights to privacy

Introducing the underlying concepts

Professor Jonathan Montgomery, Professor of Health Care Law at University College London and Chair of the Nuffield Council on Bioethics.

Professor Montgomery introduced the concepts of social duty for the greater good and an individual’s rights to privacy and choice. He explained that there is both a private interest and a public interest in each of these and introduced what this means in the context of sharing individual patient health data.

He outlined the three main ideas that need to be considered in this arena: privacy (the right to be left alone and the freedom to be yourself); public goods (common interests and the collective good) and social duties (living together in harmony or living well). While we all have a right to privacy, we are all affected by those around us.

Do our health records belong to us as individuals? Professor Montgomery pointed out that health information in our records partly comes from us and partly from the health system we interact with. Potential use of this information for research needs to be underpinned by a ‘social contract’ that sets out the fair ground rules, he suggested. Public goods include:

- common interests in which we all share equally, such as clean air and water, where there is no conflict
- collective (public) interests that may benefit each person differentially but with overall positive effects for the greatest good, such as health services
- personal (private) interests that we each hold independently, such as life and personal health, where they need to be constraints and/or trade-offs, balancing individual freedom against the good of society as a whole. He asked us to consider, whether there are some things that are so important to people that they should stop us sharing data, for example.

Moving on to consider social duties – to respect the rights and freedoms of others – Professor Montgomery explained the concepts of solidarity (making us all better off if we collaborate) and reciprocity (giving something back in return for what we have received) and how these might apply to sharing data from personal care records. He suggested we make judgements on the balance between how much a result is worth having, such as a new treatment in the future, against how far we are prepared to share our privacy. Summing up recent work by the Nuffield Council on Bioethics in this field, he argued the key elements in the use of data from personal care records for research are transparency – explaining to people why this is being done – backed up by accountability and governance, concluding that agreement of a social contract is needed in order to achieve this.
Reconciling social duty for the greater good and individual privacy

Citizens Council members considered the public and private interests relating to social duty for the greater good and individual rights to privacy, in the context of sharing information from personal care records. They considered a selection of statements representing different positions, voting on their importance and exploring the implications of prioritising each position over the others.

Ranking of statements as important/very important

Voting on these statements as individuals revealed that Citizens Council members generally considered social duty and the greater good of much greater importance that individual privacy.

1. **Public interest for social duty/greater good**
   
   *Everyone benefits when we all co-operate. We all have a responsibility to contribute towards improving the health and well-being of society as a whole.*

   Not important | Extremely important

2. **Private interest for social duty/greater good**

   *If we allow data to be collected now, it might improve the care and treatments that are available to me when I need them in the future.*

   Not important | Extremely important

3. **Public interest for individual privacy**

   *A society that respects individual privacy is stronger because it gives people choice about whether or not to share their health and care information, and confidence that their choice will be obeyed.*

   Not important | Extremely important

4. **Private interest for individual privacy**

   *I want the right to keep my life private – my health and care information is part of what makes me ‘me’.*

   Not important | Extremely important

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**Drawbacks of allowing one statement to trump the others or to be discounted**

Council members then considered what the drawbacks would be if one of the four statements were allowed to ‘trump’ all others or if a statement were discounted.

**Private interest for individual privacy**

During group discussion, Council members considered the drawbacks of allowing this statement to trump all of the others would include a negative impact on research progress as a whole, with no data being collected and no developments in medical science. “There would be no cures for cancer and other serious diseases,” one member pointed out, while another suggested it would slow research down and it would take longer. However, one delegate questioned whether this would be true: “We may just go back to randomised controlled trials,” he suggested, although he noted that these are very expensive. Council members suggested there might also be negative consequences for the individual resulting from the lack of sharing of personal health information between different health agencies “so if you take ill away from home and need treatment they may not have information on you, such as medicine you should not take.”

Groups generally agreed that discounting this issue would violate the individual’s right to privacy. “I might want to keep my life private,” one person pointed out. They also thought certain groups of people, such as those with impaired mental capacity who may be unable to give informed consent, might lose out from not being able to opt out of data sharing. There was concern that giving people no choice about sharing their data might reduce the number of people willing to participate in a research study and may also mean a sample is not representative of the population as a whole.

**Public interest for individual privacy**

A drawback of allowing this statement to trump others might be fewer participants taking part in research so it would more difficult and take longer to make progress in medicine. However, group members could see several problems in discounting this statement, including individuals feeling concerned about, or not agreeing to what their data might be used for. Some individuals may want the freedom to opt out of research, such as donating their organs, for religious reasons so group members considered it important to maintain individual choice.

Overall, several Citizens Council members considered it was important to allow individuals privacy and the right to choose to share their data because they considered this was important to society as a whole. They felt society was stronger if people had freedom of choice.

**Private interest for social duty / greater good**

Loss of individual freedom and feeling forced to take part in research would be major drawbacks of allowing this statement to trump others, group members suggested. Other potential drawbacks
might be a failure to focus on an individual’s current health needs and the collection of ‘too much data’ that could be difficult to manage. But discounting this statement would stifle research and potentially limit treatments for individuals in the future.

**Public interest for social duty / greater good**

People would feel intimidated and forced to share their data and there would be no individual choice, Council members suggested when considering the drawbacks of allowing this statement to trump all others. It would mean people were not able to hold different opinions on this issue. However, Council members considered that allowing this statement to be discounted would be very damaging to society as a whole and to progress in research. “Society would break down,” one group member warned. Others suggested, “We would be taking away faith and hope,” and, “There would be less medicines.”
Could NICE use anonymised data to fill gaps in evidence?

Bringing the discussions and insights from the two-day meeting to a conclusion, Citizens Council members were asked the question: ‘If NICE was not getting enough evidence in the usual ways and so wanted to use anonymised data to fill the gaps, would you have any concerns?’

Opinions were fairly evenly divided, with 13 people voting ‘no’, 11 voting ‘yes’ and 1 abstaining.

If NICE was not getting enough evidence in the usual ways and wanted to use anonymised data to fill the gaps, would you have any concerns?

People then shared their remaining concerns about the use of anonymised data from personal care records for research by NICE and considered practical ways in which NICE could respond to meet these concerns. Key themes that emerged were transparency and the potential for data to be sold on to other organisations and used for profit and for purposes other than research; good scientific practice and collecting and using data to benefit society; and data security.

Council members proposed that to address these concerns, NICE could ensure transparency through open days and information resources to explain what data is being used for, explaining precisely how it will be used and by giving reassurance that personal care data will not be passed on or sold to other organisations. Professor Garner explained that informed consent must be in place before a patient agrees for their data to be used in research and this should state how their information would be used and analysed.

The Council recognised the central importance of informed consent in ensuring transparency. Member recommended that informed consent procedures should be randomly checked by NICE, bearing in mind that they may be carried out by others (such as GPs) on their behalf and it was
suggested that consent should ideally be personalised, to ensure people fully understand what data they are sharing, who it will be shared with and how their data will be used.

Throughout the meeting members had raised the question about whether there was an ombudsman to oversee the governance of sharing personal care information for research. They suggested that an ombudsman should be considered to take on this governance role.
Conclusions and key outcomes

The 2015 meeting of the NICE Citizens Council set out to explore the question:

What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care?

In response to this question the Council considered that key ethical issues are:

- **Confidentiality, privacy and data security**, with questions around whether data from personalised care records can ever really be anonymised and who might have access to data.

- **Transparency** and ensuring that patients/service users are informed about exactly what is being done with their data, what else might be done with their data, and what might happen in the future.

- **Public benefit of research**, focussing on research that makes the best use of resources and ensuring that research is open to all members of society, with no discrimination.

- **Good scientific practice** to ensure the accuracy and validity of research design and data analysis. The Council felt that research that does not produce any useful findings because it is not scientifically robust is a waste of time and resources.

Citizens considered there was a difference in the level of concern for these ethical issues depending on the type of organisation doing research, with potentially more trust that the NHS or an academic group would have greater openness about the aims of research and more focus on research for public benefit than for-profit organisations.

Council members recommended that practical measures to meet these concerns should include complete transparency on how information from personal data will be used and who it will be shared with, effective informed consent procedures and strategies to ensure complete anonymisation of personal data, data security and research governance if NICE uses information from personal care records for its work in the future.

The Council considered a main strength of using information from personal care records for evaluating treatment may be better research outcomes. Other strengths included greater convenience and potentially lower cost to the patient; better continuity of care; and data being collected from a more representative population. Limitations identified were lack of time and research expertise among GPs and other care staff; risk of human error and lack of accuracy in data collection and entry; concern about security of data transfer and security; and concerns about the efficacy and safety of the intervention being researched.
Considering whether it would be reasonable to allow access to a treatment not yet approved for routine use only to those patients or service users who consent for their data to be used as part of an evaluation scheme, some Council members felt there should be no circumstances that would justify opting out of sharing data, mainly because to do so would limit the accuracy and validity of data collected. They considered it only fair that people receiving treatment or care as part of research should provide their data to allow progress in care delivery. However, some felt that access to treatments or care being evaluated should never be given only to those consenting to share their data because this would be taking away people’s freedom of choice and would be coercing people to take part in research in return for receiving treatment.

Social duty and the greater good was of much greater importance than individual privacy when it came to the use of data from personal care records for research, the Council concluded overwhelmingly. There was clear recognition that this was necessary to make advances in health and social care research and for the good of society as a whole, balanced against a desire to maintain individual freedom of choice.

Final thoughts
Reflecting on the two-day meeting Citizens Council members felt they had travelled a long way in exploring and understanding the issues associated with the use of anonymised data from personal care records for research purposes. “Talking about sharing data has made us aware there are a lot more factors to consider,” suggested one group, adding, “We all felt we learned something.”

While recognising the benefits to society of sharing personal data for research some Council members wanted to emphasise that they considered individual freedom remained important and individual rights should be respected by any system introduced to enable use of personal care data by NICE. “Individualism is still important and should be respected,” suggested one participant. There was some remaining scepticism about whether people would be given a real choice about the use of their personal care data for research because some Council members felt that Government agencies could access whatever data they wished, with or without an individual’s consent.

Some concerns remained about the potential for misuse of personal data, including the effectiveness of anonymisation of personal care data and whether it could be tracked back to an individual; what happens to data after it has been used for research; and data security as a whole. Measures to ensure confidentiality and data security are essential to reassure public concerns on these issues. Transparency and fully informed consent – achieved by explaining in a simple and easily understandable way how an individual’s data would be shared and used for research – were
considered key measures to ensuring that people felt comfortable with research involving use of their personal care data. “Researchers should state exactly what is being done with data and make it simple for people to understand,” Citizens Council members concluded.
Next steps

This report will provide a public perspective on the ethical and practical issues that need to be considered in the use of anonymised information derived from personal care records as part of the Institute’s work in evaluating treatments and the delivery of care. The report will be presented to the NICE Board and the conclusions and recommendations will be used to inform the principles set out in NICE’s Social Value Judgements document. The information provided will also, where appropriate, be used to inform specific areas of NICE’s work and be incorporated into the methods guides for individual programmes.
Acknowledgements

Many thanks to:

Members of the NICE Citizens Council, for their time, interest and willingness to share their thoughts and experiences to inform NICE’s future work by providing a public perspective on the ethical and practical issues that need to be considered in the use of anonymised information derived from personal care records.

Andrea Josephs
Calvin Beck
Charlotte Louise Bridgeman
David Goronwy
Debra Wagman
Elizabeth Bodey
Ellie Perrott
Estelle Rose
Gareth White
James Brown
Jay Williams
John Corber
Karen McTaggart
Laura Thomas-Hockey
Mary McGuinness
Nathaniel Heyliger
Nirmala Parma-Hopkins
Pauline Turgoose
Ron Jobling
Rupe Chand
Samuel Wynter
Sharon Bernard
Sherann Hillman
Trevor Betts
Zenda Mullins

The speakers who shared their insights and experiences with the meeting:

Dr Maggie Helliwell
Professor Sarah Garner
Dr Harriet Teare
Alan Campbell

Martin Rathfelder
Dr Sue Collier
Professor Vikki Entwistle
Professor Jonathan Montgomery

The NICE team involved in planning and organising the meeting:

Professor Sarah Garner, Associate Director for NICE Science Policy and Research
Gill Fairclough, Project Manager – Science and Policy Research Programme, NICE
The facilitators who guided the meeting and led discussions:
Pete Spriggs and Mandy Sims, from Clearer Thinking

Dr Susan Mayor, for writing and editing this report

Further information
Copies of the slides shared during the two-day meeting are available on request to:
Gill Fairclough
Science Policy and Research Programme
gill.fairclough@nice.org.uk
+ 44 (0)161 870 3096
## Appendix 2: public comments received

<table>
<thead>
<tr>
<th>RESPONSE 1</th>
<th>Respondent details: Researcher, University of Oxford</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Questions</strong></td>
<td><strong>Comments</strong></td>
</tr>
<tr>
<td>1. Do you have any comments about the difference in attitudes towards data collection within health and social care contexts, compared with data collection in other ‘every day’ contexts?</td>
<td>I think the public are generally not aware how much data is collected about them in everyday contexts. Were they more so, they might have similar concerns about the use of that data, particularly its use for commercial gain that they do not have any benefit from (directly or indirectly).</td>
</tr>
<tr>
<td>2. Do you have any comments about the difference in attitudes towards pharmaceutical companies compared with non-profit organisations?</td>
<td>This difference is understandable. Where data are sold for profit in a commercial market there is sense of neo-liberal, commercial gain as opposed to one of altruism or benefit to the greater good of the population where nfp organisations or public services are benefitting.</td>
</tr>
<tr>
<td>3. Do you have any further comments on ethical and practical requirements for collecting and using information from personal care records?</td>
<td>Transparency and confidentiality are fundamental. Dynamic consent is an option for practically handling public consent (Kaye et al 2014) though a quid pro quo would be easier (NHS patients’ data is used). This would require absolute adherence to confidentiality and transparency however.</td>
</tr>
<tr>
<td>4. What do you think about the Council’s conclusions around allowing access to care not yet fully approved only to those willing to share their data?</td>
<td>Absolutely disagree with limiting interventions to those who agree to data sharing. Totally unacceptable in a publicly funded system free at the point of access.</td>
</tr>
<tr>
<td>5. What do you think about the Council’s discussions about reconciling ideas of social duty for the greater good and individual rights to privacy?</td>
<td>This thorny issue could be reconciled if anonymity of data could be maintained – then both aspects could be addressed simultaneously. If this is not possible then on balance, individuals’ right to choose is uppermost - just.</td>
</tr>
<tr>
<td>6. Do you have any general comments you would like to make?</td>
<td>I feel very strongly that allowing access to care for only those willing to share their data is absolutely wrong. I also feel that anonymity is important and would negate other concerns if it</td>
</tr>
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</table>
Transparency about the use of data is important and it should not be used for commercial gain.

**RESPONSE 2**

**Respondent details:** Dame Fiona Caldicott, National Data Guardian

<table>
<thead>
<tr>
<th>Questions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you have any comments about the difference in attitudes towards data collection within health and social care contexts, compared with data collection in other ‘every day’ contexts?</td>
<td>We have limited information about public attitudes towards the use of data collected in ‘every day’ contexts; this was not specifically considered in the 2013 Information Governance Review, known as Caldicott2 or during the current the Review of Data Security, Consent and Opt-Outs. In general the findings presented in your report chime with the results of the engagement that we have undertaken with the public. Both the 2013 review and the current review have found that when a patient speaks to their health or care provider they rightly have high expectations of their confidentiality being respected. While people expect their information will be shared to support their care, there are mixed views about it being used for purposes beyond their care. Where we have heard concerns, these have been broadly in line with those expressed by your council, in particular that there must be a clear public benefit to the use of the data, that data security must be robust and that there must be transparency over how data is shared and used. We believe that the public is broadly supportive of anonymised data being used wherever possible, rather than personal confidential data.</td>
</tr>
<tr>
<td>2. Do you have any comments about the difference in attitudes towards pharmaceutical companies compared with non-profit organisations?</td>
<td>The questions and concerns raised by your council members broadly reflect those surfaced as part of Caldicott2, the engagement carried out with the public for the current review, and other work that has been undertaken in this area. All these pieces of work have shown that some people feel uneasy about commercial organisations accessing information. As with your council, concerns have tended to coalesce around fears that if people allow their data to be used they will be targeted by marketing or insurance companies. We have also heard that there is support for information being used for research, but that it is important there are clear benefits which will lead to care being improved.</td>
</tr>
<tr>
<td>3. Do you have any further comments on ethical and practical requirements for</td>
<td>Your report has provided a very helpful summary of public attitudes to the use of their health and care data. The potential benefits and drawbacks of data sharing that your council members</td>
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<td>ITEM 7</td>
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<td><strong>collecting and using information from personal care records?</strong></td>
<td>perceived are consistent with the findings of our engagement with the public and with other previous work in this area. It is important there are “no surprises” for the public in the way their data is used.</td>
</tr>
<tr>
<td><strong>4. What do you think about the Council’s conclusions around allowing access to care not yet fully approved only to those willing to share their data?</strong></td>
<td>We see from your report that this question was explored within the context of the ‘early’ use of medicines and that your council members generally concluded that it would be appropriate in some circumstances to restrict access to treatments currently being researched to those who are willing to share their data. This is not an issue on which we have engaged with the public, however we think it is important to note that this discussion took place around this specific context. We do not believe that the finding should be seen as representative of the public views on the sharing of data as a pre-condition to receiving care more broadly.</td>
</tr>
<tr>
<td><strong>5. What do you think about the Council’s discussions about reconciling ideas of social duty for the greater good and individual rights to privacy?</strong></td>
<td>We understand the public interest arguments in favour of using data to improve care, we would be in agreement with the jury’s overall conclusion these should not be prioritised over individuals’ private interests in their own privacy. The National Data Guardian position is that people should be given the chance to opt-out of their personal confidential health and care data being used for purposes beyond their direct care unless there is a mandatory legal requirement or an overriding public interest. Legally and ethically, we would always work on the principle that if the public’s data is to be used, their preferences must be being considered.</td>
</tr>
<tr>
<td><strong>6. Do you have any general comments you would like to make?</strong></td>
<td>I will shortly be publishing a review, commissioned by Secretary of State for Health, into data security standards in health and care, and the opt-outs that should be made available to the public. We believe this report will be complementary to yours, both in terms of the findings and recommendations. We strongly believe that it is vital that the health and care system should engage with patients and service users about the way data can be used to improve care and should listen to their views. We welcome the contribution the NICE Citizens Council is making to this important discussion. Finally, in further conversations with the public on this topic, we believe it is important there is a consistent understanding, and use, of the term anonymisation. As the ICO is the official regulator on this subject, we believe that reference to the ICO’s Anonymisation Code of Practice is helpful in achieving this consistency.</td>
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National Institute for Health and Care Excellence
Citizens Council
Date: 18 May 2016
Ref: 16/048
The Board is asked to receive the report which summarises the work of the Audit and Risk Committee over the 2015/16 financial year.

It is asked to note in particular our assessment of the work undertaken in 2015/16 (paragraphs 20-21); the challenges for the coming year (paragraphs 22-24) and consider the two specific recommendations made in paragraph 25.

Jonathan Tross
Audit and Risk Committee Chair
May 2016
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

AUDIT AND RISK COMMITTEE ANNUAL REPORT

Introduction

1. The Committee’s chief function is to advise the Board on the adequacy and effectiveness of the Institute’s systems of internal control and its arrangements for risk management, control and governance processes, and securing economy, efficiency and effectiveness (value for money).

2. In order to discharge this function the Audit & Risk Committee prepares an annual report for the Board and Accounting Officer. This report includes information provided by Internal Audit, External Audit and other assurance providers.

3. This is the third report for the Institute in its present form and the final year for long-standing member Rona McCandlish. We wish to record our appreciation of all her hard work during her term of appointment. She will be missed. It is also our final full year of internal audit through the call off contract with PriceWaterhouseCoopers, under a service level agreement with the Department of Health. Our thanks are due also to them for their input and advice. Going forward, DH will be providing the bulk of the work for NICE, with the option of some specialist work being delivered by private sector providers.

4. This is the latest in a series of positive annual reports from the Committee. We continue to receive reassurance from the reports of our internal and external auditors as well as the from the risk assessments, reports on specific areas such as procurement and information security, and presentations from senior managers. The Institute is an organisation that has been ready to take on new challenges, supported by clear methodologies and processes to assure the integrity of the work. That reflects the culture for the organisation set from the top and provides a source of real strength. We cannot however be complacent, as the challenges for the Institute are set to grow, which will be likely to test significantly the strong management resilience of the Institute.

Audit & Risk Committee’s Assessment

5. Members of the Board should recognise that assurance given can never be absolute. The highest level of assurance that can be provided to the Board is a reasonable assurance that there are no major weaknesses in the Institute’s risk management, control and governance processes.

6. The Committee has received reports in a range of key areas and has drawn particular assurance from the positive reports on quality standards, digital strategy and financial management, but also on NICE’s stakeholder management, foreign exchange transactions, IT general controls and risk management. The assessment of the Committee, based on the totality of the work presented to it, including but not exclusively the internal and external audit work, is that control and governance processes are well designed and managed. They provide assurance to the Board.
Information supporting Opinion

7 Summarised below is the key information / sources of assurance that the Committee has relied upon when formulating this opinion.

Internal Audit (IA)

8 The Institute’s internal audit is carried out by a firm of chartered accountants – PwC under a contract with the Department of Health. PwC were appointed by DH as part of a larger contract to provide internal audit services covering 3 financial years starting 2013/14. DH as parent has oversight of the work completed by PwC and in 2015/16 the DH audit team delivered some work themselves. This work was managed and overseen by PwC.

9 The Committee received the Head of Internal Audit’s opinion at its meeting on 20 April 2016 covering the financial year ended 31 March 2016. An opinion of moderate assurance was issued.

10 The internal audit plan was reviewed regularly by the Committee and an annual work programme of specific assignments derived from it and agreed in advance with the Committee.

11 The Committee notes that the 2015/16 opinion, ranked as moderate, is the same as the assessment for last year. We consider the current assessment as ‘usual’, and not a cause for concern. The table below sets out the full range of audit work in the year:
### Table 1 – Internal audit reviews

<table>
<thead>
<tr>
<th>Assignment</th>
<th>Final report issued</th>
<th>Opinion</th>
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</thead>
<tbody>
<tr>
<td>IT General Controls</td>
<td>January 16</td>
<td>Moderate</td>
</tr>
<tr>
<td>Financial Management</td>
<td>December 15</td>
<td>Substantial</td>
</tr>
<tr>
<td>Foreign Exchange</td>
<td>March 16</td>
<td>Moderate</td>
</tr>
<tr>
<td>Digital Strategy</td>
<td>March 16</td>
<td>Substantial</td>
</tr>
<tr>
<td>Risk management</td>
<td>January 16</td>
<td>Moderate</td>
</tr>
<tr>
<td>Quality standards</td>
<td>October 15</td>
<td>Substantial</td>
</tr>
<tr>
<td>Stakeholder management</td>
<td>March 16</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

See appendix A for explanation of assurance levels

### External Audit

13 The External audit was carried out by the National Audit Office (NAO). They give their opinion on whether the accounts give a true and fair view of the financial affairs of the Institute and also whether the funds have been applied to the purposes intended by Parliament. This opinion will follow their audit starting on 9 May, and a clean unqualified opinion is expected.

### Local Counter Fraud Service

14 As a Non Departmental Public Body there is no requirement for NICE to purchase a specific range of proactive and preventative work. Instead the SLA with DH allows for Counter Fraud work to be procured as is required. The last Fraud Awareness sessions at each office, was in 2014/15 and further sessions are planned for mid 2016/17. There were no incidents of fraud or of gross misconduct relating to travel detected during the year.

### Assurance framework

15 The audit committee oversees the operation of the Institute’s assurance framework. The assurance framework demonstrates the following features:

- structured risk identification linked to business objectives;
- assessment and management of significant risks;
- monitoring of the effectiveness of the assurance framework;
- identification of independent assurance and review functions.

16 Assurance is provided to ensure that the Board can satisfy itself that appropriate arrangements are in place for managing risk and the system of internal control is functioning and effective.
The Institute’s assurance framework involves an annual planning cycle that establishes clear business objectives for the organisation as a whole and for individual work programmes which are included in the Institute’s business plan. Individual programmes assist in identifying potential risks that could affect delivery of these objectives and develop strategies to manage them. These are incorporated into the risk register which is reported to the senior management team and audit and risk committee at the beginning of the financial year setting out the broad framework for the governance of the organisation at a strategic level, and listing controls and assurances for the management of the Institute’s risk. The SMT and Audit & Risk Committee review a summary of the high risks identified in the register every quarter and assess whether the management strategies are likely to be effective. During the year the Committee focussed on further aligning the risk assessment to the Institute’s strategic aims and ensuring that management of the risks was reflected in the scheduled action points.

Internal audit has carried out a review of the Institute’s risk management. This had a ‘moderate’ rating. However, it is worth noting that no recommendations for action were raised in respect the risk assurance framework itself or on corporate risk management. The recommendations for improvement were in respect of embedding risk management in divisions and reporting arrangements.

Management

The Committee receives a range of reports and assurance from management throughout the year. These are summarised in the table below.
### Table 2 – summary of sources of management assurance

<table>
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<tr>
<th>Management assurance</th>
<th>Description</th>
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| **Losses and compensations register** | As required by DH the Institute maintains a register of such payments. This is reported annually to the audit Committee. For 2015/16 the total value of these payments was £46,000. Of this amount £26,667 relates to train cancellation or amendment fees, reflecting the inevitable (and acceptable) consequences of encouraging the purchase of less flexible but cheaper tickets. £13,826 relates to event cancellation costs of which £11,920 relates to a cancelled iDSi international event that was funded by non-exchequer grant money without loss to NICE.

The remaining value relates to items such as bad debts written-off, exchange rate losses and cancellation fees flights. The Audit & Risk Committee reviews these and seeks assurance that management action is taken to minimise such losses. |
| **Contract waiver report** | The Committee receives a report at every meeting of the tender waivers that have been authorised since the last meeting. Details are provided of the reason for the waiver, the value and the person that authorised it. The Committee also receives an annual summary of all waivers granted during the year. In 2015/16 there were a total of 106 contracts of which 11 were subject to waivers. The Committee scrutinises waivers granted and requests specific assurance from management if it has particular concerns. There continue to be issues with some of the specialist contracts concerning the limited pool of suppliers bidding for the work. |
| **Contract waiver approvals** | In some cases the Committee is asked to approve waivers in advance. This is usually when the contract is of particularly high value. There were 2 contract waivers approved in this way during 2015/16, the Quality and Outcomes Framework (QOF) for a 12 months extension, and CCP’s Technical Support Unit due to insufficient tenders received. |
| **Technical accounting issues** | The Committee receives reports were there are significant changes to our accounting policies or practices. There were no significant changes during 2015/16. |
| **Specific Incident reports** | Where there is an incident particularly relating to a loss suffered by the Institute the Committee receives a report as part of the exercise of its risk management duties. There were none relating to a loss but two reports relating to accidental disclosure of confidential information and one relating to a temporary failure to upgrade anti-virus controls. We also reviewed one case where a FAD needed to be withdrawn due to an error in the assessment report model, being re-assured that this was due to circumstances specific to that assessment rather than an indicator of any more general loss of control. |
| **Approval of redundancy payments** | Redundancies within contractual terms are reported to the Committee. Significant severance payments which go beyond the contractual terms will be cleared with the Committee Chair. There were thirteen redundancies during 2015/16. |
| **Other matters** | There are a range of other matters that the Committee may request or receive reports for. During 2015/16 the Committee received a report on the change of provider of Payroll and ESR, changes to the Government Banking Services and internal audit arrangements. |
Key messages from the year’s work

20 Our work is part of broader governance controls overseen by the Board. As well as our work in support of them, the Board receives at each public meeting a regular report from the CEO which reports on performance and key issues arising, and a report from the Director of Business and Planning Services which sets out the finance and HR state of play and issues.

Comment on 2015/16

21 From our work we wish to highlight to the Board the following issues:

- We were pleased to receive a clean set of accounts for the financial year 2014-2015 and expect a similar clean audit this year. The work is done to very tight timetables but continues to present a positive picture of the accuracy and control of our core financial systems. This continues to be re-enforced by internal audit assessments. It is pleasing that our internal auditors gave a ‘substantial’ rating to our financial management. The only (low importance) recommendation was in relation to budget monitoring guidance to staff. The current government-wide emphasis on making efficiencies in corporate functions may increase the risks of the failure of internal controls.

- We have continued to refine our approach to risk management. We receive at each meeting a statement of the main risks facing the Institute and the mitigation action by the executive. We receive once each year the full register to assure us of the coverage and depth of risk management across the Institute. We have also distilled for our overview a list of the five major strategic risks facing the institute. Those for last year covered: the potential impact of broader changes in the health system causing loss of impact; the risk of new programmes straining corporate capacity, failure to engage effectively with social care audiences, failure to align guidance and evidence services to the needs of users; and competition from other guidance and standards produces. We have reviewed these at each meeting. It is accepted that the current overarching statement of risks needs a full overhaul to reflect the heightened risk environment facing the Institute with its reduced funding. We will receive this at our June meeting.

- We re-enforce this by asking a senior manager to present to us at Committee their take on the challenges and risks in a specific area of responsibility. We have looked at engagement with social care audiences and public health, the risks around the guidelines format and changes to the product, how we engage with the external environment, and the impact of a changing workforce. We believe this adds real world ‘life’ to our assessment of risk in NICE.

- There have been internal audit reports on quality standards, an audit on stakeholder management (its coverage focused on relationship management information systems rather than more broadly on engagement) and a more wider ranging assessment of NICE’s digital strategy. In further support of these and NICE generally, there have been audits on general IT controls, financial management, foreign exchange
transactions and risk management. We note that, of the seven rated reports, three were ‘substantial’ and the rest ‘moderate’. We received none which merited a ‘limited’ or worse rating. We were encouraged that the three ‘substantial’ reports covered the full spread of the Institute’s work and systems: core controls (financial management); strategy (digital development review); and business delivery (quality standards). We were particularly pleased to receive a ‘substantial’ rating for the management of the digital strategy following a thorough assessment from our internal auditors, which reflects well on those responsible for the strategy’s development and delivery.

- We reviewed the work and risks of the Institute’s International work. We were reassured that the work has increasingly been aligned to the government development aims of DH and DFID and to a limited number of charitable foundations. The work has helped strengthen our positive international reputation but comes with risk for the institute and indeed for the staff undertaking the work. We have encouraged more work to assess the impact of our international work.

- Action to combat fraud is important. Following the serious incidence of fraud in management of travel expenses in 2013/14, Finance had increased the number and range of audit checks performed by them. No new incidents of fraud had been detected in 2015/16. We use a system mandated for us by the Department, but we will need to continue to assure ourselves of the effectiveness of controls recognising the issue of proportionality of controls to risks. The Committee may need to take further stock following the awareness sessions planned for mid 2016/17.

- It is important to maintain a tight grip on information security. Any breaches are reported to us: we are satisfied that, where they occur (as has happened on occasion with the release of confidential commercial material, management take the issue seriously and act to put in place further proportionate safeguards. We receive annual reports on information governance (which showed no severe untoward incidents that needed to be reported beyond NICE) and on the handling of complaints and FOI requests, both of which gave assurance. This year staff underwent information governance training. We also reviewed our whistle blowing arrangements and agreed to receive reports on this area either following particular events or annually as a default.

- Effective procurement systems are in place and are applied scrupulously. The waivers we are asked to approve, where it has not been possible to run a fully competitive tender, generally reflect either the limited range of suppliers for the specialist evidence analysis we need to support the guidance work, or the fact of monopoly suppliers with ownership of the information products we wish to make available. In 2015/16 the number and value of waivers were at their lowest level in the last five years reflecting the efforts of procurement to limit their need. We are reassured that, despite the obstacles, our procurement has provided better value for money for the information and evidence materials we provide to health and social care providers and that management continue to look for ways to further improve value for money. At the year end we received notice that
our recovery of VAT paid for such services was under challenge from HMRC which may have implications for us and those we make the information available to.

- We received an advisory assessment of our estates management. There was some disagreement between management and auditors who wished to see more formalisation of the strategy. We were however satisfied that this function has been well managed through a series of moves and changes both in London and Manchester which had been well implemented and delivered significantly improved value for money. Throughout such changes the Board as well as the ARC has been well engaged in developments. We do not consider that more is needed given the scale of the organisation.

- There is a broader issue emerging of proportionality of response to risks. We continue to receive pressure to improve the documentation and formality of controls. We understand that but, at the same time we are under pressure to reduce spend on support services and above all we are facing significant losses of funding. That does highlight the need to be proportionate in designing and applying control and to accept that risks are to be managed against their likelihood and impact, not eliminated.

- In terms of the management of internal audit, this has been the second full year with the new audit service provided through the DH. The change in 2013/14 to a DH led service, with the bulk of the work delivered by PwC, has increased the costs of the programme and created complexities in the management and delivery of fieldwork. With regret, we concluded that the mixed model of private supplier and DH resource was not effective in management terms. We therefore decided to revert to a service and Head of IA provided by DH. We retain the option to supplement resources, where specific technical expertise is needed, from private sector suppliers on the government framework. This will now need to be bedded in from 2016/17.

- The Committee now has included human resource issues within its remit following the decision to end the separate Board HR Committee. We strengthened our membership with the appointment of Linda Seymour from that Committee. It has been a theme of the two committees to press for a more formal workforce strategy, identifying our approach to securing and developing our workforce. In the past we have been concerned that the function has been under-resourced for the needs of the organisation. The context to this was the (now abandoned) plans to move to a shared HR service across the DH family, which inevitably produced some planning blight. We are delighted that this is now resolved, the team has been strengthened, and a strategy presented to the Board last summer. This contains a clear programme for workforce development on which we get regular reports to the Committee from the Head of HR.

- In the past year the Institute faced its Triennial Review. The report was generally positive, confirming the continued need for NICE. It did make a number of recommendations reflecting views of stakeholders (in some cases reports of perceptions rather than evidenced assessments from the team). The Institute has been working through these and the Board has
now received a positive report following an assessment of Board effectiveness commissioned from PwC, our Internal Audit provider at the time.

Challenges and Risks for 2016/17

In the coming year we will continue to assure the range of risks, controls and their management. In terms of development focus we are conscious of the following issues and risks facing the Institute which will guide our work. We have divided these into two broad categories – those that are primarily discrete challenges within the remit of NICE and the strategy we have set, and second those where we may need to be ready to respond to further changes in the external environment.

Discrete Challenges

We would highlight the following.

- **Resource Pressures.** We are conscious of the continuing financial squeeze that the Institute, as other public bodies, will face. The Institute has adopted a cautious approach to spend commitments which has enabled it to manage pressures so far without rapid cut backs in particular areas. The squeeze for the next three years will be of a different order. The Institute will face considerable challenge in continuing to provide the broad range of services we aim to do. That will contain risks; a key dependency will be the introduction of a system of charging for Health Technology Appraisals. If that does not prove possible, then the financial strategy and the sustainability of maintaining the broad offer will need to be reviewed.

- **Provision of Social Care and Integrated Guidance.** Our remit in social care continues to develop and we continue to refine our understanding of how best to be effective in the new architecture of NHS, public health and social care responsibilities. There will be a need to keep in view the impact on our guidance production of the increased focus on integrated care in terms of closer working between health and social care. We will need to continue to test effectiveness in meeting the guidance and evidence needs of these audiences and the implementation impact on the ground of the guidance. There will be a particular challenge from the decision to phase out reliance on our current social care guidance provider and integrate its production alongside other guidance development. We will need to manage carefully the messages to our external social care audience. This change will occur at the same time as new provider arrangements for clinical guidance is being introduced, which we plan to review at one of our general risk sessions with a senior manager at our autumn meeting. The risks are that the changes in provider arrangements impacts on the quality during the period of transition, that guidance will become less sensitive to particular targeted audiences, and that the integrated management could lead to a lowest common denominator approach to the rigour of the evidence on which recommendations are based. There is a continuing need to explore how we best impact on local government and social care audiences.
• **Workforce Risks.** We and the previous Human Resources Committee have encouraged work to develop a more formal workforce strategy, while recognising the current pressures on our HR team. Following the restructure of the HR team (and the ending of the separate board committee) we expect more emphasis in 2016-17 within our own work programme on assurance of relevant HR systems. There are two broader risks facing the Institute. First, that the pressure of seeking to maintain the broad offer while resources are reduced puts excessive pressure on staff to the detriment of quality of outputs and of morale of staff. There will be particular challenge from the change management exercises that will be needed to reduce the workforce in line with future financial resources. At the same time we are conscious of the continuity of senior management we have enjoyed. That will be a risk area to keep under review in the period ahead as it cannot be assumed given the time in post of key players and current pressures on senior staff.

• **Stakeholder Management.** There have been a number of developments in the last year on how the Institute engages, influences and learns from its external stakeholders. This has included coverage in the Triennial Review and suggestions for further consideration in the PwC governance assessment; an internal audit report which highlighted the range of stakeholder management information systems currently operating; plans to consider effectiveness of our public board meetings; the role of non-executives; and consideration of how NICE involves and supports the broader public in its work. The Committee considers that there is a risk of inconsistency and overlap through such work being taken forward through a series of parallel activities and that there would be value in trying to bring the various activities together with a more strategic overview of the different activities.

• **Governance and Future Role of NICE.** The PwC assessment of board effectiveness following the Triennial Review did not contain formal recommendations for implementation but contained a number of suggestions for further consideration; in terms of values, information to the Board between meetings, stakeholder engagement and succession planning (linked to talent mapping). There is a particular issue of succession planning for the board as well as for senior management. Although recruitment to the Board is the responsibility of the DH not NICE, we are conscious of the degree of change there will be at board level. For the ARC there will be particular impact. Of the five committee members at the start of the calendar year, the term of office of one has expired, that of three further members including the chair will end by the end of the calendar year, and the membership of the remaining member is subject to his re-appointment this year by DH. There is a broader issue here. NICE has had remarkable longevity and success. But there is a need to avoid complacency and a risk of missing any signals that could suggest an organisation is reaching its sell by date. That does not appear a current risk but it is important that the Institute continues to review and test its offer and impact to ensure it remains valued. The new board members will be able to bring a fresh perspective to this.
ITEM 7

- **Internal Audit.** Following the change of Head of Internal Audit, we still need to establish a long term more strategic programme for internal audit, aligned to the risks facing the Institute, taking account of key business areas as well as the formal control systems. We will need to be conscious of the value of money of the service and the balance of resources we use. Our aim is to bed in the service and the support from a new Head Of Internal Audit in 2016/17 with a more strategic programme for 2017/18 in place by the start of that financial year. This is work in progress. The programme we received at our April meeting was a stopgap assessment. We will look for a more strategic assessment and longer forward look at our June meeting.

- **NICE International.** The current review of the basis for international work carries reputational risk. The service is highly valued and adds to our international reputation. At the same time the current basis and resourcing is not sustainable. Finding a solution based on a proper role for NICE while protecting the NICE reputation and responding to our stakeholders in this area will be challenging.

**External Environment**

24 Second, are areas where we many need to respond further to changes elsewhere.

- **Countervailing Pressures.** The Institute faces countervailing pressures. On the one hand, the serious resource challenges the NHS faces places greater emphasis on guidance which helps the service prioritise scarce resources and avoids spend on less effective provision. The Board needs to keep the focus of this ‘disinvestment’ work and the need for greater rigour in the weight of the evidence underpinning development recommendations. We need to continue making the case for evidence based practice and policy. On the other hand the Institute continues to be under pressure from initiatives such as the Accelerated Access Review to promote the introduction of new and innovative services in the NHS, adding to the cost. The risk is that our guidance ends up satisfying neither perspective to the detriment of our reputation and traction.

- **Joint Working.** The organisational landscape of service provision in which we operate gets ever more complicated; Sustainable Transformation Footprints being just the latest initiative. The Institute has established partnership agreements with bodies such as NHS England and Public Health England. That is welcome. The Committee considers that some risk remains of duplication and overlap of effort. That is particularly a risk in the public health field where we consider there remains evidence of duplication. That would be mitigated by clearer common understanding of our and PHE’s respective work programmes and distinction and fit between them. It will also be important that broader NHS England work on digital services for the public uses our expertise and capacity effectively, as our Evidence Resources Directorate is seeking to ensure.

- **Central Government Controls.** Although the specific HR shared service agenda has been parked, we can continue to expect further developments in overall government controls affecting us. This could include further
integration of the internal audit service across government, new shared service initiatives, increased emphasis on relating resources to outputs and outcomes delivered, and further review of central government controls under the banner of ‘earned autonomy’. It is not clear the extent to which such initiatives will impact on NICE but we need to be conscious of them and to engage where relevant.

25 The Committee would make two recommendations to the Board reflecting the greater challenges facing the Institute:

- First, given the heightened risk profile we would encourage the Board to engage more regularly with the risk profile of the Institute, beyond the consideration of specific risks contained in individual reports to the board. We suggest that, after the broader review of the overarching risks by the Committee in June, the Board should spend time at one of its meetings considering the general risk profile. That could then be followed by six monthly spot checks of the situation. That is formally within the current governance arrangements but it could be given greater prominence and force at board level.

- Second, we have as a board signed off on a strategy to maintain a broad service offer. That contains risks; particularly if the proposals for charging for TA work on which the financial projections depend prove problematical. We believe the Board should agree leading indicators which would identify stresses developing in three areas – loss of impact in terms of the use and reliance on our guidance products; delivery of the work programme in terms of timeliness and quality; and stress and loss of morale in the workforce. The Business Plan contains more detailed performance measures. However, we are suggesting higher level early warning signals of problems emerging.

26 We should put these in context. The Institute is well managed: with effective processes and controls in its guidance products and processes; strong financial, procurement, information, and digital service management, and recently strengthened HR capacity; and a skilled and committed workforce. That provides a resilient and strong base for the challenges ahead. There is not a current problem, rather we consider that, as a contingency, we should look to identify and be ready to mitigate any signs of emerging stress before they start to impact on the work and success of the Institute.

27 Finally, we should record our appreciation of the excellent work and support from those in the Business Planning and Resources Directorate whose work we most scrutinise and rely on. This is all the more creditworthy given the considerable pressures they have been under in the last year. We are assured that management take governance issues seriously and we have particularly valued the more informal assessments of risks with senior managers that we do at each of our meetings. We also note with pleasure the effective working relationships that continue to operate with our external auditors and the work to develop an effective working relationship with our internal auditors.
The role and operation of the Audit Committee

28 The members of the Committee during the period of the report were as follows:

Jonathan Tross CB Chair
Professor Rona McCandlish
Professor David Hunter
Bill Mumford
Linda Seymour

29 No members declared any conflicts of interests in any of the agenda items during the year.

30 The following managers attend the committee meetings regularly to support it, present reports, respond to audit reports and answer queries from the committee:

Sir Andrew Dillon Chief Executive
Ben Bennett Business Planning and Resources Director
Natalie Sargent Head of Financial Accounting
Catherine Wilkinson Associate Director – Finance & Facilities
Barney Wilkinson Associate Director – Procurement & IT
Julian Lewis Governance Manager
David Coombs Associate Director – Corporate Office

Other managers attend for specific items as required.

31 Representatives also attend from:

PwC Internal audit
The National Audit Office External Audit

32 At the end of each meeting there is a private discussion between the auditors and members of the committee without the management present. This is to give the auditors an opportunity to raise any matters of concern without the presence of the management.

33 The committee is required to meet at least 3 times a year. Meetings took place during the period and were attended as follows:
### Table 3 – Attendance at audit committee meetings 2015/16

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<tbody>
<tr>
<td>Jonathan Tross</td>
<td>P</td>
<td>P</td>
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<td>P</td>
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<tr>
<td>Rona McCandlish</td>
<td>A</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>n/a</td>
</tr>
<tr>
<td>David Hunter</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>A</td>
<td>P</td>
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<tr>
<td>Bill Mumford</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>A</td>
<td>P</td>
</tr>
<tr>
<td>Linda Seymour</td>
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<td>P</td>
<td>P</td>
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**Key** – P (Present for meeting) / A (Absent from meeting / n/a (no longer a member)

The quorum for meetings of the committee is 3, as the table above shows all meetings of the committee during the period were quorate.
## Explanation of internal audit assurance levels

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
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<tbody>
<tr>
<td>Substantial</td>
<td>The framework of governance, risk management and control is adequate and effective.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.</td>
</tr>
<tr>
<td>Limited</td>
<td>There are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.</td>
</tr>
<tr>
<td>Unsatisfactory</td>
<td>There are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.</td>
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</table>
The Evidence Resources directorate comprises two teams which provide a range of functions to NICE:

- The Digital Services team delivers NICE’s digital transformation programme and maintains all NICE’s digital services.

- The Information Resources team provides access to high quality evidence and information to support guidance development and other NICE programmes. It also supports the provision of evidence content to NICE Evidence Services and it commissions key items of content made available to the NHS via the NICE Evidence Services.

The 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 Directorate
May 2016
Performance against business plan objectives for 2015/16

1. This section of the report summarises the directorate’s performance against its objectives at the end of the financial year.

Product quality

2. In 2015/16, the directorate retained the objective to ‘deliver and continue to improve the suite of digital evidence services and evidence awareness products that constitute NICE Evidence Services’. Throughout the year, progress was made as follows:

- The Eyes on Evidence e-bulletin and the Public Health Awareness Bulletin have all been produced on a monthly basis as planned. The Medicines Awareness Daily and Weekly bulletins were also all published on schedule. It is worth noting, with our thanks, that expert resources were provided to support the medicines awareness products by a team from NHS England’s specialist pharmacy services based at Guys and St Thomas’ Hospital in London.

- In response to user feedback, continuous improvement followed the new release of the Evidence Search service in March 2015. Over the course of the year, the service has seen a 57% increase in usage. The service now receives over 450,000 visits per month.

- Improvement projects were also undertaken during the year on the federated search (HDAS) and the BNF service. The new releases will be launched in 2016/17 (see also paragraph 4).

3. 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. Progress through the year was as follows:

- Guidance Information Services (gIS) has established support for the in-house development of evidence reviews for public health guidelines. An additional 1 WTE (Band 7) was put in place to meet this new requirement;

- Evidence Information Services (eIS) has provided information support to the Centre for Clinical Practice’s (CCP) newly expanded surveillance programme according to schedule. Information support has also been provided to CCP to pilot processes for live guidance development. This includes the provision of continuous searches;

- eIS has provided information support to the Health and Social Care Directorate’s surveillance activity. Following a review of pilot processes, a process was agreed and work on the first 5 topics started;
The Information Resources team continued to co-sponsor and provide stakeholder input to the Evidence Management digital project (see paragraph for details regarding the new EPPI reviewer system).

4. A primary objective of the directorate was 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. The following projects we delivered or initiated during 2015/16:

**Strand 1: Web Services**

- NICE.org Information Architecture & User Experience – this project delivered improvements to the navigation on the NICE website, enabling users to find information relevant to them more easily – completed;
- Return on Investment (ROI) Tools – this project launched web-based tools supporting public health investment decisions by commissioners and policy makers in local authorities and the NHS – completed;
- Guidance App – this project updated the Guidance App to introduce the NICE topic browse taxonomy and improve aspects of the design of the Guidance App – completed;
- NICE.org Legacy Decommissioning – this project enabled legacy services to be switched off and de-commissioned removing technical debt – completed;
- MedTech Toolkit – these tools will support medical device companies to successfully navigate health technology assessment with an organisation such as NICE and accelerate the adoption of innovative new technologies into the NHS – prototype version completed, development of final product commencing.

**Strand 2: Pathways**

- Pathways Authoring Improvements – this project enabled the more effective development and maintenance of the Pathways Site by the Publishing team - completed.

**Strand 3: Syndication**

- Syndication Resilience and Architecture – this project closed before completion of discovery as changes to other systems architecture negated the need to continue the project.

**Strand 4: Evidence Services**

- HDAS API for new Core Content – this project delivered technical work to enable certain HDAS databases to move from OVID to the new supplier ProQuest, including for the provision of Medline and PsycINFO databases – completed;
- HDAS Performance and Stability - this project aims to provide a more
reliable, consistent HDAS service for end users by implementing a message broker solution to manage the transactions to the various database providers – currently in beta (open pilot) phase;

- BNF Feed - as part of the new contract agreed between NICE and the BNF, it has been agreed that the BNF will provide an enhanced feed. This project manages the transition from the existing BNF feed to the extended BNF digital feed. The user experience will be improved, taking advantage of the new feature of the feed – approaching beta phase.

Strand 5 – Guidance services

- Publications: Implementation – this project allowed the publication of NICE content to the syndication API and ultimately the NICE website and mobile apps by teams across the organisation. This project was core to the decommissioning of legacy nice.org infrastructure – completed;

- Publications: In-development – this project allowed the devolved management of published information about guidance in-development to the relevant teams across NICE - completed;

- Uptake database – this project replaced two existing databases and delivered a single application to hold information on the uptake of NICE guidance and quality standards – completed;

- Evidence Management (1.0) – NICE has developed a close working relationships with EPPI-Centre/UCL through its work on linked data, and successfully negotiated an agreement whereby NICE can use the EPPI-Reviewer software to support NICE work. In return NICE will contribute to the development of the software. All new NICE guidelines and Interventional Procedures developed internally will now use EPPI-Reviewer to manage the systematic review aspects of the work. Benefits of this on-going project include:
  
  o access to a sophisticated evidence management tool with flexibility to meet the needs of all NICE programmes;

  o availability of historical data when guidance is reviewed;

  o use of a priority screening tool – bringing efficiencies as analysts can screen most relevant articles first (currently being methodologically tested);

  o use of machine learning models to run predictive surveillance processes – new publications can be automatically flagged when relevant for inclusion in a historical review (currently being methodologically tested).

- Knowledge Base (1.0) – the project developed a content platform for the authoring and editing of quality statements. The content housed in the
platform is written in an agreed structure and enriched with labels (metadata) about the content. Changes have been made to the NICE web site to enable the enhanced content to be accessed by internal and external users via a 'discovery tool'. Users of quality standards have provided feedback on the QS knowledge base via the discovery tool. We know that people find it much easier to find the content they need. The majority of users (97.9%) in a recent survey told us the tool is applicable to their work, and 87.5% would use it again.

5. Alongside new projects, it is essential that ‘live services are maintained and continuously improved based on service performance against agreed key indicators’. This continued to be a core function of the digital strategy team in 2015/16. The following activities have taken place during the year:

- During the past year, 428 defects have been raised, and 363 fixed. Work to fix defects has improved over the year:
  - There was a reduction in the number of defects open per week from 89/week in April 2015 to 52/week in March 2016;
  - The number of defects open outside their KPI per week decreased from 72/week in April 2015 to 33/week in March 2016;
  - The graph below shows the long term trend in respect of defect resolution per month, good progress is being made in reducing the number of open defects.

- There were 236 Change Control Requests (CCRs) opened and 156 CCRs completed in the past year. CCRs are small continuous improvement changes which typically require less than 10 days of work.
  - The graph below shows the long term trend in respect of CCRs delivered per month including work in progress. This indicates that the
team is managing current demand for continuous improvement over time.

- The re-procurement of hosting capability (data centres, infrastructure and servers) for NICE Digital Services has been completed and the contract agreed. The migration of digital services to the new cloud based platform, is progressing well.

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 continued 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 through the year has been as follows:

- Links with the Health and Social Care Information Centre (HSCIC) have continued 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 has attended regular showcases of the
nhs.uk new platform for healthcare transactions and met 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 NICE Digital Services team is 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 access 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 put in place 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. NICE has granted HEE a test syndication licence for NICE guidance, CKS and Evidence Search;

- NICE is continuing to work with the NIHR Dissemination Centre to explore opportunities for joint working. The Centre’s products are now ingested into Evidence Search. Discussions are now focusing on how the Dissemination Centre can support NICE’s surveillance activities and cross promotion of each organisation’s products.

8. Throughout 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 contributed to the development of a framework for the assessment of digital applications’. The broader NIB programme has received a substantial funding allocation from the Comprehensive Spending Review. NICE is awaiting confirmation of the funding which the app workstream will receive and of the governance arrangements which will be put in place by NHS England and HSCIC going forward.

**Adoption and impact**

9. A key objective of the directorate with regard to Adoption and Impact is to ‘formally launch and scale-up the NICE syndication service’. Achievements in 2015/16 include:
• Refined and formalised the application and approval process, developed background information and a ‘how to guide’ and launched the syndication website pages which are now generating expressions of interest and applications;

• Completed a review of the clinical decision support market and developed new relationships with leading decision support system providers. Straight syndication of NICE content into such systems is unlikely but other opportunities to embed NICE content into such systems are being investigated;

• As of March 2016, there had been 114 expressions of interest to access content via the NICE syndication service. Out of these expressions of interest, 17 syndication licences have now been issued and signed. These comprise 7 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 including one licence that was re-issued) and 8 test licences (allowing the applicant to test the feasibility of developing a product). To date, 2 of the test licences are due to be converted to full licences, and 1 to a pilot licence. Full licences include Public Health England (awaiting signature) and 2 NHS Trusts; Test licences also cover HSCIC and HEE-eLearning for Health.

10. In conjunction with the development of the syndication service offering, the Evidence Resources team is exploring the business opportunities and challenges involved in granting permissions to use NICE content to 3rd parties, including associated requests for NICE to quality-assure the use of NICE content in these 3rd party products. The team has completed some ground work including:

• Reviewed the potential impact of the amended Directive on the Re-use of Public Sector Information on the future commercial and non-commercial activities of NICE associated with permission to use the NICE content;

• In relation to the above Directive, published a statement of the NICE ‘public task’ based on statute and provided advice on how the ‘Re-use of Public Sector Information Regulations (2015)’ apply to NICE;

• Made available a top-level Information Asset Register.

11. Further work is on-going to explore the potential for revenue to be generated from these activities. The team is engaging with a range of interested parties, in the UK and abroad, and is working with teams across NICE to understand their potential value-added offers. The team is also putting in place basic tools to support revenue generation including developing a pricing model and licensing options. The team is considering new means to protect NICE’s IP, including trademarks.
**Resource management**

12. The objective to *operate within the approved 2015/16 IM&T budget* was 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 ‘Working for NICE’ information on the website and other advertising and social media prompts. Offers have been made for 12 permanent posts with 7 people already in post.
- The re-procurement of Hosting Services is now complete and migration to the new service will yield significant savings in FY16/17.

13. The Information Resources team continued 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 was 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 monitoring the cost savings;
- Exploring the viability of creating full-text electronic repositories for NICE guidance, and the potential for cost saving. This objective is now encompassed within the Evidence Management Project.

14. In 2015/16, the Digital Services team *explored new methods and approaches, and where suitable delivered improvement in the provision of NICE Digital Services*. Specific effort was 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. 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. Two new tools to support the collection of data on user experience were introduced during the year: a tool to observe and analyse how users move across a website and another tool allowing A/B testing of specific features of a website. These tools do not require developer input to be used.

15. 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 for the next 4 years and develop implementation plans.

Selected activity indicators – 1st April 2015 to 31st March 2016

NICE Evidence Services: statistics

16. In line with performance reporting across the board at NICE, this document 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’.
- 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 and user loyalty.
These dashboards and similar dashboards including online versions provide a consistent framework for recording digital services performance.

**Evidence Search**
- 456,836 visits
- 75% meaningful interactions
- 21% return within 10 days

**BNF**
- 461,174 visits
- 34% meaningful interactions
- 29% return within 10 days

**BNFc**
- 68,873 visits
- 33% meaningful interactions
- 36% return within 10 days
17. As detailed above the performance of Evidence services has improved significantly over the last year, with an overall increase in both meaningful interactions and returns within 10 days. Highlights include:

- Visits to Evidence Search are up by 57, and meaningful interactions are up by 9% points;
- BNF and BNFc have had increases in visits by 340% and 300% respectively, and the BNF and BNFc apps have had increases in visits by 47% and 71% respectively.

18. HDAS performance has declined over FY15/16 with fewer visits but is expected to improve with the implementation of the new improved service in July 2016.
**NICE Apps: statistics**

19. The reporting for NICE Apps follows the same new performance reporting model. Downloads are now omitted from this report.

<table>
<thead>
<tr>
<th>Source</th>
<th>Visits</th>
<th>Meaningful Interactions</th>
<th>Return within 10 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>BNF</td>
<td>447,867</td>
<td>81%</td>
<td>87%</td>
</tr>
<tr>
<td>BNFc</td>
<td>99,837</td>
<td>77%</td>
<td>83%</td>
</tr>
<tr>
<td>Guidance</td>
<td>44,065</td>
<td>%</td>
<td>53%</td>
</tr>
</tbody>
</table>

![BNF visits and meaningful interactions chart](chart_BNF.png)

![BNFc visits and meaningful interactions chart](chart_BNFc.png)

![Guidance visits and meaningful interactions chart](chart_Guidance.png)
**Information Services: activity levels**

20. The number of searches undertaken by guidance Information Services (gIS) during 2015-16 to support teams across NICE are summarised in the graph below. The number of searches undertaken for each programme closely mirrors the planned activity levels stated in the 2015/16 business plan. Support for pre-referral technology appraisal topics has increased over the year from a planned 70 topics to 120 topics. This increase in requirement has been achieved by streamlining our support for pre-referral technology appraisal topics.

![Graph showing gIS core activity Apr 2015 - Mar 2016](image-url)
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  
May 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 34 planned topics, 33 published in the 2015/16 business year. The 33 publications are listed in Appendix A. This represents the highest number of guideline publications within a business year, to date.

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. However, the interim findings of the committee are available on the NICE website.

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.

6. The update of the Motor neurone disease guideline published early. This publication was not planned as part of 2015/16 business planning.

Surveillance Reviews

7. 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.

8. To publish 45 surveillance reviews. Of the 45 planned surveillance reviews, 34 have been completed and published up to the end of March 2016, including 5 ad hoc or exceptional reviews. These were due to challenges to decisions or as a
result of identified safety issues being raised. The 33 publications are listed in Appendix A.

9. Twenty scheduled surveillance reviews are in progress as at 31 March 2016 and a further 4 have been scheduled. Four exceptional reviews are currently in progress. This is below the planned output for the 2015/16 year, 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. The 4 and 8 year full reviews have been prioritised for delivery in 2016/17 and it is anticipated we will be able to review the majority of all 6 year reviews. Reviews at 2 years post publication have been deprioritised and will be deferred to their 4 year review.

10. Processes have been developed for a living guidelines approach to searching, including, continuous searching methods for the diabetes suite of guidelines and trial tracking based on NIHR and NCRI trial outputs. A strategy meeting is set for April to discuss these proposals with the senior team in CCP and to plan their implementation into the surveillance work programme.

11. We have developed a reference panel and database of topic experts for CCP activities. We have recruited over 198 topic experts so far from the previous GDG membership. 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 is scheduled to begin in April based on that analysis. This panel of experts will help us speed up the process of finding expert advice for the surveillance programme and in recruiting topic experts to the standing committees.

**Clinical Guideline Updates – standing committee**

12. 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 focus on generalist topics.

- Committee C will focus on updates of condition specific guidelines. Recruitment for condition specific standing members, Cardiovascular and Diabetes and other endocrine disorders for Committee C is also currently underway.

- 25 topics in total have now been referred to the programme for updating of which 13 have published to date. Seven topics have been published in
2015/16. A further 10 topics are currently in development and 8 of these are due to be published in 2016/17

- An evaluation of the first two years of the programmes activities and processes is currently underway.

**New Contracts**

13. 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, have 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 came into effect on 1st April 2016. The RCOG has agreed the title of the new centre as National Guideline Alliance and the RCP has agreed the title of the new Centre as the National Guideline Centre.

- The Statement of Transfer has been agreed and signed by the current host organisations, RCOG, RCPsych and the Velindre NHS Trust.

- A Transition contract between the RCOG and NICE has been agreed and signed by all parties.

- We have agreed with the RCOG to continue to manage the transition of the new centre in a phased approach to mitigate the risk of high staff turnover which could impact on business continuity. This includes, the consultation with staff that starts in April 2016 and maintaining a small satellite office in Cardiff for a period of up to one year. This will allow time for staff to test out new ways of working (home-based), consider relocation to London or seek alternative local employment in a timely manner.

- The NICE steering group continues to meet 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 commenced on the 1 April 2016.
14. 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 complete. Estimated year-end financial positions are being monitored and actioned.

- The CCP end of year financial position is provisionally reporting an overspend of approx. £32,000, representing an overspend of <0.2% of the annual budget. We have utilised some of the NICE underspend by commissioning two additional guideline updates in year, Chest pain and Heavy menstrual bleeding, as well as 2 surveillance reviews.

- £600,000 of CCP underspend, that had accumulated from the Safe Staffing budget, was transferred to NICE reserves resulting in a more accurate financial position for the directorate.

15. 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 January 1st 2015. The Centre is also supporting the implementation of revised considerations as to how resource impact is considered during guideline development for those guidelines in development from April 1st 2016.

- 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. And, we presented to MONITOR on NICE’s methods and application of health economics in guideline development.

- We have representation on the advisory group for a National Institute for Health Research (NIHR) 4 year funded project on “Techniques to include carer quality of life in economic evaluation” that aims to adapt conventional economic evaluation methodology to consider the ‘spillover’ impact of healthcare interventions on family carers.

- We have participated in an NIHR Health Service & Delivery Research (HS&DR) Programme expert seminar to formulate and prioritise the agenda.
for their future programme of research focusing on quality, access and delivery of health services.

- We continue to contract the Technical Support Unit (TSU) to provide specialist technical and methodological advice for challenges in guideline development. We have maintained involvement with the international Grading of Recommendations Assessment Development and Evaluation (GRADE) working group. We have also maintained involvement with the Prediction Model Studies Risk Of Bias Assessment Tool (PROBAST) project, amongst others. A member of staff is sitting on the Delphi panel for three projects.

- 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.

- We continue to attract interest from students and researchers seeking short-term placements to gain experience in clinical guideline development. We attended the launch of the EU-funded project ‘Methods in Research on Research (MIROR) of which we are a partner organisation. We have also agreed with the European Respiratory Society to host, with the Cochrane Collaboration, 2 research fellows for 3 month placements in 2016.

- 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.

**Medicines and Prescribing Programme (MPP)**

16. 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:

17. To publish 30 Evidence Summaries, including New Medicines, Unlicensed/off-label medicines and one Medicines and prescribing briefing. Of the 30 planned topics, 25 have been published up to the end of March 2016.

18. Sixteen Evidence summaries new medicines have been published and are listed in *Appendix A*. 
19. The Evidence summary medicines and prescribing briefing published in March as planned and is listed in *Appendix A*.

20. Seven Evidence summaries unlicensed or off-label medicines have been published and are listed in *Appendix A*.

21. Two rapid Evidence summaries unlicensed or off-label medicines commissioned by NHSE have been published and are listed in *Appendix A*.

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 evidence summary slots scheduled for publication in 2015/16 were removed. The MPP published 25 evidence summaries against a target of 30 for 2015/16 which is within the KPI tolerance of 80%.

23. To publish 2 Medicines Practice Guidelines. Of the 2 planned topics, 1 has been published up to the end of March and is listed in *Appendix A*. The second topic covering the safe use and management of controlled drugs was published in April 2016.

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

**BNF Print and Distribution**

25. The stickers issued by the BNF Publisher which correct errors in the September print editions have now been distributed nationally. Some organisations had already implemented corrective measures internally and have rejected the stickers.

**BNF Online**

26. The steering group comprising representatives from NICE, the BNF Publisher, HSCIC, NHS BSA, DoH, Pharmaceutical Advisors Group and the Devolved Administrations which was established to develop an NHS owned information standard to replace the legacy BNF hierarchy is now meeting quarterly. Work between the BNF, HSCIC and NHSBSA to develop a mapping between the old and new hierarchies is progressing well.

27. Development of the new BNF platforms on NICE Evidence has been delayed due to staffing and technical issues with NICE IM&T. An alpha platform is expected to be delivered in April for feedback by NICE MPP staff and Associates. A public beta version is expected in May or June 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.

BNF Accreditation

29. The BNF Publisher submitted a draft Accreditation application in April, which was reviewed by analysts in the Accreditation team. Feedback highlighted some areas requiring further refinement. The BNF Publisher must submit its final application by 27 May.

Cross Institute Work

Guidance Development Project (GDP)

30. 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:

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

32. NICE has entered into a strategic partnership with the EPPI Centre/UCL which enables NICE to use the EPPI-Reviewer tool to support systematic review and other evidence management tasks across NICE programmes. The tool is now being rolled out across NICE programmes, and the potential to introduce efficiencies is being investigated. Work will be undertaken over the next few months to provide an integrated solution to improve the efficiency of the document supply process.

33. The transformation of NICE guidance involves breaking down NICE content into elements that can be discovered outside the document in which they were created. The first project in the knowledge base stream, creating a new searchable dataset of quality statements, is almost complete.

Recent developments

Access and Waiting Times - working in Partnership with NHSE

34. The Access and Waiting Times work programme has transferred to the Health and Social Care Directorate.
Contextualisation of clinical guidelines for non-UK settings

35. 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.

36. Following an oral presentation showcasing this work was presented at the Guidelines International Network (GIN) conference in October ’15, 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 met with the Clinical Effectiveness Unit Team at the Department of Health, Ireland.

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. There are now 77 associates (including 5 on sabbatical/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. The MPP published 40 MECs as planned in 2015/16. The MECs are published on NICE Evidence search.

43. 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.

44. Between May 2015 and end of March 2016 the MPP have completed 26 surveillance reviews and continue to provide ad hoc medicines related advice and support to the team.

45. The MPP also provide formal targeted support to CGUT for standing committee updates. Formal arrangements have now been agreed and disseminated and will be fully implemented during 2016/17. 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 is investigating options for implementation resources to support the Care of the dying adult guideline. The guideline published in December 2015.

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.

50. NHS England has accepted a proposal to develop up to 10 evidence summaries in 2016/17 on a fee-based model to support the Commissioning support document (CSD) work lead by CHTE. The topics are likely to be mainly new medicines and are intended to bridge the gap until the CSD programme is fully up and running in 2016/17. Work is scheduled to begin in Q2 June 2016. The MPP are working with CHTE and engaging with NHS England to explore and agree the process for topic selection.

51. The MPP are also working alongside CHTE and other NICE teams to develop the CSD process and company submission template. The CSD working group is engaging with NHS England on a regular basis to agree requirements and formalise the process. The CSD work is intended to provide NHS England with a product in between a STA and an Evidence summary to help inform commissioning policies.
Key indicators

CCP Activity Summary

Clinical Guidelines Activity Summary

Published clinical guidelines

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

Published Surveillance Reviews of Clinical Guidelines

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

Published Evidence Summaries

Cumulative Evidence Summaries Publications 2015/16

- Planned
- Actual
- Variance
Appendix A

Clinical Guidelines Publications (April 2015 – March 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)

**Surveillance Reviews Publications (April 2015 – March 2016)**

Two year reviews:
- Antisocial behaviour and conduct disorders in children and young people (CG158)
- Crohn's disease (CG152)
- Developing and updating local formularies (MPG1)
- 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)
- Urinary incontinence in women (CG171)
- 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)
- Lung cancer (CG121)
- Ovarian cancer (CG122)

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:
- Acutely ill adults in hospital (CG50)
- 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) x 2
- Surgical management of otitis media with effusion in children (CG60)
- Caesarean section (CG132)
- Depression in children and young people: Identification and management in primary, community and secondary care (CG28)

**Medicines Prescribing Programme Publications (April 2015 – March 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
• ESNM 69: Prevention of chemotherapy induced nausea and vomiting in adults: netupitant/palonosetron
• ESNM 70: Attention deficit hyperactivity disorder in children and young people: guanfacine prolonged-release
• ESNM 71: Moderate to severe acute post-operative pain: sufentanil sublingual tablet system

Evidence summaries medicines and prescribing briefings:

• ESMPB 2: Chronic wounds: advanced wound dressings and antimicrobial dressings

Evidence summaries unlicensed or off-label medicines:

• ESUOM 43: Interstitial cystitis: oral pentosan polysulfate sodium
• ESUOM 45: Symptoms of peripheral arterial disease: Ramipril
• ESUOM 46: Hypersexuality: fluoxetine
• ESUOM 47: Infantile haemangioma: topical timolol
• ESUOM 48: Excessive daytime sleepiness in Parkinson’s disease: modafinil
• ESUOM 49: C3 glomerulopathy in the native kidney: eculizumab
• ESUOM 51: Pulmonary hypertension in neonates: sildenafil

Rapid Evidence summaries unlicensed or off-label medicines:

• ESUOM 44: Prevention of recurrence of C3 glomerulopathy post-transplant: eculizumab
• ESUOM 50: Hormone-sensitive metastatic prostate cancer: docetaxel

Medicines Practice Guidelines:

• Antimicrobial Stewardship (AMS) (NG15)
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  
May 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 2015-16. It also highlights other recent developments within the Centre that may be of interest to the Board.

Business Plan Objectives 2015-16

Technology Appraisals Programme
1. The technology appraisal programme achieved the business plan target of publishing 45 pieces of final guidance. By 31 March 2016, the programme published 47 pieces of final guidance. 20 topics were cancer topics, and 27 topics were non cancer topics.

Patient Access Scheme Liaison Unit
2. The patient access scheme liaison unit exceeded its target of producing 12 pieces of advice to Ministers and has provided advice on 36 patient access schemes in the business year.

Medical Technologies Evaluation Programme
3. Based on MTAC’s past selection and routing decisions, 8 medical technology guidance documents were expected to be published in 2015/16. The programme published 4 pieces of guidance during 2015/16. The timelines on the other 4 topics needed to be extended due to either alignment with related guidelines, regulatory delays or the need to wait until the availability of key clinical data.

4. The programme published 36 medtech innovation briefings (MIB) compared with a business plan target of 40. More topics than expected (12/48) were delayed or stopped for reasons outside NICE’s control, for example, products withdrawn from UK market.

5. The MTEP team has implemented the process of reviewing its published guidance, commencing the review of 8 topics as planned in 2015/16.

Interventional Procedures Programme
6. The interventional procedures programme published 34 pieces of guidance.

Diagnostics Assessment Programme
Highly Specialised Technologies Programme

8. The HST programme published 1 piece of guidance in the 2015/16 business year and ran 4 scoping workshops

Observational Data Unit

9. 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.

10. Activity for 2015/16 progressed to target.

NICE Scientific Advice

11. NICE Scientific Advice achieved recovery of all programme and overhead costs and exceeded its annual business targets for 2015/16.

12. By the end of March 2016, NICE Scientific Advice completed 48 advice projects since the beginning of the financial year, hosted 4 educational seminars and attended over 40 external events whilst also working on the development of the novel Medtech Early Technical Assessment (META) Tool.

Science Policy and Research Programme

13. The Science Policy and Research programme is continuing its work on two IMI (Innovate Medicines Initiative: an EU funded project to speed up the development of better and safer medicines) funded projects – “GetReal”, a pan-European consortium of medicines regulators, health technology assessment bodies, pharmaceutical companies, patients and other stakeholders to explore the role of real-world evidence for informing decision making; and “ADAPT-SMART” which is exploring the design of 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 grants to deliver our work.

14. The team is exploring the potential of participating in a range of EU funded research projects, including IMI and Horizon 2020 (EU Research and Innovation programme with nearly €80 billion of funding between 2014 to 2020). Currently, NICE is an active partner on three IMI research project funding submissions.

15. The team commissioned four projects through its Research Support Unit (RSU); including work to map the social care research funding landscapes and a project exploring how a range of real-world data sources in clinical, health and social care might be able support NICE guidance production.

16. In collaboration with guidance producing teams, the SP&R team led the identification “key priority” research recommendations for fast-tracking
through NIHR prioritisation processes. This arrangement was introduced in January 2015 following negotiations with the NIHR, which established closer cooperation between NICE and NIHR during guidance production. This provision is proving very beneficial. Since the new process was implemented, research recommendations identified through guidance production has resulted in five topics being considered or accelerated through NIHR. There has also been an increase in requests from committee Chairs and Centre Directors for NIHR input and advice.

17. 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 is being presented to the Board at this meeting. 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.

18. A paper on proposals for the development of the SP&R programme was presented to SMT in March; SMT approved the proposal to increase NICE’s involvement in research via participating directly in research grant-funded activity. This activity will focus of identifying key research projects of strategic importance across all directorates.

Cancer Drugs Fund

19. On 1 April 2016, the Technology Appraisal programme implemented new methods and process in line with the new operating model of the Cancer Drugs Fund (CDF).

20. Products that are currently on the CDF will go through a rapid reconsideration process. The first products to go through this process will be considered by the appraisal committee on 25 May 2016.

The Office for Market Access (OMA)

21. 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 face to face meetings with companies.

Topic Selection

22. During the 2015/16 business year, the Topic Selection team considered 305 topics for either the Technology Appraisal or Highly Specialised Technologies programmes.
Key indicators

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

![Figure 1. Programme activity April 2015 - March 2016]

<table>
<thead>
<tr>
<th>KEY</th>
<th>Ref</th>
<th>Programme</th>
<th>Unit of output</th>
</tr>
</thead>
<tbody>
<tr>
<td>TA</td>
<td>Technology Appraisal</td>
<td>Final Published Guidance</td>
<td></td>
</tr>
<tr>
<td>IP</td>
<td>Interventional Procedures</td>
<td>Final Intervention Procedures Document</td>
<td></td>
</tr>
<tr>
<td>DAP</td>
<td>Diagnostics Assessment</td>
<td>Diagnostics Guidance Document</td>
<td></td>
</tr>
<tr>
<td>MTEP</td>
<td>Medical Technologies Evaluation</td>
<td>Medical Technology Final Guidance Document</td>
<td></td>
</tr>
<tr>
<td>HST</td>
<td>Highly Specialised Technologies</td>
<td>Final Published Guidance</td>
<td></td>
</tr>
</tbody>
</table>
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

COMMUNICATIONS DIRECTORATE PROGRESS REPORT

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 Directorate
May 2016
Communication directorate’s activities in 2015-16

1. This paper looks back at our communications activities during the past 12 months and demonstrates how we met our 2015-2016 business plan objectives.

   **Objective 1**

   **NICE's offer**: Communicate the narrative about NICE’s role (USP) within the health and social care system

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**External relations**

2. In 2015-2016 a restructure of the external communications team brought together the media, public affairs and policy, and events teams into a smaller, integrated group. The change has bedded down well.

**Media**

3. Over the year, we have responded to analytics about uptake of our press releases by producing fewer releases, summarising several topics or pieces of guidance in one release and targeting their distribution more carefully.

4. The tone of articles has remained consistent month on month. Over the coming months, we will work toward changing neutral coverage into positive coverage:

   ![Tone of articles chart](image)

   - April 15: 69% Positive, 31% Neutral
   - May 15: 70% Positive, 30% Neutral
   - June 15: 70% Positive, 30% Neutral
   - July 15: 66% Positive, 34% Neutral
   - August 15: 64% Positive, 36% Neutral
   - September 15: 80% Positive, 20% Neutral
   - October 15: 82% Positive, 18% Neutral
   - November 15: 80% Positive, 20% Neutral
   - December 15: 57% Positive, 43% Neutral
   - January 16: 70% Positive, 30% Neutral
   - February 16: 66% Positive, 34% Neutral
   - March 16: 66% Positive, 34% Neutral

5. We have continued to respond to queries over the year and there is clearly a demand for our reactive press function:
6. The press team has now become a fully functioning multimedia team and will continue to adapt to develop alternative platforms. The team is finding new and effective ways to reach our audiences directly while continuing its traditional role of working with journalists.

7. An example of the multimedia approach was the launch of the draft guidance on multimorbidity. It received a good amount of coverage particularly in trade publications including *PharmaTimes*, *GP Online* and *Pulse*. Most notably, Dr Mark Porter covered the draft guidance in his column for *The Times* calling it “one of the most important” that NICE has produced. A video and blog by David Haslam explaining multimorbidity was published online, with nearly 500 views of his video.

8. A press conference in September 2015 launched our guideline for the social care sector to promote high-quality home care services for older people. 11 journalists from key outlets including BBC, Sky, Daily Mail and Daily Telegraph attended. The guideline was reported widely across national and regional media. It ran all day, including in the evening news programmes. All of the pieces were positive. This was echoed on Twitter, where reaction was also extremely positive. There was also widespread coverage for our key audiences through trade media including *Community Care*, the *Local Government Chronicle* and in local and regional newspapers and broadcasts.

9. On Twitter, over the past year, the overall number of impressions and interactions continued to increase significantly and we passed the 100k followers mark. This has largely been driven by an increase in the number of tweets.

10. Top tweets all included multimedia content. A tweet about our new TB guidelines with a simple graphic was retweeted 91 times with 21.3k impressions.

11. Over the year, our interaction rate dropped slightly but replying to followers will address this and is likely to drive up impressions further.
12. The table below shows the analytics package that we will be using this year to monitor and evaluate our work through Twitter. The board reports going forward will contain a summary of this information but we thought it would be useful to demonstrate in this year end report, the breath of statistics available to us.
13. Our tweet with the most interaction included a link to our video featuring a GDG member describing the need for the low back pain update. The video has
become our channel's most viewed uploads on YouTube, with around 1,800 views so far. The draft guideline was covered extensively in the national, local and specialist media including the Guardian, Daily Mail, Independent, Times and Daily Mirror. The focus of much of the coverage was on the recommendation not to use acupuncture for treating back pain, a reversal of NICE’s previous recommendation.

14. Other key stories in 2015-2016 included the draft NICE guideline for the care of the dying adult which was published at the end of July. It generated 68 individual pieces of media coverage. 95% was positive in tone while the rest, 3 opinion pieces, took a neutral stance. Pre-recorded interviews for BBC News, Sky News and Channel 5 News, and a live lunchtime interview for ITV News, ensured that NICE spokespeople were present in all major TV news bulletins throughout the day. BBC R4’s Today Programme also featured a live NICE interview about our draft recommendations and the differences between our guideline and the now-defunct Liverpool Care Pathway. The guideline also featured prominently and positively in The Times, Daily Mail, Telegraph, The Sun, Daily Mirror and the Guardian.

15. In June, The Times, Daily Mirror and Daily Express splashed NICE’s updated suspected cancer guidance on their front pages. The guideline also led BBC and Sky News bulletins and summaries.

The coverage in all the national newspapers was prominent and positive – overshadowing the health news from the BMA and RCN conferences. The guideline generated a very positive column piece by Simon Jenkins in the Guardian. It achieved more than 133 individual pieces of media coverage on its publication day. Our spokespeople carried out a wide range of interviews and were featured by ITV News, Channel 4 News and the Today programme on BBC Radio 4. The story was covered extensively – unusually achieving prominent broadcast interest for more than 24 hours. We worked with a number of charities to generate supportive third-party comments. The most notable of these were Cancer Research UK and Macmillan Cancer Support, whose comments were featured widely by the media. She produced videos in support of the guideline
(on the NICE YouTube channel) which have been frequently watched and shared on social media.

16. Our embargoed press conference for the clinical guideline, Menopause: diagnosis and management generated blanket positive media coverage in November. The guideline headlined all morning national and regional news broadcasts and included additional interviews and features on BBC Breakfast, BBC News, Sky News, ITN, Good Morning Britain and Victoria Derbyshire TV programmes. Radio 4 Today programme, Radio 5 Live, Radio 4 Woman's Hour and range of BBC regional radio stations also featured interviews on top of running it as their lead story. Daytime TV magazine shows discussed the guideline, including Loose Women and The Wright Stuff. The guideline was the front page story on the Daily Telegraph and The Times, and featured in all national newspapers, as well as a range of regional titles and health trade journals and magazines. There is a diary of the coverage on Storify which gives details of the story through social media – especially Twitter.

**Annual review**

17. In July, we published the NICE Annual Review. The review is an interactive, web-based snapshot of our work in 2014-15. It also contains the annual report and accounts which were laid before Parliament on 15 July. Work on the next review is nearly complete.

**External events and speaking engagements**

18. We also supported speaking engagements for SMT, Board members and other NICE colleagues at 182 events.

19. The NICE conference in October was well received with nearly 1000 delegates in attendance. They felt the conference was well organised and ran smoothly and this year’s topics were more challenging and engaging. NICE will lead a key strand of the Quality and Patient Safety Conference in July. NICE’s next conference will take place in May 2017.

**Enquiry handling**

20. Over the year we responded to 12,485 enquiries, an increase of 5% from 2014/15.

21. We are continuing to receive a growing number of highly complex enquiries. For example the decision to stop the guidance programme for safe staffing topics led to a number of requests for unpublished documents and the rationale behind the decision. The extension of the funding directive for the technology appraisal on sofosbuvir for hepatitis C has also attracted a high level of scrutiny.
22. We responded to 159 requests made under the Freedom of Information Act over the year which represents a 12% increase from the previous year. MP correspondence also rose by 10% to a total of 164 in 2015/16.

23. The source of enquiries has remained broadly the same over the year with the NHS accounting for 34% and members of the public accounting for 35% of enquiries received. Enquiries from international organisations and individuals accounted for 6% and enquiries from pharmaceutical companies and manufacturers, 5%.

24. During the year we have identified recurring themes from enquiries to inform service improvements. For example we have responded to a growing number of enquiries from stakeholders frustrated they are unable to quickly find out who is registered in their organisation for a particular guideline. We are now implementing a solution to enable the enquiry team to provide the information for stakeholders directly, reducing the workload for guidance teams and providing a much better customer service for our stakeholders.

Objectives

**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.

**Easy to use content**

25. The content editors worked on all stages of development of the nearly 200 guidance products published in 2015-16, as well as on the costing tools, information for the public and other products that supported them. We aimed to help make recommendations as clear and easy to use as possible. The 2 ‘suites’ of guidelines, on diabetes and trauma, that were published posed particular challenges. We planned and worked with the developers to ensure NICE issued consistent, coherent and high-quality products.

26. Other user-focused activities this year included working with developers on tables to help healthcare professionals explain risks associated with taking or not taking HRT, and preparing specially designed materials for presentations to the committee for the guidelines for people with learning disabilities.

27. We have provided editorial expertise to a wide range of projects. The content editors shared their experience of working on and presenting NICE guidelines to support the NCC and NICE social care team on NICE’s first social care guidelines. We also worked with teams on new, shorter formats for products such as MIBs, using information from user research to help meet the needs of the audience. And during the year we launched a writing and style hub on NICE
Space. It includes a new, shorter and easier to read style guide, information about Writing for NICE training and an Ask the editor blog.

**Guidance transformation project**

28. The Publishing team is involved in most of the workstreams to transform the way NICE develops and presents guidance. One important part of the project is to ensure NICE content is quick to find, easy to read and consistent. Our users need to be able to find what they need when they need it. Activities in 2015-16 to support this included:

- Standardising formats for guidance titles to improve consistency.
- Developing and launching a new, easier to navigate format for on-line versions of guidelines – the update to the coeliac disease guideline was the first to be published, in September 2015.

29. We have led a project to publish discussion sections as part of the NICE online (web viewer) version of guidelines. The aim is to be more transparent and visible about how decisions are made during guidance production. The format will be used for all NICE guidelines, and will include new information, such as resource impact. This work has involved a lot of collaboration with colleagues in the collaborating centres and in NICE. We shared the draft template widely with teams within NICE and refined the template based on their feedback, including aligning with international standards for developing evidence-based guidelines (GRADE and DECIDE). We have written detailed notes for users to accompany the template that underpins the new format. The new format is now being tested out.

30. The digital publishing team made a major contribution to the knowledge base (KB) project. This is working towards a vision where NICE content is managed as smaller pieces of information (components) and the relationships between them. The first stage of this project (KB1) focused on quality standards. We have worked closely with the quality standards team and digital services and are currently quality assuring the content before it goes live. After launch, the digital publishing team will be the first users of the knowledge base system - updating and maintaining the quality standard content. This project is a first step towards new ways of authoring structured content – an end to authoring in MS Word.

**Presenting guidance to our users**

31. The digital publishing team is responsible for getting all of NICE’s guidance and advice onto the website. In 2015-16, this has meant converting about 40 documents to web format every month and making sure they are published on time. In October, we moved to using NICE Publications, a system developed by Digital Services. Before the launch of the live system we carried out intensive
work to quality assure and improve the presentation of information on the website. We took the opportunity to make improvements to the overview pages for new guidelines. We found that the changes increased the numbers of people going to and staying on the recommendations pages. We are now working on making improvements to the overview pages for CHTE outputs and improving the overview pages for published guidelines.

**NICE Pathways**

32. The NICE Pathways site was launched in May 2011, with 15 pathways. Since launch, the site has been continually developed. In April 2016, we achieved the objective of having 100% of NICE guidance – making Pathways truly a visual, integrated view of everything NICE has said. From May 2015 to April 2016, we published 42 new or fully updated pathways and did over 400 updates to take account of new guidance, add or change links to related pathways, or carry out routine maintenance.

![NICE Pathways from 2011 to 2016](image)

33. NICE Pathways help to increase access and uptake of NICE recommendations. Web stats from February to March 2016 shown in the table below demonstrate the number of users accessing recommendations via Pathways and via the web-based guideline is very similar.

<table>
<thead>
<tr>
<th>Topic</th>
<th>NICE website sessions (recommendations chapter)</th>
<th>NICE Pathway sessions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>20,000</td>
<td>23,000</td>
</tr>
<tr>
<td>Type 2 diabetes</td>
<td>22,500</td>
<td>16,200</td>
</tr>
<tr>
<td>COPD</td>
<td>12,000</td>
<td>12,500</td>
</tr>
</tbody>
</table>

34. The remit of the former pathways team in the HSC directorate changed with the reorganisation in 2015. From April 2016, the Publishing team will be responsible for developing, maintaining and reporting on pathways objectives. HSC will continue to be responsible for clinical oversight of pathways.
NICE website

35. The website had 17 million visits over the last year and we are seeing an ongoing increase in visits per month. In March 2016 there were over 1.6 million visits.

36. The percentage of visits that result in a meaningful interaction such as downloading a guideline or completing a form is also steadily increasing. Over the last year we saw a total increase of 6% of meaningful interactions from the previous year.

37. During 2015/16 the web team led the implementation of a new publishing system to enable guidance teams to publish documents directly to the website. The system has been well received and has made the publishing process quicker and simpler.

38. Over the year the web team has created a wide range of new online content to promote services such as Scientific Advice and the new Office for Market Access. Content has included videos, infographics, and blogs.

39. The web team has implemented new ways to gather feedback from website users and to monitor how our audiences navigate through the site. We are now able to watch and record user journeys to identify any problem areas. We are also running regular usability tests directly with users to get more in-depth feedback.

40. We have used the analytics and feedback from the site to implement a series of improvements. For example they have worked with the digital services team to re-design the stakeholder registration form and to make the navigation to guidance simpler for users.

41. NICE launched a new design for the website homepage in January 2016 which continues to perform strongly. In particular we have seen improvements for users accessing the site through their mobile or tablet.

42. We completed a review of over 200 pages of the ‘About NICE’ section of the website to identify content that needed refreshing and updating. A series of content workshops has been conducted and new content will be published over the coming weeks.
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

43. The changes made to the audience and user research function are working well. Over the year we have streamlined our processes for delivering research projects and refocused the work to provide more proactive insights. We have also begun to work with external partners to increase our reach and achieve more with reduced resources.

44. We have delivered more than 20 audience research projects to inform a broad range of work programmes from the development of new digital products to the future direction of the public involvement programme.

45. We have created a new Insight Community which now has over 1,500 members representing our many varied audiences and is continuing to grow. The Insight Community is a valuable resource and enables us to get feedback and insight quickly where there are time critical projects and also enables us to track general perceptions of NICE over time.

46. The team have also developed mechanisms to centralise the insight data captured through internal teams. As part of this new approach we have established an internal insights group looking specifically at insights and feedback on our digital products including the website. This group identifies and validates emerging issues to inform ongoing digital improvements. For example improvements are being made to the stakeholder registration form, guidance list pages on the website and also the search function as a result of the group’s work.

47. Our expertise in audience research was recognised by the Cabinet Office when we were selected recently to lead a pilot project to develop a reputation survey for rolling out to other ALBs and government departments.

48. Work also began last month to support the Cheshire and Merseyside public health collaborative with a programme of insight work to identify solutions to increase the uptake of NICE guidelines as part of a regional hypertension strategy. Through a programme of interviews, focus groups and an online survey we will gain valuable insights from GPs and other primary care professionals.
Objective 4

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

49. During 2015/16 we successfully delivered a fully responsive version of our intranet, NICE Space. This later went on to win an award from our software provider for ‘most engaging intranet’. We celebrated the intranet’s first birthday with a virtual birthday party, including video, poll and blog. Feedback about NICE Space from employees over the last year has been hugely positive. More staff are routinely posting comments and feedback on articles, and our polls are completed by 120 staff on average each week.

50. We ran Healthy Work Week in January 2016. Events included mindfulness sessions in partnership with the National Gallery and Manchester Art Gallery. We had social media shares (including Fitbit), staff ate nearly 2,000 pieces of fruit and went on lunchtime walks and runs.

51. We added video to our communication channels, including 2 videos produced for Healthy Work Week. The 'highlights' video premiered at our all staff meeting.

52. Our weekly staff newsletter has been refreshed and we have seen the average open rate rise from 65% to 78% in the last 12 months which is above industry average.

53. We also produced 4 editions of our staff magazine, NICEtimes. Features included an interview with George Freeman MP, the devolution agenda, NHS England’s vanguard sites and a day in the life of our chief executive. We are now working to develop a new digital format of NICEtimes which will launch in July.

Objective 5

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

54. During 2015-2016 the directorate went through a restructure that identified significant overall savings and helped us find efficiencies in the way we work. In the year ahead we will be identifying further budget reductions in line with the organisation’s cost savings programme. These changes give us an opportunity to explore new and innovative ways to communicate with our key stakeholders and to help NICE fulfil its strategic objectives.
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 alongside key programme indicators.

The Board is asked to review the progress report.

Professor Gillian Leng  
Director, Health and Social Care Directorate  
May 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 March 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. All business milestone have been met this year including the publication of:

- Four social care guidelines as planned:
  - 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

- Seven public health guidelines as planned:
  - Workplace health: older people
  - Community engagement: Improving health and wellbeing and reducing health inequalities
  - Sunlight exposure: risks and benefits
  - Oral health promotion: general dental practice
  - Older people: independence and mental wellbeing
  - Dementia, disability and frailty in later life – mid-life approaches to delay or prevent onset
  - Workplace health: management practices

- All 6 surveillance review decisions scheduled for public health guidelines.

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. The programme has successfully completed its objectives for 2015/6 including:

- Hosting 26 student champion training events over the year, more than the predicted target of 15 events for the year
- Identifying 46 examples of Local Authority public health teams using NICE public health related quality standards in their contracts (target 20)
- Identifying 107 examples of Health and Wellbeing Boards using NICE guidance, advice and quality standards to improve population health (target 40)
- Identifying 107 (51%) 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 (target 50%)
- Tracking the use of quality standards within hospital trusts – 221 (86%) trusts have been identified as using quality standards to improve clinical services (target 80%)
- Achieving 100% of NICE guidance being available via NICE Pathways. This programme of work has now become part of the Institute’s routine programmes of work and progress will be monitored by the Communications team from April 2016.

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. Over 2015/16, the programme has:

- Received 501 applications for 92 vacancies across 59 guideline and standing committees. Of these:
  - 94 places were offered, slightly more than anticipated because of the exceptional quality of applications
  - A further 44 lay people were invited to join the Quality Standards, Public Health, Diagnostics and Guidelines Update Committees as specialist members
  - 76 people gave testimony to the Technology Appraisals and Highly Specialised Technologies Committees as patient experts
- Delivered the following training events:
  - Seven training sessions for guideline committee members
– Two masterclasses for North West HealthWatches
– One ‘Introduction to NICE’ masterclass
– Four 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. The programme has delivered against its objectives in 2015/16 including publishing:

- Thirty eight quality standards, exceeding the planned 36 for 2015/16
- An indicator menu for the Quality and Outcomes Framework and the Clinical Commissioning Outcome Indicator Set
- Twelve final accreditation decision reports comprising 4 new accreditations and 8 renewals
- Seventeen endorsement decisions, which exceeded the plan and interest in the programme continues to grow. A plan to promote the programme externally is in development. Work is being undertaken to explore options for income generation in 2016/17
- The following additional outputs: 8 quality and productivity case studies; 6 Cochrane reviews that highlight ineffective interventions; and 59 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, resource impact tools and responsibility for tracking the uptake of NICE guidance. Over 2015/16, the programme has successfully:

- Produced 16 adoption scoping reports for guidance teams to advise them of the likely barriers to adoption and completed 87 ‘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
- Published 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.

- Continued to develop NICE’s uptake resource. The database now contains 1,533 data points, of which 890 were identified during 2015/16. This resource is being used to support guidance and quality standard reviews.

- Continued 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.

- Published an updated version of the quality standards service improvement template in March 2016. This allows people to select individual statements from all quality standards to target their service improvement activities to their own area of practice, and measure their progress against relevant measures.

- Conducted 42 implementation need analyses and produced 12 associated implementation chapters. Supported the publication of 22 shared learning case studies. Supported publication of endorsement statements for 10 resources developed by other organisations.

**Notable recent developments**

**Public health guidelines**

7. A process for involving Public Health England (PHE) staff during guideline development has been established by working closely with PHE. This will enable staff with experience in specific public health topics to help inform the guideline scope, identify key stakeholders and work with NICE throughout the guideline development process. They will also help gather information from local practitioners via the PHE Centres. This process of engagement will result in joint badging of the final guideline.

**Stakeholder engagement**

8. Work started in 2015/16 to identify key stakeholders and priorities for engagement. This work will be refined further during 2016/17, and an overarching strategic engagement plan will be developed outlining the future approach to engagement.

9. The Points of Engagement meetings between NICE, Public Health England (PHE) and the Department of Health continue to provide strategic oversight to ensure complementarity and coordination of actions relating to NICE’s public
health activities. Work is also progressing through the associated thematic subgroups.

10. The internal Social Care Forum set up during 2015/16 has recently refreshed the action plan for social care engagement. The plan now includes:

- Development of a secondary guidance output to better support those working in social care. This output will be based on Quality Standards and pilot work is scheduled to start in April 2016
- A programme of training for NICE staff about social care, which will be undertaken during 2016/17.

11. In addition, the partnership agreement with the Social Care Institute for Excellence (SCIE) has been renewed, and the strategic engagement work undertaken by the Chair of NICE has been extended to a range of organisations across the social care sector.

Choosing Wisely

12. Choosing Wisely is an initiative established by the Academy of Medical Royal Colleges (AoMRC) to avoid wasteful or unnecessary medical tests, treatments and procedures. In April 2016, NICE submitted 5 ‘do not do’ recommendations to the Choosing Wisely initiative, spanning different physical and mental health conditions. These recommendations were chosen from those included in Quality Standards, and then assessed on the basis of the population affected, the applicability of shared decision making, the cost of the practice being recommended and the potential for significant cost saving. AoMRC is scheduled to implement Choosing Wisely during 2016.

Resource impact

13. The new NICE resource planner was published on the 30 March 2016 (previously known as the forward planner). The planner (<https://www.nice.org.uk/about/what-we-do/into-practice/resource-impact-assessment#planner>) focuses on recently published and forthcoming guidance and provides an indication of resource impact together with a link for more detailed information. Clinical Commissioning Group (CCG) chief financial officers are being informed on a monthly basis of updates to the planner and any new resource impact tools.

14. Work to develop the methodology for providing guideline development groups with potential resource impact is progressing well. Over 50% of CCGs nationally have been approached to seek their views about what constitutes a “significant” resource impact.
The Asthma project

15. The Asthma project to test the feasibility of implementing the draft recommendations relating to specific diagnostic tests is now underway. 78 expressions of interest have been received from GP practices across England and 7 sites have been selected. The selected sites cover a range of urban and rural settings and practice types. Project induction visits to collect baseline data are now underway, with full testing and data collection running from 01 May - 31 October 2016.

Quality Standards committees

16. The standing orders and terms of reference for the Quality Standards Advisory Committees (QSAC) have been reviewed in line with the corporate schedule. A minor update was made relating to the number of specialist committee members usually in attendance.

17. The chairs of all four QSACs have had their term of appointment extended following discussion with the Director. They have subsequently been involved in the review and reappointment of committee members approaching the end of their initial 3 year term of appointment.

Shared decision making

18. NICE is continuing to work with NHS England to develop proposals supporting their shared decision making agenda, including identifying and presenting the underpinning evidence to support a suite of NHS England patient decision aids (http://sdm.rightcare.nhs.uk/pda). Part of this work includes looking at ways of supporting shared decision throughout the guideline development process, including creating the conditions for external organisations to develop their own patient decision aids based on NICE guidance. Options for developing a quality assurance mechanism for decision aid developers are also being developed.

19. NICE will host the third Shared Decision Making Collaborative on 23 June and will explore future national-level policy developments in relation to shared decision making, including how these concepts can achieve greater traction in the system through education, culture change and initiatives such as Choosing Wisely.
Key programme indicators

21. 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**
Examples of Local Authority public health teams using NICE public health related QS as part of contracts
Examples of Health and Wellbeing boards evidencing use of NICE guidance, advice and quality standards to improve population health

Examples of Local Authorities using NICE outputs

Annual Target  Actual to date

20  46  40  107
Public Involvement Programme

Lay member recruitment summary - April 2015-March 2016

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</table>

Quality Programme

Quality Standards

[Graph showing cumulative published and cumulative plan for Quality Standards from April 15 to March 16]
Accreditation reports

Adoption and Impact Programme

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.
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
AUDIT AND RISK COMMITTEE

Unconfirmed minutes of the meeting held on 20 April 2016 in Manchester and VC to London

Present
Jonathan Tross, Non Executive Director (Chair)
Linda Seymour, Non Executive Director
Bill Mumford, Non Executive Director
David Hunter, Non Executive Director

In attendance
Ben Bennett, Business Planning and Resources Director
Gill Leng, Deputy Chief Executive
Natalie Sargent, Head of Financial Accounting, Finance
Barney Wilkinson, Associate Director, Procurement & IT
Felicia Wright, NAO
Mark Wood, PwC
Jeremy Nolan, DH
Wajid Shafiq, DH
Julian Lewis, Governance Manager

APOLOGIES FOR ABSENCE
Andrew Dillon, Chief Executive; David Coombs, Associate Director, Corporate Office; Catherine Wilkinson, Associate Director of Finance & Estates; Karen Finlayson, PwC.

DECLARATIONS OF INTEREST
1. The Committee expressed their appreciation for the help and support provided by Mark Wood and Karen Finlayson (PwC) as it is their last meeting, and welcomed Jeremy Nolan and Wajid Shafiq (DH) to their first meeting.
2. There were no declarations of interest.

MINUTES OF THE LAST MEETING
3. The minutes were agreed as a correct record.
4. Action log: The progress detailed in the action log was noted.
   o Points 149 and 152: the committee suggested that Chris Carson attend the October meeting instead of June.
   o Larraine Howard-Jones is to attend the June meeting in relation to point 150.
MATTERS ARISING

Lung Cancer FAD

5. Meindert Boysen explained that NICE did not publish the document when it said it would, because NICE found an error in the financial model. Although the outcome remained broadly the same after the error had been corrected, NICE felt that it would be better to withdraw the document than to publish it with the error.

6. He further advised that NICE now provide the financial models to the companies who normally can be expected to test it, but even so there is no guarantee that the companies would find any errors. NICE does not have a particular internal process for testing models, relying on the evidence review group.

7. The Committee noted that the company did not test the model, which is unusual. It noted further that it appears to be an isolated event rather than an indicator of more general quality problems. It asked that any future FAD withdrawals be reported to the committee.

RISK MANAGEMENT

Assurance Framework and Risk Register

8. The Committee noted that the statement of strategic risks is in need of overhaul. It should come to the June ARC meeting. The risk register is somewhat out of date as it is based on prior year objectives. A full review of the register and a more engaged discussion is needed at the June meeting.

9. Generally, the Committee commented that wording and terminology needed to be refined and updated. It noted that the report on the services and tools (due in quarter 2), supporting the System Partnership objective, would be helpful. Further, that the list of 23 partnership agreements be circulated to members. Generally it would help to bring out the measures used to show effectiveness in managing the risk.

   Action: JL/GL

10. The Committee discussed how Directors make the Board aware of changes in risks and it was felt that it would be helpful if a marker could be added that would highlight any risk changes. Although the Board has expected the ARC to deal with the detail, they should from time to time wish to look at the key risks themselves.

   Action: GL

11. The risks around the Resource Management objective could be broken down into current and longer term issues, as well as those that are ‘trackable’. Further, that additional controls, like Change Management Policy to manage sickness absence, be included.

   Action: JL
INTERNAL AUDIT

Stakeholder Engagement

12. Mark Wood presented the report. Jane Gizbert attended for this item.

13. The Committee discussed the report and noted that the title is somewhat misleading – to complete an audit on engagement with stakeholders would be a much larger and more complicated issue. The committee noted that the audit focused on the Communications team stakeholder database management. It had highlighted the parallel systems in place. The Committee noted that significant steps have already begun to improve consistency and coherence.

Digital Development

14. Mark Wood presented the report. Nick Titterington attended for this item.

15. The Committee noted that the audit had thoroughly tested what NICE does, and gave strong reassurance on the management of the strategy. It welcomed and endorsed the recommendations. The Committee extended its congratulations to Nick and his team on the positive report.

Foreign Exchange

16. Mark Wood presented the report, which was noted by the Committee. The issue primarily related to NICE International activity which was subject to a broader review.

Assurance report

16. Mark Wood presented the Assurance report, which included the Head of Internal Audit's opinion of Moderate Assurance, which is the same rating as last year.

17. The Committee noted the report and that, of the seven rated audits, three were ‘substantial’ and the remainder ‘moderate’. It thanked PwC for their support over the last three years. The committee also thanked them for the Board Effectiveness report which was provided at the Board meeting earlier.

Draft Audit Plan

18. Jeremy Nolan presented the draft, advising that the plan is based on PwC work. The Committee requested that the terminology be improved, and considered that, although this reflected past plans, further thought was needed to produce a more strategic plan based on the key risk areas following the new strategic register. The Committee reminded the auditors of the need to spread audit work throughout the year to avoid bottlenecks.

Action: BB/DH
WHISTLEBLOWING report

19. Ben Bennett confirmed that there have been no incidents to report.

20. The Committee briefly discussed whether a question could be included in a future staff survey to establish awareness of the policy among staff although the survey did test people’s confidence in raising difficult issues. The Committee noted the report and that in future an annual report will be satisfactory if there are no incidents to report.

Action: BB

LOSSES AND COMPENSATIONS report

21. The committee noted the report. It recognised that a degree of loss was the acceptable price to pay for encouraging cheaper, less flexible, travel tickets and that the international conference loss had not been borne by NICE

2015/16 ACCOUNTS – Forecast Outturn

22. Ben Bennett gave a verbal update - an expected underspend of £0.5mil against Revenue budget, which includes a provision of £1.5mil for Management of Change.

23. Felicity Wright advised, that due to the EU referendum, Parliament will have an additional summer recess which may impact on when the Comptroller & Auditor General will be able to sign off on NICE’s Annual Report and Accounts.

CONTRACT WAIVERS

Waivers report

24. Barney Wilkinson presented the report, which was noted.

Annual Waiver Summary

25. Barney Wilkinson presented the report, adding that this year had the fewest number of waivers.

26. The Committee noted that despite the increase in number of contracts, the number and value of waivers have reduced which gives assurance that the best possible deals are being procured.

USE OF SEAL

27. The Committee noted the report.
ANY OTHER BUSINESS

28. There was no other business.

PRIVATE DISCUSSION

29. As normal the Committee briefly reviewed progress with auditors without officers present.

30. The Committee reviewed their draft Annual ARC Report. The discussion was reflected in the revised Report to the Board.

Future meeting dates

20 June 2016  1:30pm
13 October 2016  2pm