## AGENDA

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<tr>
<td>16/093</td>
<td><strong>Apologies for Absence</strong></td>
<td>To receive apologies for absence (Oral)</td>
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<td>16/094</td>
<td><strong>Declarations of Interests</strong></td>
<td>To record any conflicts of interest (Oral)</td>
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<td>16/095</td>
<td><strong>Minutes of the Board Meeting</strong></td>
<td>To approve the minutes of the meeting held on 21 September 2016 (Item 1)</td>
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<tr>
<td>16/096</td>
<td><strong>Matters Arising</strong></td>
<td>To consider matters arising from the minutes of the last Meeting (Oral)</td>
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| 16/097 | **Chief Executive’s Report**  | To receive the Chief Executive’s report (Item 2)  
Andrew Dillon, Chief Executive |
| 16/098 | **Finance and Workforce Report** | To receive a report on NICE’s financial position to the end of September 2016 and an update on the workforce strategy (Item 3)  
Ben Bennett, Director, Business Planning and Resources |
| 16/099 | **Accelerated Access Review** | To note the report and the implications for NICE (Item 4)  
Professor Carole Longson, Director, Centre for Health Technology Evaluation |
| 16/100 | **NICE Charter**             | To approve the updated charter (Item 5)  
Jane Gizbert, Director, Communications Directorate |
| 16/101 | **Appropriate Disinvestment and Investment: Support from NICE** | To approve the proposals (Item 6)  
Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate |
| 16/102 | **Audit and Risk Committee Membership** | To approve the revised membership of the Committee (Item 7)  
David Haslam, NICE Chair |
To appoint the Vice Chair and Senior Independent Director David Haslam, NICE Chair

**Director’s Report for Consideration**

16/104 Health and Social Care Directorate

Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate

**Directors’ Reports for Information**

16/105 Centre for Guidelines

16/106 Centre for Health Technology Evaluation

16/107 Communications Directorate

16/108 Evidence Resources Directorate

16/109 Committee Minutes

To receive the unconfirmed minutes of the Audit and Risk Committee held on 13 October 2016

16/110 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 18 January 2017 in the University Hospital, Lewisham, SE13 6LH

**PART 2 (if required)**

Representatives of the press and other members of the public will be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest [Section 1(2) Public Bodies (Admission to Meetings) Act 1960].
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Annual General Meeting and Public Board Meeting held on 21 September 2016 at Nottingham Council House, Old Market Square, Nottingham, NG1 2DT

These notes are a summary record of the main points discussed at the meeting and the decisions made. They are not intended to provide a verbatim record of the Board’s discussion. The agenda and the full documents considered are available in accordance with the NICE Publication Scheme.

Present

Professor David Haslam Chair
Dr Rosie Benneyworth Non-Executive Director
Professor David Hunter Non-Executive Director
Elaine Inglesby-Burke Non-Executive Director
Tim Irish Non-Executive Director
Andy McKeon Non-Executive Director
Linda Seymour Non-Executive Director
Jonathan Tross Non-Executive Director

Executive Directors

Sir Andrew Dillon Chief Executive
Professor Gillian Leng Health and Social Care Director and Deputy Chief Executive
Ben Bennett Business Planning and Resources Director
Professor Carole Longson Centre for Health Technology Evaluation Director

Directors in attendance

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

In attendance

David Coombs Associate Director – Corporate Office (minutes)

16/076 APOLOGIES FOR ABSENCE

1. None.

16/077 CONFLICTS OF INTEREST

2. None.
16/078 MINUTES OF THE LAST MEETING

3. The minutes of the Board meeting held on 20 July 2016 were agreed as a correct record.

16/079 MATTERS ARISING

4. The Board reviewed the actions arising from the Board meeting held on 20 July 2016. It was noted that progress with the strategic savings programme and NICE’s relationship with the Care Quality Commission (CQC) will both be discussed further at the October Board away-day. The consultation paper on proposed changes to patient and public participation in developing NICE guidance is being revised in light of the discussion at the July Board, and will be issued to Board members for comment.

5. All other actions were complete.

16/080 CHIEF EXECUTIVE’S REPORT

6. Andrew Dillon presented his report, describing the main programme activities and financial position for the five months to the end of August 2016. He highlighted the amendments to the format of the report and stated that a new template to standardise the content and presentation of the Directors’ reports to the Board is being produced. This should be in place for the November Board meeting.

7. Linda Seymour asked about progress with reviewing the longer term approach for supporting the implementation of NICE’s social care guidance, which is currently part of the contract with the Social Care Institute for Excellence (SCIE). Gill Leng confirmed this review remains underway, and the Board will be kept updated on this matter.

8. Andy McKeon asked whether the Technology Appraisal Committee (TAC) chairs are fully supportive of the proposal for the committees to discuss five topics a day, given the feedback from one of the chairs at the August Board strategy meeting. Carole Longson confirmed the TAC chairs were fully engaged with, and supportive of, this development.

9. The Board received the report.
16/081 FINANCE AND WORKFORCE REPORT

10. Ben Bennett presented the report which outlined the financial position as at 31 August 2016 and provided an update on the workforce strategy. The full year forecast out-turn is a £2.1m underspend against the revenue resource limit. This includes provision of £1m to meet liabilities arising from planned restructures as part of the strategic savings programme.

11. Rosie Benneyworth highlighted the need to ensure that decisions to hold posts vacant are managed to avoid inappropriate workloads for remaining staff. She asked whether the policy of recruiting staff internally could affect the quality of those recruited. Ben Bennett stated that current vacancies are largely due to turnover. However, as the restructuring progresses, it will be necessary to hold open some posts to minimise the loss of staff. The impact of this will need to be carefully managed. Whilst the default is to seek to recruit internally, there is the ability to recruit externally where there are not sufficient internal candidates.

12. The Board received the report. It was agreed that sickness absence should be presented graphically to identify any changes over the course of the savings programme, and appendix A should be revised to reflect the transfer of the staff previously working on NICE International.

ACTION: Ben Bennett

16/082 ANNUAL REPORT AND ACCOUNTS 2015-16

13. Andrew Dillon presented the annual report and accounts 2015-16 which had been laid before Parliament. He highlighted the ‘clean’ external audit opinion.

14. Jonathan Tross, chair of the Audit and Risk Committee, stated that the positive audit opinion demonstrates the strength of NICE’s financial management. Looking forward, he stated that it would be helpful for NICE to be able to calculate the cost of producing its respective guidance products. Ben Bennett stated that the project to recover the costs of the technology appraisal and highly specialised technologies programmes will be a first step in providing this visibility.

15. The Board formally received the annual report and accounts.

16/083 ANNUAL WORKFORCE REPORT

16. Ben Bennett presented the annual workforce report 2015-16 that provided a summary of the workforce profile at 31 March 2016 and particular workforce issues of note in 2015-16. He highlighted that as the workforce has grown, the average cost of each whole time equivalent (WTE) has continued to fall since 2011-12. Ben noted that staff from black, Asian and minority ethnic groups continue to be underrepresented in higher pay bands, and this issue is one of NICE’s equality objectives. He noted that there continues to be a disparity
between the proportion of applicants for staff roles that are from black, Asian and minority ethnic groups and those that are appointed. Ben thanked Larraine Howard-Jones, Associate Director – Human Resources, for the production of the report.

17. In response to a question from the Board, Ben stated that the current pressures on the HR team have affected the completion rate for exit interviews. He acknowledged the scope to improve the completion rate.

18. The Board received the report. It was requested that future reports provide further analysis of the expenditure on training to demonstrate take-up by directorate/centre as a proportion of staff, and to outline expenditure compared to previous years and, if possible, other organisations.

ACTION: Ben Bennett

16/084 STAFF SURVEY

19. Ben Bennett presented the report that outlined the results of the 2016 survey, and the proposed action plan in response. The report also provided an update on the action taken in response to the 2015 survey.

20. Linda Seymour welcomed the results which indicate staff continue to view NICE as a good place to work. She queried the proposed actions in relation to stress and mental health. Given the level of research available from organisations such as MIND and the Work Foundation, and the evidence underpinning NICE’s own guidance on work-place health, she stated that NICE does not need to undertake further research in response to the survey. Ben Bennett agreed with the comment and highlighted that the health and wellbeing group will actively look to include mental wellbeing as part of healthy work week. He agreed that the group could also benchmark NICE against its own work-place health guidance.

21. Andy McKeon expressed surprise that only 54% of staff felt they had good opportunities to use their skills. It was agreed to benchmark this response against other organisations if possible.

ACTION: Ben Bennett

22. The Board received the report and supported the proposed action plan. The Board congratulated the Senior Management Team for maintaining the positive results given the challenges faced by NICE. Board members highlighted the importance of management analysing variations within NICE, and identifying any areas of concern, particularly in relation to bullying and harassment. The Board noted the importance of being alert to staff morale, and the heightened risk of behaviours that could be perceived as bullying and harassment behaviours during the upcoming management of change exercises.
16/085 UPTAKE AND IMPACT REPORT

23. Gill Leng presented the first of the new six monthly uptake and impact reports that provided an overview of the information NICE has about how its products are being used, and information on NICE’s impact in the wider health and care system. Gill welcomed Sally Chisholm, Programme Director – Adoption and Impact, to the meeting who led the production of the report and will be leaving NICE this week. Sally provided further background to the report and highlighted that future iterations will include more information on NICE’s impact.

24. The Board welcomed the report and the evidence of NICE’s impact. Several Board members noted the graphic that summarised the outcome of national audits or reports that included audit criteria relating to recommendations from NICE products. It was suggested that it would be helpful to understand why some audits found improved uptake of NICE guidance, and others showed reduced uptake from previous audits.

25. Board members noted that the report will continue to evolve and highlighted suggestions for future reports. Further information on the uptake of NICE’s productivity and decommissioning products was requested, including figures on the resultant savings from the use of NICE guidance. The imbalance in the level of information available on public health and social care, compared to healthcare was noted. It was suggested that it would be helpful to provide further information on the reasons for this, and the rationale for selecting the case studies in the report. It was requested that the charts showing uptake of technology indicate the dates guidance was published and updated.

ACTION: Gill Leng

26. The Board received the report and thanked Sally Chisholm for her contribution to NICE.

16/086 ANNUAL EQUALITY REPORT

27. Ben Bennett presented the annual equality report for 2015-16. The report provided information on the characteristics of those applying to join the advisory committees in 2015-16, and those subsequently appointed, along with the results of the annual survey of committee members. The report also included information on equality considerations in guidance published in 2015-16 and summarises the workforce profile at 31 March 2016. Ben thanked David Coombs, Associate Director – Corporate Office, for producing the report.

28. Andy McKeon highlighted the underrepresentation of those from black, Asian and minority ethnic groups on the committees and in the workforce. He highlighted that such staff are particularly underrepresented compared to the populations of London and Manchester, where NICE is based. Ben Bennett stated that NICE has an equality objective to increase applications to its committees from individuals from black, Asian and minority ethnic groups. The issue with the workforce is that the proportion of individuals from black and
minority ethnic groups who are appointed to the workforce is much lower than the proportion of applicants. NICE cannot positively discriminate in favour of such applicants to address this.

29. Gill Leng noted the upcoming requirement for organisations to report on pay by gender and suggested NICE should seek to be an exemplar in this reporting.

30. The Board received the report.

31. A NICE Fellow in the audience referred to the requirement for all organisations with more than 250 staff to report information on pay by gender. She also urged NICE to support any employees who may wish to raise equal pay claims.

16/087 DIRECTOR’S REPORT FOR CONSIDERATION

32. Jane Gizbert presented the update from the Communications Directorate. She drew the Board’s attention to key items of note in the report, including the promotion of the Fellows and Scholars programme, the delivery of savings within the directorate, and developments in NICE’s digital activities. She highlighted that the NICE website has recently been ranked as the third most visited in the NHS, behind NHS Choices and the Care Quality Commission.

33. The Board discussed and welcomed the ongoing development of NICE’s multimedia activities. In response to feedback from the recent regional engagement event, Jane Gizbert confirmed that the website continues to be reviewed and refined. David Haslam asked for information on the level of visits to the NICE website from outside of the UK.

ACTION: Jane Gizbert

34. The Board received the report and thanked Jane Gizbert for the work of the Directorate.

16/088-16/091 DIRECTORS’ REPORTS FOR INFORMATION

35. The Board received the Directors’ Reports.

36. Rosie Benneyworth asked whether consideration is being given to how NICE guidelines can promote integrated care following the establishment of the Centre for Guidelines. Mark Baker suggested this matter is explored further in a future discussion.

16/092 ANY OTHER BUSINESS

37. David Haslam noted this was David Hunter’s and Linda Seymour’s last public Board meeting. On behalf of the Board, he paid tribute to their contribution.
38. The Board then passed the following resolution to move to a brief part 2 meeting to discuss confidential matters:

“That representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest”.

NEXT MEETING

39. The next public meeting of the Board will be held at 1.45pm on 16 November 2016, in UHSM Academy, Wythenshawe Hospital, Southmoor Road, Manchester, M23 9LT.
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CHIEF EXECUTIVE’S REPORT

This report provides information on the outputs from our main programmes to the end of October 2016 and for the financial position to the end of September, together with comment on other matters of interest to the Board.

The Board is asked to note the report.

Andrew Dillon
Chief Executive
November 2016
1. This report sets out the performance of the Institute against its business plan objectives and other priorities, for the 7 months ending 31 October 2016 (6 months to the end of September for the financial position). It also reports on guidance published since the last public Board meeting in September and refers to business issues not covered elsewhere on the Board agenda.

Performance

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

3. Extracts from the Directors’ reports, which refer to particular issues of interest, are set out at Appendix 2. The performance of the main programmes between April and August 2016 is set out in Charts 1 and 2, below.

**Chart 1: Main programme outputs: April to October 2016**

![Chart 1: Main programme outputs: April to October 2016](chart.png)

**Notes to Chart 1:**

a) IP refers to Interventional procedures (minimally invasive surgery)
b) HST refers to the highly specialised technologies programme (drugs for very rare conditions)
c) Medicines summaries consist of both summaries (information on indications, harms and costs) of newly licensed medicines, and advice on the use of licensed medicines in diseases and conditions for which they are not licensed
d) The variance is the difference between the target output for the reporting period, as set out in the business plan and the actual performance

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

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

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

**Notes to Chart 2:**

a) MIBs (medtech innovation briefings) are reviews of new medical devices
b) QP (Quality and Productivity) and Cochrane reviews report on opportunities for making better use of resources
c) Medicines summaries provide information on new medicines and on the unlicensed or off label use of medicine
Finance position (Month 6)

6. The financial position for the 6 months from April 2016 to the end of September 2016 is an under spend of £1.3m (4.4%) against a budget of £28.7m, compared to £1.0m (4.2%) against a budget of £23.9m at the end of month 4. Non pay is under spent by £0.3m (2.0%) against budget. Pay is £0.9m (4.9%) under spent against budget. The currently estimated year end position is an under spend of £3.0m. The position of the main budgets is set out in Chart 3. Further information is available in the Business Planning and Resources Director’s report.

Chart 3: Main programme spend: April 2016 to September 2016 (£m)

Senior management

6. The Board governance review earlier this year noted the importance of talent management and succession planning. When considering the review, the Board noted and welcomed NICE’s active participation in the Department of Health talent management process. Board members also discussed the arrangements to ensure appropriate cover for the Senior Management Team (SMT) in the event of a director’s absence.

7. Other than for the Chief Executive, the management structure at NICE has not identified permanent deputies for the directors. This has not caused any particular difficulties, during routine absences, such as annual leave. During longer absences, such as when the director posts have become vacant, satisfactory interim arrangements have been put in place. As part of assuring the
Board that continuity of management arrangements is clear in advance of any absences, planned or unplanned, deputies have now been appointed in each of the centres and directorates.

8. In absences of less than 4 weeks, the deputy will act for the director when necessary, supporting their senior directorate colleagues as required, enabling decisions to be taken at the appropriate level. The deputy will attend the Board, SMT and Guidance Executive, unless the director has previously indicated that other arrangements are more appropriate. In absences over 4 weeks, the deputy will assume the director’s responsibilities, including line management of the senior team and will be paid an acting up allowance. The precise range of functions covered will be agreed with the Chief Executive on a case by case basis.

9. Nominations were invited from eligible candidates, (the highest graded senior managers immediately accountable to the directors) the following deputies have been designated:
   - Business Planning and Resources: Catherine Wilkinson
   - Centre for Guidelines: Christine Carson
   - Evidence Resources: Mark Salmon
   - Communications: Moya Alcock
   - Health and Social Care Directorate: Paul Chrisp (directorate deputy) and Judith Richardson (deputy medical director)

   Judith Richardson, a registered medical practitioner, will deputise for Gill Leng in her capacity as the Institute’s senior clinically qualified executive. The deputy in the Centre for Health Technology Evaluation will be confirmed in due course.

10. Our participation in the Department of Health-led talent management programme has already enabled a number of senior managers to take part in development programmes. As part of an exercise being coordinated across the national agencies, I am currently working with each director on their career aspirations.

**Balanced scorecard**

11. The balanced scorecard for the first 6 months of the financial year is set out at Appendix 5. The scorecard tracks the Institute’s performance in managing its affairs against a series of measures.
Appendix 1: Business objectives for 2016-17

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

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<th>Objective</th>
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<tr>
<td>Content</td>
<td>Guidance, standards and evidence services published and provided in accordance with the schedule set out in Appendix 2 and the balanced scorecard Delivery within the range allowed for in the balanced scorecard</td>
<td>Performance against our business plan objectives is set out elsewhere in the Chief Executive’s report. The balanced score card report is published with the Board papers in November.</td>
</tr>
<tr>
<td>Publish guidance, standards and indicators, and provide evidence services against the targets set out in the Business Plan and in accordance with the metrics in the balanced scorecard.</td>
<td>Continue to engage with the social care and public health sectors to understand their needs and expectations of NICE guidance Redesign processes and methods to better deliver against these expectations and produce definitive plans by September 2016</td>
<td>This work is being taken forward as part of an updated, Institute-wide implementation strategy. The leadership role for engaging with the social care communities rests with the Health and Social Care Director. New processes are now in place to improve strategic engagement across social care and public health. Two new Short Guides have been published based on NICE guidance for social care, and have been very well</td>
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<td>Develop and then implement the first year of a three year strategy to</td>
<td>Strategy agreed with the Board and principal stakeholders by July 2016 Actions monitored through regular reports to the Senior Management Team and the Board Balanced budget set for 2017-18</td>
<td>The Board agreed the strategic basis for NICE’s offer to the health and care system at its meeting in October 2015 and through discussion at subsequent meetings. In June it received a report on the detail of the structural changes and in October it received a report on progress to date.</td>
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<td>reshape the offer from NICE, to take account of the reduction in Department of Health Grant-in Aid funding.</td>
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<td>Develop the methods, processes and capacity to implement the new Cancer</td>
<td>CDF transition arrangements completed, in accordance with the schedule for 2016-17 agreed with NHS England New methods and processes operational from April 2016 Additional capacity in place by end July 2016</td>
<td>The NICE methods and processes were put into operation from 1 April 2016. Subsequently, the new CDF went live on 29 July. We are continuing to implement the transitional arrangements from the old CDF as scheduled, including the publication of the first rapid reconsideration topics. More than 75% of the additional posts funded by NHS England have been filled.</td>
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<td>Drugs Fund, in conjunction with NHS England.</td>
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<td>Manage the change from the existing to the new commissioning arrangements for social care guidance efficiently and sympathetically.</td>
<td>Agree the terms of the transition process with the current contractor by July Put in place the 2016-17 actions in the transition process</td>
<td>Arrangements have been agreed with the Social Care Institute for Excellence (SCIE) on the transfer of their work in developing NICE social care guidelines by the end of 2017-18. A schedule for the completion of current guideline development work has been agreed. The longer term approach for supporting the implementation of our guidance for social care, currently part of the contract</td>
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<td>Implement the relevant recommendations in the final report of the Accelerated Access Review</td>
<td>Assess and report to the Board on the financial, operational and reputational implications of the final report for NICE guidance programmes Develop an implementation plan and report to the Board on progress with its implementation</td>
<td>The Accelerated Access Report has been published. We are now engaging actively with the Office for Life Sciences and the Department of Health to plan the implementation of the recommendations relevant to NICE, including identifying additional resource requirements where necessary.</td>
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<td>Review options for the long term development of NICE International's health systems development work in low and middle income economies</td>
<td>Identify and evaluate the options for the long term future of NICE International Board consideration of the preferred option in June Complete the actions for the preferred option by December</td>
<td>The Board received a report on the options for the future of NICE international's work in low and middle income economies at its June meeting. The NICE International team transferred to Imperial College in September, to develop the Gates and DFID-funded work on the International Decision Support Initiative.</td>
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**Engagement**

<p>| Share the stewardship of the Five Year Forward View with the other Arm’s Length Body signatories. | Regular participation in the governance arrangements (the main Board and its programme groups) of the Five Year Forward View Strategies and policies, developed by the Five Year Forward View Board are | The Chief Executive and Deputy Chief Executive attend the Five Year Forward View Board meetings and NICE is represented on the associated programme boards. We have been engaged with the development of the |</p>
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<td>Ensure that all new guidance topics that are commissioned align with a health and care system priority, strategy or policy and that each guidance publication clearly articulates the case for adoption for its key audiences.</td>
<td>Each topic associated with a system priority, strategy or policy System owner identified for each topic The case for adoption published for each topic</td>
<td>A senior clinical lead in NHS England is engaged with each clinical guideline. All guidance topics have been confirmed as priority topics with the Department of Health and/or NHS England.</td>
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<td>Identify and operate systems and processes, with NHS England and Public Health England, which ensure that business critical functions are delivered, duplication avoided and opportunities to contribute to and participate in complementary activity are identified and acted on.</td>
<td>Identify the key business relationships between the two organisations by April 2016 Develop and track metrics to assess and monitor the successful operation of these relationships in line with updated partnership agreements</td>
<td>All relationships between NICE and NHS England and Public Health England (PHE) have been mapped, and an updated Partnership Agreement has been signed with PHE. We are tracking progress in the relationships through regular quarterly meetings.</td>
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<td>Work with the MHRA, the Office for Life</td>
<td>Ensure the timeline for all EAMS</td>
<td>Our process for engaging with</td>
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<td>Sciences and NIHR to ensure timely technology appraisal guidance on EAMS products is delivered on the timeline agreed with the Department of Health</td>
<td>designated products in the technology appraisal programme is consistent with the Scheme’s expectations</td>
<td>companies and the MHRA on EAMS (Early Access to Medicines Scheme) products is in place and continues to be applied successfully to EAMS products.</td>
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| Ensure that NICE is compliant with its duties under the Equalities Act 2010 | Publish annual equality report in September 2016  
Develop an action plan to deliver equality objectives | The annual equality report was presented to the September Board meeting. The newly established cross Institute equality and diversity group is overseeing actions to deliver the equality objectives at its quarterly meetings. |

**Adoption and Impact**

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<td>Develop a consolidated set of metrics and data to assess the uptake and impact of the guidance and evidence services provided by NICE.</td>
<td>Measure and report against a set of indicators that enable the Senior Management Team and the Board to exercise a judgement about the uptake and use of a defined range of guidance and evidence services.</td>
<td>The first biannual uptake and impact report was considered and accepted by the Board at its September meeting.</td>
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| Continue to work with CQC to ensure that NICE quality standards and guidelines complement and reinforce essential standards, building on existing work to map NICE Quality Standards into the CQC inspection work. | Agree with CQC on the extent of use of relevant guidance and quality standards in their inspection regime.  
Put in place a process for sampling the use made of the guidance and standards | NICE and CQC held a joint workshop in July to review how we are working together, and to consider the extent to which guidance and standards might be used in the future. Further work is in progress to determine how we can assess the use made of guidance and standards. |
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<td>Redesign and promote, in conjunction with NHS Improvement, NHS England and the Local Government Association, a comprehensive resource for commissioners and providers on the use of NICE guidance to help make savings, improve productivity and promote optimal use of interventions.</td>
<td>Redesigned resource available from April 2016 Usage monitored and reported to the senior Management Team and the Board</td>
<td>There is an ongoing project to improve the online NICE disinvestment resource so it provides a more useful experience for users. This is combined with a more strategic review, in conjunction with partners, to determine the best role for NICE in identifying significant opportunities for making savings. New ideas are being tested, and a more detailed report has been brought to the Board in November.</td>
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<td>Subject to the release of budget for this programme of work, Contribute to the National Information Board Framework for Action through the development of an endorsement scheme for health apps, working closely with Public Health England and HSCIC.</td>
<td>Secure the resources necessary for NICE to be able to make a meaningful contribution to the work Subject to adequate resourcing, agree a programme of work with the key partners Deliver against the 2016-17 elements of the agreed work plan</td>
<td>Arrangements for the distribution of funds and the delegation of their management are still in discussion. However, some funds were released in July, which will enable us to maintain our commitment to developing a system for evaluating digital apps.</td>
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<tr>
<td>Take into account the views and concerns expressed by key stakeholders through the government-wide RepTrak reputation research project</td>
<td>Report RepTrak metrics to the Senior Management Team and the Board</td>
<td>Discussions are currently underway with colleagues at the Cabinet Office Government Communications Service (GCS) who commissioned the Reputation Institute to work with NICE on a pilot project to assess our reputation with key stakeholder groups (not the informed public). Severe delays in the Reputation Institute’s contribution to the project</td>
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</table>
The 4th wave of the Reptrak survey of informed public was reported to us in July. NICE’s reputation amongst the informed public was calculated by measuring the organisation’s strength in several dimensions including product/services, governance, leadership, performance, and positive impact on society. The survey found that NICE has a strong reputation (70.4), which is significantly above that of the UK Public Sector average (62.7). Across the 64 ALBs and government departments that were ranked in this wave, NICE was within the top 15.

<table>
<thead>
<tr>
<th>Objective</th>
<th>Actions</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operate within resource and cash limits in 2016-17. Actively manage the appropriate application of any non-recurrent funding as early as practicable in the financial year.</td>
<td>Performance against plan for all budgets monitored and reported to the Senior Management Team and the Board</td>
<td>The Institute is on track to operate within its resource and cash limits. Further information is available in the Business Planning and Resources Director’s report.</td>
</tr>
<tr>
<td>Complete the implementation of the Cabinet Office’s Triennial Review recommendations published in July 2015</td>
<td>Review progress and complete a ‘one year on’ report in July 2016 Complete all actions by December 2016</td>
<td>Most of the recommendations have now been actioned. A full progress report, ‘one year on’ was provided to the July Board meeting.</td>
</tr>
<tr>
<td>Objective</td>
<td>Actions</td>
<td>Update</td>
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<tr>
<td>Promote a culture of continuous improvement within the organisation and</td>
<td>Identify the programmes which might be suitable for benchmarking and assess what, if any, international benchmarking is possible by September. Identify 10 publications in peer reviewed international journals which assess and provide an opinion on one or more aspects of NICE’s work and submit to the Board for consideration in March.</td>
<td>This work is on hold until the Chief Executive can identify sufficient capacity to take it forward. It will be completed by the end of the financial year.</td>
</tr>
<tr>
<td>uphold the ambition to remain a world-renowned organisation, benchmarking</td>
<td></td>
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<tr>
<td>where possible its systems, processes and outcomes against best players</td>
<td></td>
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<tr>
<td>internationally</td>
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</tr>
<tr>
<td>Implement the first year of a three year strategy to manage the reduction</td>
<td>Centres and directorates identify savings in order enable the Institute to manage within the reduced Grant in aid funding it received from DH by April. Management of change exercises completed in accordance with a schedule agreed and monitored by the SMT.</td>
<td>The savings required for the first year (2016-17) have been achieved and we are currently on track to achieve the structural changes and savings required for 2017-18. The SMT devotes a full meeting each month to the savings plan and the Board receives a written or oral update at each meeting. The first management of change exercise, related to implementing the savings targets in the Evidence Resources Directorate, was approved in August 2016 and implementation completed in October. Management of change exercises are now underway in Guidelines, Health and Social Care and Communications directorates.</td>
</tr>
<tr>
<td>in the Department of Health’s Grant-In-Aid funding and plan for a balanced</td>
<td></td>
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<tr>
<td>budget in 2017-18</td>
<td></td>
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</tr>
<tr>
<td>Put in place arrangements to charge the cost of the technology appraisal</td>
<td>Key stakeholder agreement to charging obtained by September Board regularly appraised of the financial, Project management arrangements, including appropriate resources are in place. Costing and pricing analyses.</td>
<td></td>
</tr>
<tr>
<td>programme to industry users, from April 2017</td>
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</tr>
<tr>
<td>Objective</td>
<td>Actions</td>
<td>Update</td>
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</tr>
<tr>
<td>operational and reputational risks</td>
<td>Financial and operational arrangements designed and tested by April 2017 Charging arrangements are able to go live from September 2017 at the latest</td>
<td>have been completed. A timeline for seeking the necessary Treasury and Parliamentary approvals has been agreed with the Department of Health. Engagement with industry stakeholders is underway. Subject to the necessary approvals, we are on track to begin charging from May 2017.</td>
</tr>
<tr>
<td>Develop a strategic plan to grow the commercial activity over the next 10 years. This should explore, for example, offering advice, digital protocols, assessments or a subscription service to other countries.</td>
<td>Identify and evaluate the options for increasing income from non-Grant-in-Aid sources, inside and beyond the UK Evaluate the options for the most effective vehicle for delivering this activity, by June 2016 Prepare business cases for each element of the programme by December 2016</td>
<td>Arrangements are in place to review NICE’s international offer following the transfer of the international Decision Support Initiative work, together with the associated staff, to Imperial College in September. Requests for support will be monitored in the coming months to establish the scale and nature of the demand for NICE’s services internationally. Conversations will be held with the Department of Health, Healthcare UK and the Department for International Trade regarding this demand and how best NICE can respond to it in the context of its broader duties.</td>
</tr>
<tr>
<td>Enthuse and enable staff to deliver on the Institute’s objectives, ensuring that every member of staff has a clear set of personal objectives, a personal development plan and an annual appraisal.</td>
<td>All staff have clear objectives supported by personal development plans Staff are fully briefed on the strategy to manage the changes needed to reshape NICE as a consequence of the reduction of Department of Health Grant-in-Aid</td>
<td>Arrangements are in place for all staff to have objectives and an annual appraisal. Briefings at Institute and team level have taken place on the changes associated with the Institute’s business plan and the savings programme. The</td>
</tr>
<tr>
<td>Objective</td>
<td>Actions</td>
<td>Update</td>
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</tr>
<tr>
<td>Current global job satisfaction index in the annual staff survey is maintained or improved</td>
<td>Current global job satisfaction index (percentage of staff who think that NICE is a good, very good or excellent place to work, which was 77% in 2015), will be published in September.</td>
<td></td>
</tr>
<tr>
<td>Develop an approach to succession planning and attracting and retaining talent and recruiting appropriately skilled staff to key posts, including achieving the specified 2.3% of apprenticeships</td>
<td>As an addition to the workforce strategy, develop a proposal for the Board which defines succession planning as it should apply to NICE, together with a set of actions to deliver on its objectives Secure compliance with the target for apprentices by July 2016</td>
<td>We are now fully engaged with the Department of Health and Arm’s Length Body-wide arrangements for talent management. As outlined elsewhere in this report, enhanced arrangements are in place to secure leadership continuity in the Institute’s centres and directorates. We currently have 8 apprentices against a target of 15, which we are confident will all be employed by the end of the financial year.</td>
</tr>
<tr>
<td>Director</td>
<td>Featured section</td>
<td>Section/ reference</td>
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<tr>
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<tr>
<td>Health and social care</td>
<td>The Shared Decision Making Collaborative, an initiative led by NICE, published its consensus statement on promoting shared decision making throughout the health and care system. This covers 7 domains including development of decision support tools and the role of local leadership. To support the consensus statement, members of the collaborative have signed up to some short term actions and long term ambitions as outlined in an action plan. Further information - <a href="https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making">https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making</a>. We are continuing to develop our internal work on Shared Decision Making Aids, and will consider how resource can be identified to support this.</td>
<td>Section/para; Table 1</td>
</tr>
<tr>
<td>Guidelines</td>
<td>The most pressing and important work during the summer months has been the preparation for a major Management of Change process to redesign the Centre’s staffing and, alongside that, the redesign of a number of processes. In particular, we are changing the way in which Standing Public Health Committees are supported technically and we are reshaping the way in which we complete large updates of clinical guidelines in house. These changes will impact on overall staffing levels and skill mix but should result in a significant increase in productivity. The changes will contribute £1m towards NICE’s savings target.</td>
<td>Section/para: notable developments</td>
</tr>
<tr>
<td>Technology evaluation</td>
<td>The NICE Scientific Advice Programme has recently joined forces with the US Food and Drug Administration (FDA) Payer Communication Task Force (PCTF) to assist companies developing medical devices and diagnostics to generate relevant evidence to facilitate market access. Medtech companies seeking advice through the FDAs Centre for Devices &amp; Radiological Health (CDRH) pre-submission program are now able to invite NICE Scientific Advice to participate in the process. NICE Scientific Advice will provide advice on the company’s proposals for evidence generation in parallel to the FDA’s regulatory advice and views from American payer organisations</td>
<td>Section/para 11</td>
</tr>
<tr>
<td>Evidence resources</td>
<td>The risk associated with the delivery of the National Information Board app assessment work is increasing as further change to the governance of the cross-agency programme have been introduced. The risk is mitigated for NICE as follows: NICE is pushing for</td>
<td>Section/para: 11</td>
</tr>
</tbody>
</table>
clarity on which agency is to provide cross-agency programme leadership and management function. We have submitted and seeking the sign off of NICE’s second investment justification to cover NICE’s related costs in Q3 and Q4. Finally work will start in November to pilot the development of a couple of Health App Briefings by March 2016 which will demonstrate the contribution from NICE.

Communications

The External Engagement team is leading a project working jointly with Digital Services to refresh the NICE brand and visual identity. Initial work is underway researching and devising options for the corporate colour palette. Once new corporate colours have been chosen, we will implement the new colour palette across all of NICE’s communications channels and brand assets including the website, intranet, newsletters and PowerPoint. A new set of brand guidelines will support the roll-out of the new colour palette, and staff will be updated in the coming months prior to the changes being made. The NICE logo itself will not be changed. *(Note: no costs beyond those associated with currently employed staff are being incurred in this work).*

Finance and workforce

Human resources continue to deliver ‘bitesize’ learning sessions across Manchester and London to support managers in leading through change. Alongside these, the HR team has also offered two-hour Preparing for Change workshops for managers at both sites, which cover change from a technical HR perspective (for example, what individual and collective consultation is) and an emotional perspective (how change might affect individuals, and how to support yourself and your teams). Resilience workshops have also been offered across both sites for those going through management of change.
### Appendix 3: Guidance development: variation against plan April - October 2016

<table>
<thead>
<tr>
<th>Programme</th>
<th>Delayed Topic</th>
<th>Reason for variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Guidelines</td>
<td>2 topics delayed</td>
<td>Chest pain - stable (standing committee update): This update is ready to be published, but has been delayed to publish alongside the full Chest Pain guideline update on 30 November 2016 (Q3 2016-17).&lt;br&gt;Low back pain update: Delayed due to receiving a large number of comments during the consultation phase. Additional time is needed consider and fully respond to all of the points raised. The anticipated guidance publication date is to be confirmed.</td>
</tr>
<tr>
<td>Interventional procedures</td>
<td>4 topics delayed</td>
<td>Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy: Unable to discuss at the Interventional Procedures Advisory Committee Meeting in July 2016 due to other topics being prioritised for discussion at the meeting. Discussed at September 2016 meeting and due to be published in November 2016 (Q3 2016-17).&lt;br&gt;Percutaneous endoscopic laser lumbar discectomy: Unable to discuss at the Interventional Procedures Advisory Committee Meeting in July 2016 due to other topics being prioritised for discussion at the meeting. Discussed at September 2016 meeting and due to be published during December 2016 (Q3 2016-17).&lt;br&gt;Extracorporeal shockwave therapy for refractory Achilles tendinopathy: Unable to discuss at the Interventional Procedures Advisory Committee Meeting in July 2016 due to other topics being prioritised for discussion at the meeting. Discussed at September 2016 meeting and due to be published during December 2016 (Q3 2016-17).&lt;br&gt;Endoscopic transluminal pancreatic necrosectomy: Unable to discuss at the Interventional Procedures Advisory Committee Meeting in July 2016 due to other topics being prioritised for discussion at the meeting. Discussed at September 2016 meeting and due to be published during November 2016 (Q3 2016-17).</td>
</tr>
<tr>
<td>Programme</td>
<td>Delayed Topic</td>
<td>Reason for variation</td>
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<tr>
<td>Medical technologies</td>
<td>1 topic delayed</td>
<td>XprESS: Delayed as committee meeting cancelled due to lack of a quorum. Now planned to publish December 2016 (Q3 2016-17).</td>
</tr>
<tr>
<td>Public Health</td>
<td>No variation against plan 2016-17</td>
<td></td>
</tr>
<tr>
<td>Quality Standards</td>
<td>2 topics delayed</td>
<td>Hip fracture (update): Second consultation taking place after changes were made at the second meeting that committee members wanted to test with wider stakeholders. Now planned to publish in November 2016 (Q3 2016-17). Transition between health and social care: Before quality standards can publish, they need to be formally endorsed by the relevant commissioner, in this case the Department of Health. The topic will now publish in November 2016 (Q3 2016-17).</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>No variation against plan 2016-17</td>
<td></td>
</tr>
<tr>
<td>Technology Appraisals</td>
<td>6 topics delayed</td>
<td>Lung cancer (non-small-cell, non-squamous, metastatic) - nivolumab (after chemotherapy): Following the committee meeting on Wednesday 15 June 2016, the company that markets nivolumab (Bristol-Myers Squibb), requested to make a further submission including a Patient Access Scheme. NICE agreed that the appraisal could be referred back to the appraisal committee. Anticipated guidance publication date is still to be confirmed. Idiopathic pulmonary fibrosis – pirfenidone: An appeal has been received. The final guidance publication date is now to be confirmed. Neuroblastoma (high risk, children) - dinutuximab (maintenance): An appeal hearing was held on 30 September 2016. NICE awaits the outcome of the Appeal Panel decision. The final guidance publication date is now to be confirmed. Renal cell carcinoma (advanced or metastatic) – nivolumab: This appraisal of nivolumab was due to be discussed at the Technology Appraisal Committee meeting on 4 August 2016. However, this discussion did not take place as NICE were informed that the company wished to submit additional cost-effectiveness modelling, including a Patient Access Scheme, in response to the ACD. An independent critique of the new modelling was also needed before the Committee could discuss the appraisal. The discussion therefore took place on 7 September</td>
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<tr>
<td>Programme</td>
<td>Delayed Topic</td>
<td>Reason for variation</td>
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<tr>
<td>4 additional topics published in 2016-17, that were not planned for this financial year</td>
<td>lumacaftar–ivacaftor for treating cystic fibrosis homozygous for the F508del mutation: At the time of planning the 2016-17 work programme, we had intelligence that this appraisal may not follow routine timescales and would be delayed. At this point, the scale of the delay was not known, therefore was not listed as a planned output for this year. Published in July 2016 (Q2 2016-17).</td>
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<td></td>
<td>Prostate cancer (advanced, hormone dependent) - degarelix depot: An appeal was received against the original FAD in 2014, which resulted in the requirement for the appraisal committee to reconsider the topic. At the time of planning the 2016-17 work programme the scale of the delay was not known, therefore this topic was not listed as a planned output for this year. Published in August 2016 (Q2 2016-17).</td>
<td></td>
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<td></td>
<td>Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases: It was not clear at the point of submitting topics planned for 2016-17 that this appraisal would actually publish in this business year, therefore, it was not included in the planned projects. Published in September 2016 (Q2 2016-17).</td>
<td></td>
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<td></td>
<td>Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor: It was not clear at the point of submitting topics planned for 2016-17 that this appraisal would actually publish in this business year. Therefore, it was not included in the planned projects. Published in October 2016</td>
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<td><strong>2016 in order to enable this critique to be completed and the Patient Access Scheme to be considered. Anticipated guidance publication is November 2016 (Q3 2016-17).</strong></td>
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<td></td>
<td>Leukaemia (chronic lymphocytic, relapsed, refractory) - ibrutinib (post prior therapy): Following the NICE Technology Appraisal Committee meeting on 4 August 2016 the company submitted additional information. NICE has agreed to consider this additional information and the Committee will therefore have a follow-up discussion on 5 October 2016. Anticipated guidance publication is to be confirmed.</td>
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<td></td>
<td>Asthma (eosinophilic, severe) – mepolizumab: Following the release of a second ACD the timelines have been delayed. Anticipated guidance publication is now January 2017 (Q4 2016-17).</td>
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<tr>
<td>Programme</td>
<td>Delayed Topic</td>
<td>Reason for variation</td>
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<td></td>
<td>1 topic planned for this financial year but published early</td>
<td>Hepatitis C (chronic, genotypes 1, 4, 5, 6) - grazoprevir–elbasvir: This appraisal went straight to a FAD publication. Originally planned to publish in December 2016, but published early in October 2016 (Q3 2016-17).</td>
</tr>
<tr>
<td>Highly Specialised Technologies (HST)</td>
<td>2 topics delayed</td>
<td>Hypophosphatasia - asfotase alfa (1st line) [ID758]: The third Evaluation Consultation Document has been published and consultation comments are being processed. Publication date to be confirmed.</td>
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<td>Lysosomal acid lipase deficiency - sebelipase alfa [ID737]: The manufacturer of sebelipase, Alexion, made an additional submission which may have an impact on the recommendations. Therefore, the appeal stage for this topic has been suspended. The publication of the FED will be postponed until this information is reviewed and discussed with NHS England. Publication date to be confirmed.</td>
</tr>
<tr>
<td>Social Care</td>
<td>No variation against plan 2016-17</td>
<td></td>
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</table>
### Appendix 4: Guidance published since the last Board meeting in September

<table>
<thead>
<tr>
<th>Programme</th>
<th>Topic</th>
<th>Recommendation</th>
</tr>
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<tbody>
<tr>
<td>Clinical Guidelines</td>
<td>Mental health problems in people with learning disabilities: prevention, assessment and management</td>
<td>General guidance</td>
</tr>
<tr>
<td></td>
<td>Multimorbidity: clinical assessment and management</td>
<td>General guidance</td>
</tr>
<tr>
<td>Interventions procedures</td>
<td>Miniature lens system implantation for advanced age-related macular degeneration</td>
<td>Special arrangements</td>
</tr>
<tr>
<td></td>
<td>Single-incision short sling mesh insertion for stress urinary incontinence in women</td>
<td>Special arrangements</td>
</tr>
<tr>
<td>Medical technologies</td>
<td>No publications</td>
<td></td>
</tr>
<tr>
<td>Diagnostics</td>
<td>No publications planned</td>
<td></td>
</tr>
<tr>
<td>Public Health</td>
<td>Harmful sexual behaviour among children and young people</td>
<td>Develop and support population level initiatives</td>
</tr>
<tr>
<td>Quality Standards</td>
<td>Children’s attachment</td>
<td>Sentinel markers of good practice</td>
</tr>
<tr>
<td></td>
<td>Contraception</td>
<td>Sentinel markers of good practice</td>
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<td></td>
<td>Skin cancer</td>
<td>Sentinel markers of good practice</td>
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<tr>
<td></td>
<td>Intravenous fluid therapy in children and young people in hospital</td>
<td>Sentinel markers of good practice</td>
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<td></td>
<td>Social care for older people with multiple long-term conditions</td>
<td>Sentinel markers of good practice</td>
</tr>
<tr>
<td></td>
<td>Coeliac disease</td>
<td>Sentinel markers of good practice</td>
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<tr>
<td></td>
<td>Preterm labour and birth</td>
<td>Sentinel markers of good practice</td>
</tr>
<tr>
<td>Technology Appraisals</td>
<td>Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer</td>
<td>Recommended</td>
</tr>
<tr>
<td></td>
<td>Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors</td>
<td>Recommended</td>
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<tr>
<td></td>
<td>Pegasparagase for treating acute lymphoblastic leukaemia</td>
<td>Recommended (Optimised for 1st line treatment for ALL)</td>
</tr>
<tr>
<td></td>
<td>Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion</td>
<td>Recommended</td>
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<tr>
<td></td>
<td>Talimogene laherparepvec for treating unresectable metastatic melanoma</td>
<td>Optimised</td>
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<tr>
<td>Programme</td>
<td>Topic</td>
<td>Recommendation</td>
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<tr>
<td></td>
<td>Necitumumab for untreated advanced or metastatic squamous non-small-cell lung cancer</td>
<td>Not recommended</td>
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<tr>
<td></td>
<td>Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases (CDF reconsideration topic)</td>
<td>Optimised</td>
</tr>
<tr>
<td></td>
<td>Melanoma (BRAF V600, unresectable, untreated, metastatic) - cobimetinib (with vemurafenib)</td>
<td>Not recommended</td>
</tr>
<tr>
<td></td>
<td>Hepatitis C (chronic) - elbasvir-grazoprevir</td>
<td>Recommended</td>
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<tr>
<td></td>
<td>Rheumatoid arthritis - certolizumab pegol (after TNF inhibitor)</td>
<td>Optimised</td>
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<tr>
<td></td>
<td>Lung cancer (non-small-cell, EGFR and T790M positive, metastatic) - osimertinib</td>
<td>Recommended within CDF</td>
</tr>
<tr>
<td>Highly Specialised Technologies (HST)</td>
<td>No publications</td>
<td></td>
</tr>
<tr>
<td>Evidence summaries – new medicines</td>
<td>Truvada for pre-exposure prophylaxis of HIV in high-risk groups</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td>Evidence summaries – unlicensed/off label medicines</td>
<td>No publications</td>
<td></td>
</tr>
<tr>
<td>Medtech Innovation Briefings (MIB)</td>
<td>UrgoStart for chronic wounds</td>
<td>Summary of best available evidence</td>
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<tr>
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<td>Woundchek Protease Status for assessing elevated protease status in chronic wounds</td>
<td>Summary of best available evidence</td>
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<td>QuikRead go for C-reactive protein testing in primary care</td>
<td>Summary of best available evidence</td>
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<tr>
<td></td>
<td>VitalPAC for assessing vital signs of patients in hospital</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td>Programme</td>
<td>Topic</td>
<td>Recommendation</td>
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<td></td>
<td>FLEXISEQ for osteoarthritis</td>
<td>Summary of best available evidence</td>
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<tr>
<td></td>
<td>Alere Afinion CRP for C-reactive protein testing in primary care</td>
<td>Summary of best available evidence</td>
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<tr>
<td></td>
<td>Absorb Bioresorbable Vascular Scaffold System</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td></td>
<td>Needle-free arterial non-injectable connector</td>
<td>Summary of best available evidence</td>
</tr>
<tr>
<td>Evidence Surveillance Reviews</td>
<td>Myocardial infarction with ST-segment elevation: acute management</td>
<td>Surveillance review decision</td>
</tr>
<tr>
<td>Evidence Surveillance Reviews</td>
<td>Unstable angina and NSTEMI: early management</td>
<td>Surveillance review decision</td>
</tr>
<tr>
<td>Evidence Surveillance Reviews</td>
<td>Autism spectrum disorder in under 19s; support and management</td>
<td>Surveillance review decision</td>
</tr>
<tr>
<td>Evidence Surveillance Reviews</td>
<td>Autism spectrum disorder in under 19s; recognition, referral and diagnosis</td>
<td>Surveillance review decision</td>
</tr>
<tr>
<td>Evidence Surveillance Reviews</td>
<td>Self-harm in over 8s: long term management</td>
<td>Surveillance review decision</td>
</tr>
<tr>
<td>Evidence Surveillance Reviews</td>
<td>Self-harm in over 8s: short-term management and prevention of recurrence</td>
<td>Surveillance review decision</td>
</tr>
<tr>
<td>Quality and Productivity case studies</td>
<td>Community triage for lower limb vascular concerns: reducing the burden on hospitals</td>
<td>Examples of quality and productivity improvements</td>
</tr>
<tr>
<td>Quality and Productivity case studies</td>
<td>Medicines optimisation peer review: improving prescribing and lowering costs</td>
<td>Examples of quality and productivity improvements</td>
</tr>
<tr>
<td>Cochrane case studies</td>
<td>No publications</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 5: Balanced scorecard: April 2016 to September 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 &amp; Q2</th>
<th>Actual Q1 &amp; Q2</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish 5 public health 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 25 clinical guidelines, including updates</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>15</td>
<td>13</td>
<td>87%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 2 medicine practice guidelines</td>
<td>Publication within year</td>
<td>75%</td>
<td>1</td>
<td>1</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 1 social care guideline</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>1</td>
<td>1</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 50 technology appraisals guidance (including up to 15 CDF reconsiderations)</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>22</td>
<td>23</td>
<td>105%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 35 interventional procedures guidance</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>18</td>
<td>13</td>
<td>72%</td>
<td>Amber</td>
</tr>
</tbody>
</table>

Notes:
- 5 topics were delayed by the end of Q2. 4 of the 5 delayed topics were unable to be discussed at the Interventional Procedures Advisory Committee Meeting in July 2016 due to other topics being prioritised for discussion at the meeting. These topics were discussed at the September 2016 meeting.
  - Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy: Due to be published during November 2016.
  - Percutaneous endoscopic laser lumbar discectomy: Due to be published during December 2016.
  - Extracorporeal shockwave therapy for refractory Achilles tendinopathy: Due to be published during December 2016.
  - Endoscopic transluminal pancreatic necrosectomy: Due to be published during November 2016.
  - Single incision sub-urethral short tape insertion for stress urinary incontinence in women (formerly TVT Secur): Delayed due the receipt of a resolution request. This request has now been reviewed and guidance published on 12 October 2016.

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Planned Q1 &amp; Q2</th>
<th>Actual Q1 &amp; Q2</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish 6 diagnostics guidance</td>
<td>Publication within stated quarter</td>
<td>75%</td>
<td>2</td>
<td>2</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 3 highly specialised</td>
<td>Publication within stated quarter</td>
<td>100%</td>
<td>1</td>
<td>1</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td>Outputs</td>
<td>Measure</td>
<td>Target</td>
<td>Planned Q1 &amp; Q2</td>
<td>Actual Q1 &amp; Q2</td>
<td>Cumulative performance</td>
<td>RAG</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>---------</td>
<td>----------------</td>
<td>----------------</td>
<td>------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>technologies guidance</td>
<td>Publish 7 medical technologies guidance</td>
<td>75%</td>
<td>1</td>
<td>1</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td></td>
<td>Publish 36 medtech innovation briefings (MIBs)</td>
<td>75%</td>
<td>20</td>
<td>18</td>
<td>90%</td>
<td>Green</td>
</tr>
<tr>
<td></td>
<td>Submit advice to Ministers on 12 Patient Access Schemes</td>
<td>75%</td>
<td>7</td>
<td>15</td>
<td>214%</td>
<td>Green</td>
</tr>
<tr>
<td></td>
<td>Deliver up to 14 Commissioning Support Documents to NHS England</td>
<td>75%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Green</td>
</tr>
</tbody>
</table>

Notes:
The MOU between NICE and NHSE which indicates the creation of the CSD programme was only signed in September 2016. We are waiting to receive the Purchase Order from NHSE in order to formally allow the programme to commence.

| Publish 40 evidence surveillance reviews                               | Publication within stated quarter                                      | 75%     | 18             | 17             | 94%                    | Green |
| Publish 20 evidence summaries - new medicines, unlicensed and off-label medicines | Publication within year                                                | 80%     | 10             | 8              | 80%                    | Green |
| Publish 33 quality standards                                            | Publication within stated quarter                                      | 75%     | 19             | 17             | 89%                    | Green |
| Publish 1 indicator                                                     | Publication within year                                                | 100%    | 1              | 1              | 100%                   | Green |
| Publish 10 new and updated Quality and Productivity case studies        | Publication within stated quarter                                      | 80%     | 4              | 4              | 100%                   | Green |
| Publish at least 6 Cochrane quality and productivity commentaries       | Publication within stated quarter                                      | 80%     | 2              | 1              | 50%                    | Amber |

Notes:
One item was removed from the schedule as during the review process, there was no evidence that the intervention is current practice. Therefore it was agreed that there was no benefit from publication.

| Publish 30 endorsement                                                 | Publication within stated quarter                                      | 80%     | 13             | 13             | 100%                   | Green |
### Outputs

**Measure**: 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 &amp; Q2</th>
<th>Actual Q1 &amp; Q2</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conduct a minimum of 30 first adoption engagements</td>
<td>Publication within year</td>
<td>100%</td>
<td>15</td>
<td>18</td>
<td>120%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 80 Resource impact assessment products</td>
<td>Publication within year</td>
<td>75%</td>
<td>37</td>
<td>40</td>
<td>108%</td>
<td>Green</td>
</tr>
<tr>
<td>Complete a minimum of 5 adoption support products</td>
<td>Publication within year</td>
<td>75%</td>
<td>3</td>
<td>3</td>
<td>100%</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 Q2</th>
<th>Actual Q1 to Q2</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<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>12</td>
<td>100%</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>154</td>
<td>154</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>0</td>
<td>0</td>
<td>100%</td>
<td>Green</td>
</tr>
<tr>
<td>Publish 25 medicines evidence commentaries</td>
<td>Publishing within stated quarter</td>
<td>80%</td>
<td>13</td>
<td>19</td>
<td>146%</td>
<td>Green</td>
</tr>
<tr>
<td>5 education and dissemination events for NICE medicines and prescribing associates</td>
<td>Publishing within stated quarter</td>
<td>80%</td>
<td>2</td>
<td>2</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 Q2</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>Year-to-date budget as at 30 September 16 was £28.6m</td>
<td>Net spend in Quarter 2 was £27.3m (Net underspend £1.3m)</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 £21,000 as at 30 September 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 other income was a surplus of £6,000 as at 30 September 2016. Net income and expenditure for NICE International was a £106,000 deficit at 30 September 2016. This was offset by other income sources (e.g. EU research grants and commercialisation of NICE products)</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>67%</td>
<td>Amber</td>
</tr>
<tr>
<td>Notes:</td>
<td>This is largely due to candidates having long notice periods (3+ months).</td>
<td></td>
<td></td>
<td></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>N/A</td>
<td>N/A</td>
<td>Green</td>
</tr>
<tr>
<td>Notes:</td>
<td>This will be reported in Q4.</td>
<td></td>
<td></td>
<td></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>79%</td>
<td>Green</td>
</tr>
<tr>
<td>Staff involvement</td>
<td>Hold monthly staff meetings</td>
<td>80%</td>
<td>67%</td>
<td>Amber</td>
</tr>
<tr>
<td>Notes:</td>
<td>Two meetings not held - due to the closure of the London office and availability of the Chief Executive.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 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>99%</td>
<td>Green</td>
</tr>
</tbody>
</table>

### Improving stakeholder satisfaction

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved satisfaction</td>
<td>Complaints fully responded to in 20 working days</td>
<td>80%</td>
<td>67%</td>
<td>Amber</td>
</tr>
</tbody>
</table>

Notes:
One of the responses in Q1 breached the target by 2 working days – this was a complex complaint that was investigated by the Chief Executive as it related to a Director.

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved satisfaction</td>
<td>Enquiries fully responded to in 18 working days</td>
<td>90%</td>
<td>98%</td>
<td>Green</td>
</tr>
<tr>
<td>Improved satisfaction</td>
<td>Number of Freedom of Information requests responded to within 20 working days</td>
<td>100%</td>
<td>96%</td>
<td>Amber</td>
</tr>
</tbody>
</table>

Notes:
54 FOI requests were received within the first two quarters of 2016-17. Two highly complex requests were responded to outside of the required timeframe. One request required a meeting between NICE Centre for Health Technology Evaluation and the enquirer’s solicitors to provide the initial information followed by NHS England’s review of the correspondence. The other request required legal advice and coordination with NHS England.

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved satisfaction</td>
<td>PQs contribution provided within requested timeframe</td>
<td>90%</td>
<td>90%</td>
<td>Green</td>
</tr>
<tr>
<td>Improved satisfaction</td>
<td>DPA requests responded to within 40 calendar days</td>
<td>100%</td>
<td>N/A</td>
<td>Green</td>
</tr>
</tbody>
</table>
In Q1 and Q2 no DPA requests were received.

<table>
<thead>
<tr>
<th>Ensuring stakeholders have access to our websites as the main communication channel</th>
<th>Percentage of planned availability, not including scheduled out of hours maintenance</th>
<th>98%</th>
<th>100%</th>
<th>Green</th>
</tr>
</thead>
</table>

### Outputs

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target</th>
<th>Planned Q1 to Q2</th>
<th>Actual Q1 to Q2</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>2 to 1 (or greater) each quarter</td>
<td>100%</td>
<td>2 to 1</td>
<td>3.6 to 1</td>
<td>100%</td>
</tr>
</tbody>
</table>

### Maintaining and developing recognition of the role of NICE

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Annual target</th>
<th>Planned Q1 to Q2</th>
<th>Actual Q1 to Q2</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health and social care providers and commissioners gain an understanding of using NICE guidance and quality standards</td>
<td>Engagement with 123 (80%) of acute and specialist trusts during 2016-17</td>
<td>100%</td>
<td>61.5</td>
<td>60</td>
<td>98%</td>
<td>Amber</td>
</tr>
<tr>
<td>Health and social care providers and commissioners gain an understanding of using NICE guidance and quality standards</td>
<td>Engagement with 120 (80%) of local authority social care commissioners</td>
<td>100%</td>
<td>60</td>
<td>91</td>
<td>152%</td>
<td>Green</td>
</tr>
<tr>
<td>Ensure ongoing awareness of NICE equality strategy and implementation across all</td>
<td>Produce an annual Equality report</td>
<td>100%</td>
<td>1</td>
<td>1</td>
<td>100%</td>
<td>Green</td>
</tr>
</tbody>
</table>

Notes:

Target of 123 organisations to be achieved by year end. On track at Q2 to meet annual target.
<table>
<thead>
<tr>
<th>Outputs</th>
<th>Measure</th>
<th>Target</th>
<th>Cumulative performance</th>
<th>RAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coverage of NICE in the media</td>
<td>% of positive coverage of NICE in the media resulting from active programme of media relations</td>
<td>80%</td>
<td>69%</td>
<td>Amber</td>
</tr>
</tbody>
</table>

**Notes:**
There has been a large amount of neutral coverage within Q1 and Q2 of 2016-17. In Q1 this was due to two high-profile negative draft TAs: pertuzumab for breast cancer and orkambi for cystic fibrosis. In Q2, this was due to NHS England’s judicial review into NICE’s recommendation on hepatitis C drugs and also a story about a breast cancer drug that people are not accessing routinely because NICE is yet to appraise it.

**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>75%</td>
<td>Amber</td>
</tr>
</tbody>
</table>

**Notes:**
In Q1 and Q2, 3 topics have been delayed by the timing of the referral, meaning that marketing authorisation had not been received by the time topics were referred:
- Melanoma (BRAF V600, advanced, unresectable, metastatic) - cobimetinib (with vemurafenib): due to the company having issues with the submission of their economic analysis which led to the appraisal being suspended. The original scheduling would have led to a timely ACD.
- Multiple myeloma (relapsed, refractory) - ixazomib citrate: due to the company receiving a negative CHMP opinion. A positive opinion has since been received, however, timelines have had to be revised.
- Colorectal cancer (metastatic) - MABp1 (after previous treatment): due to ongoing discussions with the company regarding their
submit and economic model. Timelines have had to be revised.

<table>
<thead>
<tr>
<th>Speed of production</th>
<th>% of multiple technology appraisals from invitation to participate to ACD in 41 weeks, or where no ACD produced to FAD in 44 weeks</th>
<th>85%</th>
<th>N/A</th>
<th>Green</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speed of production</td>
<td>% of Appeal Panel decisions received within 3 weeks of the hearing</td>
<td>80%</td>
<td>0%</td>
<td>Red</td>
</tr>
</tbody>
</table>

Notes:
Two appeal decisions were received outside of the required timeframe.
- Kidney transplantation in adults [ID456] and kidney transplantation in children [ID346] had their appeal hearing on the same day. Due to the large amount of work taken to write up both hearings and the complexity of its content, the decisions were received 4 days later than expected.
FINANCE AND WORKFORCE REPORT

This report gives details of the mid-year financial position as at 30 September 2016, the forecast outturn for 2016-17, progress against plans to cope with reductions in grant funding from the DH and information about the workforce.

The Board is asked to review the report.

Ben Bennett
Business Planning and Resources Director
November 2016
Summary

1. Table 1 summarises the mid-year financial position as at 30 September 2016. There is a full analysis in Appendix A.

<table>
<thead>
<tr>
<th></th>
<th>Year to date</th>
<th>Estimated Outturn</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Budget £m</td>
<td>Expenditure £m</td>
</tr>
<tr>
<td>Guidance &amp; Advice</td>
<td>26.8</td>
<td>26.6</td>
</tr>
<tr>
<td>Corporate</td>
<td>6.4</td>
<td>6.6</td>
</tr>
<tr>
<td>Income</td>
<td>(5.0)</td>
<td>0.0</td>
</tr>
<tr>
<td>Reserves</td>
<td>0.5</td>
<td>0.2</td>
</tr>
<tr>
<td>Net Operational Total</td>
<td>28.7</td>
<td>33.4</td>
</tr>
<tr>
<td>NICE International</td>
<td>0.0</td>
<td>2.2</td>
</tr>
<tr>
<td>Scientific Advice</td>
<td>(0.1)</td>
<td>0.5</td>
</tr>
<tr>
<td>NICE Total</td>
<td>28.6</td>
<td>36.1</td>
</tr>
</tbody>
</table>

Table 1: Financial Position at 30 September 2016

2. The current position shows a total under spend of £1.3m (4.4%) for the first six months of 2016-17. This is attributable to vacant posts, under spends on the non-pay budget and additional unbudgeted income generation.

3. The full year forecast outturn is a £3.0m (5.0%) under spend against the revenue resource limit. The reasons for material variances are detailed in this report.

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

5. Work is progressing across the whole organisation to manage the expected 30% reduction in our Department of Health grant funding by 2019-20. Plans are in place for this to be achieved.

6. Progress on the implementation of the workforce strategy is detailed in Appendix C. It includes information and updates relating to transformational change, resourcing, maximising potential, pay and reward and the culture of the organisation.
Financial Position as at 30 September 2016

7. Total net operational expenditure for the first six months of 2016-17 was £27.3m (see Appendix A for a breakdown). This was a £1.3m (4.7%) under spend against budget. This is attributable to vacant posts resulting in lower pay costs (£0.9m), under spends on non-pay (£0.3m) and additional income (£0.1m).

Pay

8. Net operational pay expenditure for the first six months of 2016-17 was £16.8m, which was £0.9m (4.9%) under spent against budget. £0.4m of this under spend is reported in the pay reserves section of the table in Appendix A rather than against directorate budgets. This is as a result of the exercise carried out at the beginning of the year were under spend due to known recruitment slippage was transferred to reserves.

9. As at 30 September 2016 there were 626 whole time equivalent (wte) staff in post, which included 20.8 wte agency and contractor staff.

10. There were 47 wte vacant posts in a budgeted establishment of 673wte, which equates to 7.0% of the total budgeted workforce. For the remainder of the year, recruitment is likely to be mostly from internal candidates due to the measures being taken to avoid redundancies during the forthcoming restructures. Therefore the level of under spend due to vacancies is unlikely to reduce over the rest of the year.

11. There was an overall net increase in staff of 4.9 wte from April to September 2016. This was net of an increase in the Evidence Resources, Centre for Health Technology Evaluation and Business Planning & Resources directorates but a decrease for Communications, Centre for Guidelines and Health & Social Care.

12. Most of the starters in the Evidence Resources directorate related to the Digital Services teams as they continue to replace external contractors with substantive staff on payroll. Within the Centre for Health Technology Evaluation directorate the budgeted headcount rose by 28 from 2015-16, with additional Cancer Drugs Fund and Commissioning Support Documents posts added to the budget. There was however only a net increase of 7.2 wte as many posts were filled by internal staff, causing a knock on effect across the rest of the directorate.

13. The remaining 3 directorates (Communications, Centre for Guidelines and Health & Social Care) are affected by upcoming management of change. Vacancies are currently being held so it is likely that very few, if any, vacant posts in these teams will be filled by external candidates during the rest of the year. This means
pay is likely to continue to under spend for these directorates in the second half of the year.

14. We currently employ eight apprentices and work is progressing well with managers to ensure we reach our DH target to have 2.3% of the workforce comprised of apprentices (14 people) by the end of March 2017.

**Agency staff**

15. Spending on agency staff continues to fall. Chart 1 below shows agency spend by quarter for the last financial year and the first two quarters of 2016-17. The most recent quarter shows a fall in spend of 15.2% compared to spend at the end of the 2015-16 financial year and a fall of 22.0% compared to the same period last year (September 2015).

![Chart 1: Agency spend by quarter since April 2015](image-url)
Sickness Absence

16. Table 1 below shows the average sickness rate by directorate for the first 2 quarters of this year compared to 2015-16 annual rate. The public sector average for the UK in 2013 was 2.9% (ONS data).

<table>
<thead>
<tr>
<th>Centre / Directorate</th>
<th>2015-16 Annual (%)</th>
<th>Quarter 1 2016-17 (%)</th>
<th>Quarter 2 2016-17 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre for Health Technology Evaluation</td>
<td>1.29</td>
<td>1.71</td>
<td>1.53</td>
</tr>
<tr>
<td>Communications</td>
<td>2.35</td>
<td>1.03</td>
<td>1.60</td>
</tr>
<tr>
<td>Evidence Resources</td>
<td>1.79</td>
<td>1.11</td>
<td>0.90</td>
</tr>
<tr>
<td>Health and Social Care</td>
<td>2.18</td>
<td>0.73</td>
<td>1.51</td>
</tr>
<tr>
<td>Centre for Guidelines</td>
<td>2.74</td>
<td>2.30</td>
<td>2.87</td>
</tr>
<tr>
<td>Business Planning and Resources</td>
<td>0.82</td>
<td>4.19</td>
<td>4.69</td>
</tr>
<tr>
<td><strong>% Total</strong></td>
<td><strong>1.86</strong></td>
<td><strong>1.85</strong></td>
<td><strong>2.18</strong></td>
</tr>
</tbody>
</table>

Table 1: Percentage absence per WTE by Directorate

Non-Pay expenditure

17. Net operational non pay expenditure in the first six months of 2016-17 was £16.6m, which was an under spend of £0.3m (2.0%) against budget.

18. Most sub-categories of non-pay are close to break-even, with the exceptions being under spends arising from the knock-on effect of vacancies and committee costs. Notable examples are lower than budgeted travel, subsistence and programme support costs (£0.2m under spent against a budget of £1.6m).

19. Additional non-pay costs (£0.1m) have been incurred in Digital Services due to the dual running of hosting contracts during the transition to our new provider at the start of the year and additional one-off computer hardware purchases in IT to upgrade the existing infrastructure. These are offset by under spends on library services within the Evidence Resources directorate and the Research Support Unit contract within the Centre for Health Technology Evaluation.
Other operating income

20. Other operating income is showing as £0.1m greater than expected for the first six months of the year. This is due to income generated by the Office for Market Access and receipts for copyrighted documents and content being above target.

Forecast outturn

21. The net operational forecast under spend for 2016-17 is £3.0m (5.0%). Of this, £1.4m relates to pay and the vacancies across the Institute noted above. This forecast makes assumptions about the likely dates posts will be recruited to, but if there is any slippage in these timescales, or teams recruit from elsewhere within the Institute (therefore creating a knock-on vacancy), an under spend within the team’s pay budget arises.

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

- The Centre for Health Technology Evaluation is expected to under spend by £0.1m on non-pay, against a budget of £5.5m. The main reason for this is an under spend against the Research Support Unit contract in Science Policy & Research (£0.1m).
- The Centre for Guidelines is forecast to under spend by £0.3m due to lower than budgeted costs for committees, mainly in the Internal Updates team (£0.2m).
- The Communications and Business Planning and Resources directorates are forecasting a combined under spend of £0.3m on non-pay. The Communications directorate under spend is due to reduced spend on external communications and market research, whilst the Business Planning and Resources under spend is mainly due to unutilised external meeting room budgets in facilities, legal fees and computer software licenses in IT.
- The Evidence Resources directorate is forecasting a non-pay under spend of £0.1m against a budget of £5.6m. This mainly relates to library services, which is offset in part by an over spend on the web hosting contract in Digital Services.
- The remaining under spend on non-pay is due to unutilised reserves of £0.4m.

23. Other operating income is expected to be £0.3m more than budgeted. This is due to the additional income generated by the Office for Market Access Team,
Medicines and Prescribing Programme and copyright / content as well as ad-hoc additional income for grants and travel / speaker fee reimbursements.

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

25. Scientific Advice is currently forecast to generate a surplus of £115,000 in 2016-17 as well as carrying an accumulated reserve of £232,000 from previous financial years.

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

2017-18 Business Planning

27. The Department of Health has not yet issued the 2017-18 business planning guidance and timelines for ALBs. However, it is likely that the guidance will follow the principles and timetables set in previous years.

28. Following the 2015-20 Spending Review (SR), the Department of Health indicated that NICE can expect a reduction of 30% in its Grant-in-Aid administration funding and a 10% reduction in programme funding, from the 2015-16 baseline to be achieved by 1 April 2019.

29. The SMT and Board agreed a strategic savings programme (the NICE 2020 project) to deliver these savings in the four financial years from April 2016. The Board also agreed a strategic vision for NICE that seeks to retain the broad scope of NICE’s offer at the end of this period. Specific schemes have been identified to deliver these savings summarised in the NICE 2020 section below.

NICE 2020

30. The Board received a detailed report on progress on the 2020 project at its strategy meeting in October. A summary of the progress to date is given here. Overall the project is risk rated “green”.
31. Table 2 below details the baseline deficit projection of the savings required to achieve the 30% budget reductions, the savings achieved to date and the phasing of further planned savings.

<table>
<thead>
<tr>
<th></th>
<th>2016-17</th>
<th>2017-18</th>
<th>2018-19</th>
<th>2019-20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Deficit Projection</td>
<td>0.2</td>
<td>4.4</td>
<td>8.8</td>
<td>14.0</td>
</tr>
<tr>
<td>Cumulative Savings achieved to date</td>
<td>1.2</td>
<td>2.6</td>
<td>2.7</td>
<td>3.2</td>
</tr>
<tr>
<td>Planned savings</td>
<td>0.0</td>
<td>3.1</td>
<td>8.9</td>
<td>10.8</td>
</tr>
<tr>
<td><strong>Expected budget variance Surplus / (Deficit)</strong></td>
<td><strong>1.0</strong></td>
<td><strong>1.3</strong></td>
<td><strong>2.8</strong></td>
<td><strong>0.0</strong></td>
</tr>
</tbody>
</table>

Table 2: Savings achieved and planned

32. Since the previous board report, the savings achieved to date has increased by £1m. This is due to the following changes being recognised in the budgets:

- £0.3m confirmed savings from the recent Evidence Resources restructure
- £0.1m relating to recently vacated posts that will not be recruited to in the future
- £0.1m reductions to existing non-pay contracts
- £0.25m confirmed reduction to the 2017-18 SCIE contract
- £0.25m relating to posts previously funded through grant-in-aid budgets but will now be funded by other sources (for example NHS England with regard to Commissioning Support Documents)

33. The table shows that a further £3.1m planned savings are expected to be recognised in the run-up to and during 2017-18. Of this, £1.7m relates to the Management of Change processes within Centre for Guidelines, Health and Social Care and Communications directorates that launched at the beginning of November 2016.

34. A further £1.1m relates to the part-year effect of charging for Technology Appraisals. It is assumed here that cost recovery through making charges to Industry for Appraisals will begin during 2017-18 but this is still subject to Ministerial and Treasury approval. To mitigate the risk associated with charging not going ahead the SMT is preparing alternative options for the Board to consider.
35. The remaining £0.3m is expected from reducing agency costs, income generating opportunities and reductions in non-pay costs such as committee expenses.

36. Because savings have been front-loaded where possible, there is planned contingency in 2017-18 of £1.3m, assuming the savings mentioned above materialise. This will be used for any short-term cost pressures in 2017-18, transition costs that may arise from future savings programmes or used to set up any new activity such as new outputs produced in response to the accelerated access review.

**Measures of Financial Control (Mid-year review)**

37. This section sets out the mid-year (end of September 2016) position on the key formal financial statements.

**Outstanding debt**

38. The table below shows a snapshot of the aged debt position as at 30 September 2016. This is money owed to us and how long we have been waiting for the debtor to pay us. The payment terms for sales invoices issued by NICE are usually 30 days. The total value of debts outstanding for more than 30 days was £385,000. This was mainly due to two large invoices for NHS England funding (£262,500) and one for funding from the Scottish Devolved Administration (£34,000) which have all subsequently been paid. We do not normally have a problem with debt collection with the vast majority of debt paid without the need to use formal debt recovery proceedings. In 2016-17 no debts have been written off.

<table>
<thead>
<tr>
<th></th>
<th>0-30 Days</th>
<th>31-60 Days</th>
<th>61-90 Days</th>
<th>&gt;91 Days</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Invoices</td>
<td>45</td>
<td>10</td>
<td>8</td>
<td>11</td>
<td>74</td>
</tr>
<tr>
<td>Value of Invoices (£000’s)</td>
<td>1,304</td>
<td>16</td>
<td>319</td>
<td>50</td>
<td>1,689</td>
</tr>
</tbody>
</table>

% No. of Invoices

- 0-30 Days: 60.8%
- 31-60 Days: 13.5%
- 61-90 Days: 10.8%
- >91 Days: 14.9%
- Total: 100.0%

% Total Value

- 0-30 Days: 77.2%
- 31-60 Days: 1.0%
- 61-90 Days: 18.9%
- >91 Days: 2.9%
- Total: 100.0%

Table 3: Aged debt analysis at 30 September 2016

**Better Payment Practice Code**

39. 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 later. NICE’s performance against this code is shown in table 4 below.

<table>
<thead>
<tr>
<th>Number</th>
<th>£000's</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total non-NHS bills paid 2016-17</td>
<td>1,755</td>
</tr>
<tr>
<td>Total non-NHS bills paid within target</td>
<td>1,636</td>
</tr>
<tr>
<td>Percentage of non-NHS bills paid within target</td>
<td>93.2%</td>
</tr>
<tr>
<td>Total NHS bills paid 2016-17</td>
<td>93</td>
</tr>
<tr>
<td>Total NHS bills paid within target</td>
<td>84</td>
</tr>
<tr>
<td>Percentage of NHS bills paid within target</td>
<td>90.3%</td>
</tr>
</tbody>
</table>

Table 4: BPPC Quarter 2 2016-17

40. There has been an improvement in the payment of Non NHS invoices within 30 days by value of 3.1% compared to the last report with continued improvement anticipated. Payment of NHS invoices by number has also increased to 90.3% which is a rise of 7.4% compared to the last report.

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

**Statement of Financial Position**

42. Appendix B shows the Statement of Financial Position (more commonly known as the balance sheet) at the mid-year position 30 September compared to the start of the year 31 March and the forecast position at the year end.

43. Cash balances were £6.4m at 31 March 2016 but is expected to be nearer £2.5m at 31 March 2017. This is mainly due to the fact that we still held cash associated with NICE International grants at the end of September. These have now been paid over to University College London and the cash balance therefore reduced significantly.

44. The total owed to NICE by its suppliers (termed Trade and other payables) was £9.5m at 30 September 2016 which is high compared to 31 March 2016. This is due to significant accruals (for example the National Collaborating Centres in Centre for Guidelines and the Evaluation Assessment Centres in Medical
Technologies) which we had not received invoices for by 30 September 2016. These large accruals are not expected to remain at year end as the majority of invoices should have been received and paid by 31 March 2017. Provisions for liabilities and charges are expected to remain at a similar level due to ongoing management of changes over the 2020 savings period.
### Appendix A – Summary of financial position as at 30 September 2016

#### Comparison of budget with expenditure and year end projection - 30th September 2016

<table>
<thead>
<tr>
<th>Centre / Directorate</th>
<th>Year to Date</th>
<th>Estimated Outturn</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Budget £000s</td>
<td>Expenditure £000s</td>
</tr>
<tr>
<td><strong>Centre for Guidelines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>3,410</td>
<td>3,408</td>
</tr>
<tr>
<td>Non pay</td>
<td>6,576</td>
<td>6,410</td>
</tr>
<tr>
<td>Income</td>
<td>(336)</td>
<td>(351)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>9,650</td>
<td>9,467</td>
</tr>
<tr>
<td><strong>Centre for Health Technology Evaluation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>3,733</td>
<td>3,476</td>
</tr>
<tr>
<td>Non pay</td>
<td>2,714</td>
<td>2,655</td>
</tr>
<tr>
<td>Income</td>
<td>(187)</td>
<td>(236)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>6,261</td>
<td>5,895</td>
</tr>
<tr>
<td><strong>Health and Social Care</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>3,847</td>
<td>3,669</td>
</tr>
<tr>
<td>Non pay</td>
<td>1,194</td>
<td>1,139</td>
</tr>
<tr>
<td>Income</td>
<td>0</td>
<td>(23)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5,041</td>
<td>4,784</td>
</tr>
<tr>
<td><strong>Evidence Resources</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>3,088</td>
<td>3,073</td>
</tr>
<tr>
<td>Non pay</td>
<td>2,781</td>
<td>2,817</td>
</tr>
<tr>
<td>Income</td>
<td>(15)</td>
<td>(48)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5,855</td>
<td>5,842</td>
</tr>
<tr>
<td><strong>Subtotal Guidance and Advice</strong></td>
<td>26,806</td>
<td>25,988</td>
</tr>
<tr>
<td><strong>Communications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>1,857</td>
<td>1,823</td>
</tr>
<tr>
<td>Non pay</td>
<td>205</td>
<td>188</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2,062</td>
<td>2,011</td>
</tr>
<tr>
<td><strong>Business Planning and Resources</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pay</td>
<td>1,307</td>
<td>1,338</td>
</tr>
<tr>
<td>Non pay</td>
<td>2,882</td>
<td>2,718</td>
</tr>
<tr>
<td>Income</td>
<td>(392)</td>
<td>(410)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>3,797</td>
<td>3,647</td>
</tr>
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</table>
### Appendix A (Continued)

<table>
<thead>
<tr>
<th>Centre / Directorate</th>
<th>Year to Date</th>
<th>Estimated Outturn</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Budget £000s</td>
<td>Expenditure £000s</td>
</tr>
<tr>
<td>Income</td>
<td>(5,020)</td>
<td>(5,021)</td>
</tr>
<tr>
<td>Total</td>
<td>(5,020)</td>
<td>(5,021)</td>
</tr>
<tr>
<td>Depreciation / Capital Adjustments</td>
<td>Non pay</td>
<td>500</td>
</tr>
<tr>
<td>Total</td>
<td>500</td>
<td>483</td>
</tr>
<tr>
<td>Reserves</td>
<td>Non pay</td>
<td>404</td>
</tr>
<tr>
<td>Total</td>
<td>546</td>
<td>238</td>
</tr>
<tr>
<td>NICE Operational Total</td>
<td>Non pay</td>
<td>17,646</td>
</tr>
<tr>
<td>Total</td>
<td>16,994</td>
<td>16,647</td>
</tr>
<tr>
<td></td>
<td>Income</td>
<td>(5,950)</td>
</tr>
<tr>
<td>Total</td>
<td>28,691</td>
<td>27,345</td>
</tr>
<tr>
<td>NICE International</td>
<td>Non pay</td>
<td>431</td>
</tr>
<tr>
<td>Total</td>
<td>1,385</td>
<td>1,834</td>
</tr>
<tr>
<td></td>
<td>Income</td>
<td>(1,816)</td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>107</td>
</tr>
<tr>
<td>Scientific Advice</td>
<td>Non pay</td>
<td>434</td>
</tr>
<tr>
<td>Total</td>
<td>145</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Income</td>
<td>(705)</td>
</tr>
<tr>
<td>Total</td>
<td>(126)</td>
<td>(148)</td>
</tr>
<tr>
<td>NICE Grand Total</td>
<td>28,565</td>
<td>27,305</td>
</tr>
</tbody>
</table>
## Appendix B

### Statement of Financial Position

<table>
<thead>
<tr>
<th></th>
<th>Total 31 Mar 2016</th>
<th>Total 30 Sep 2016</th>
<th>Total 31 Mar 2017</th>
<th>Forecast £000</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-current assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property, plant and equipment</td>
<td>2,556</td>
<td>2,574</td>
<td>3,000</td>
<td></td>
</tr>
<tr>
<td>Intangible assets</td>
<td>127</td>
<td>127</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td><strong>Total non-current assets</strong></td>
<td><strong>2,683</strong></td>
<td><strong>2,701</strong></td>
<td><strong>3,200</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Current assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>2,330</td>
<td>1,795</td>
<td>2,000</td>
<td></td>
</tr>
<tr>
<td>Other current assets</td>
<td>1,725</td>
<td>2,601</td>
<td>2,000</td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>6,379</td>
<td>5,334</td>
<td>2,500</td>
<td></td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td><strong>10,434</strong></td>
<td><strong>9,730</strong></td>
<td><strong>6,500</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td><strong>13,117</strong></td>
<td><strong>12,431</strong></td>
<td><strong>9,700</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Current liabilities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>(7,710)</td>
<td>(9,510)</td>
<td>(6,000)</td>
<td></td>
</tr>
<tr>
<td>Provisions for liabilities and charges</td>
<td>(1,245)</td>
<td>(1,245)</td>
<td>(1,000)</td>
<td></td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td><strong>(8,955)</strong></td>
<td><strong>(10,755)</strong></td>
<td><strong>(7,000)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Non-current assets less net current liabilities</strong></td>
<td><strong>4,162</strong></td>
<td><strong>1,676</strong></td>
<td><strong>2,700</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Non-current liabilities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provisions for liabilities and charges</td>
<td>(1,210)</td>
<td>(827)</td>
<td>(1,000)</td>
<td></td>
</tr>
<tr>
<td><strong>Total non-current liabilities</strong></td>
<td><strong>(1,210)</strong></td>
<td><strong>(827)</strong></td>
<td><strong>(1,000)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Assets less liabilities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>2,952</strong></td>
<td><strong>849</strong></td>
<td><strong>1,700</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Taxpayers’ equity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General fund</td>
<td>2,334</td>
<td>317</td>
<td>1,077</td>
<td></td>
</tr>
<tr>
<td>Non-exchequer trading reserves</td>
<td>618</td>
<td>532</td>
<td>623</td>
<td></td>
</tr>
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<td><strong>Total</strong></td>
<td><strong>2,952</strong></td>
<td><strong>849</strong></td>
<td><strong>1,700</strong></td>
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Appendix C – Workforce Strategy Update at 30 September 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**

HR has continued to deliver bitesize learning sessions across Manchester and London to support managers in leading through change. Alongside these, the HR team has also offered two-hour Preparing for Change workshops for managers at both sites, which cover change from a technical HR perspective (for example, what individual and collective consultation is) and an emotional perspective (how change might affect individuals, and how to support yourself and your teams).

Resilience workshops have also been offered across both sites for those going through management of change.

**Resourcing**

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

A new recruitment system, TRAC, was introduced on 18 July 2016. The roll-out was supported by live webinars. Recorded webinars will be hosted on the new Learning Management System when this is launched later this year. In the meantime, extra support materials have been added to NICE Space and face-to-face manager workshops will be offered in the new year.

**Maximising potential**

- **Leadership and management**
- **Managing performance**
- **Succession planning and talent management**

NICE has launched the first phase of its talent management programme with the pilot group (Band 8d and above) conducting career conversations which we will use to form a picture of our current talent pool and succession plans. This information will in turn feed into our resourcing and development plans. This pilot completes in November and will be reviewed by the end of 2016 with a view to the programme being rolled out to Stage 2 (remaining Band 8 staff) early in 2017.

Work continues on NICE’s new Learning Management System, which is due to launch in December 2016, and will provide staff and managers with a range of e-learning solutions, and greatly streamline reporting on mandatory training such as Information Governance and Equality and Diversity. Later phases of the launch will enable e-appraisal.

**Pay and Reward**

- **Total reward**
- **Pay review**

On 1 November 2016, NICE employees who had opted out of the NICE pension scheme before 1 November 2015 will be automatically re-enrolled, as per the requirements of The Pensions Act 2008. Communications have been sent out via NICE Space and Your Week at NICE to ensure that those affected are aware of the process. Government legislation prevents us from specifically targeting individuals or providing...
assistance to prevent them from re-enrolling, but we have provided as much communication as is reasonable under the legislation. The £95k exit payment cap for public sector workers will be introduced when the regulations are confirmed. HR will continue to communicate with staff as soon as an enactment date is received.

Culture

- Engaged workforce
- Inclusive workforce
- Wellbeing at work

The directorate-level staff survey results have been shared with the HR Business Partners who will be using the results to shape conversations with managers, to build on successful results and address any issues at a local level.

The action plan from the 2016 staff survey is now being implemented. A commitment to address bullying and harassment has been continued through a recent blog on NICE Space which launched a new Raising Concerns page, which provides staff with advice on how to broach a range of issues including grievances and whistleblowing.
The Board is asked to note the recommendations in the Accelerated Access Review and its implications for NICE. The full report is attached to this paper, which identifies some of the key recommendations and their impact on NICE.

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

1. The Accelerated Access Review (AAR) final report was published on 24 October 2016. It makes 18 recommendations, most of which have implications for NICE and some requiring changes in the way we undertake the evaluation of health technologies. A number of these changes will require additional funding. The specific recommendations in the report are set out in the appendix.

2. The AAR calls for:
   - Streamlined mechanisms for prioritising emerging technologies and identifying strategically important innovations;
   - The NHS to work with innovators to accelerate approvals, speed up adoption and evaluate technologies efficiently using new data sources; and
   - Alignment of national organisations to transform the NHS’s ability to adopt the right innovations rapidly.

3. The AAR argues that while ‘patients expect the NHS to provide emerging, transformational innovations as soon as they become available and for our health outcomes to keep pace with those of other countries, the evidence shows that we sometimes lag behind other countries in the adoption of innovation. It says that the NHS needs to become more agile in managing the adoption of an increasing number of ‘transformative technologies’, such as drugs for chronic diseases that target specific sub-populations; diagnostics such as genomic sequencing that allow treatments to be targeted more effectively and curative medicines for diseases like Hepatitis C’.

4. The report wants the NHS to make a clear and attractive offer to those innovators that are willing to work with it: ‘a simplified and aligned system; dialogue with national bodies; accelerated diffusion across the whole health system; and the opportunity to gather the data they need to market their products around the world’. To deliver this, the report recommends the creation of an Accelerated Access Partnership, involving NICE, NHS England, NIHR, MHRA and NHS Improvement.

Accelerating access

5. The report suggests that perhaps 5 to 10 innovations a year might need to be accorded a ‘transformative designation’, being then managed through an ‘Accelerated Access Pathway’, receiving ‘additional support and guidance to navigate the market and to reach patients’, through a NICE ‘conditional recommendation, where appropriate. The report suggests that some products with this designation ‘could bring forward reimbursement access by up to 4 years’, taking advantage of existing processes, such as the Early Access to Medicines Scheme and NICE’s new approach to appraising cancer medicines,
which brings final guidance to within 90 days of the marketing authorisation being granted.

6. The ARR argues the importance of clinical leadership, recommending that: ‘each product’s journey along the accelerated pathway should be supported by clinical engagement and leadership from National Clinical Directors (NCDs) and their colleagues; overseeing and directing the right clinical engagement during development, integrating the use of new innovative technologies and therapies into clinical pathways, and promoting the diffusion of the most effective and innovative new products amongst their peers’.

7. In an important proposal, with implications for NICE, the report recommends the creation of a ‘strategic commercial unit’ (SCU) in NHS England. The unit ‘should be able to enter into a wide range of commercial arrangements that deliver better value, share the benefits of accelerated access and recognise any uncertainty in the evidence base’.

8. The report notes that ‘a large number of flexible pricing schemes are in use internationally, such as price-volume agreements, conditional reimbursement, deferred payments or annuity-based pricing, outcome-based payments, product-service bundling and deferred payments, amongst others, and the SCU may wish to consider, for each product, whether using one or more of these schemes would deliver value and help a product to achieve reimbursement in an affordable way’.

9. The report encourages ‘flexibility and innovation in the type of arrangements that might be achieved to maximise the potential benefits for all parties. Over time, the commercial arrangements may change depending on the emergence of new evidence or changes in population size. Payment could be linked to the delivery of value, whereby no payment is made if the expected value has not been delivered’. The report recommends that commercial discussions should take place before NICE issues its final guidance and is therefore consistent with the current consultation proposals on changes to the technology appraisal processes.

10. The current range of national commissioning routes is complex and difficult to navigate, according to the report. The new routes, including NICE appraisal processes, ‘should be clearer, fewer in number, and there should be transparency about the time each step is expected to take. They should enable well-organised innovators to reach patients quickly through the most appropriate route’.

Digital technologies

11. The AAR recommends that the ‘route for digital products should build on the Paperless 2020 simplified app assessment process. The pathway for healthcare apps requires improvements in assessment, commissioning, procurement and prescribing. It should be suitable for fast-moving technology areas and products developed by SMEs. Some of the apps evaluated by NICE
as part of the Paperless 2020 process could be made available through the new Innovation and Technology Tariff’.

**NICE’s appraisal processes**

12. This review is ‘extremely supportive of NICE as a global leader in health economic evaluation and evidence-based guidance. Since its inception, NICE has continued to evolve so that it can best consider the innovations that it is asked to assess. This review sees NICE technology appraisals as continuing to form the basis of value assessment, but suggests that NICE should now undertake a review of its methods and processes to ensure they are fit for purpose to enable access to the products the NHS needs most. This should include:

- Changes that support NHS England in agreeing commercial arrangements for strategically important products.

- Evolution of NICE’s processes to support acceleration, allowing products with sound evidence of increased efficiency to undergo a lighter-touch process’.

13. The report argues that NICE should place a greater emphasis on medical devices and diagnostics in its evaluative programmes, identifying opportunities for using these products to improve the efficiency of current care pathways.

**Improving and measuring uptake**

14. The Accelerated Access Partnership ‘should ensure that NICE’s guidance for strategically important innovations includes a bespoke incentive framework that supports diffusion across the NHS. This could include national tariffs or proposals for local changes to support collaboration across organisations. NICE should track uptake of the products and publish this information’.

15. It is recommended that ‘NICE should build on the work of the NICE Implementation Collaborative to develop a new role that reaches beyond the evaluation of a technology into its subsequent clinical pathway. Its guidance, for example, could include proposed structured incentives or tariffs to support the uptake of innovative technologies. The details of these incentives should be developed through the Accelerated Access Partnership with advice coming from NHS England and NHS Improvement on their areas of responsibility’.

16. The AAR proposes that the Innovation Scorecard should be ‘the single source of information on the use of innovation in the NHS. It should be owned by NICE and used by the rest of the Accelerated Access Partnership, particularly NHS England and NHS Improvement, to hold the system to account and assess the progress of local areas. Patients and clinicians, as well as NICE, the Department of Health and NHS England, should help to define the products and outcomes that are included, and there should be an emphasis on NICE-approved technologies. This information should be accessible to patients and the public’.
Impact on NICE

17. Much of the work involved in implementing the AAR recommendations could be incorporated into the transformation programme that has already been identified for the Centre for Health Technology Evaluation. The Board considered this change programme at its meeting in October and approved a business case for the appointment of external consultants. Some of the detailed actions arising from the AAR can, therefore, only be planned in detail from January 2017 onwards, once the required capacity has been brought into NICE.

18. We will need additional resources to enable us to put a number of the recommendations into place, where they require additional guidance capacity, new functions or substantial additional commitments for existing staff. The Office for Life Sciences (OLS) Accelerated Access Review team has asked to meet for a meeting to discuss these additional resource requirements.

Status of the report

19. The report has been welcomed by the Government and by NHS England. It is likely that the OLS will lead on its implementation, in conjunction with the Department of Health. We have not been asked to undertake any work to take forward any of the recommendations but we stand ready to do so, subject to adequate resources being put in place.
Appendix: Accelerated Access Review recommendations

1. The NHS should develop an enhanced horizon scanning process and clarify its needs to innovators.

2. A new transformative designation should be applied to those innovations with the potential for greatest impact.

3. Patients should be involved in horizon scanning and prioritisation, and this involvement should continue along the whole innovation pathway.

4. An Accelerated Access Pathway for strategically important, transformative products should align and coordinate regulatory, reimbursement, evaluation and diffusion processes to bring these transformative products to patients more quickly.

5. A new strategic commercial unit should be established in NHS England.
   - SCU commercial dialogue should be informed by NICE and should take place before final guidance is issued (report para 2.6)
   - Industry should seek advice from MHRA and NICE to trial cancer medicines in early stage disease where QALY benefits may be more easily demonstrated (report para 2.7)
   - Support for strategically important medical technologies from the Accelerated Access Partnership should be aimed at post-CE mark data collection (report para 2.9)

6. The accelerated access pathway should be suitable for medical technologies, diagnostics and digital products as well as medicines and emerging forms of treatment.

7. There should be a single set of clear national and local routes to get medical technologies, diagnostics, pharmaceuticals and digital products to patients.

8. National routes to market should be streamlined and clarified.

9. Many products will benefit from regional and local routes to market, which should be enhanced to operate consistently across the NHS.

10. The route for digital products should build on the Paperless 2020 simplified app assessment process.

11. The digital infrastructure should enable the system to capture information on the use of innovations and associated outcomes.
   - NICE should support uptake by extending its role beyond evaluation (report para 4.5)

12. The process of assessing emerging technologies should be evolved so that it is fit for the future.
   - NICE should review its health technology assessment processes and methods to ensure they are fit for purpose to assess new types of emerging products and enable access to the products the NHS needs. (report para 4.2)

13. A range of incentives should support the local uptake and spread of innovation, enabling collaboration and with greater capacity and capability for change.
14. AHSNs, tertiary academic teaching hospitals and clinical leaders across the NHS should drive and support the evaluation and diffusion of innovative products.

15. Improved accountability and transparency around uptake of innovation should be supported by NICE.
   - There should be a single, accessible source of information on the uptake of technologies for the NHS, patients and industry (report para. 5.7)

16. An Accelerated Access Partnership should align national bodies around accelerating innovation.

17. The Accelerated Access Partnership should be established immediately.

18. Implementation of the report’s recommendations should be led by the Accelerated Access Partnership and clinicians.
Accelerated Access Review: Final Report

Review of innovative medicines and medical technologies

An independently chaired report, supported by the Wellcome Trust
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Letter from Sir Hugh Taylor, independent chair of the Accelerated Access Review, to Lord Prior, Parliamentary Under-Secretary of State for Health

Dear Lord Prior

In November 2014 the government asked me to chair a review of how we could speed up access to innovative drugs, devices, diagnostics and digital products to NHS patients. I was pleased and proud to accept the challenge. Since then we have sought views from over 600 people and organisations, ranging from clinicians, NHS commissioners and patient groups and charities, to the life sciences industries and academia, to the national bodies that influence the innovation pathway.

The resulting report sets out an ambitious framework for how we can transform our NHS, pulling innovation – medical technologies, diagnostics, digital and biopharma products alike – through the system for the benefit of patients and improving the international competitiveness of our country.

Countless people have contributed to the ideas contained within the report. In particular I would like to thank the review’s champions: Dr Stuart Dollow, Professor Richard Barker, Richard Murray, Rob Webster and Hilary Newiss, as well as John Jeans and Charles Lowe. I would also like to thank Dr Nicole Mather, Director of the Office for Life Sciences; the AAR team; the Wellcome Trust, which has supported the review right from the start, and George Freeman MP, who originally commissioned the review and whose enthusiasm was a great asset as we took it forward.

Special thanks go to our advisory group and in particular its chair, Professor Sir John Bell. John has provided valuable guidance and wisdom throughout the review and I think it is fitting for him to provide an introduction.

Sir Hugh Taylor
Introduction from Professor Sir John Bell, Regius Professor of Medicine at the University of Oxford and chair of the review’s external advisory group.

This report addresses one of the most important issues the National Health Service is confronting; how best to access innovation for the benefit of patients and to improve health care efficiency. The approach to accessing innovation in the NHS has become increasingly challenging; creating frustration for innovators who see the NHS as an interesting environment for demonstrating the value of their products, for patients who often have to wait long periods of time before life-saving therapies are available, and for clinicians who are frustrated by the multiple barriers to both approval and adoption. We wanted to obtain the views of these varied constituencies and create a new and more agile approach to the prioritisation and adoption of NHS innovation. Now more than ever, with a tidal wave of exciting new technologies approaching, the system needs a way to do this.

The difficulties encountered by the NHS’s previous attempt to resolve this issue through Innovation, Health and Wealth meant that it was crucial for us to obtain strong support from NHS England as the sponsor of this new framework. Success will be highly dependent both on their actions centrally and throughout NHS organisations locally. We welcome the recognition NHS England has given to the importance of this agenda and I am particularly pleased that Simon Stevens, the Chief Executive of NHS England, has demonstrated this commitment in his letter on page 10.

It was our intention to propose a new system for accelerating access to all types of innovation in the NHS, including drugs, medical devices and diagnostics and digital tools. We saw opportunities for acceleration at every stage of approval and adoption. We have recommended a process for identifying and pulling transformative innovations into the NHS quickly, using the range of emerging regulatory pathways and facilitating the generation of patient data that define the benefits of innovation to both outcomes and pathways. We have also encouraged a much more streamlined approach to reimbursement for innovators, both through conditional licensing and through a new mechanism for pricing individual products using a range of new pricing tools. Why should a large single payer not benefit from volume-based contracts, from paying based on outcomes, or paying differentially in different diseases where the efficacy of a treatment might vary?

Collaboration and early dialogue between innovators and the NHS will be critical to enable agreements that exploit this more streamlined approach and the opportunity of new agreements being reached to deliver a win for both parties. For the NHS, we recognise the importance of NHS England being able to work with NICE as part of this process. Finally, we have encouraged the creation of incentives in the system both locally and nationally to enable the rapid adoption and diffusion of these new products. At each stage acceleration has been an important focus and this should greatly improve rapid access, particularly for transformative innovations.

A second important feature of this report is that it encourages the NHS to work more collaboratively with patients and innovators to provide the type of data all innovators and thus health care systems need to make decisions about the real benefits of innovation. The historical model where innovators simply throw new products at health care systems and allow them to layer these onto existing pathways is no longer viable. We believe that health care systems and innovators need to work together to demonstrate the way in which innovations change pathways.
and improve outcomes. This is particularly true with digital, medtech and diagnostic innovations but has also been true for pharmaceutical innovations which have created enormous impacts on the way that patients with diseases such as vascular disease, inflammatory disease and cancer are treated. If the NHS is to see the continued benefits of such innovation it needs to contribute more actively to its development.

The beneficiaries of this new system should be:

- The NHS, creating a much more cost-effective and informed but dynamic system for pulling the required innovation intelligently into the health system to change the way it treats disease.
- Patients, who have often found the current approach to accessing new products in the NHS cumbersome, slow and bureaucratic. Patients have been among the strongest supporters of our work on these new pathways and clearly deserve a system where they are allowed to be more engaged participants.
- Innovators, who could also find this new approach to accelerating adoption transformative. They largely recognise that a state-funded health care system such as the NHS must take issues of affordability seriously but find the approach to innovation, the slow track to reimbursement, and low prices without generating wider diffusion and volumes, all make the UK a challenging market. With a different approach to generating the evidence of an innovation’s value within a closed system and speeding up reimbursement and adoption, the UK could become a very attractive environment for the life sciences industry to flourish.

When we began this report, the UK was firmly in the European Union, and had a strong life sciences industry based on outstanding biomedical research in both world-class universities and internationally-renowned teaching hospitals. We also perceived the NHS as being a potentially crucial asset in further developing the life sciences industry. It was not unreasonable, we believe, to assume that some of the £120 billion spent annually on the NHS should be helping to drive success in this sector, fuelling economic growth and generating increased tax income on which to base our public services. Since the UK voted to leave the European Union, the importance of these principles have, if anything, been amplified. Given the uncertainty for the financial sector and heavy manufacturing in a future potentially outside the single market, it seems clear that the life sciences industry will provide a crucial pillar for future economic growth. This will, of course, require a targeted industrial strategy and may benefit from a future regulatory regime.

These ‘sunny uplands’ are not likely to be easily reached. More effort and resource will be needed to ensure the success of this sector both by creating a system in which the NHS is allowed to be a receptive market for useful innovations and by ensuring that the commercial entities that are required to support economic growth are viewed as partners in making the UK a global hub for innovation in healthcare.

The AAR therefore creates a first essential step in ensuring that the UK builds a capability in life sciences that leads to strong economic growth and also provides patients and the NHS with much needed tools and technologies at an affordable cost. A UK outside the EU, with no system for ensuring a dynamic market and a competitive research environment for one of its most important industries, could precipitate a decline in economic activity in the life sciences. It could also lead to a health care system that cannot ensure its patients benefit from the rapid advance of innovation and this risks taking us to the ‘cloudy and windswept lowlands’ pretty quickly.
There are a few important steps that need to be taken to assure the success of this report. NHS England needs to continue to engage at the highest level in this agenda; early signs are positive, though a sustained focus and engagement will be essential to realise the vision we set out. NHS Improvement also has a key leadership role to play as the lead agency for innovation, working closely with providers to enable local NHS economies to facilitate this programme. More integrated health systems and facilitation by a reinvigorated AHSN network will help, as will the engagement of the major academic teaching hospitals where creation and evaluation of innovation is already part of the culture.

Resource will be required to make this happen both centrally and locally. Some headroom may be created by accelerating the use of biosimilars and more active delisting of drugs and technologies that no longer have utility. These savings need to be captured in such a way that they can be re-targeted at the innovation agenda. If the programme is implemented as we recommend, there should be much better evidence of the efficiency gains from technologies, as used in the health system, that can be shared to enable faster uptake of innovation. Given the importance of this agenda to an industrial policy to support life sciences, additional resource to ensure a viable market should be seen as a high priority both within the NHS and more widely in government.

Finally, most of the major recommendations of this report will need enhancement of digital capabilities within the NHS. This is clearly in progress but must occur more quickly for the benefits of the AAR to be realised.

We are grateful to the many participants in the AAR programme who have given up their time to inform and advise us on this journey. Interestingly, we have not encountered anyone who believed that innovation adoption was not a problem that required a new solution and there are many patients, innovators and clinicians who will work hard to make this new model work. Ultimately, responsibility for success will lie with the leadership provided by NHS England and NHS Improvement. With this in place we see no reason for the benefits of innovation not to flow rapidly and widely to patients in the NHS, delivering a more efficient healthcare system, better outcomes and a thriving life sciences sector.

Professor Sir John Bell
Letter from Simon Stevens, Chief Executive Officer of NHS England

At a time of national debate and NHS pressure it's easy to forget an important truth: Health care is better than it's ever been. Cancer survival in this country is at an all-time high. Deaths from cardiovascular disease are down by over 40%. Worldwide, life expectancy is rising by five hours a day.

But, as the saying goes, 'better is possible'. One recent estimate suggests that humanity still only has around 500 viable treatments for more than 10,000 known health problems.

As a nation we therefore need to pursue at least three goals simultaneously.

First, we must actively support new discovery and further development of innovative treatments and care.

Second, we have no choice other than to drive value and affordability across the NHS if we're going to create headroom for faster and wider uptake of important new patient treatments.

And third, in the run-up to Brexit we need not only to secure - but actually enhance - our vibrant and globally successful UK life sciences sector.

Sometimes these three goals are thought to be in tension. By contrast, this Accelerated Access Review provides practical and welcome proposals for squaring the circle.

NHS England is fully committed to playing our part in doing so. We agree there needs to be better alignment between regulatory approvals, NICE HTA assessment, NHS England commissioning/reimbursement, and local innovation diffusion processes - encompassing the broad family of diagnostics, medicines, medtech and devices, and digital health.

We'll support the AAR's streamlined pathway to identify high value innovations. We'll then help pull them through into mainstream care - building on our AHSNs, innovation testbeds, and our new Innovation and Technology Tariff. And where it makes sense, we'll increasingly be open to agreeing innovative win/win product-specific reimbursement models, incorporating a mix of outcomes-based, annuity-based and volume-based pricing deals.

None of which is to pretend this is easy. Or that there aren't hard choices, and difficult trade-offs along the way.

But that shouldn't obscure the huge gains within our grasp, both for patients across the NHS, and for the wider success of our country.

Simon Stevens
A. Executive Summary

The Accelerated Access Review was asked to make recommendations to Government on how to accelerate access for NHS patients to innovative medicines, medical technologies, diagnostics and digital products, making our country the best place in the world to design, develop and deploy these innovations.

The Review's independent chair, Sir Hugh Taylor, published an interim report in October 2015, setting out the key themes emerging from the review team's engagement with a wide range of stakeholders. Since then the review team has been carrying out further engagement and refining the recommendations.

This report sets out the final recommendations of the Accelerated Access Review. We believe that these recommendations will enable our country to improve patient outcomes, leverage the UK’s strong biosciences research and life sciences industrial base and enhance the international competitiveness of our life sciences industry. These recommendations will, of course, always need to be delivered within the budgetary envelope set by the Government for the NHS.

The recommendations are:

Chapter 1
1. The NHS should develop an enhanced horizon scanning process and clarify its needs to innovators.
2. A new transformative designation should be applied to those innovations with the potential for greatest impact.
3. Patients should be involved in horizon scanning and prioritisation, and this involvement should continue along the whole innovation pathway.

Chapter 2
4. An Accelerated Access Pathway for strategically important, transformative products should align and coordinate regulatory, reimbursement, evaluation and diffusion processes to bring these transformative products to patients more quickly.
5. A new strategic commercial unit should be established in NHS England.
6. The accelerated access pathway should be suitable for medical technologies, diagnostics and digital products as well as medicines and emerging forms of treatment.

Chapter 3
7. There should be a single set of clear national and local routes to get medical technologies, diagnostics, pharmaceuticals and digital products to patients.
8. National routes to market should be streamlined and clarified.
9. Many products will benefit from regional and local routes to market, which should be enhanced to operate consistently across the NHS.
10. The route for digital products should build on the Paperless 2020 simplified app assessment process.
Chapter 4

11. The digital infrastructure should enable the system to capture information on the use of innovations and associated outcomes.
12. The process of assessing emerging technologies should be evolved so that it is fit for the future.

Chapter 5

13. A range of incentives should support the local uptake and spread of innovation, enabling collaboration and with greater capacity and capability for change.
14. AHSNs, tertiary academic teaching hospitals and clinical leaders across the NHS should drive and support the evaluation and diffusion of innovative products.
15. Improved accountability and transparency around uptake of innovation should be supported by NICE.

Chapter 6

16. An Accelerated Access Partnership should align national bodies around accelerating innovation.

Chapter 7

17. The Accelerated Access Partnership should be established immediately.
18. Implementation of the report’s recommendations should be led by the Accelerated Access Partnership and clinicians.
B. The Vision

Getting the best technologies to patients more quickly and more cheaply, in a system that is quick to adopt innovation

This Accelerated Access Review sets out a bold new vision of better, cheaper and faster adoption of innovation, through:

- establishing **streamlined mechanisms for prioritising emerging technologies** and identifying strategically important innovations;
- working with innovators to **accelerate approvals**, speed up adoption and evaluate technologies efficiently using new data sources; and
- **aligning national organisations** to transform the NHS’s ability to adopt the right innovations rapidly.

Patients, clinicians, the NHS and industry will all benefit and will need to work in partnership to deliver a win:win for all, improving the competitiveness of our country in life sciences and improving investment in the UK.

The offer to patients…

- Earlier access to important, life-changing innovations that improve outcomes, through an Accelerated Access Pathway.
- A greater say in determining what innovations are important to them.
- Participation at the earliest stage of the evaluation of new products so they can help influence the products that will go on to reach patients.
- A clear package of transparent information to help understand the impact that innovation has on patients and on the NHS.

The offer to innovators…

- The opportunity to collaborate with the NHS to collect real-world as well as clinical trial data to evaluate product outcomes and pathway changes, and use this data elsewhere.
- A simplified and streamlined system for market access, including:
  - earlier dialogue with regulators, NICE and the NHS;
  - faster and more integrated decision-making by national bodies;
  - the opportunity to engage at an early stage with key decision-makers on a realistic value proposition;
  - fast, reimbursed access to the NHS market for promising products whose development has been accelerated and where the evidence base is not yet mature; and
  - mechanisms for evidence collection and accelerated diffusion across the whole NHS.
- A clear signal of the needs of the health system, to which they can respond.
- Access to a strengthened AHSN network which can facilitate local evidence-collection and adoption of innovation.
The offer to clinicians…

- The opportunity to work in a flexible and empowered health system that works together to adopt the best new technologies for its patients.
- The ability to lead and publish world-class translational research and develop evidence of a product’s performance in real-world settings.
- Better data on the impact of clinical pathway change on their patients’ outcomes.
- Better professional recognition of innovation and clearer messages on best clinical practice.

The offer to the NHS…

- A quicker and simpler way of finding those innovations that can improve efficiency and patient outcomes.
- The opportunity to deliver the most transformative products to patients in a way that offers better value, within the budgetary framework set for the NHS by the Government.
- Faster local and national spread of innovations by supporting the capacity and capability required to make the associated clinical pathway changes.
- Better ways of procuring products that generate greater value.
- Collaborations with innovators that will generate valuable evidence on the impact and efficacy of new innovations.
- Improved clinical pathways as a result of innovation adoption.
- A more efficient NHS that chooses the best innovations over interventions of lesser impact.

The diagram below sets out the Accelerated Access Review’s vision of a faster and more streamlined pathway for innovation, driven by patients and clinicians and supported by an Accelerated Access Partnership.

Figure 1: A summary of the Accelerated Access Review’s proposed approach
C. The Challenge

Patients rightly expect the NHS to provide emerging, transformational innovations as soon as they become available and for our health outcomes to keep pace with those of other countries. Evidence shows, however, that we sometimes lag behind other countries in the adoption of innovation.1

This situation cannot continue. Enabling clinicians, including doctors, nurses, healthcare scientists, pharmacists and allied health professionals, to access emerging innovations is essential if the NHS is to rise to meet its current and future challenges. Innovation has the potential to transform patient outcomes, modernise the delivery of care, make services more efficient, and help address some of the major challenges this country is facing, such as antimicrobial resistance. Our country is a world-leader in health research, our life sciences industry punches well above its weight internationally, and – in the NHS – we have the ideal infrastructure to test and adopt innovation. And yet throughout the review we have heard extensively from stakeholders how our health system currently struggles to prioritise even the best new products. Their frustrations are outlined in Sir John Bell’s introduction.

Now is a critical time to address the health system’s capacity to adopt innovation. In recent years the life sciences industry has generated an increasing number of transformative technologies. New technologies are coming down the pipeline at a rate we have never seen before: medical devices that use ground-breaking nano-technology or digital capability; drugs for chronic diseases that target specific sub-populations; diagnostics such as genomic sequencing that allow treatments to be targeted more effectively and curative medicines for diseases like Hepatitis C. The NHS needs to be ready to respond: flexing clinical pathways to get the most out of innovations, and generating datasets that allow a much more thorough evaluation of benefits and risks. Medicines regulators have already responded by adapting their processes to increase the speed of approval;2 but these opportunities will be lost and patients will be disadvantaged if the rest of the healthcare system is not equally agile.

This report provides the NHS with the ability to make a clear and attractive offer to those innovators that are willing to work with us: a simplified and aligned system; dialogue with national bodies; accelerated diffusion across the whole health system; and the opportunity to gather the data they need to market their products around the world. In the face of a rising medicines bill, however, this report is clear that those innovators who benefit from this system must also be prepared to offer significant value to the NHS to enable change to be delivered at better value and within the overall budget for the NHS.

The UK’s exit from the EU, far from altering the overall proposition set out in this report, gives us a chance to look afresh at our systems and identify steps to improve our international competitiveness in life sciences. We need to grasp the opportunities presented by leaving the EU

2 For example the US’s ‘breakthrough designation’, or PRIME in Europe
and – where possible – use any freedoms to create opportunities for our country: focusing on our global-leadership position in biosciences research and emerging industry subsectors; growing promising SMEs; building on our regulatory expertise and our reputation for health economic assessment; transforming the NHS into a system that welcomes innovation; and further developing our world-leading life sciences sector.

This report sets out an approach to selecting, accessing, funding and adopting the best innovations. This will allow the NHS to work positively and collaboratively with innovators and provide reassurance that system-wide, innovation-led changes will have significant benefits in streamlining clinical pathways, improving patient outcomes and generating efficiencies. Developing such an approach to adopting cost-effective innovations at scale is an important component of our efficiency drive and critical in ensuring that the UK and the NHS retain their globally competitive position in clinical research and investment.

The NHS is the ideal place to develop this new paradigm:

- It has the most integrated health research system in the world – the National Institute for Health Research – allowing access to defined population cohorts, providing research funding and world-class facilities and expertise that support early translational, clinical and applied health and care research across the pathway.
- It is the biggest and most integrated single payer healthcare system – a ‘closed loop’ where economic value can be quantified to allow the total impact of a product to be assessed.
- Our emerging health data and genomics platform will give us unrivalled capability in data collection and assessment, along with a host of diagnostic tools such as molecular pathology for improving the targeting of medicines.
- Our world-leading system of value for money assessment qualifies us well to lead rigorous evaluation.
- It has demonstrated a willingness to partner with innovators to test their product claims on real clinical pathways.

Our strong charitable sector will be an important voice for patients, carers and the public as we undergo this change. Patients not only have an interest in the availability of innovative products, but are ideally placed to influence the early development of these products so they can get what they need and go on to hold the NHS to account for uptake. The involvement of patients, their families, charities and the public will be critical to the successful implementation of this review’s recommendations.

This report provides a model through which strategically important innovations can be identified early, tested in the NHS to generate evidence of their impact, evaluated, and have reimbursement agreed promptly using a set of novel tools that reward innovators appropriately, and then adopted.

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and diffused across the NHS in a way that enables clinical pathway changes and generates efficiencies. A dynamic system like this needs to be flexible and rapid, and should be underpinned by good quality data. This will only be achieved if the life sciences industry and the NHS work together to deliver innovations that offer cost savings and patient benefits: accelerating access, rewarding the most innovative companies, and helping the NHS to manage its finite resources.
D. The Report

The review’s analysis and recommendations

This report describes the pathway to market for both strategically-important innovations (section 2) and products with more incremental benefits (section 3), and makes recommendations for each. In describing these pathways, it uses the terminology of the six basic steps in that process, as described below. The sequencing of the steps will vary product by product. The report makes recommendations on how each of these steps could be streamlined and accelerated so that patients get access to the most innovative products more quickly and more cheaply.

Figure 2: The six steps in a product’s pathway to market
1. Improved horizon scanning and targeting to identify the greatest potential benefits

The NHS should develop an enhanced horizon scanning process and clarify its needs to innovators

1.1. Improved horizon scanning to identify products that have the most potential to deliver improved outcomes or efficiencies.

1.1.1. It is difficult for the NHS to understand which innovations are likely to have the greatest benefit for the NHS and its patients from the multitude under development. Many of the existing horizon scanning systems only consider pharmaceuticals and not medical technologies, diagnostic, or digital products. We believe a simpler, more comprehensive and transparent system is necessary. We recommend that existing horizon-scanning mechanisms are brought together in a joined-up approach so that all major emerging products are considered consistently and thoroughly. The enhanced horizon-scanning function should include arrangements for medical technologies, diagnostics and digital products and should consider the wider financial and organisational potential of pipeline products. For example, cancer diagnostics that identify patients who would benefit from chemotherapy can avoid unnecessary treatments as well as save money for the NHS.

Figure 3: Forecast number of new chemical entities to launch between now and 2018

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4 The period 2008-2015 is based on European Medicines Agency (EMA) data on NCEs (new chemical entities) and biologics. The figures from 2016 onwards are a forecast for NCEs provided by the Horizon Scanning Research and
1.2. Innovators need to understand the NHS’s key priorities to help them focus on developing the right products – this should be one of the roles of an Accelerated Access Partnership.

1.2.1. Stakeholders have called for greater coordination across the innovation pathway and supported the proposal for a partnership model in the interim report. This ‘Accelerated Access Partnership’ would bring together the main national organisations in this landscape – NIHR, MHRA, NICE, NHS England, NHS Improvement and the Department of Health, as well as patient and industry representatives – and is described further in section 7.

1.2.2. Amongst its other roles, the Accelerated Access Partnership should, building on the gaps in the technology pipeline exposed by horizon scanning and using the approach of the Small Businesses Research Initiative (SBRI), enable the NHS to articulate to innovators the technology requirements that would best support its needs. This is expected to be more effective for technologies than biopharmaceuticals.

SBRI Healthcare

The SBRI Healthcare programme co-develops technology with the NHS, working with clinicians to identify key challenges and priorities. The resulting technologies bring the opportunity to transform health and care, and grow economic value for the UK. The programme is led by the Academic Health Science Networks and in 2015/16 was able to disburse nearly £20m to almost 50 companies.

Solutions have been identified for a number of conditions. In diabetes, for example, Sedgefield-based Polyphotonix has developed a non-invasive treatment for macular eye disease using organic light-emitting diodes housed in a fabric mask which is worn overnight, avoiding costly outpatient visits. The mask (Noctura 400) can be used to prevent and treat diabetic retinopathy and Diabetic Macular Oedema and is currently undergoing phase III trials and a NICE assessment.

SBRI-backed companies are reporting jobs and trade growth, private investment of over £45m and a pipeline value to the NHS evaluated by health economists at over £510m.

1.2.3. In parallel, it will be vital to provide innovators with simple access to research infrastructure. To support this, the NIHR is combining its Healthcare Technology Cooperatives (HTCs) and Diagnostic Evidence Co-operatives (DECs) schemes in order to hold a single, new, open competition to fund new Medtech and In vitro diagnostic Cooperatives (NIHR MICs). NIHR MICs will work collaboratively with the NHS, industry and patients to both develop new concepts, demonstrate proof of principle and devise intelligence Centre (HSRIC) based on what products companies expect to launch. The EMA figures include combination products and certain blood products that have been excluded from the forecast; therefore the figures are not directly comparable. The forecast is a best case scenario and should be treated as an upper bound.

research protocols, for new medical technologies, and generate evidence on commercially-supplied IVDs. The review is supportive of this step.

1.3. A digital health technology catalyst should be established to deliver the digital solutions the NHS needs.

1.3.1. Some digital technologies offer the opportunity to deliver improved outcomes at lower cost. We therefore recommend that the government explores how a digital health technology catalyst could be funded. This should be modelled on the Biomedical Catalyst and aligned with the work of Innovate UK.

1.3.2. A catalyst could provide matched public sector funding, alongside private investment, to address areas of failure in the digital healthcare market and support the growth of those promising small companies who are developing the digital technologies that the NHS and patients need and help bring their products to market.

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**Biomedical Catalyst**

The Biomedical Catalyst is a competitive challenge fund, run in partnership by Innovate UK and the Medical Research Council. It supports the translation of research into therapies, devices and diagnostics into commercial success and increases the confidence of those private investors who can help support a product to reach the market. It is considered to be highly successful; during phase 1 of the catalyst, companies in its portfolio realised over £1bn in post-project financing, licensing deals and acquisitions.

The Biomedical Catalyst provides three main phases of funding:

- **Feasibility awards** to explore the commercial potential of a scientific idea
- **Early-stage awards** to evaluate feasibility in a model system
- **Late-stage awards** to demonstrate effectiveness in a relevant environment.

In the Accelerated Access Review’s consultation process, stakeholders consistently identified a scarcity in funding for late-stage testing of digital health products in a real-world environment as a significant barrier to digital health innovation. Creating a digital health catalyst to address this issue would help provide a sustainable pipeline of digital health products designed to meet NHS needs and support the growth of UK companies.

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6 http://www.mrc.ac.uk/funding/science-areas/translation/biomedical-catalyst/
A new transformative designation should be applied to those innovations with the potential for greatest impact

1.4. A transformative designation should identify the most strategically important products (medical technologies, diagnostics, pharmaceuticals or digital innovations) that have the potential to deliver significant benefits in cost or outcomes.

1.4.1. The transformative designation should signal, within the UK and internationally, a product’s strategic importance to the NHS. It should be reserved for the small number of products that have the potential to provide significant benefits in either patient outcomes or NHS costs. Its immediate practical effect should be to act as a trigger for these strategically important innovations to enter an accelerated pathway to patients, receiving additional support and guidance to navigate the market and to reach patients. This accelerated pathway for transformative products is a key plank of this report and is described in more detail in section 2.

1.4.2. Determining which products should receive a transformative designation will therefore be of critical importance, and the Accelerated Access Partnership should develop a transparent and robust process for this, bringing together skills in NICE and NHS England and drawing on a range of evidence of potential impact. For pharmaceuticals, the criteria should build on ‘breakthrough designation’ in schemes such as PRIME7 in Europe and the UK’s Early Access to Medicines Scheme (EAMS).8 Criteria for designation could include:

- magnitude of health gain;
- impact on unmet need;
- alignment with NHS England’s clinical priorities and other national priorities;
- impact on system efficiency;
- potential cost impact, from cost saving to significantly cost increasing;
- opportunity for clinical pathway transformation;
- innovative nature of the technology.

1.4.3. As well as considering the potential cost impact of individual products, the cumulative cost impact of all products should be considered, in the context of the budgetary envelope for the NHS set by the Government, with a view to ensuring overall affordability within that budget.

1.4.4. We expect that only around five to ten innovations per year would receive the transformative designation and not all of these will travel down the entire Accelerated Access Pathway as described in section 2; products can enter and leave at multiple points. While many products of strategic importance may be in specialised services, this designation should be applicable to all products, regardless of their commissioning

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7 http://www.ema.europa.eu/ema/index.jsp%3Fcurl%3Dpages/regulation/general/general_content_000660.jsp%26mid%3DWC0b01ac058096f643
8 https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams
method, and available to medical technologies, diagnostics, pharma and biotech as well as emerging types of innovation such as cell therapies and digital health.

Figure 4: The Accelerated Access Partnership will identify a small number of strategically important products

Patients should be involved in horizon scanning and prioritisation, and this involvement should continue along the whole innovation pathway

1.5. The NHS should use a common set of principles describing what good partnership with patients and the public looks like along the whole innovation pathway.

1.5.1. We are seeing a shift from a one-size-fits-all model of blockbuster drug development to a new age of personalised medicine, enabling patients to take greater control in their health care. Patients’ strong interest in the development and availability of new innovations means that their involvement, either directly or through charities, is critical, from influencing innovators to develop the products they need, participating in research, championing the uptake of innovations into the NHS to holding the NHS to account for the adoption and spread of the best innovations. This means that meaningful dialogue with patients has never been more important.
1.5.2. Alongside the review, National Voices, the coalition of health and social care charities, developed a set of principles or ‘I statements’ that describe what good collaboration with patients and service users throughout the innovation process looks like in practice. We propose that NHS organisations – and other organisations involved with innovation – should develop their own set of principles, using the I statements as a basis, to underpin all stages of the innovation pathway and help everyone along that pathway to put the patient first.

1.5.3. This applies equally to the national bodies that form part of the Accelerated Access Partnership who, in addition, should consider how to best ensure patient involvement in the process of designing the criteria for transformative designations.

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9 http://www.nationalvoices.org.uk/publications/our-publications/involving-patients-and-service-users-i-statements-research-and
A collaborative approach in myeloma

In 2007, Myeloma UK developed an innovative approach to gain approval from NICE for bortezomib, a treatment for patients with relapsed myeloma. Although bortezomib had initially been turned down, Myeloma UK worked collaboratively with Janssen and NICE to develop the first patient access scheme of its type, which is still in operation today. It reduces the level of risk to the NHS by ensuring that the NHS only pays for patients that respond to the drug. Failure of a patient to respond means that the company reimburses the NHS for the costs of the drug.

Myeloma UK was pivotal in pushing compromise between all parties and ensuring that the outcomes data reporting systems were put in place so that the scheme operated effectively, with minimal additional burden to the NHS.

Myeloma UK, reflecting on the first unsuccessful NICE appraisal, has developed a collaborative approach to health technology appraisals, ensuring engagement as early as possible with companies. This has meant successful appraisals of the majority of new medicines for myeloma. In addition, Myeloma UK established a clinical trial network to accelerate the set-up of and recruitment to a strategic portfolio of trials. This network also created the capability to partner with industry to generate real-world UK data alongside registration programmes to improve the evidence suitable for the UK assessment, and thus the value proposition, and increase data certainty ahead of the health technology appraisal.
2. An Accelerated Access Pathway for transformative products

An Accelerated Access Pathway for strategically important, transformative products should align and coordinate regulatory, reimbursement, evaluation and diffusion processes to bring these transformative products to patients more quickly

Figure 6: Key differences between existing pathways and the accelerated access pathways

2.1. Strategically important products should benefit from an Accelerated Access Pathway to patients.

2.1.1. The Accelerated Access Pathway should allow products with a transformative designation to meet regulatory requirements, agree commercial arrangements, receive revenue and achieve market access as quickly as possible. We expect that this could bring forward reimbursed access by up to four years in some cases (see section 2.3.2). This should be enabled by the Accelerated Access Partnership, which will provide specific, tailored support from an early stage of the pathway.
2.2. Strategically important products with a transformative designation should be given access to clinical research opportunities to support evidence collection, for the benefit of patients and industry.

2.2.1. The Accelerated Access Partnership should support innovators with strategically important products to navigate the system, hold early dialogue with national decision-makers such as NICE, NHS England, NHS Improvement and MHRA, and increase understanding of product impact. This should include:

- Using our state-of-the-art translational clinical research base to provide access to clinical research cohorts.
- Generating real-world, in addition to other, clinical trial data on the most responsive patient populations, using genomic sequencing and other personalisation tools to identify more precisely who can benefit from the intervention.
- Undertaking research in collaboration with the NHS, sharing cost and risk and allowing the NHS to benefit (for example through a lower price) if and when the product receives a licence.
- Gathering real world data on medical technologies and their impact on a clinical pathway through a ‘commissioning through evaluation’ type approach or a managed access agreement (described in more detail in section 2.9).

Figure 7: The innovator’s perspective

2.2.2. Many innovations come to market with incomplete evidence of impact on patients, clinical pathways and efficiency. The NHS, as a single system where cost and outcomes data can be collected, can offer innovators significant value in building their evidence base. Combined with the scale and strength of its early translational and clinical research through NIHR, its emerging genomic sequencing capabilities through
Lessons from Ebola

The UK’s rapid response to the licensing needs for the Ebola virus demonstrated not only the willingness of the population to participate in ground-breaking research, but also how our regulatory processes can be accelerated. The MHRA’s Clinical Trials Unit (CTU) prioritised Ebola studies over other clinical trial applications. This resulted in approval timeframes of approximately one week compared to an average for phase I studies of about three weeks.

The MHRA CTU worked closely with the trial sponsors to provide ad hoc scientific advice and review prior to official submission of the application. The MHRA also sought independent expert advice from the Commission on Human Medicines’ Clinical Trials, Biological and Vaccines Expert Advisory Group who supported the review through their willingness to provide expert input remotely and at short notice.

Trial sponsors ensured that any questions raised by the MHRA and independent experts were answered as quickly as possible, allowing a rapid approval without compromising the MHRA’s stringent assessment standards. This demonstrates that MHRA is a world-leading regulator and has the ability to flex its resources and processes where necessary to enable a rapid response to public health emergencies.
Overcoming regulatory challenges in dementia

In dementia, interventions are more likely to be successful in the early stages of disease before symptoms present. But that means it can take years to generate the evidence of efficacy required for regulatory approval. Between 2002 and 2012, 99.6 per cent of clinical trials in Alzheimer’s disease – the most common cause of dementia – failed due to a combination of scientific, trial design and regulatory challenges*. This enormous failure rate creates a risk that innovators will become reluctant to invest in this important area, and patients will lose out, unless new regulatory approaches are found.

Raj Long’s 2015 report *Finding a path for the cure for dementia** recognised the seriousness of this situation. Its recommendations were shaped by a collaboration of ten regulatory agencies from North America, Europe and Japan, which convened to draw attention to these challenges and find a solution. The report called for a radically new approach to drug development that takes into account the unique characteristics of dementia. It sets out a strategic solution, involving regulators, clinicians and academics, acting at multiple levels in the current regulatory framework. The specific recommendations include:

- Reconsidering previously rejected molecules to see if they can be developed in a different way;
- Embracing new approaches to drug development such as ‘adaptive pathways’ that can apply existing accelerated regulatory pathways to dementia;
- Employing a sensitive and patient-centric approach to the risk-benefit balance;
- Creating an advisory panel of research experts who can work in conjunction with regulators to advise on optimal development strategies.

Alzheimer’s Research UK and the OECD are now taking forward the report’s recommendations and appraising an integrated solution to the drug development challenges in dementia. This work aims to address the high failure rate and help bring effective new treatments to people living with dementia and potentially serve as a model for other diseases.


2.3. A number of early access or breakthrough schemes exist for pharmaceutical products: the Accelerated Access Pathway for medicines should fit seamlessly with these schemes and should allow time to be taken out of the process by better aligning regulation and evaluation.

2.3.1. The Accelerated Access Pathway for medicinal products should build on existing breakthrough designations such as PRIME and EAMS’s ‘Promising Innovative Medicine’ (PIM) designation. The pathway should enable patients to access strategically important products early, through a NICE conditional recommendation where appropriate, and allow additional evidence to be collected to fully demonstrate the product’s value and impact.
2.3.2. Closer alignment of regulatory and NICE data requirements and processes, including timing NICE’s decision as close to the opinion of the Committee for Medicinal Products for Human Use (CHMP) as possible, will, alongside the other measures identified in this report, accelerate access to strategically important pharmaceuticals. Our analysis shows that patient access can be brought forward by up to four years where an EAMS scientific opinion is used (saving 12-18 months), and where there are no delays in the technology appraisal (which can take up to two years) or in NHS commissioning and adoption (which can take two years or even longer). Companies can also reduce clinical development timelines if decisions are taken at global level to use novel approaches to clinical trial evidence generation and regulators are showing increasing willingness to consider evolving datasets for high-impact products. Truly breakthrough products with promising early clinical trial results also tend to accelerate through clinical development.

The EAMS experience: bringing forward access to pembrolizumab

Through the Early Access to Medicines Scheme (EAMS), MHRA worked with MSD to ensure that UK patients with advanced melanoma were among the first in the world to access the breakthrough treatment, pembrolizumab. EAMS offers patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need.

Pembrolizumab was available through EAMS around a year earlier than if it had gone through all the conventional processes and MSD estimated that around 500 UK patients accessed it during the EAMS period. For pembrolizumab, the company proposed a patient access scheme (PAS) at the earliest opportunity after licencing which helped NICE to publish guidance as quickly as possible. EAMS helped accelerate routine patient access by seven to eight months through a combination of expedited NICE scheduling and a 30 day implementation period by NHS England rather than the usual 90 day period.

Following the successful implementation of the first EAMS scientific opinion, MSD is continuing to engage with MHRA and other stakeholders on further EAMS applications, including other indications of pembrolizumab.

2.3.3. There is always a balance to be struck between accelerating access to medicines and ensuring that patients can be confident those medicines are safe. It is therefore important to note that this review does not make any recommendations that change the evidentiary standards needed for regulation. In EAMS, medicines are only approved for use in the scheme if companies can provide good quality, clinical and non-clinical supporting data, along with a risk management plan, similar to that provided for marketing authorisation.
Figure 8: The Accelerated Access Pathway could enable widespread patient access to pharmaceutical products up to four years earlier

2.4. SMEs and not-for-profit organisations with products on the EAMS pathway should, in some cases, receive some funding.

2.4.1. EAMS continues to hold significant value for innovators on the Accelerated Access Pathway: giving patients access to medicines prior to marketing authorisation, accelerating the path to NICE evaluation, and shortening the time to reimbursement.

2.4.2. As part of the Accelerated Access Review, the government commissioned a review of EAMS. Following extensive engagement with stakeholders, this was published in March 2016 and makes seven recommendations that build on what EAMS has achieved to date.10

2.4.3. One of these recommendations relates to funding. The EAMS review’s analysis suggests that, in order for the UK to remain internationally competitive, products participating in EAMS should receive some level of funding prior to NICE assessment. To direct monies most effectively, this funding could be focused on strategically

important products manufactured by SMEs and not-for-profit organisations. It could depend on the level of risk associated with the product and include risk-sharing arrangements where appropriate. We recommend that the government makes between £20m and £30m available for this support over five years.

The EAMS experience: bringing forward access to osimertinib

Osimertinib is an innovative product discovered and developed in the UK by AstraZeneca to treat lung cancer where there is high unmet medical need. Osimertinib went through the regulatory system using accelerated assessment and conditional marketing authorisation and was approved based on single arm studies. In addition, 22 UK patients benefited directly from the EAMS scientific opinion which allowed them earlier access. The conditional marketing authorisation came only eight months after the regulatory submission was filed at the EMA, and less than three years after osimertinib was first trialled in humans. In October 2016, osimertinib became the first medicine to be made available to NHS patients through the reformed CDF process, following a recommendation by NICE.

A new strategic commercial unit should be established in NHS England

2.5. A strategic commercial unit should have the capacity and capability to consider a range of flexible pricing models as part of a commercial dialogue with innovators.

2.5.1. Win-win scenarios, where innovators benefit from earlier, and, in some cases, guaranteed market access and the NHS and patients benefit from better value through a reduced price, are possible. They depend, however, on having the right expertise in place and require innovators and NHS England to undertake a commercial dialogue so that mutually advantageous commercial arrangements can be agreed quickly. They are more likely to be successful if all parties are willing to engage early in this dialogue.

2.5.2. We propose that NHS England creates a new strategic commercial unit (SCU) to enable the NHS to agree such commercial arrangements with companies. The unit should consider a product’s overall affordability, and its dialogue with innovators should take into account the wider value of accelerated access, such as early approval from NICE, the potential for confidential commercial arrangements, increased – and in some cases guaranteed – volumes across England, and the generation of real-world observational data on top of clinical trials data. This offer to industry should be reflected in a cost proposition that delivers additional value for the taxpayer beyond that achieved through the current system.

2.5.3. Building the evidence base for a strategically important product is of value to innovators, and should be taken into account in the commercial negotiations described above. This could involve novel risk-sharing arrangements between the NHS and the innovator that enable both parties to benefit from a product’s success.

2.5.4. The unit should be able to enter into a wide range of commercial arrangements that deliver better value, share the benefits of accelerated access and recognise any uncertainty in the evidence base. A large number of flexible pricing schemes are in use internationally, such as price-volume agreements, conditional reimbursement, deferred payments or annuity-based pricing, outcome-based payments, product-service
bundling and deferred payments, amongst others, and the SCU may wish to consider, for each product, whether using one or more of these schemes would deliver value and help a product to achieve reimbursement in an affordable way. The most appropriate scheme will depend on the product’s value proposition and should be considered and modelled on a case by case basis. We would encourage flexibility and innovation in the type of arrangements that might be achieved to maximise the potential benefits for all parties. Over time, the commercial arrangements may change depending on the emergence of new evidence or changes in population size. Payment could be linked to the delivery of value, whereby no payment is made if the expected value has not been delivered.

2.5.5. As the unit develops its capacity and capability, we suggest that its scope could extend beyond strategically important technologies to cover a wider range of products. This would give NHS England the ability to reach agreements with companies that allowed it to manage its resources more effectively. We note that NHS England and NICE are currently consulting on proposals that include entering into commercial access agreements with companies where products exceed a budget impact threshold¹¹, and we propose that the way this consultation is taken forward is aligned with the implementation of this review.

Figure 9: The sequencing of the Accelerated Access Pathway for strategically important pharmaceuticals

2.6. **SCU commercial dialogue should be informed by NICE and should take place before final guidance is issued.**

2.6.1. The SCU should hold commercial dialogue with the small number of companies whose product has a transformative designation, in parallel with that product’s assessment by

NICE. The discussions should include the level and timing of reimbursement and, as with the new Cancer Drugs Fund (CDF),\(^\text{12}\) the resulting commercial arrangements should be able to remain confidential. As outlined in section 2.5.2, the discussion should take into account the benefits to the company of the Accelerated Access Pathway and the opportunity to enter into confidential, flexible arrangements, and as a result should aim where possible to achieve a significantly higher level of cost effectiveness. **Final NICE guidance on these strategically important products should ideally not be published until after SCU's commercial dialogue has concluded, and the three month funding requirement should apply where SCU agrees a mutually acceptable commercial deal with the innovator and NICE guidance recommends the product for routine use.** Where the SCU fails to reach a commercial deal, the NICE guidance would be based on the price agreed with the company under existing rules and, in the event that this would result in a positive recommendation, NHS England could ask NICE to consider varying the funding requirement where they had concerns about resources, including budget impact.

2.6.2. Should a company choose not to take advantage of the benefits of the Accelerated Access Pathway they should be able to opt out of their transformative designation and proceed down the standard pathway as they would have done under normal circumstances.

> "Immunocore supports the NHS in its initiative to treat high medical unmet need patients earlier than traditionally possible. In a collaborative partnership, Immunocore will invest alongside the NHS in improving pathway efficiency (for uveal melanoma patients) that expedites earlier access to treatment, improves patient care and shares financial benefits that align with the benefits of expedited access to patients."

Eliot Forster, Chief Executive, Immunocore

2.6.3. Where a product’s evidence base is immature but shows strong potential, NICE should be able to issue a conditional recommendation leading to a period of managed access, building on the approach for the new CDF. This should only be available to those strategically important products whose development and regulatory timetable has been accelerated, and should also be dependent on NHS England reaching satisfactory commercial arrangements with the company. **In a managed access period, the commercial arrangements for these products should reflect the uncertainty of their evidence base to limit the financial risk being borne by the NHS. It would be reasonable for products with uncertainty to be tested against more stringent requirements than those products where benefit is well understood.**

2.6.4. CDF monies should be used to fund any managed access agreements for licensed cancer products on the accelerated access pathway.

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Figure 10: Products that reach a commercial deal will move swiftly to reimbursement

2.7. Industry should seek advice from MHRA and NICE to trial cancer medicines in early stage disease where QALY benefits may be more easily demonstrated.

2.7.1. Cancer medicines are typically first trialled on patients with late stage disease, where it is challenging to significantly extend life. These patients are also seriously ill and it would deliver more health gains if products were able to extend life, potentially for longer, for patients before their condition has seriously deteriorated. Treating patients with early stage cancer could reduce the number of treatments they need over time and be a significant opportunity for innovators to improve outcomes for patients and demonstrate more value from their products. Industry should work with MHRA and NICE to understand whether more cancer medicines can be tested to support a first-line indication, where this can be justified for ethical and scientific reasons.

The Accelerated Access Pathway should be suitable for medical technologies, diagnostics and digital products, as well as medicines and emerging forms of treatment

2.8. Strategically important medical technologies may require support for data collection.

2.8.1. For medical technologies, diagnostics and digital products, the pathway may look slightly different to the pathway for strategically important pharmaceuticals. Medical technologies will often come to market with a less formed evidence base than medicines due to the different regulatory requirements. This means that a transformative designation is more likely to be given after a CE marking, and products may need further clinical and cost effectiveness data before the NHS can be clear about their benefits. These benefits will usually arise due to the product’s impact on a clinical pathway.
2.8.2. Innovative med tech products frequently fail to achieve reimbursement and adoption because the small firms involved have limited resources for the additional clinical testing required to generate the evidence to inform cost-effectiveness decisions. We propose that a small amount of funding – around £20m to £30m over five years – would support the commercialisation of disruptive innovative technologies that significantly change care pathways and have the potential to improve outcomes and create efficiencies. The funding should be targeted at SMEs to promote a vibrant and varied industry.

**Six key questions that medical technology innovators should ask**

- How will this innovation change clinical pathways and establish a new standard of care?
- What will be the clinical, social and economic impacts from this new standard of care?
- How will we measure the impacts with sufficient precision to provide evidence for adoption?
- What changes in workflow will be required?
- How will the re-engineering of this workflow be resourced?
- How can the benefits be spread across and between healthcare delivery systems?

2.9. Support for strategically important medical technologies from the Accelerated Access Partnership should be aimed at post-CE mark data collection

2.9.1. This data collection should focus on demonstrating the product's impact on the system. One way of approaching this is through a commissioning through evaluation pathway, where complex medical technologies or diagnostic products that significantly change clinical pathways are rolled out in a number of specialist providers who are well-placed to collect impact data and build expertise around pathway change. Following this period, should the technology prove its value after assessment by NICE, it should enter routine commissioning and benefit from supported uptake, driven by AHSNs.

2.9.2. The best evidence of costs and benefits to the health system will arise in settings where data is collected digitally and is integrated across the whole health economy. This is explored further in section four
2.9.3. The new Innovation and Technology Tariff, announced by the Chief Executive of NHS England in June 2016, provides a reimbursement route for a selected number of value-proven, strategically-important medical technologies and digital products, including standalone digital technologies such as apps, removing the need for multiple local price negotiations.

How innovative diagnostics can save money and improve patient experience

Innovative diagnostic tools have the potential to improve patient experience and save operational costs. High sensitivity troponin assays, for example, can rule out or confirm a type of heart attack.

In 2014 NICE recommended the use of Elecsys Troponin T high-sensitive (Roche Diagnostics) and ARCHITECT STAT High Sensitive Troponin-I (Abbott Diagnostics), alongside other investigations, to help emergency clinicians determine whether patients experiencing chest pain are having a heart attack. Both these tests measure the level of troponin, a protein released into the blood when heart muscle is damaged. Standard cardiac troponin tests have to be carried out on admission and 10-12 hours later, but the high-sensitivity troponin tests are able to detect a change in levels of troponin much earlier, within as little as three hours.

Ruling out heart attacks earlier means patients can be discharged from A&E sooner and fewer patients need to be admitted to hospital for observation while the testing is carried out, saving the cost of unnecessary admissions. It reduces length of hospital stay and improves patient experience by reducing waiting time for results and putting patients on the appropriate treatment pathway sooner. Based on NICE’s assessments and industry data, it is estimated using these tests with the earlier discharge protocol has the potential to save the NHS £30 to £40 million per year.

2.9.4. As with medicines, the costs of adoption of strategically important medical technologies should be negotiated centrally through the SCU (see section 2.5) in order to secure

13 https://www.england.nhs.uk/2016/06/treatment-innovations/
value for the NHS as a whole. The Accelerated Access Partnership should be able to refer particular products for procurement within the NHS Supply Chain programme where they deem this more appropriate, and should ensure that new procurement and supply chain arrangements due to be in place from 2018 become the default procurement process for strategically important products coming through the Accelerated Access Pathway. The Accelerated Access Partnership may also submit some medical technologies for inclusion in the model hospital proposals as set out by Lord Carter in his review of operational productivity.14

Episcissors: an innovative approach to procurement

The NHS identified an opportunity to improve care and make savings by the national use of Episcissors-60, an innovation which was supported by the NHS’s National Innovation Accelerator. Episcissors take away human error in estimating safe episiotomy angles during childbirth. Data suggests that obstetric anal sphincter injuries, which occur during vaginal childbirth, have a direct cost to the NHS of £48.75m per year, and an additional indirect cost of £3.1m per year in litigation costs. Trials at Hinchingbrooke and Poole Hospitals NHS trusts suggest that use of Episcissors-60 reduces the risk of obstetric injury by up to 20 per cent and they have reduced the risk of obstetric injury at Croydon University Hospital by nearly 50 per cent.

The Department of Health instructed NHS Supply Chain to bulk purchase this innovative surgical instrument through an upfront commitment contract. This commercial agreement is delivering:

- improved patient outcomes
- significant upfront savings from bulk purchasing
- savings over time from reduced harm to patients
- an easy route for the product to the NHS market, to stimulate demand
- reduced investment risk for the company.

This innovative partnership model also benefits the taxpayer by paying the Department of Health a royalty on all international sales of Episcissors-60.

2.10. Each strategically important innovation and associated clinical pathway should have a bespoke incentive package for the NHS, developed alongside NICE guidance, to support collaboration and track adoption.

2.10.1. The Accelerated Access Partnership should take every step to support uptake and diffusion of products on the accelerated access pathway for the benefit of patients. It should ensure that NICE’s guidance for strategically important innovations includes a bespoke incentive framework that supports diffusion across the NHS. This could include national tariffs or proposals for local changes to support collaboration across organisations. NICE should track uptake of the products and publish this information.

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3. Simpler national and local routes to get products to patients

There should be a single set of clear national and local commissioning arrangements to get medical technologies, diagnostics, pharmaceuticals and digital products to patients

3.1. The current range of national commissioning routes is complex and difficult to navigate. The new routes should be clearer, fewer in number, and there should be transparency about the time each step is expected to take. They should enable well-organised innovators to reach patients quickly through the most appropriate route.

3.1.1. Whilst all commissioning routes will be based around the six steps identified earlier, the sequence of the steps may vary depending on product type. It is not feasible for every product to be evaluated nationally, so local routes should be available.

![Figure 12: The six steps in a product’s pathway to market](image)

3.1.2. Section two described the accelerated routes through which strategically important products will reach patients. However, products whose benefit is incremental, rather than transformative, should also have a small number of clearly-defined arrangements that are easy for the health system to articulate and for innovators to understand. These routes should be clearly laid out for all stakeholders to see.

3.1.3. The routes for incremental products should include:

- a national route to specialised commissioning via NHS England or NICE;
- a national route to secondary and primary care via NICE; and
- a local route to secondary and primary care via regional medicines optimisation committees or AHSNs.
3.2. A ‘how to’ guide should support innovators, particularly SMEs, in navigating national and local paths to market.

3.2.1. We have received extensive feedback that the arrangements for getting products to patients are too complex and opaque. A ‘how to’ guide, available online,\textsuperscript{15} will enable

\textsuperscript{15} https://www.gov.uk/government/publications/innovation-pathway-for-nhs-products
innovators to see clearly how their products can best navigate the system to reach patients.

3.3. **NHS England should vigorously pursue its work to streamline local medicines assessment.**

3.3.1. Companies have reported that local medicines assessment hubs sometimes increase bureaucracy without adding value. We therefore strongly support the work already underway within NHS England to streamline local medicines assessment into four hubs, using a standardised assessment approach. The hubs should not duplicate any activity that is being carried out nationally, for example by NICE.

3.3.2. Local uptake support for medicines should be enabled by AHSNs, underpinned by incentives that promote collaboration. This is detailed in section five.

**National routes to market should be streamlined and clarified**

3.4. **National evaluation and commissioning should be aligned across NICE and NHS England.**

3.4.1. Pharmaceuticals, medical technologies and diagnostics that are not selected for the accelerated pathway but which require national assessment should undergo a streamlined process that is aligned across the system.

3.4.2. Currently, products that form part of specialised services may be evaluated by NICE through a technology appraisal, assessed by NHS England’s Clinical Priorities Advisory Group, or tested in a small number of centres through the Commissioning through Evaluation programme. We propose that NHS England and NICE work together to ensure that their separate topic selection processes are better integrated. Whilst it is not feasible for one national body to assess every specialised commissioning product, it is essential that NICE and NHS England are clear about their decision-making processes and criteria and that they clearly articulate to innovators the circumstances in which products would take each route. It is important that no groups of products can ‘fall between the cracks’ and struggle to find a decision-making process.

3.4.3. Products that form part of primary care or CCG-commissioned services that are suitable for national assessment should be assessed by NICE. Products that are not referred to NICE should be assessed only once, by NHS England’s regional medicines optimisation committees.

3.4.4. These pathways should be described simply and clearly and reflected in the next iteration of the *how to* guide.\(^{16}\)

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Many products will benefit from regional and local routes to market, which should be enhanced to operate consistently across the NHS

3.5. Many innovations will be unsuitable for national evaluation but have the potential to create value in the healthcare system and should be tested and adopted locally into the NHS.

3.5.1. Many of these innovations will be medical technologies and digital products or tools that enable incremental improvements to clinical pathways and processes.

3.5.2. Evaluation of these innovations is best done at a regional level, in collaboration with providers who can flex local pathways in the manner of the NHS test beds, to provide clinicians and the NHS with evidence of utility, value and pathway redesign. This in turn provides innovators with the data they need to commercialise their products.

New and innovative commercial partnerships to support the delivery of better care in a more efficient way

Medtronic Integrated Health Solutions is a partnership between Medtronic and the NHS that supports access to capital infrastructure facilities and decreases costs to the NHS. In the UK, Medtronic has partnered with NHS organisations to modernise their catheterisation laboratories (cath labs), moving away from the traditional, transactional, supplier-customer relationship to build a shared risk-and-reward model that delivers value under a long term service agreement through a fee per-procedure approach. The partnerships have resulted in reduced waste and increased activity in NHS trusts.

3.5.3. We believe that a refreshed network of AHSNs, alongside local clinical leaders, should help identify the innovations that are suitable for this local pathway and establish evaluative studies that follow a nationally agreed format and standard. For medtech and diagnostics in particular, AHSNs should support the formation of partnerships with local NHS organisations to build a cost-effectiveness case and a body of knowledge around pathway change, and should signpost to the right kinds of specialist support such as the regional Medilink organisations or NHS Innovation Hubs. This structured evidence gathering would allow effective innovations of all types to be badged with an ‘NHS warrant’, recognised by commissioners and procurement teams across the NHS, and be diffused across the system via the national AHSN network and with patient input. The AHSNs should act as innovation exchanges, working with their local health economies to understand local areas of unmet clinical need and then working with innovators to meet those needs, providing advice and support throughout product development.

3.5.4. Medical technology innovators using this local pathway should be able to apply for their product to be included in the Innovation and Technology Tariff and the product should be considered for inclusion in the NHS Supply Chain products catalogue. Some

17 http://www.medilinkuk.com/about-us/medilink-uk-member-organisations
products may benefit from national procurement and in such cases the NHS Supply Chain could take a lead role in negotiating bulk deals.

Innovative medical technologies with cost saving potential

NeoTract’s UroLift system is recommended by NICE for treating the symptoms of benign prostatic hyperplasia, a condition where an enlarged prostate can make it difficult for a man to pass urine, which can lead to urinary tract infections and, in some cases, renal failure.

Existing treatments involve cutting away excess tissue, which risks loss of sexual function and requires a hospital stay. The UroLift system uses implants to move excess tissue away and prevent it from blocking the flow of urine. NICE’s Medical Technology Advisory Committee concluded that, as well as benefiting patients, for example by preserving sexual function, it could also save up to £286 per patient through, for example, carrying out the surgery as a day procedure. The treatment can also be delivered under local anaesthetic, thus avoiding the risks of general anaesthesia and further reducing costs.

The route for digital products should build on the Paperless 2020 simplified app assessment process

3.6. **AHSNs should play a key role in digital health, advising innovators on local areas of unmet need and working with providers, CCGs and clinicians to generate evidence of the utility of digital products.**

3.6.1. AHSNs should build on their role as innovation exchanges to ensure that digital product development meets the NHS’s needs. They should have a specific mandate to identify, test and disseminate digital technologies, particularly those that are demonstrating locally the potential to deliver efficiencies. This should build on AHSNs’ current work to support demand and supply needs in digital health, such as DigitalHealth.London, a collaboration between the three London AHSNs, the three London AHSCs, NHS England and the Greater London Authority.

3.7. **Digital products’ route from idea generation to patients should be clarified.**

3.7.1. The pathway for healthcare apps requires improvements in assessment, commissioning, procurement and prescribing. It should be suitable for fast-moving technology areas and products developed by SMEs.

3.7.2. The Paperless 2020 app assessment process, due to be launched in early 2017, provides a comprehensive mechanism for app evaluation that assesses efficacy, cost impact and usability. This will increase commissioner, clinician and patient confidence in digital products. The Crown Commercial Service, in partnership with NHS Digital, NHS England, the Department of Health and other system and technology partners, should consider how best to develop an accessible, simple and swift competitive process for procuring digital products from SMEs. There would be benefit in aligning the processes for medical technologies and digital products, and both these technology
types should benefit from the new procurement and supply chain arrangements due to be in place from 2018.

3.7.3. Additionally, some of the apps evaluated by NICE as part of the Paperless 2020 process could be made available through the new Innovation and Technology Tariff. This will provide a national route to market for a small number of technologies and will incentivise providers to use digital products with proven health outcomes and economic benefits.

3.7.4. NHS England, working with NHS Digital, should develop a generic framework for app prescription that obviates the need for multiple, local systems and is as easy to use as existing prescribing systems for medicines. This will clarify the mechanism that healthcare professionals should use and the wrap-around services required to enable patients to access suitable digital products.

3.7.5. The final stage of the Paperless 2020 app assessment process, the NICE independent evaluation, should include specific advice on how the app should be adopted by the system and delivered to patients. This advice should be developed in collaboration with the Accelerated Access Partnership. It may also identify where the product should be used within the existing NICE care pathway and how this might change other aspects of the care pathway.

3.7.6. A representation of the digital pathway is included in technical annex C.

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**Using digital health to redesign care delivery**

Digital health products can transform models of care to simultaneously provide excellent patient outcomes and NHS cost-savings. Big White Wall is a digital platform and community offering a range of therapeutic mental health interventions to support members to self-manage their care with support from clinicians, care-givers and peers. It allows members to access mental health services instantaneously and anonymously, eliminating waiting times. Recovery rates for Big White Wall therapy services in the UK are 12 per cent above the national average and 8 per cent above the national target. An independent review of the economic savings to the NHS from Big White Wall’s support network service found an average saving of £36,935 per 100 members. Due to its clinical and economic benefits, it has been widely commissioned; it is currently available to 31 per cent of the UK adult population.
4. Future capabilities: evidence generation and NHS evolution

The digital infrastructure should enable the system to capture information on the use of innovations and associated outcomes

4.1. Systems that collect electronic information on prescribing, procurement, dispensing, pricing and outcomes will be essential in enabling improvements to patient care.

4.1.1. This report’s recommendations cannot succeed without a significant improvement in digitisation across the NHS, including electronic patient records and e-prescribing. The need for this digitisation to be properly resourced and phased, with the appropriate workforce to support it, is clearly set out in Robert Wachter’s recent report on harnessing the power of health information technology. We wholeheartedly support the recommendations in Professor Wachter’s report and in particular the focus on ensuring regional then national interoperability of systems.

4.1.2. In parallel, the National Information Board is undertaking work on secondary uses of pharmacy data under its programme. Without the right information on prescribing, dispensing and pricing – linked to outcomes – systems of conditional approval, new pricing models and real-world data collection will not be possible, and this review therefore strongly supports the National Information Board’s work in this area. In order to assess costs and benefits across the whole system it will also be critical to link primary, secondary, tertiary and community care data – something that is already in progress in several areas of the UK.

4.1.3. Our ability to generate data on product impact, at scale, will be a significant selling-point for the NHS and, critically, it will also give the NHS information about product value with which it can negotiate fair reimbursement levels with companies. Existing disease registries and their relevant patient groups provide ideal opportunities to pilot this approach. These registries should be linked with patient records to provide trials cohorts and support the evaluation of products.

4.1.4. In his report, Professor Wachter recognises the importance of striking a balance between an individual’s right to privacy and the enormous opportunity for patient benefit through the systematic secondary use of the NHS’s valuable data. We strongly agree, and the Accelerated Access Review’s recommendations will need to be underpinned by clear standards for data consent and guardianship. Whilst it is not the job of this review to develop these standards, we are supportive of the approach for developing these standards, we are supportive of the approach.

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advocated by Dame Fiona Caldicott’s review,\textsuperscript{19} which recommends new data security standards and a new consent model for sharing patient confidential data.

4.1.5. A robust approach to the quality and privacy of digital patient records will have a range of benefits, including giving patients increased confidence to share their data for research purposes. Charities and patient groups can play a key role in explaining the benefits of giving consent for sharing health data, and in clarifying how the NHS is working to keep confidential data safe.

Digitisation to support better patient care

The Hampshire Health Record (HHR) brings together key patient information from hospitals, general practice, community care and social services. This data can be accessed in a range of clinical environments to help deliver enhanced patient care, and anonymised data is analysed to identify where improvements in patient care can be made.

The process of assessing emerging technologies should be evolved so that it is fit for the future

4.2. NICE should review its health technology assessment processes and methods to ensure they are fit for purpose to assess new types of emerging products and enable access to the products the NHS needs.

4.2.1. This review is extremely supportive of NICE as a global leader in health economic evaluation and evidence-based guidance. Since its inception, NICE has continued to evolve so that it can best consider the innovations that it is asked to assess. This review sees NICE technology appraisals as continuing to form the basis of value assessment, but suggests that NICE should now undertake a review of its methods and processes to ensure they are fit for purpose to enable access to the products the NHS needs most. This should include:

- Changes that support NHS England in agreeing commercial arrangements for strategically important products.
- Evolution of NICE’s processes to support acceleration, allowing products with sound evidence of increased efficiency to undergo a lighter-touch process.

4.2.2. Given the value to industry of a technology appraisal, we endorse the recommendation in NICE’s triennial review\textsuperscript{20} that NICE should consider recovering the costs of their assessments.

4.3. **NICE should develop a flexible health technology assessment pathway that can be tailored to a product's value proposition.**

4.3.1. NICE’s pathway for health technology assessment should be open to all innovations, be they medical technology, diagnostics, digital or pharmaceutical. It should be flexible, able to be tailored to a product’s value proposition, and should anticipate future types of healthcare innovation.

4.4. **NICE should refocus its work to place more emphasis on medical technologies, diagnostics and precision medicine tools, and a funding requirement should apply for those products that improve efficiency.**

4.4.1. The majority of NICE’s technology appraisals are focused on pharmaceuticals, with relatively few assessments of medical devices, diagnostics or digital products such as apps. When NICE does issue positive guidance for a medical technology or diagnostic, it does not carry a funding requirement because it has not been assessed within the technology appraisal programme.

4.4.2. NICE should rebalance its work towards products which, accompanied by appropriate changes in clinical pathways, can improve system efficiency whilst delivering equivalent or better patient outcomes. This is likely to include more medical technologies, diagnostics, including companion diagnostics for precision medicine, and digital products. It could also include those products that support national and international priorities, such as new, rapid diagnostics that inform the use of antimicrobials. NICE’s review of its methods and processes should consider how funding requirements could be introduced for innovations that improve outcomes and improve efficiency.

4.5. **NICE should support uptake by extending its role beyond evaluation**

4.5.1. NICE should build on the work of its NICE Implementation Collaborative (NIC) to develop a new role that reaches beyond the evaluation of a technology into its subsequent clinical pathway. Its guidance, for example, could include proposed structured incentives or tariffs to support the uptake of innovative technologies. The details of these incentives should be developed through the Accelerated Access Partnership with advice coming from NHS England and NHS Improvement on their areas of responsibility.

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4.6. NICE, NHS Improvement and NHS England should have a greater focus on disinvestment, and outdated products and services should be made less attractive in the national tariff.

4.6.1. In order to create headroom for the cost of new innovations, there should be a greater system emphasis on disinvesting in outdated products or pathways.

4.6.2. NHS England’s medicines optimisation programme aims to improve value and patient outcomes from medicines use, including safe and effective prescribing and de-prescribing of medicines, improved medication review and monitoring, as well as working with patients to understand their beliefs about medicines which in turn supports better adherence. This approach has helped to deliver significant efficiencies. The programme should be accelerated through NHS Right Care and should focus on eliminating those products and procedures that are not cost-effective or are outdated, supporting the concept of ‘value exchange’ where headroom for important new innovations is found by removing less impactful activities.

4.6.3. NICE should take a greater role in this value exchange, expanding on its list of cost savings opportunities and implementing them through the NHS Right Care programme. NHS Improvement should also support value exchange, for example including consideration of whether tariff amendments would support providers in prioritising more cost-effective products.

In future, we propose that NICE should...

<table>
<thead>
<tr>
<th>Accelerated Access Pathway</th>
<th>Methods and processes</th>
<th>Med tech</th>
<th>Supporting adoption</th>
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<tbody>
<tr>
<td>...be able to make a ‘conditional’ recommendation where the evidence base is immature</td>
<td>...review its methods and processes to ensure they are fit for the future</td>
<td>...refocus its work on technologies that deliver efficiencies including med tech, diagnostics and digital</td>
<td>...reach through to adoption and diffusion stage by including AAP recommendations on incentives in its guidance</td>
</tr>
<tr>
<td>...inform NHS England’s commercial discussions, which ideally conclude before NICE issues its guidance</td>
<td>...consider recovering the costs of its assessments</td>
<td>...issue a funding requirement for med tech, diagnostics and digital products that can release efficiencies</td>
<td>...have a greater focus on ‘value exchange’ including disinvestment opportunities, e.g. through tariff</td>
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<tr>
<td>...evolve its processes to support acceleration, including a lighter-touch process for some products</td>
<td></td>
<td></td>
<td>...support accountability and transparency around uptake, for example through the innovation scorecard</td>
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...develop a flexible health technology assessment pathway that can be tailored to each value proposition

Figure 14: Proposed changes to NICE’s methodologies
5. Incentives, local infrastructure and clinical leadership to enable the spread of innovation

A range of incentives should support the local uptake and spread of innovation, enabling collaboration and with greater capacity and capability for change

5.1. A package of coordinated incentives should support the changes outlined in this report.

5.1.1. We want to create an environment in which clinicians and local NHS organisations can rapidly adopt and diffuse innovations which are shown to transform the way care is delivered. Removing barriers, providing incentives and building local capacity and capability for change will be critical to the evolution of clinical practice.

Figure 15: The four levels of approach to innovation adoption in the NHS

5.1.2. A range of different measures can incentivise the uptake of innovation. These incentives should focus on removing national or local barriers, providing capacity for change, and supporting cross-organisational collaboration. NHS Improvement with NHS England should take the lead in developing this package. Incentives could include:

- Budgetary incentives, such as centralised procurement as proposed by Lord Carter’s review, gain-share arrangements whereby any efficiencies are distributed amongst the relevant organisations (at individual department level where appropriate), pooled budgets, or outcome-based payments. The NHS
vanguards21 and Test Beds22 are good examples of where pooled budgets are driving collaboration across a health economy.

- Financial incentives, such as the creation of best practice tariffs, the use of CQUIN, or – for medical technologies and digital products – inclusion in the Innovation and Technology Tariff. Tariffs for outdated or ineffective interventions could be removed or made less attractive, and the use of pass through costs as a route to reimbursement for these products could be controlled.

- Transparency, such as the better presentation of uptake information for an agreed set of products, and the wider use of data by charities and patient groups (see section 5.7).

- Professional or reputational, through the promotion of innovation within clinical excellence awards; through local health economies being at the cutting edge in adopting new technologies proven to improve local outcomes; or through empowering patients by enabling them to pioneer the use of new therapies and technologies.

AHSNs, tertiary academic teaching hospitals and clinical leaders across the NHS should drive and support the evaluation and diffusion of innovative products

5.2. A new mandate for AHSNs should support the local spread of adoption and enable a standard framework for local evaluation.

5.2.1. AHSNs, with their existing local networks that include NHS providers and commissioners, academia and industry, should play a vital role in supporting the testing and diffusion of technologies in the NHS. This role should be set out in a new charter with input from NHS England and NHS Improvement which clearly articulates what is expected from AHSNs and enables them to be held to account for delivery. AHSNs should galvanise and support local innovation partners to create a network of ‘innovation exchanges’, responsible for diffusing clinically- and cost-effective technologies across the system. Products with strong evidence of potentially transformative benefit should be routed to the Accelerated Access Partnership.

5.2.2. We recommend that AHSNs are more closely integrated with local health economies via the new sustainability and transformation footprints, and that the NHS Test Beds programme acts as a pilot for this new, strengthened remit for AHSNs. The Test Beds evaluation will provide a framework for assessing the impact of innovations in real-world settings; AHSNs should build on their current involvement in the Test Beds programme by using this learning for their own evaluation role and seeking to

22 https://www.england.nhs.uk/ourwork/innovation/test-beds/
collaborate to promote mutual recognition of local evaluations using the national framework.

5.2.3. AHSNs are ideally placed to play a role in the post-CE mark testing and dissemination of medical technologies, diagnostics and digital products in particular, with a focus on determining their clinical utility, cost effectiveness and whole pathway benefits. AHSNs could, for example, work with clinicians to build on approaches such as the IDEAL\textsuperscript{23} framework for medical technologies, or other methodologies, to rapidly develop high-quality evidence without delaying access.

5.2.4. AHSNs should be funded to a level that allows them to fulfil the role outlined in this report and to bring them all up to the level of the best. From 2017, we recommend that the government releases an additional £10m to £20m into AHSN baselines. Given budget constraints, further work should be carried out to determine the expected return on different levels of funding. We also recommend that NHS Improvement plays a greater role in leading AHSNs, including supporting them to undertake these activities.

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\textsuperscript{23} http://www.ideal-collaboration.net/
5.3. **AHSNs should be responsible for providing support for delivering change.**

5.3.1. Providing capacity and capability to deliver change will be critical. Change management capability is not available in all NHS organisations, and we recognise that additional capacity is required to undertake any reconfiguration following the implementation of a new technology. We propose that this additional capacity and capability is provided by and delivered through the AHSN network.

5.3.2. This change needs to be funded, in advance of AHSNs move to new licensing arrangements in April 2018. From 2017, we recommend that government makes available up to £30m per annum for this purpose. We recommend that the release of half of this sum should be conditional on the AHSNs matching it with funding from external sources such as industry or charities. This fund would need to be managed transparently and awards clearly linked to outcomes.

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**The NHS Test Beds Programme**

The NHS test beds programme is supporting the testing and uptake of innovations across the NHS. Seven test bed partnerships between local healthcare economies, industry and the third sector are evaluating innovative combinations of digital technologies and new service delivery models. The innovations are being tested in real-world clinical settings to identify those interventions that offer better care and better patient experience at the same or lower overall cost.

For example, one area will test wearable devices linked into mobile technologies, implemented alongside technology-enabled housing, to help people with dementia to live in their own homes for longer. At the end of the programme, successful innovations will be available for other parts of the country to adopt and adapt to the particular needs of their local populations.

The NHS test beds programme shows how industry and the NHS can create partnerships and pool resources to enable change and innovation focused on local clinical challenges.

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5.4. **Tertiary academic hospitals that host Academic Health Science Centres (AHSCs) or Biomedical Research Centres (BRCs) should champion innovation and lead collaborations in their local health economies**

5.4.1. We have heard throughout the review that clinical leadership is a key driver for rapid uptake of innovation. We want to build on this to maximise the potential of our highest performing tertiary and specialist providers to translate research and product innovation into cutting-edge clinical practice, recognising that the significant majority of innovations assessed by NICE form part of services that go through specialised commissioning.

5.4.2. At the same time it is vital to use the opportunity of place-based planning and the devolution of healthcare budgets to local geographies. Based on the NHS’s sustainability and transformation plan footprints, we believe that using a combination of outcomes-based commissioning, an integrated budget across a whole health economy,
and joint decision-making would improve efficiency and outcomes by allowing the whole patient pathway to be considered holistically.

5.4.3. We believe that such change should be actively led by research-active tertiary hospital trusts, such as those that host AHSCs and BRCs. They should be active partners in the Accelerated Access Pathway: pioneering the evaluation and fast uptake of transformative products in their own organisations; championing the early adoption of these products in referring organisations and the health systems in which they work; acting as centres of excellence in innovation; capturing real-world evidence on how a product is used in a clinical setting, and supporting wider roll-out. This approach is exemplified by the role of Genomics Medicines Centres, which operate a hub and spoke model with their local delivery partners.

5.4.4. These trusts should be enabled and incentivised to act as local system leaders in innovation, and for this reason we recommend that, from 2017, £4m to £8m is made available to each centre.

5.5. Clinical revalidation processes and professional reward schemes should require demonstration of evidence-based innovative practice.

5.5.1. The medical royal colleges should support an increased focus on innovation by providing access to training and development which is then reflected in relevant clinical revalidation processes. Where health professionals are demonstrating evidence-based innovative practice, this should be recognised in appraisals, through awards schemes such as the Royal College of Nursing awards scheme, or through pay advancement such as that awarded by the Advisory Committee on Clinical Excellence Awards (ACCEA).

5.5.2. Innovative clinical practice can also be supported centrally. The National Clinical Lead for Innovation should host a network of innovation champions to develop a culture of continuous learning amongst their clinical colleagues. Trusts should identify a senior clinician who can participate in this network.

5.6. Professional leadership bodies, including Royal Colleges, should include adherence to NICE clinical guidance as a criterion for achieving professional standards in clinical care.

5.6.1. Professional leadership bodies can provide a clear picture of what good clinical practice looks like and support the uptake of innovation, by building on NICE clinical practice guidance and standards, and by ensuring that the promotion and use of the best, evidenced, value for money innovations is included within continuing professional development.

5.6.2. Healthcare professionals themselves are often the innovators, responding to the challenges they encounter in practice and finding practical solutions. These individuals should be identified and supported by employers locally.
Professional recognition of innovation

The Academy of Medical Royal Colleges is working with NHS England on the development of a ‘Continuing Clinical Innovation Scheme’ which provides a framework to identify how innovation can be recognised in appraisal processes and also as part of a doctor’s continuing professional development (CPD). Recognising innovation as a professional development activity could be a vehicle that supports and facilitates the activity of frontline innovators. At the same time the Academy is seeking to ensure that innovation is recognised as part of the generic professional capabilities in quality improvement required of all doctors in training.

Improved accountability and transparency around uptake of innovation should be supported by NICE

5.7. There should be a single, accessible source of information on the uptake of technologies for the NHS, patients and industry.

5.7.1. Open, transparent and accessible data on the uptake of innovations, including those with a transformative designation, and their impact on patient outcomes, would be a powerful force for driving adoption and reducing unwarranted variation across the NHS. It would underpin the Accelerated Access Partnership’s ability to hold the system to account for uptake and diffusion of innovation across the NHS.

5.7.2. Information on uptake can currently be found in the Innovation Scorecard, but due to its format it is not widely used within the NHS. We propose that, in future, the Innovation Scorecard should be the single source of information on the use of innovation in the NHS. It should be owned by NICE and used by the rest of the Accelerated Access Partnership, particularly NHS England and NHS Improvement, to hold the system to account and assess the progress of local areas. Patients and clinicians, as well as NICE, the Department of Health and NHS England, should help to define the products and outcomes that are included, and there should be an emphasis on NICE-approved technologies. This information should be accessible to patients and the public.

24 http://content.digital.nhs.uk/article/2021/Website-Search?productid=21974&q=innovation+scorecard&sort=Most+recent&size=10&page=1&area=both#top
6. Coordination and infrastructure to support delivery

An Accelerated Access Partnership should align national bodies around accelerating innovation

6.1. An Accelerated Access Partnership should coordinate the actions of key national bodies around the principle of accelerating the innovations we need, and provide a single point of access for innovators.

6.1.1. We are clear that a new body or a restructuring is not the right way to implement this review. We believe there is an opportunity for existing national bodies to work in strategic partnership, as part of an Accelerated Access Partnership, with clear links to local networks. This is borne out of experience with EAMS where each national body was able to work in alignment with other ALBs to deliver product acceleration.

6.1.2. The Accelerated Access Partnership should be a light-touch umbrella organisation that brings together the existing activities of NIHR, MHRA, NICE, NHS England, the Department of Health and NHS Improvement. It should align their innovation-related functions around the principle of accelerating patient access to key products, and also include a small number of new functions as laid out in section 6.2.

The Early Access to Medicines Scheme (EAMS) is coordinated by the Office for Life Sciences (OLS) and provides a valuable opportunity for early dialogue and collaboration between industry and government.

A Government-Industry Stakeholder Task Group, coordinated by OLS, brings together key stakeholders from the bio-pharmaceutical industry, NHS, the government and arm’s length bodies including MHRA and NICE, on a regular basis. OLS leadership and coordination, as well as the clear alignment of goals across ALBs, is critical in driving progress and collaboration across the ALBs involved in access pathways. It is a forum for industry to raise questions and discuss issues with the national bodies and helps ensure the smooth uptake of EAMS products in the NHS.

6.2. The Accelerated Access Partnership should provide strategic planning and operational advice to the national bodies and should have an independent chair who is accountable to ministers.

6.2.1. The Accelerated Access Partnership’s strategic activities should include:

- horizon scanning for and prioritisation of strategically important products;
- designing the selection criteria and process for making a transformative designation; and
- articulating the healthcare system’s priorities to innovators to help them focus their investment.

6.2.2. Its operational activities should include:

- overseeing the Accelerated Access Pathway;
• helping innovators navigate and collaborate with the system;
• providing guidance on pathways to market; and
• enabling the use of the products the NHS wants through commercial arrangements we can afford.

Figure 17: The Accelerated Access Partnership’s proposed structure

6.2.3. The Accelerated Access Partnership should have an independent chair, responsible to ministers, who holds each member to account for delivery through a concordat that describes the partnership’s vision and objectives and the roles and responsibilities of each organisation. This will be discharged through the Accelerated Access Partnership.

6.3. The Accelerated Access Partnership should build on the Five Year Forward View infrastructure and collaborate with AHSNs.

6.3.1. In implementing this review, the Accelerated Access Partnership should align itself with the local infrastructure for transformation, including the Sustainability and Transformation footprints, and should build on existing programmes such as the New Models of Care, RightCare, the NHS Test Beds and the Carter implementation programme.
6.3.2. The Accelerated Access Partnership should have strong links to the local innovation exchanges facilitated by the AHSNs, so that there can be an exchange of information from national to local level. The refreshed network of AHSNs should be aligned with the emerging sustainability and transformation footprints as well as local clinical senates.

**Figure 18:** The relationship between AHSNs and the Accelerated Access Partnership
7. Recommendations for implementation

The Accelerated Access Partnership should be established immediately

7.1. The Accelerated Access Partnership should be set up immediately so that the collective leadership can be effective in 2016/17, along with a priority programme to reshape the AHSNs.

7.1.1. This will enable work to begin on coordination and collaboration across the system, criteria for prioritisation, operational advice to companies, and tools to support transparency and accountability. We recommend that a small amount of additional resource should be provided to enable AHSNs to provide the capacity and capability for change during 2017/18, building upon the Test Beds approach.

Implementation of the report’s recommendations should be led by the Accelerated Access Partnership and clinicians

7.2. Implementation should begin immediately and be led through the Accelerated Access Partnership with visible leadership from NHS England and NHS Improvement and a strong mandate to engage clinicians and patients.

7.2.1. Clinicians are the front-line decision-makers on innovation and must be at the heart of this system transformation.

7.2.2. During the review we have engaged with clinical leaders and have consistently heard that there needs to be much greater clinical influence and better co-ordination in the development, adoption and diffusion of innovative products.

7.2.3. Each product’s journey along the accelerated pathway should be supported by clinical engagement and leadership from National Clinical Directors (NCDs) and their colleagues; overseeing and directing the right clinical engagement during development, integrating the use of new innovative technologies and therapies into clinical pathways, and promoting the diffusion of the most effective and innovative new products amongst their peers.

7.2.4. This programme will not succeed without a strong commitment from NHS England to working in an integrated way with the rest of the system. It has much to gain: improved patient care; efficiencies created by transformed care pathways; greater negotiating power to collaborate with companies; a pre-emptive system to anticipate patient demand; and more proactive disinvestment to provide capacity and release funding.

7.2.5. In leading this work, the Accelerated Access Partnership should work closely with NHS Improvement which is the lead agency for promoting innovation and the adoption of evidence-based technologies by NHS providers. NHS Improvement has a key role in providing leadership across all steps in the innovation pathway and galvanising local NHS organisations to prioritise, test and adopt transformative new technologies.
7.2.6. Patients, carers and charities provide crucial advice on what innovations are needed, their value to patients and how best to pull them into use. Integrating the patient voice at all points in the pathway will be essential.

7.3. Some immediate actions could demonstrate that the proposed model can deliver change.

7.3.1. The AAR team has worked closely with NHS England to support its vanguards of new models of care to develop partnerships with those companies whose products align with their priorities. These relationships, brokered by AHSNs, are helping these vanguards act as early adopters of the AAR proposals by, for example, devising new innovative clinical pathways for respiratory disease, supporting the frail and elderly, and promoting medicines optimisation. As these projects begin to show results over the next few months, NHS England and the Office for Life Sciences should promote their success and share emerging good practice.
# Glossary

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAP</td>
<td>Accelerated Access Partnership</td>
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<tr>
<td>AAR</td>
<td>Accelerated Access Review</td>
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<tr>
<td>ACCEA</td>
<td>Advisory Committee on Clinical Excellence Awards</td>
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<tr>
<td>AHSC</td>
<td>Academic Health Science Centre</td>
</tr>
<tr>
<td>AHSN</td>
<td>Academic Health Science Network</td>
</tr>
<tr>
<td>ALB</td>
<td>Arm’s length body</td>
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<tr>
<td>App</td>
<td>“App” is shorthand for application software, which may include either a mobile app, a web-based application or in certain cases a digital service.</td>
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<tr>
<td>BRC</td>
<td>Biomedical Research Centre</td>
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<tr>
<td>CCG</td>
<td>Clinical Commissioning Group</td>
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<tr>
<td>CDF</td>
<td>Cancer Drugs Fund</td>
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<tr>
<td>CHMP</td>
<td>Committee for Medicinal Products for Human Use</td>
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<tr>
<td>CPD</td>
<td>Continuing Professional Development</td>
</tr>
<tr>
<td>CQUIN</td>
<td>Commissioning for Quality and Innovation</td>
</tr>
<tr>
<td>CTU</td>
<td>Clinical Trials Unit (part of MHRA)</td>
</tr>
<tr>
<td>DEC</td>
<td>Diagnostic Evidence Co-operative</td>
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<tr>
<td>EAMS</td>
<td>Early Access to Medicines Scheme</td>
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<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>HSRIC</td>
<td>Horizon Scanning Research and Intelligence Centre</td>
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<tr>
<td>HTA</td>
<td>Health Technology Assessment</td>
</tr>
<tr>
<td>HTC</td>
<td>Healthcare Technology Co-operative</td>
</tr>
<tr>
<td>IVD</td>
<td>In vitro diagnostic</td>
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<tr>
<td>MA</td>
<td>Marketing authorisation</td>
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<tr>
<td>MHRA</td>
<td>Medicines and Healthcare products Regulatory Agency</td>
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<tr>
<td>MIC</td>
<td>Medtech and In vitro diagnostic Co-operative</td>
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<tr>
<td>NCD</td>
<td>National Clinical Director</td>
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<tr>
<td>NCE</td>
<td>New Chemical Entity</td>
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<td>NHSI</td>
<td>NHS Improvement</td>
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<tr>
<td>NIB</td>
<td>National Information Board</td>
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<tr>
<td>NIC</td>
<td>NICE Implementation Collaborative</td>
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<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<tr>
<td>NIHR</td>
<td>National Institute for Health Research</td>
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<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<td>OLS</td>
<td>Office for Life Sciences</td>
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<tr>
<td>PIM</td>
<td>Promising Innovative Medicine designation (part of EAMS)</td>
</tr>
<tr>
<td>PRIME</td>
<td>PRIority MEdicines (EMA scheme)</td>
</tr>
<tr>
<td>QALY</td>
<td>Quality-adjusted life year (used as part of a cost effectiveness calculation)</td>
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<tr>
<td>SBRI</td>
<td>Small Business Research Initiative</td>
</tr>
<tr>
<td>SCU</td>
<td>Strategic Commercial Unit</td>
</tr>
<tr>
<td>SMEs</td>
<td>Small and medium-sized enterprises</td>
</tr>
<tr>
<td>SO</td>
<td>Scientific Opinion (part of EAMS)</td>
</tr>
<tr>
<td>STP</td>
<td>Sustainability and Transformation Plan</td>
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Annexes

Annex A: The Accelerated Access Pathway for medicinal products

This diagram and accompanying narrative describe the new accelerated access pathway for medicines (including pharmaceuticals, biopharmaceuticals and advanced therapies such as cell and gene therapies) from the perspective of products that have successfully navigated the pathway.

<table>
<thead>
<tr>
<th>Stage of development</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creation / idea generation:</td>
<td>Pre-clinical development is carried out in an academic or a commercial setting. Although there is little formal regulatory interaction during this time, developers will be able to approach the Accelerated Access Partnership to discuss initial development of their product, the pathway it might follow and any unique challenges they might face. Innovators can use information on system priorities, as set out by the AAP, to ensure they develop products that should meet the NHS’s needs.</td>
</tr>
</tbody>
</table>
| Accelerated Access Partnership (AAP) | The new Accelerated Access Partnership will manage the whole pathway and is overseen by an independent chair accountable to ministers. It is made up of the national organisations responsible for regulating, evaluating and delivering new innovations to patients including NIHR, MHRA, NICE, NHS England, NHS Improvement and the Department of Health.  

The partnership’s initial role is in horizon scanning and prioritisation and it will continue to oversee the entire journey to patients, for strategically important products, including adoption support. Products can join the pathway at any time and will be considered on a case-by-case basis.  

Academic Health Science Centres (AHSCs) or Biomedical Research Centres (BRCs), provide a destination for medicines to be tested in a clinical trial or real world setting, providing evidence through clinical use and supporting wider adoption through local delivery partners and clinical networks. The AHSN Network will reduce barriers to entry, by directing pathway transformation funding to provide additional capacity/capability for providers, such as staff training, communication for service users, change costs and providing additional capacity.  

The Innovation Scorecard will collate information on the adoption and diffusion of medicines and present this information in an easy to understand format. This will allow innovators, patients and clinicians to call for additional support for the adoption and diffusion of transformative medicines, where this is low. It will also allow the AAP to strategically understand where further support is required. |
| --- | --- |
| **Development: contains Phase I, Phase II, Phase III.** | To obtain regulatory approval, innovators need evidence to demonstrate that a product is safe and performs as intended. The AAR does not change any of the evidentiary standards associated with medicine development.  

Innovators can enter into discussions with MHRA, NIHR and NICE around how novel clinical trial evidence-generation methodologies may improve or shorten global clinical development programmes. |
| **Regulation:**  
  - Early Access to Medicines Scheme  
  - Regulatory approval | Early Access to Medicines Scheme (EAMS)  
EAMS will be an integral part of the accelerated access pathway, providing pre-licence access, where appropriate, for strategically important products. The AAR proposes that SMEs and non-for profit organisations with products on the EAMS pathway should receive some funding to cover the cost of the product to recognise their commitment to early access.  

The Accelerated Access Pathway will also fit seamlessly with other early access schemes or breakthrough designations such as PRIME or adaptive licensing.  

**A marketing authorisation** (regulatory approval) can be issued from Phase II onwards depending on the evidence and level of unmet need. The AAR proposes concurrent regulatory and HTA processes (see below) |
| **Transformative designation** | This new designation made by the Accelerated Access Partnership will identify strategically important products that can deliver a step change in cost or outcomes and places the product on the accelerated access pathway. The designation will usually be made around the time of Phase III clinical trials when there is also some data on the product’s value and affordability and will vary on a case-by-case basis. Following this designation, the Accelerated Access Partnership will develop a bespoke plan for each product, to support development. |
| **Health Technology** | Products with a transformative designation will be evaluated by NICE with a |
### Assessment (HTA)
- Greater alignment of regulatory and HTA assessment timetables

### NICE
- HTA decision
- Mini HTA

A mini HTA timetable that begins earlier in the regulatory process. This will mean a HTA decision can be made soon after marketing authorisation, providing the company is able to supply data at a suitable time.

In parallel with NICE’s value assessment, NHS England will undertake the commercial discussion with innovators referred to below. NICE’s evaluation will be based on the terms of any deal agreed between NHS England and innovators. Where a product’s evidence base is uncertain because of accelerated development, and there is high potential, NICE will be able to give a conditional recommendation.

<table>
<thead>
<tr>
<th>Commissioning and adoption:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Commercial dialogue</strong> A new strategic commercial unit within NHS England will consider a range of flexible pricing models as part of a commercial dialogue with innovators.</td>
</tr>
<tr>
<td><strong>Managed access</strong> Where NICE has issued a provisional recommendation and a deal can be reached with NHS England, a product can enter a period of managed access to collect evidence to satisfy the uncertainty. At the end of the managed access period, NICE can conduct a further appraisal to determine whether and under what commercial arrangements the product would enter baseline commissioning.</td>
</tr>
<tr>
<td><strong>Full supported commissioning</strong> Where the NICE technology appraisal recommends the product as clinically and cost-effective, and NHS England consider it affordable, a product will move into baseline commissioning with a funding requirement, supported by a bespoke package of incentives. This could be within specialised commissioning, commissioned by a CCG, or primary care.</td>
</tr>
<tr>
<td><strong>Incentives</strong> The Accelerated Access Partnership will develop a bespoke package of incentives along the pathway to ensure Accelerated Access Partnership organisations involved along the pathway of a transformative medicine are incentivised to support them and make them available to patients faster. This could range from increasing budgetary capabilities and providing new funding routes through to training and education.</td>
</tr>
</tbody>
</table>
Annex B: The Accelerated Access Pathway for medical technologies and diagnostics

This diagram and accompanying narrative describe the new accelerated access pathway for medical technologies and diagnostic innovations, from the perspective of products that have successfully navigated the pathway.

<table>
<thead>
<tr>
<th>Stage of development</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creation / idea generation:</td>
<td>Pre-clinical development is usually carried out in an academic or commercial setting. Although there is little formal regulatory interaction during this time, developers are encouraged to approach the new Accelerated Access Partnership (AAP) to discuss their product and the pathway it might follow. Innovators can use information on system priorities, as set out by the AAP, to ensure they develop products that should meet the NHS’s needs.</td>
</tr>
<tr>
<td>Accelerated Access Partnership (AAP)</td>
<td>The new Accelerated Access Partnership will manage the whole pathway and is overseen by an independent chair accountable to ministers. It is made up of the national organisations responsible for regulating, appraising and delivering new innovations to patients including NIHR, MHRA, NICE, NHS England, NHS Improvement and the Department of Health. The partnership’s initial role is in horizon scanning and prioritisation and it will continue to oversee a strategically important product’s entire journey to patients, including adoption support. Products can join or leave the pathway at any time and will be considered on a case-by-case basis.</td>
</tr>
</tbody>
</table>

- Horizon scanning
- Early dialogue
- Prioritisation
- Bespoke plan development and support
The Innovation Scorecard will collate information on the adoption and diffusion of medical technologies and present this information in an easy to understand format. This will allow innovators, patients and clinicians to call for additional support for the adoption and diffusion of transformative medical technologies, where it is low. It will also allow the AAP to strategically understand where further support is required.

### Development:
- **Product development**
- **Non-clinical Product testing**
- **Clinical evidence development**
- **Further evidence development**

The AAP will offer innovators a single point of contact to seek advice on development.

Development continues after regulation, and when given a transformative designation by the AAP, a bespoke support package will be created to assist developers through the remaining process steps.

Academic Health Science Centres (AHSCs) or Biomedical Research Centres (BRCs), provide a destination for medical technologies to be trialled in a real world setting, providing evidence through clinical use and supporting wider adoption through local delivery partners and clinical networks. The AHSN Network will reduce barriers to entry, by directing pathway transformation funding to provide additional capacity/capability for providers, such as staff training, communication for service users, change costs and providing additional capacity.

### Regulation:
- **Regulatory approval**

For products that meet the definition of a medical device, presence of a CE mark will indicate the device has gone through the relevant regulatory process. The shorter development times for medical technologies (compared to medicines) mean that the timing of CE marking is unlikely to change under the new pathway.

### Transformative designation

A transformative designation will identify strategically important products that can deliver a step change in costs or outcomes and places a product on the accelerated access pathway. This is most likely to happen post CE mark for medical devices, and could happen at any point in a product’s development. In particular it will support post-CE mark data collection that demonstrates a product’s value to the system, and may also help attract outside investment in a product, particularly for SMEs.

### Health Technology Assessment
- **NICE appraisal**

Products with a transformative designation will be evaluated by NICE. In parallel, NHS England will undertake a commercial discussion with innovators (referred to below). NICE’s evaluation will be based on the terms of any deal agreed between NHS England and innovators. Where the evidence base is uncertain, and there is high potential, NICE will be able to give a recommendation for the development of further evidence.
<table>
<thead>
<tr>
<th>Commissioning</th>
<th>Adoption</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Commercial dialogue</td>
<td>• Incentives</td>
</tr>
<tr>
<td>• Managed access</td>
<td></td>
</tr>
<tr>
<td>• Full supported commissioning</td>
<td></td>
</tr>
</tbody>
</table>

**Commercial dialogue**
A new strategic commercial unit within NHS England will consider a range of flexible pricing models as part of a commercial dialogue with innovators.

**Managed access**
Where NICE has issued a conditional recommendation and a deal can be reached with NHS England, a product can enter a period of managed access to collect evidence to satisfy the uncertainty. A “commissioning through evaluation”-type approach will allow those complex medical technologies and diagnostic products that significantly change clinical pathways to be delivered through a number of specialist providers that have the expertise to gather impact data and build expertise around pathway change. At the end of the managed access period, NICE can conduct a further appraisal to determine whether and under what commercial arrangements the product could enter baseline commissioning.

**Full supported commissioning**
Where the NICE technology appraisal recommends a product as clinically and cost-effective, and NHS England considers it affordable, a product will move into baseline commissioning with a funding requirement, supported by a bespoke package of incentives. This could be within specialised commissioning, commissioned by a CCG, or primary care.

**Incentives**
The AAP will develop a bespoke package of incentives along the pathway to ensure agencies and actors along the pathway of a transformative product are incentivised to support them and make them available to patients faster. This could range from increasing budgetary capabilities and providing new funding routes through to training and education.

**The new innovation and technology tariff**
This provides a reimbursement route for selected value-proven, strategically important medical technologies and digital products, removing the need for multiple local price negotiations.
Annex C: The Accelerated Access Pathway for digital products

This diagram and accompanying narrative describe the new accelerated access pathway for digital products, including apps and wearables, from the perspective of products that have successfully navigated the pathway. The pathway incorporates relevant parts of the Paperless 2020 app assessment process due to launch in 2017. More detail will be included in revised versions of the ‘how to guide’ in due course.

<table>
<thead>
<tr>
<th>Stage of development</th>
<th>New process when Accelerated Access and Paperless 2020 assessment processes take effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idea generation: includes pre-clinical development</td>
<td>AHSNs and, in a small number of cases the Accelerated Access Partnership, will identify the unmet needs of the NHS so that digital developers can respond to these needs. They will support them in building evidence about real world use and the most appropriate route to market. AHSNs will be key to ensuring that products can be taken up locally and move through the system quickly. AHSNs might refer products to the AAP that require national coordination and support if developers would find this useful.</td>
</tr>
</tbody>
</table>
### Accelerated Access Partnership and horizon scanning

The new Accelerated Access Partnership will manage the whole pathway for strategically important products, and is overseen by an independent chair accountable to ministers. It is made up of the national organisations responsible for regulating, appraising and delivering new innovations to patients including NIHR, MHRA, NICE, NHS England, NHS Improvement and the Department of Health.

The partnership’s initial role is in horizon scanning and prioritisation but it will continue to oversee a strategically important product’s entire journey to patients, including adoption support. Products can join or leave the pathway at any time and will be considered on a case-by-case basis.

### Development:

- **Product development**
- **Product testing**
- **Clinical evidence development**

Product prototyping is an iterative process.

It is good practice for digital health technologies to develop clinical evidence around their safety and efficacy. In addition to this, some digital health technologies may be classed as medical devices which means clinical evaluation is required.

The Paperless 2020 assessment process (see below) will include information about evidence development for app developers and their academic partners to use, such as studies types, economic evidence and case studies.

### Regulation:

- **Regulatory approval**

As at present, if a product meets the definition of a medical device it will need to be CE marked in accordance with the Medical Device Directives. For these products, a developer can still choose on a voluntary basis to undertake the Paperless 2020 assessment process, once the CE mark has been obtained. The Paperless 2020 assessment process itself is not a regulatory process.

### Transformative designation

For a small number of strategically important digital products, that have the potential to deliver a step change in costs or outcomes and that would benefit from national coordination, a transformative designation will place the product on the accelerated access pathway. The Accelerated Access Partnership will consider the support required by transformative digital products on a case-by-case basis.

The designation will usually be awarded after CE-marking for products that need medical device regulation.

### Paperless 2020 assessment to identify high quality apps

The Paperless 2020 assessment process, due to launch in 2017, will identify high quality apps (and in the future other digital products) that are then promoted to patients, citizens, healthcare professionals and commissioners.

The process, which will be digitally enabled, is designed to evaluate how well an app meets best practice standards for data security, safety, interoperability, usability and technical stability. It also considers the evidence on whether an app is effective, has a beneficial impact on cost and resource use in the health and care system, and positively influences factors important to users.

The process is likely to require developers to register their digital product(s) and make a self-declaration against the set of best practice standards described above. Responses are then validated by an expert community. For a subset of the digital products considered, this process will also include a topic selection step based on the overall value proposition of the app to the health and care system and, for selected apps, an independent evaluation of the evidence by NICE.

Transformative products that are prioritised by the Accelerated Access Partnership
Partnership will be supported to complete the above Paperless 2020 assessment process by the AAP and all these transformative products will be evaluated by NICE as part of the process.

Whilst the AAP may identify digital products to enter the Paperless 2020 assessment process, this process itself may identify promising digital products for the AAP to prioritise.

### Evaluation by NICE

NICE will undertake a review of the evidence on the effectiveness of an app (clinical or behavioural effectiveness), its impact on cost and resource use in the health and care system, and how well it serves patients and users. The output of the NICE evaluation is a commissioner briefing to support local decision making.

This evaluation will apply to all transformative products identified by the AAP and some of the other digital products from the Paperless 2020 assessment process.

### Commissioning:

- Local purchasing
- Crown Commercial service SME procurement process
- Innovation and Technology Tariff

The Crown Commercial Service will work in partnership with NHS England, the Department of Health and other partners to consider how best to develop an accessible, simple and swift competitive process for procuring digital health products from SMEs.

NHS England will develop a new generic framework for app prescription that is easy to use and eliminates the need for multiple local systems. This will help healthcare professionals understand the mechanism they should use, and the wrap-around services required, to enable patients to access these products.

The new Innovation and Technology Tariff will provide a reimbursement route for a selected number of value-proven digital products, removing the need for multiple local price negotiations.

### Adoption

AHSNs will play a key role in supporting the adoption of the truly transformative digital products that it prioritises. Uptake and adoption data on digital health products will be published as part of the updated innovation scorecard to showcase where the most innovative digital technologies require more support and empowering innovators, patients and clinicians with this information to call for additional support.

This will be further supported by uptake support activities that will accompany all digital products which complete the Paperless 2020 assessment process. This will include promotion through NHS websites, such as nhs.uk, in the context of specific conditions and targeted public communications, for example Public Health England’s ‘Stoptober’ campaign.
Annex D: The Accelerated Access Review’s champions

The following people provided advice and support throughout the review:

Policy: Dr Stuart Dillow, Vermilion Life Sciences

Professor Richard Barker, Centre for the Advancement of Sustainable Medical Innovation (CASMI)

Richard Murray, The King’s Fund

Rob Webster, NHS Confederation (now South West Yorkshire Partnership NHS Foundation Trust)

Patients: Hilary Newiss, National Voices

Medical technologies: John Jeans, Life Sciences Advisor

Digital: Charles Lowe, Digital Health and Care Alliance
The Board is asked to consider the updated NICE Charter detailed in Annex 1, to make any comments, and to approve the newly updated version of the Charter for publication on the NICE website.

Jane Gizbert
Director of Communications
November 2016
National Institute for Health and Care Excellence

NICE CHARTER

Introduction

1. The NICE Charter was first published on the NICE website in 2013. NICE was asked by the Department of Health to produce a Charter document which outlines in simple terms what NICE is, who we are, what we do and how we work.

2. The Department of Health requested that the Charter should be updated every three years, so we need to publish any updates this calendar year.

3. The Communications team has worked with colleagues across NICE to update the document to reflect changes and developments in our work programmes that have occurred since 2013.

4. The Communications team has also taken this opportunity to sense-check the content of the Charter and have re-ordered some of the content where we thought it would improve the document.

Updates and changes to the NICE Charter for 2016

5. An updated version of the NICE Charter can be seen in Annex 1 of this paper. Notable updates include:
   - The first section on “Who we are and what we do” has been re-ordered to put the focus firmly on our core business of developing guidance and standards (paragraphs 1-12)
   - A bullet on the Office for Market Access has been added to the “working with the healthcare industries” section (paragraph 28)
   - A bullet on the Patient Access Schemes Liaison Unit (PASLU) has been added to the section on “working with the healthcare industries” (paragraph 30)
   - The section on “communicating about our guidance, standards and other resources” has been expanded (paragraph 35-36)
   - The section on “putting our guidance and standards into practice” has been updated (paragraph 38-39)
   - The section on “managing resources” has been updated to reflect ongoing developments to our cost saving support (paragraph 40-43)

6. The original version of the Charter, published in 2013, is available on the NICE website at www.nice.org.uk/about/who-we-are or on request.

Recommendations/Considerations for Board

7. The Board is asked to:
   - Consider the updated Charter
ITEM 5

- Detail any amends that need to be made
- Approve the updated Charter for publication on the NICE website.

Jane Gizbert
Director of Communications
November 2016
Annex 1: the NICE Charter, incorporating all updates for 2016

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE CHARTER

Who we are and what we do

1. The National Institute for Health and Care Excellence (NICE) is the independent organisation responsible for providing evidence-based guidance on health and social care. NICE guidance, standards and other resources help health, public health and social care professionals deliver the best possible care based on the best available evidence.

2. NICE is at the heart of the health and social care system. We work closely with local and national organisations including NHS England, the Care Quality Commission, Public Health England, NHS Improvement, and Health Education England. Together we encourage and support a quality- and safety-focused approach, in which commissioners and providers use NICE guidance and other NICE-accredited sources to improve outcomes.

3. NICE guidelines make evidence-based recommendations on a wide range of topics in health, public health and social care. Our guidelines recommend the most effective ways to: prevent and manage specific conditions; to improve health and manage medicines in different settings; to provide social care to adults and children; to plan services and interventions to improve the health of communities; and to provide integrated health and social care services that meet the needs of patients and people who use services.

4. Our recommendations about the use of new medicines, medical technologies and diagnostics identify the most clinically- and cost-effective treatments available. We work openly and transparently with the pharmaceutical and medical technology industries to evaluate their products, facilitating access to the NHS market for those products which are found to offer the best value for patients, and making a clear case for their adoption in the NHS.

5. NICE quality standards are a key component of the drive to develop an outcomes-based approach to improving quality and consistency of care. They identify priority areas for quality improvement, and contain a set of statements and measures to enable organisations to assess the quality of care they are providing or commissioning.

6. Our quality standards, along with other NICE products, underpin the menu of indicators that NICE produces each year. NICE Indicators are used nationally and locally to help the NHS to measure the delivery of safe, effective, and cost-effective care and services. NICE indicators measure the quality of care a person receives and the impact it has on their health – and they focus on where improvements can be made. The NICE indicator menu comprises both indicators for Clinical Commissioning Groups and indicators for general practice.
7. Our support for organisations committed to improving the quality of care is accompanied by a responsibility to ensure careful and targeted use of finite resources. NICE guidance and our other advice products set out an evidence-based case for investment and disinvestment. This can help commissioners and providers in health and social care make the best use of their money while delivering high-quality care for patients and service users.

8. All of our guidance, quality standards and other advice products are independent and authoritative. They are based on the best available evidence and set out the best ways to prevent, diagnose and treat disease and ill health, promote healthy living, and care for vulnerable people.

9. Our guidance, advice and quality standards are made available in a variety of formats to ensure they are easily accessible to users through the NICE website, NICE Pathways and smartphone apps.

10. Our online NICE Evidence service provides a portal for easy access to evidence, accredited guidance and other products in health and social care. We commission evidence-based resources such as the British National Formulary on behalf of the health service, which can be accessed digitally from NICE Evidence via the NICE website.

11. Our guidance and other products are for the NHS, local authorities, social care organisations, charities and anyone with a responsibility for commissioning or providing healthcare, public health or social care services. Following our recommendations can help these organisations to reduce variations in practice across the country.

12. Through our digital programme, including NICE Evidence and NICE Pathways, we collate and disseminate high-quality guidance, research and information from NICE and other organisations to help health, public health and social care professionals deliver the best care and services. Patients, people using services, carers and the public can also use NICE guidance and other products as a guide to the high-quality care they should expect to receive.

How we work – core principles

13. We are internationally recognised for the rigorous processes we use to produce our recommendations and for the quality and accuracy of our products. All NICE guidance, quality standards and other products are developed to a high standard in accordance with a set of core principles that underpin all of our work:

Evidence

14. All NICE recommendations are based on the best available evidence of what works, in terms of both clinical effectiveness and cost effectiveness. We conduct and commission comprehensive reviews, drawing on published literature, to ensure that our advice is based on the most up-to-date evidence available.
Expert input

15. Every piece of NICE guidance and every quality standard is developed by an independent committee of experts, which includes lay members and representatives from clinical practice, public health, social care and where appropriate, from industry.

Public involvement

16. All of our committees include at least two lay members: patients, carers, service users or the general public. The expertise, insight and input of these lay members is essential to the development of all NICE guidance and advice, and helps us to make sure that our work reflects the needs and priorities of those who will be affected by them.

Independence, genuine consultation and transparency

17. All NICE committees are independent and unbiased. Once a topic has been referred to us by the Department of Health, or NHS England, neither organisation has any more influence over the final guidance than any other stakeholder. All of our guidance, quality standards and other products are developed independently of government influence. We have a consultation process, which allows individuals, patient groups, professional and statutory bodies, commissioners, charities and industry to comment on our recommendations throughout the development of our guidance and quality standards. We also have a formal appeal process for final recommendations in our technology appraisals and highly specialised technologies guidance.

Review

18. Once published, all NICE guidance is regularly considered for review, and updated in light of new evidence, if necessary.

Social values and equity considerations

19. The recommendations and decisions that NICE makes involve value judgements. We are committed to ensuring that the judgements we make reflect the values of society. Our Citizens Council – an advisory body made up entirely of members of the public from across the UK – helps NICE understand the views of the public and incorporate them into the decision-making process.

Methodological developments

20. Our independent advisory committees use a wealth of scientific methodology to help underpin and inform their decisions and recommendations. This includes internationally recognised scientific methods for evaluating and comparing the benefits and cost effectiveness of different forms of practice.

21. The science that the committees use when making their recommendations is constantly evolving. To make sure that NICE stays at the forefront of this challenging field, our Science Policy and Research (SP&R) team oversees a
range of research activities that are undertaken across NICE to ensure that our processes, methods and policies remain up-to-date and fit for purpose.

How we involve people

22. All of our guidance, quality standards, and other products are developed taking into account the opinions and views of the people who will be affected by them, including patients, carers and members of the public, as well as health and social care professionals, NHS organisations, industry, social care businesses and local government.

23. Our consultation process allows a range of individuals and organisations to comment on our recommendations throughout the development of our guidance and quality standards. Our guidance is created by independent and unbiased advisory committees that include a diverse range of experts from surgeons and midwives, to health economists and social workers, as well as patients or carers or other members of the public.

24. In the case of our technology appraisals and highly specialised technologies guidance, in which we make recommendations about the use of new drugs and technologies within the NHS, we work with manufacturers to ensure that evidence they submit on the effectiveness of their products is the most appropriate to enable an evaluation to be undertaken.

25. We value the input of patients, carers and the general public in the development of our guidance and other products. By involving the people for whom the guidance will be relevant, we put the needs and preferences of patients and the public at the heart of our work. Our Public Involvement Programme supports individual patients, carers and members of the public, as well as voluntary, charitable and community organisations involved with NICE's work.

Working with the healthcare industries

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

27. NICE digital services manages UK Pharmascan, a horizon scanning database for information on new medicines in development which can be accessed by national horizon scanning organisations to support NHS budget and service planning to enable the faster uptake of new medicines across the NHS.

28. The NICE Office for Market Access (OMA) works with drugs, devices and diagnostics companies on a fee-for-service basis. OMA gives any commercial
stakeholders access to a dedicated team at NICE, offering tailored support to help them optimise their products’ journey through NICE and the rest of the pathway to market.

29. Our fee-for-service Scientific Advice programme allows life sciences companies to better prepare to present their case for adoption of their products in the event that they need to engage in one of our evaluative programmes.

30. We operate the Patient Access Scheme Liaison Unit (PASLU) to review and evaluate proposed Patient Access Schemes that pharmaceutical manufacturers plan to submit to the Department of Health. Patient Access Schemes involve innovative pricing agreements designed to improve cost effectiveness and facilitate patient access to specific drugs or technologies. PASLU advises the Department of Health on the feasibility of proposed Patient Access Schemes.

How our guidance is used

31. Different types of NICE guidance have a different status within the NHS, public health and social care. Our technology appraisals and highly specialised technologies guidance are unique because the NHS in England and Wales is legally obliged to fund and resource medicines and treatments recommended through our technology appraisal programme. The legal status of these programmes is reinforced in the NHS Constitution, which states that patients have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if the doctor responsible for the patient’s care says they are clinically appropriate.

32. None of our other guidance and products is subject to the same legal obligations as our technology appraisals and highly specialised technologies guidance. Nevertheless, health and social care professionals are actively encouraged to follow our recommendations to help them deliver the highest quality care. Of course, our recommendations are not intended to replace the professional expertise and clinical judgement of health professionals, as they discuss treatment options with their patients.

33. We are aware that NICE guidance sometimes recommends changes in practice which the NHS, local government and social care providers may find difficult to implement, especially when faced with limited resources and differing local budget priorities. We help local organisations by providing a programme of implementation support to put our guidance into practice locally.

34. Our guidance is relevant to charities, voluntary and community organisations, residential care homes, private sector employers as well as the NHS and local government. We do our best to provide support for all these groups to put our recommendations into practice locally.
Communicating about our guidance, standards and other resources

35. Our guidance, quality standards and other advice products are disseminated and communicated clearly to those responsible for putting them into practice. We also raise awareness about our broader role among those who use the NHS and social care and to members of the public whose health is influenced by our public health guidance.

36. Through our audience insights work we ensure that the views and expectations of NICE’s audiences are systematically gathered and interpreted. We deliver a full suite of multi-channel communications activities, telling the story of NICE’s work and role through our website, social and traditional media, speaking engagements, exhibitions and conferences, internal platforms, public affairs and stakeholder engagement. We provide a timely, responsive service to approximately 1,000 enquiries per month from health and care professionals, patient groups, charities, parliamentarians and members of the public.

Access to our guidance

37. We use a number of innovative ways to help all users access all of our products. Through our digital programme including NICE Pathways, NICE Evidence and mobile apps, health and social care staff are better able to implement our recommendations to make a difference to the nation’s health and wellbeing.

Putting our guidance and standards into practice

38. NICE guidance and advice can both drive and enable the design and delivery of services provided by the health and care system. When used effectively, NICE resources can support local improvement initiatives, improve outcomes and reduce variation.

39. We deliver a substantial programme of support to encourage improvement and change in practice. For example: we work with third party organisations to motivate individuals to adopt NICE guidance and standards; we facilitate the availability of support tools which make following our guidance more straightforward at a local level; we provide a suite of online educational modules; and we also have a team of regional implementation consultants and prescribing advisors who provide practical support and advice to our audiences on a local level.

Managing resources

40. NICE is committed to supporting commissioners and providers, local authorities and organisations in the wider public and voluntary sector to make the best use of their money, setting out the case for investment and disinvestment through our guidance programmes and our other advice.

41. We have a collection of cost-saving resources on our website which can help commissioners and providers make sure they are spending money on the
right things. We are committed to promoting the provision of appropriate care, and supporting the health and care system to stop ineffective care and treatments.

42. Our guideline manual sets out NICE’s commitment only to recommend new treatments or interventions with an increased cost implication if they are underpinned by a solid evidence base and robust economic analysis.

43. NICE is equally committed to operating within the budget available to us through securing income opportunities, finding cost improvements and by effectively managing our resources.
The Board is asked to consider and approve the proposal to redesign the disinvestment offer from NICE.

Professor Gillian Leng
Director, Health & Social Care Directorate
November 2016
INTRODUCTION

1. An objective in the NICE 2016-17 business plan is to redesign and promote, in conjunction with NHS Improvement, NHS England and the Local Government Association, a comprehensive resource for commissioners and providers on the use of NICE guidance to help make savings, improve productivity and promote optimal use of interventions.

2. The Accelerated Access Review (October 2016) recommends that NICE, NHS Improvement and NHS England should have a greater focus on disinvestment. It calls for NHS England’s medicines optimisation activities to be accelerated through its RightCare programme and to focus on opportunities to eliminate products and procedures that are not cost effective, and for NICE to play a greater role by expanding its list of cost saving opportunities and implementing them through RightCare.

3. The Healthcare Financial Management Association (HFMA) policy and research committee supports NICE in its work to do more to support disinvestment in healthcare where appropriate, and to use its reputation to demonstrate how disinvestment in services can sometimes result in better clinical outcomes and patient experiences.

4. The importance of disinvestment was further emphasised at a recent NHS stakeholder event, hosted by NICE. Participants identified the need for more support from NICE for disinvestment decision making.

5. This paper describes NICE’s current online offer, why it needs to change, and provides a clear rationale for future work to support disinvestment. The DH medicines and pharmacy policy team and Chief Pharmaceutical Officer support the proposal.

THE CURRENT NICE DISINVESTMENT OFFER

6. NICE’s current online offer to support disinvestment is found on a ‘Savings and Productivity’ page on the NICE website. It includes a collection of information some of which directly relates to NICE guidance and some of which, such as Cochrane topics, have no links to our guidance but are quality assured by NICE. The offer includes:

- Do not do recommendations
- Cost saving guidance (including the resource planner)
- Return on investment tools linked to public health guidance
- Medicines optimisation key therapeutic topics
7. In addition to the online offer, NICE also works with external partners to encourage use of the Savings and Productivity collection. In particular, there is scope to improve prescribing and appropriate use of medicines to support disinvestment. An analysis by NICE estimated likely savings if 30 potentially inappropriate medicines were not used in older patients in England. NHS England Business Services Authority (BSA) Pacific Programme has provided insight from prescribing data from England on 9 of these medicines. Although the potential savings are lower than those estimated in NICE’s original estimate, we are working with other system partners to realise the benefits in limiting the use of these medicines.

8. We are working with NHS England RightCare and the CQC on coordinating and aligning medicines optimisation activities. A list of medicines optimisation programmes and initiatives at national and regional level, and other tools, services and support has been mapped to the RightCare approach of maximising value by reducing variation using the 3 steps of where to look, what to change and how to change. This is available on the RightCare medicines optimisation web page (https://www.england.nhs.uk/rightcare/innovation/mo/). NICE is also contributing to the establishment of regional medicines optimisation committees (RMOCs) with NHS England.

9. As part of the external partnership working, NICE contributed five Do Not Do recommendations to the Academy of Medical Royal Colleges’ Choosing Wisely. The list of recommendations was launched in October: (http://www.choosingwisely.co.uk/i-am-a-clinician/recommendations/#147665466854-3440a395-8fd9). It includes recommendations from the Royal Colleges and links to NICE guidance and patient decision aids, where present.

Rationale for refocussing the disinvestment offer

10. There are a number of reasons why we need to change our approach to supporting disinvestment. These relate to lack of awareness of our current work, to the usefulness and relevance of the products found on the online collection, and to the need to align our future portfolio more closely to NICE’s core work.

Lack of awareness

11. User research indicates low awareness of the collection. Users don’t routinely look to NICE as a key resource for disinvestment decision making. Google analytics indicate low use of keywords such as ‘decommissioning’, ‘disinvestment’, ‘savings’ and ‘NHS value’ related to NICE disinvestment work. In contrast, keywords such as ‘value’, ‘efficiency’, ‘quality’ and ‘productivity’ are

12. Audience research conducted in July 2016 yielded just 4 responses from 240 people contacted to seek their views on the collection. Similarly, feedback from the NICE field team consistently indicates lack of awareness of the collection.

13. Lack of awareness is probably not helped by the description ‘Savings and Productivity Collection’, which is not an accurate description of the resources it includes.

Usefulness and relevance of the current online collection

14. We have carefully reviewed the six components of the current online offer. Some of these have limited use and could be discontinued, others are important but may require modification.

15. **Do Not Do recommendations.** Although they represent a comprehensive set of advice, over 90% of do not dos are not related to cost saving, and those that are cannot be readily displayed by the user. The complete set is therefore of questionable relevance, as it has not been prioritised according to current practice or quality improvement opportunities. In addition, feedback indicates that there are very few ‘never’ do’s on the grounds of effectiveness or cost effectiveness.

16. **Cost saving guidance and the resource planner.** A resource impact report and resource impact template is produced for NICE guidance that have a positive recommendation where costs or savings can be estimated with a reasonable degree of certainty and are deemed to be significant. Where costs and savings may be significant but cannot be estimated with a reasonable degree of certainty, a resource impact report with a resource impact table is produced that can be used in local settings to highlight areas of costs and savings that should be considered. The resource planner is therefore potentially an important component of a future offer as it gives indicative costs and savings for upcoming guidance, in step with financial planning time frames.

17. **Return on investment tools.** The collection includes five return on investment tools linked to public health guidance on tobacco; physical activity; alcohol; social and emotional wellbeing; and children, young people and pregnant women. Because they are resource intensive to produce, we are not planning to develop any new tools ourselves, but will work with Public Health England to produce tools linked to our guidance. They are important resources for local government.

18. **Medicines optimisation.** We inform local medicines optimisation through Key Therapeutic Topics, which summarise the evidence in areas where there are potential opportunities for maintaining or improving quality and improving value in medicines use. The topics are part of NHS England medicines optimisation programme, and signpost to prescribing indicators, where available. An annual process is in place to review, retain or retire topics. These are important resources for efficient use of resources.
19. **Quality and Productivity case studies.** The collection includes quality and productivity (formerly QIPP) case studies of local cost savings activities. NICE took on the role from the DH of curating the QIPP collection in 2010. We now receive fewer than 10 submissions each year and have agreed with the DH that we will no longer accept new case studies. Existing case studies will remain available in a specific legacy site on the website as long as they remain current. A process has been developed to review, retain or retire topics.

20. **Cochrane case studies.** The collection includes 65 Cochrane case studies, intended to help the NHS identify practice that could be significantly reduced or stopped, releasing cash and/or resources without negatively affecting the quality of care. An external contractor provides a monthly list of topics that meet these criteria from the Cochrane Database of Systematic Reviews (CDSR). The topics are assessed by NICE staff and a clinical fellow for suitability for the collection. Only one topic of 39 assessed between August 2015 and September 2016 was deemed eligible for the collection. We therefore consider the effort in screening potential topics to be disproportionate to the output. It is proposed that new Cochrane topics are no longer added to the collection. Existing Cochrane topics can be archived in a legacy site.

**Alignment to NICE’s core work**

21. We need to develop a more effective narrative around our place in supporting disinvestment that builds on our core purpose: to help improve the quality, sustainability and productivity of health and social care. NICE’s position should be reframed and made clearer that we produce guidance and information on effective practice, which enables people working in health and social care to make better decisions with and for those for whom they are providing services. In doing so we take account of value for money in developing our guidance, both by recognising that new forms of practice need to demonstrate the benefits they bring against what they displace, and by recommending better targeting of interventions of limited value and opportunities for disinvesting from ineffective practice.

**The future disinvestment offer from NICE**

**A clear narrative**

22. As part of reinvigorating our future work in this area, we need a clear narrative to help communicate with core audiences and work with partners. We need to emphasise that NICE’s core business is about spending on the right things (allocative efficiency), and that this includes a full range of recommendations for new treatments and interventions, as well recommendations for substitution, restriction and retraction. The narrative could also support NICE’s proposed positioning set out in the Accelerated Access Review.

23. The suggested narrative for our future work is: “NICE enables the NHS, local government and social care providers make the best use of resources by setting out the case for investment and disinvestment through our guidance programmes and our other advice. Our position is to work with system partners to realise the
benefits from appropriate care and spending on the right things. This includes identifying specific recommendations that can save money, to enable conversations at a patient and population level on appropriate treatments and interventions”.

24. Explaining how NICE’s work helps inform disinvestment, and investment, decisions, could be helped by a clear figure. The illustration below shows the spectrum of NICE recommendations, from those where there are clear savings, through to those that may result in additional costs in the system. The majority of our recommendations have minimum impact, if implemented appropriately and supported by shared decision making.

Figure: relationship between volume of NICE recommendations and potential cost impact. A relatively small number of recommendations are always cost savings (left side of the curve), and some will result in added cost (right side of the curve). The majority of recommendations will have minimal impact. Shared decision making runs across all the recommendations but is more important and has greater impact for this majority, and underpins true evidence based practice, fusing the evidence, clinical judgement and patient preferences.

Redesigning the online offer

25. The proposed redesign is based on the principle that appropriate care offers opportunities for disinvestment. It will be presented to allow analysis based on pathways and programme budgets, and framed and organised in a way that our audiences understand, with appropriate terminology (e.g. don’t use ‘disinvestment’ with clinicians). A series of small disinvestment steps at various stages in the pathway could aggregate towards large efficiency savings. We will offer products that enable the health and care system to stop ineffective treatments / interventions.
26. In terms of content, we will:

- Focus and prioritise do not dos
  - Appropriateness of interventions for different populations and patients is more realistic than a long list of absolute do not dos
  - We will focus and prioritise do not dos, and limit absolute do not dos to practices that are unsafe; where there is strong evidence practice is absolutely ineffective in terms of quality and/or cost; and where there is strong evidence practice is relatively ineffective in terms of quality and/or cost, compared with alternative(s)
  - Other do not dos will be recast to reflect the range of appropriate decisions (e.g. offering, substituting or restricting interventions) for different populations and patients, based on the strength of evidence of effectiveness and cost effectiveness substitution and restriction
  - This model is supported by shared decision making and ‘guidelines not tramlines’, particularly for those interventions when the evidence is equivocal and/or absolute benefits are likely to be small

- Simplify the collection
  - Include the recast do not do recommendations with criteria to enable conversations around appropriate care at population level
  - Continue to include cost saving guidance and the resource planner
  - Continue to include existing return on investment tools linked to public health guidance
  - Continue with the key therapeutic topics as part of the national medicines optimisation agenda
  - We will not be accepting new quality and productivity case studies or Cochrane topics

**Raising awareness of NICE’s work**

27. We will align our offering and engage with key partners NHS Improvement and NHS England, e.g. the RightCare ‘where to look, what to change, how to change’ model, and the Shared Decision Making Collaborative.

28. We will continue to keep DH medicines and pharmacy, and strategy, system oversight and performance policy teams informed of progress.
Next steps

29. By 31 March 2017, agree methods and process for implementing the new do not do inclusion criteria, during development of guidance rather than the current mechanism of identifying do not do recommendations after guidance is published. This should link to work underway in the Centre for Guidelines which identifies preference sensitive decisions, and the resource impact of recommendations and the strength of evidence.

30. The redesign of the digital offer will be in two stages. Stage 1, to be completed by 31 March 2017, will involve simplifying the resources in the collection. Stage 2 will be an alternative presentation of the resources, informed by a discovery phase to be completed by January 2017. The aim is to have an initial iteration of the new alternative presentation in place by the NICE conference in May 2017.

31. Identify key messages that will resonate with all appropriate audiences with a communication strategy to be in action by May 2017.

32. Liaise with NHS England and NHS Improvement to ensure alignment with NICE’s offer, and with other activities related to the Accelerated Access Review, including support for cost saving medical technologies and NHS England’s medicines optimisation programme.

Professor Gillian Leng
Director, Health & Social Care Directorate
November 2016
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

AUDIT & RISK COMMITTEE MEMBERSHIP

The terms of reference of the Audit and Risk Committee state that the committee shall be appointed by the Board and will comprise five non-executive directors (NEDs) of NICE.

Two NEDs reached the end of their term of office at the end of July and a further two at the end of the October 2016. This led to three vacancies on the Audit & Risk Committee. In addition, Jonathan Tross, chair of the committee, reaches the end of his term of office as a NED on 31 December 2016.

An open recruitment process to appoint five new NEDs to the Board is almost complete and it is anticipated that the appointments will be confirmed shortly. One of these NEDs has been recruited specifically to succeed Jonathan Tross as chair of the Audit & Risk Committee.

To ensure the Audit & Risk Committee is appropriately constituted for its next meeting in January, the Board is asked to appoint Elaine Inglesby-Burke to the committee and delegate to the Chair the authority to appoint two further NEDs to the remaining two vacancies on the committee once the current appointments are confirmed.

David Haslam
Chair
November 2016
The Board is asked to consider the attached paper in respect of the role of the Vice Chair and Senior Independent Director (SID).

In particular, the Board is asked to:

1. Appoint Dr Rosie Benneyworth as the next Vice Chair when Andy McKeon retires from the Board.
2. Agree the approach for appointing the next Senior Independent Director and whether to:
   a. Retain the existing approach that combines the appointment of the Vice Chair and SID, or
   b. Separate the appointment process for the SID and Vice Chair and remove the reference to the SID from the Vice Chair’s role description.

Professor David Haslam
NICE Chair
November 2016
VICE CHAIR AND SENIOR INDEPENDENT DIRECTOR

Background

1. The Institute’s Standing Orders make provision for the appointment of a Vice Chair. In summary, the role of the Vice Chair is to perform the duties of Chair when the Chair is unable to discharge their responsibilities. In addition, the NICE Vice Chair has a central role in the technology appraisal and highly specialised technologies appeal process.

2. At its meeting in September 2015, the Board approved an amended role description for the Vice Chair (appendix 1). This included formally adding the duties of Senior Independent Director (SID), which were designated to the Vice Chair subsequent to the previous Vice Chair role description being agreed in 2013.

3. At the same meeting, the Board appointed Andy McKeon as the Vice Chair from 1 January 2016 to the end of his tenure on the Board.

Vice Chair appointment

4. Andy McKeon’s current term of office ends on 20 May 2017. It is therefore appropriate to consider the arrangements for the next Vice Chair to ensure opportunity for sufficient handover particularly in relation to the appeals role.

5. NICE’s Standing Orders state that the Vice Chair will be appointed by the Chair and the Board. In practice, the Chair has proposed to the Board a candidate for appointment, drawing on discussions during the Non-Executive Directors’ appraisals. In line with this established process, the Board is asked to appoint Dr Rosie Benneyworth as the Vice Chair following Andy McKeon’s retirement from the Board in May 2017. This will give opportunity for Rosie to observe aspects of the appeals role as part of a handover.

Senior Independent Director

6. The Senior Independent Director (SID) is established practice in the corporate sector. The current UK Corporate Governance Code states the following on the role of the SID in listed companies:

“The board should appoint one of the independent non-executive directors to be the senior independent director to provide a sounding board for the chairman and to serve as an intermediary for the other directors when necessary.”

7. The role of the SID in the health sector began in the NHS foundation trust (FT) sector partly to reflect the greater degree of autonomy for FT boards compared to previous NHS organisations. In an FT, the SID facilitates the processes to appraise, appoint and remove the Chair. As a Non Departmental Public Body (NDPB) these matters are led by our sponsor, the Department of Health rather than the SID.
8. Whilst it is not uncommon to combine the roles of Vice Chair and SID, during recent discussions with Board members a question was raised as to whether it is appropriate for the Chair to propose a candidate for SID given the SID’s role when there are concerns around the Chair’s performance.

9. The Board is therefore asked to consider whether to maintain the existing approach, which retains responsibility for appointing the Vice Chair and SID with the Board, drawing on a recommendation from the Chair. Or alternatively, separate the appointment process for the SID and Vice Chair. Under this latter option, Non-Executive Directors would be asked to express an interest in being the SID, and the Board would decide who to appoint without a recommendation from the Chair. The existing approach to appointing the Vice Chair would remain.

10. If the Board decides to separate the appointment process for the Vice Chair and SID, the reference to the SID in the Vice Chair’s role description will be removed. It would though be possible for the Vice Chair to be the SID.

Actions for the Board

11. The Board is asked to:

- Appoint Dr Rosie Benneyworth as the next Vice Chair when Andy McKeon retires from the Board.
- Agree the approach for appointing the next Senior Independent Director and whether to:
  a. Retain the existing approach that combines the appointment of the Vice Chair and SID, or
  b. Separate the appointment process for the SID and Vice Chair and remove the reference to the SID from the Vice Chair’s role description.

Professor David Haslam  
NICE Chair  
November 2016
APPENDIX 1

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

VICE CHAIR ROLE DESCRIPTION

Main duties

The main duties of the vice chair are:

1. Deputising for the Chair in their absence at Board meetings and on other occasions when they are otherwise unavailable.

2. Undertaking the duties of the Vice Chair outlined in the ‘Guide to the technology appraisal and highly specialised technologies appeal process’.* This includes:
   a. Determining the arguability and validity of each of the appeal points lodged and deciding if an appeal (oral or written) will be held.
   b. Writing to the appellant with the outcomes of the Vice Chair’s initial and final scrutiny of the appeal.

As part of this role, the Vice Chair will also work with the Corporate Office to:
   c. Appoint individuals able to hear appeals and present these appointments to the Secretary of State for approval.
   d. Ensure that the panel for each individual appeal is appropriately constituted from members whose appointment has been approved by the Secretary of State.
   e. Ensure that those appointed to hear appeals receive appropriate induction and ongoing training.
   f. Ensure that the policies associated with the Appeal process are kept up to date.

3. Acting as the Senior Independent Director (SID), being available to Board members if they have concerns relating to the performance of the Chair, or the performance of the organisation that they consider have not been dealt with appropriately by the Chair.

4. Being a member of the Board’s Remuneration Committee.

5. Other duties as a Non-Executive Director of the Board.

* NB If the Vice Chair is unable to consider a specific appeal due to conflict of interest or other reason, an alternate will be nominated to undertake these duties
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
DIRECTORS’ PROGRESS REPORTS

The next 5 items provide non-executive directors and the public with reports on the progress of the individual centres and directorates listed below. These reports give an overview of the performance of each centre or directorate in September and October, and outline the challenges and risks they face.

Professor Gillian Leng, Director, Health and Social Care Directorate (Item 9)
Professor Mark Baker, Director, Centre for Guidelines (Item 10)
Professor Carole Longson, Director, Centre for Health Technology Evaluation (Item 11)
Jane Gizbert, Director, Communications Directorate (Item 12)
Alexia Tonnel, Director, Evidence Resources Directorate (Item 13)

November 2016
National Institute for Health and Care Excellence
Health and Social Care Directorate progress report

1. This report sets out the performance of the Health and Social Care Directorate against our business plan objectives during September and October 2016. It also highlights notable developments and key risks.

Performance

2. The following quality standards published in September and October:
   - Social care for older people with multiple long-term conditions
   - Intravenous fluid therapy in children and young people in hospital
   - Skin cancer
   - Contraception
   - Children’s attachment
   - Coeliac disease
   - Preterm labour and birth

3. The following Evidence-based Treatment Pathways were delivered to NHS England (NHSE) in September. These are part of a specific commission to support work on improving mental health services:
   - Dementia
   - Urgent and emergency: children and young people’s mental health services.

4. The following Evidence Summaries on use of medicines were completed in September and October:
   - Levofloxacin (Quinsair) nebuliser solution for the management of chronic pulmonary infections due to Pseudomonas aeruginosa in adults with cystic fibrosis
   - Triethyleneetramine for hepatic, neurological and neuropsychiatry sequelae of Wilson’s disease
   - Pre-exposure prophylaxis of HIV in adults at high risk: Truvada (emtricitabine/tenofovir disoproxil).
5. The following Medicine Evidence Commentaries were completed in September and October:

- New MHRA drug safety advice: June to August 2016
- Medicines optimisation: adverse outcomes from potentially inappropriate prescribing in older people living in the community
- Fracture risk associated with melatonin and other hypnotics
- Medicines optimisation: impact of inappropriate prescribing on mortality and hospitalisation in older people
- Chronic obstructive pulmonary disease: indacterol/glycopyrronium compared with salmeterol/fluticasone for reducing exacerbations (the FLAME study)
## Table 1 Performance update for September and October 2016

<table>
<thead>
<tr>
<th>Objective</th>
<th>Actions</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish Evidence Based Treatment Pathways for mental health</td>
<td>Agree and consult on a process and methods manual with NHSE for the Evidence Based Treatment Pathways for Mental Health programme</td>
<td>A methods manual was drafted in September, and was subject to consultation with NHSE in October</td>
</tr>
<tr>
<td>Produce intelligence on the impact and uptake of NICE guidance</td>
<td>Publish the Uptake and Impact report</td>
<td>The first Uptake and Impact report published in September</td>
</tr>
<tr>
<td></td>
<td>Provide quarterly Innovation Scorecard Estimate reports</td>
<td>The quarterly Innovation Scorecard Estimate report published in October</td>
</tr>
<tr>
<td>Support public involvement across NICE</td>
<td>Plan, organise and deliver the 3rd Shared Decision Making Collaborative meeting</td>
<td>The Shared Decision Making Collaborative, an initiative led by NICE, published its consensus statement on promoting shared decision making throughout the health and care system. This covers 7 domains including development of decision support tools and the role of local leadership. To support the consensus statement, members of the collaborative have signed up to some short term actions and long term ambitions as outlined in an action plan. Further information - <a href="https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making">https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making</a></td>
</tr>
<tr>
<td></td>
<td>Work collaboratively with NHSE in relation to their shared decision making work</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Work with other teams across NICE on any ongoing work relating to shared decision making, including the communications team.</td>
<td></td>
</tr>
<tr>
<td>Coordinate and operate a programme of external engagement</td>
<td>Deliver 15 student champion training events</td>
<td>5 NICE Evidence Search ‘train the trainer’ workshops took place across September and October attended by 89 student champions</td>
</tr>
<tr>
<td>Objective</td>
<td>Actions</td>
<td>Update</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>----------------------------------------------</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>Provide an endorsement and quality assurance function to support implementation</td>
<td>Publish 30 endorsement statements</td>
<td>4 endorsement statements published in September and October</td>
</tr>
<tr>
<td></td>
<td>Publish 50 shared learning examples</td>
<td>7 shared learning examples published in September and October</td>
</tr>
</tbody>
</table>


6. The resource impact assessment due to publish in October was delayed due to a delay in publication of TA282. The date of publication of the technology appraisal is to be confirmed.

7. Production of evidence summaries was managed in accordance with other workload commitments and timed to maximise use of available resources. The annual target of 20 is on track for completion.

8. Publication of the hip fracture quality standard was delayed due to the committee requesting a second consultation, and will now publish in November. The Department of Health asked that the quality standard on transition between hospital and community or care home settings be delayed during formal endorsement, to enable questions from new ministers to be addressed. This quality standard is expected to publish in November.
Figure 2 Lay member recruitment performance by the Public Involvement Programme in April to October 2016

Figure 3 Performance against plan for System Engagement key outputs in April to October 2016
Notable developments

9. This section includes significant developments or issues that occurred during September and October.

Strategic engagement

10. At the October strategy meeting, the Board considered approaches to engagement and measures of success within social care and the Five Year Forward View and for 4 key partners: NHS England; NHS Improvement; Public Health England; and the Care Quality Commission. The Board provided a helpful discussion on the most critical aspects of these relationships and the potential risks, and outlined where future board reports should focus.

11. The first meeting of NICE’s new internal Strategic Engagement Oversight group was held in October. The group is developing a framework for supporting the coordination of strategic engagement activities across NICE.

12. NICE continues to support the implementation of the Five Year Forward View. Members of NICE’s executive team visited the Mid Nottinghamshire Better Together sponsored vanguard in September and NICE has been referenced in 2 New Care Model frameworks published in September.

13. Work was carried out in September to summarise the scope, priorities and deliverables of the cancer, maternity and mental health taskforce and implementation plans. This will support NICE in determining where we can add value and prioritise our engagement.

Directorate developments

14. On 1 October, the Medicines and Prescribing and Adoption and Impact programmes came together to form the Medicines and Technologies Programme. The programme will align work on medicines and technologies and will provide a robust, efficient, single resource to support the appropriate uptake and use of medicines and technologies across England. The implementation support team has moved from Adoption and Impact to the System Engagement Programme. This creates closer links with the field team to strengthen and align external engagement activities to deliver the revised Implementation Strategy.

15. Proposals for change within the HSC Directorate were submitted to the Joint Consultative Committee in September and to NICE’s Senior Management Team in October.
16. On 13 October NICE launched a joint consultation with NHS England that recommends changes to arrangements for evaluating and funding treatments appraised through our technology appraisal and highly specialised technologies programmes. As a result, the resource impact assessment team is developing its methodology for assessing the likely resource impact that takes into account affordability and speed of uptake of treatments appraised by NICE.

External activity

17. In partnership with the field team, the education team delivered 3 bespoke workshops to around 100 undergraduate and postgraduate social workers during September and October about NICE and NICE Evidence Search.

18. A project to assess the feasibility of implementing recommendations proposed in the draft asthma guideline was completed in October. This looked at the impact and feasibility of implementing the spirometry and fractional exhaled nitric oxide (FeNO) objective tests in primary care. The draft report will be available in December.
Risks

Table 2 Risks identified September and October 2016: key controls and ratings

<table>
<thead>
<tr>
<th>Risk</th>
<th>Key controls</th>
<th>Risk rating now</th>
<th>Risk rating year end</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delay in the development of service guidance and quality standards resulting from an inability to access record level HES data from NHS Digital</td>
<td>The information governance steering group are considering a number of options to manage the potential future risk. The Centre for Guidelines has confirmed that aggregated data supplied by the Adoption and Impact team will be sufficient to produce current guidance.</td>
<td>Red</td>
<td>Amber</td>
</tr>
</tbody>
</table>
### Appendix 1 Guidance and advice published since April 2016

The table below provides a list of guidance and advice produced between April 2016 and October 2016. For the Health and Social Care Directorate this includes quality standards, evidence based treatment pathways, and evidence summaries.

<table>
<thead>
<tr>
<th>Guidance title</th>
<th>Publication date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic obstructive pulmonary disease: tiotropium/olodaterol (Spiolto Respimat)</td>
<td>May 2016</td>
<td>Evidence summary</td>
</tr>
<tr>
<td>Reversal of the anticoagulant effect of dabigatran: idarucizumab</td>
<td>May 2016</td>
<td>Evidence summary</td>
</tr>
<tr>
<td>Complicated urinary tract infections: ceftolozane/tazobactam</td>
<td>June 2016</td>
<td>Evidence summary</td>
</tr>
<tr>
<td>Complicated intra-abdominal infections: ceftolozane/tazobactam</td>
<td>June 2016</td>
<td>Evidence summary</td>
</tr>
<tr>
<td>Visual impairment due to myopic choroidal neovascularisation: aflibercept</td>
<td>June 2016</td>
<td>Evidence summary</td>
</tr>
<tr>
<td>Moderate to severe acute post-operative pain: fentanyl transdermal system</td>
<td>June 2016</td>
<td>Evidence summary</td>
</tr>
<tr>
<td>Levofloxacin (Quinsair) nebuliser solution for the management of chronic pulmonary infections due to <em>Pseudomonas aeruginosa</em> in adults with cystic fibrosis</td>
<td>Delivered to NHS England - September 2016</td>
<td>Evidence summary</td>
</tr>
<tr>
<td>Triethylenetetramine for hepatic, neurological and neuropsychiatry sequelae of Wilson’s Disease</td>
<td>Delivered to NHS England - September 2016</td>
<td>Evidence summary</td>
</tr>
<tr>
<td>Pre-exposure prophylaxis of HIV in adults at high risk: Truvada (emtricitabine/tenofovir disoproxil)</td>
<td>October 2016</td>
<td>Evidence summary</td>
</tr>
<tr>
<td>Adverse events associated with off-label medicine use in adults</td>
<td>April 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Meniere’s disease: betahistine not shown to be superior to placebo</td>
<td>April 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Chronic disease in people with severe mental illness: reducing excess mortality</td>
<td>May 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Urinary tract infection: antibiotic resistance in children in primary care</td>
<td>May 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Guidance title</td>
<td>Publication date</td>
<td>Notes</td>
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<tr>
<td>Supporting adherence to medicines in people with long-term conditions: New Medicines Service community pharmacy scheme</td>
<td>May 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Text messaging to help medicines adherence</td>
<td>May 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>New MHRA drug safety advice: March to May 2016</td>
<td>May 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Antibiotic stewardship interventions in hospitals: effect on clinical outcomes</td>
<td>June 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Chronic kidney disease: increased risk with proton pump inhibitors</td>
<td>June 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Statins: modelling study suggests lifespan benefits are not evenly distributed and that people may not choose the mathematically optimal option for benefit</td>
<td>June 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Antibiotics for infected eczema: the CREAM study</td>
<td>June 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Type 2 diabetes: meta-analysis finds no increased risk of mortality, MI or stroke with sulfonylureas</td>
<td>July 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Medicines optimisation: effect of a combined education, informatics and financial incentive intervention on high-risk prescribing in general practice</td>
<td>July 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Type 2 diabetes: increased risk of hypoglycaemia with combined use of dipeptidyl peptidase-4 (DPP-4) inhibitors and sulfonylureas</td>
<td>July 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Type 2 diabetes: liraglutide reduces cardiovascular risk in people at high risk of having a cardiovascular event</td>
<td>August 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Osteoarthritis: network meta-analysis finds no statistically significant benefit with lower doses of some NSAIDs and paracetamol on pain or physical functioning compared with placebo</td>
<td>August 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Inhaler use: has technique improved</td>
<td>August 2016</td>
<td>Medicines Evidence</td>
</tr>
<tr>
<td>Guidance title</td>
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<td>Notes</td>
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<tr>
<td>New MHRA drug safety advice: June to August 2016</td>
<td>September 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Medicines optimisation: adverse outcomes from potentially inappropriate prescribing in older people living in the community</td>
<td>September 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
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<td>Fracture risk associated with melatonin and other hypnotics</td>
<td>October 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
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<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease: indacaterol/glycopyrronium compared with salmeterol/fluticasone for reducing exacerbations (the FLAME study)</td>
<td>October 2016</td>
<td>Medicines Evidence Commentary (MEC)</td>
</tr>
<tr>
<td>Antimicrobial stewardship</td>
<td>April 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Suspected cancer</td>
<td>June 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Home care for older people</td>
<td>June 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Bronchiolitis in children</td>
<td>June 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Motor neurone disease</td>
<td>July 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Diabetes in adults*</td>
<td>August 2016</td>
<td>Quality standard - updated</td>
</tr>
<tr>
<td>Early years: promoting health and wellbeing in under 5’s</td>
<td>August 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Obesity: clinical assessment and management*</td>
<td>August 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Social care for older people with multiple long-term conditions</td>
<td>September 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Intravenous fluid therapy in children and young people in hospital</td>
<td>September 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Skin cancer*</td>
<td>September 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Contraception</td>
<td>September 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Children's attachment</td>
<td>October 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Coeliac disease</td>
<td>October 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Preterm labour and birth</td>
<td>October 2016</td>
<td>Quality standard</td>
</tr>
<tr>
<td>Guidance title</td>
<td>Publication date</td>
<td>Notes</td>
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<td>----------------------------------------------------------------</td>
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</tr>
<tr>
<td>Urgent and emergency psychiatric liaison mental health services</td>
<td>Delivered to NHS England - June 2016</td>
<td>Evidence based treatment pathway</td>
</tr>
<tr>
<td>Urgent and emergency mental health: blue light services</td>
<td>Delivered to NHS England - July 2016</td>
<td>Evidence based treatment pathway</td>
</tr>
<tr>
<td>Perinatal mental health services</td>
<td>Delivered to NHS England - August 2016</td>
<td>Evidence based treatment pathway</td>
</tr>
<tr>
<td>Dementia</td>
<td>Delivered to NHS England - September 2016</td>
<td>Evidence based treatment pathway</td>
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<tr>
<td>Urgent and emergency: children and young people's mental health services</td>
<td>Delivered to NHS England - September 2016</td>
<td>Evidence based treatment pathway</td>
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</table>

*NB: these quality standards combine 2 or more referred topics. Therefore the numbers in this list will not correlate with data in the graphs, which report on publication of referred topics.*
National Institute for Health and Care Excellence
Centre for Guidelines progress report

1. This report sets out the performance of the Centre for Guidelines against our business plan objectives for the months of September and October 2016. It also highlights key developments and any high risks.

Performance

2. The following guidelines were published in September and October:
   - NG54 Mental health problems in people with learning disabilities: prevention, assessment and management
   - NG56 Multimorbidity: clinical assessment and management
   - NG55 Harmful sexual behaviour among children and young people

3. The following surveillance reviews were published in September and October:
   - CG167 Myocardial infarction with ST-segment elevation: acute management
   - CG127 Hypertension in adults: diagnosis and management
   - CG133 Self-harm in over 8s: long term management
   - CG170 Autism spectrum disorder in under 19s; support and management
   - CG94 Unstable angina and NSTEMI: early management
   - CG128 Autism spectrum disorder in under 19s; recognition, referral and diagnosis
   - CG16 Self harm in over 8s: short-term management and prevention of recurrence
   - CG175 Prostate cancer: diagnosis and management
<table>
<thead>
<tr>
<th>Objective</th>
<th>Actions</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop sustainable processes and methods for reviewing clinical guidelines</td>
<td>Evaluate the new processes/methods. Complete ‘live’ guidelines pilot topics and plan broader implementation of such approach including tracking system for key trials. Complete registration for Topic Expert panel</td>
<td>Senior strategic meetings have been held and plans are being developed for sustainable methods and processes for the future, including the introduction of continuous searching for live guideline pilots and trial tracking. The expert adviser panel has recruited over 500 former GDG members from approximately 1259 invites sent out. The fifth of the adverts to recruit to expert advisers to fill gaps in the panel went out in September 2016.</td>
</tr>
<tr>
<td>Operate the Centre within budget and put in place plans to meet the agreed efficiency savings</td>
<td>Centre budget balanced at year-end and demonstrates ability to make agreed efficiency savings. Agree a management of change process that will demonstrate efficiency savings. Deliver management of change exercises.</td>
<td>External contractors are operating to an agreed budget. Proposals for the management of Change were submitted to the Joint Consultative Committee in September and agreed by the NICE’s Senior Management Team on the 25th October. Informal 1-1 meetings with staff have taken place between 4-14 October ‘16.</td>
</tr>
<tr>
<td>Put in place plans to ensure that contractors (including the BNF) and developers embed new processes and methods that will maintain and improve the quality of work and contribute to efficiencies.</td>
<td>Put in place plans to support business continuity to minimise risks to the work programme during the transition period of the new contractors. Demonstrate delivery of quality to time and to budget through performance managing the contracts through quarterly review meetings. Develop new contract monitoring systems for all contractors and developers. Develop new processes that will improve quality assurance of clinical guidelines.</td>
<td>The National Guideline Alliance has completed a restructuring process following a new contract in 2016/17. To date 2 redundancies have been identified through TUPE. Quarter 2 review meetings with all contractors are being undertaken, at the time of reporting all contractors are within budget and reporting no high risks. New contract monitoring systems are in place. New processes to improve quality assurance of clinical guidelines are in place.</td>
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<tr>
<td>Objective</td>
<td>Actions</td>
<td>Update</td>
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<tr>
<td><strong>Develop new methods and processes of updating clinical guidelines to contribute to agreed efficiencies</strong></td>
<td>Develop new sustainable methods and processes to reduce the time interval between review and publication of updates. Set up a working group to develop new ways of working. Pilot new ways of working internally</td>
<td>The NCSSC contract deliverables are still being met. BNF and BNFC 2016 print formats published in September ‘16. The incumbent supplier (PROLOG) of BNF distribution for England was awarded the recent retender. The new BNF &amp; BNFC platforms on the NICE website were launched in public beta during October ‘16. Operation plans are being developed on a pilot project for scoping medium sized topics in-house. Recruitment to a fixed term band 7 analyst is underway. The first topic to pilot the new ways of working internally has been commissioned.</td>
</tr>
<tr>
<td><strong>Develop the methods of clinical guideline development to maintain enhance the Centre’s reputation for methodological quality and efficiency.</strong></td>
<td>Contribute to the management of change process to bring together health economists from across CfG in to a single team to provide for enhanced access to health economics resource across CfG functions; Develop service delivery guidelines to expected quality and time, Contribute to the development of methods and processes for considering resource impact in guideline development; Establish and maintain links and networks with external research initiatives, organisations and projects to address our methodological needs and ensure our methods continue to reflect internationally</td>
<td>In October 2016, a member of staff joined Cochrane UK in delivering GRADE training for the Cochrane UK managing editors. We continue to promote the advance of methodological and process innovation in guideline development. Our approach to updating guidelines formed a plenary session at the 2016 Guidelines International Network (GIN) conference in Philadelphia in September ‘16. Three members of staff attended GIN and presented the work of the Surveillance and Clinical Guidelines Updates teams. The Centre’s guideline contextualisation service continues to attract interest from international guideline developers. The Centre presented to a visiting delegation from Bahrain in September 2016. We also hosted a visiting delegation</td>
</tr>
<tr>
<td>Objective</td>
<td>Actions</td>
<td>Update</td>
</tr>
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</tr>
</tbody>
</table>
| recognise best-practice.  
Continue to develop the methodology supporting the NICE guideline contextualisation service. |                                                                                                                                                                                                           | from Ireland’s Department of Health and National Clinical Effectiveness Committee in October 2016.                                                                                                 |
| Support the Implementation of the guidelines manual and the NICE content strategy; oversee the transforming guidance development programme | Consider required revisions and amend processes and templates accordingly. 
Plan and deliver projects aimed at improving NICE content and the development and delivery of NICE guidance                                      | Work continues on digital development projects to improve the quality standards knowledge base, and planning is underway for a new phase of work that will enable efficiencies through reuse of content. 
Development of functionality to support the administration of document supply is progressing well, and will be integrated into the EPPI-Reviewer tool once complete. |
The clinical guideline, Low back pain was due to publish on the 7 September 2016. We received a large number of comments related to the recommendations around acupuncture during the consultation phase, so we are taking additional time to ensure that all points raised are considered fully and responded to appropriately.
Notable developments

4. This section includes significant developments or issues that occurred during September and October.

5. The most pressing and important work during the summer months has been the preparation for a major Management of Change process to redesign the Centre’s staffing and, alongside that, the redesign of a number of processes. In particular, we are changing the way in which Standing Public Health Committees are supported technically and we are reshaping the way in which we complete large updates of clinical guidelines in house. These changes will impact on overall staffing levels and skill mix but should result in a significant increase in productivity. The changes will contribute £1m towards NICE’s savings target.
**Risks**

**Table 2 Risks identified September and October 2016: key controls and ratings**

<table>
<thead>
<tr>
<th>Risk</th>
<th>Key controls</th>
<th>Risk rating now</th>
<th>Risk rating year end</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management of change – risk of reduction in delivery of outputs due to altered structures to deliver guidance production</td>
<td>Effective plans are being developed to ensure new structures are developed and are in place following agreement through a management of change.</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>
Appendix 1 Guidance and advice published since April 2016

Total number of guidelines and surveillance reviews published in 2016-17 to date.

<table>
<thead>
<tr>
<th>Guidance title</th>
<th>Publication date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical guidelines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Routine preoperative tests for elective surgery (NG45)</td>
<td>April 2016</td>
<td>(update)</td>
</tr>
<tr>
<td>Crohn's disease: management (standing committee update) (CG152)</td>
<td>May 2016</td>
<td></td>
</tr>
<tr>
<td>Psychosis and schizophrenia in children and young people: recognition and management (CG155)</td>
<td>May 2016</td>
<td></td>
</tr>
<tr>
<td>Haematological cancers: improving outcomes (NG47)</td>
<td>May 2016</td>
<td></td>
</tr>
<tr>
<td>Non-alcoholic fatty liver disease (NAFLD): assessment and management (NG49)</td>
<td>July 2016</td>
<td></td>
</tr>
<tr>
<td>Cirrhosis in over 16s: assessment and management (NG50)</td>
<td>July 2016</td>
<td></td>
</tr>
<tr>
<td>Sepsis: recognition, diagnosis and early management (NG51)</td>
<td>July 2016</td>
<td></td>
</tr>
<tr>
<td>Non-Hodgkin's lymphoma: diagnosis and management (NG52)</td>
<td>July 2016</td>
<td></td>
</tr>
<tr>
<td>Fertility problems: assessment and treatment (CG156)</td>
<td>August 2016</td>
<td>(standing committee update)</td>
</tr>
<tr>
<td>Heavy menstrual bleeding (CG44)</td>
<td>August 2016</td>
<td>(standing committee update)</td>
</tr>
<tr>
<td>Multimorbidity: clinical assessment and management (NG56)</td>
<td>September 2016</td>
<td></td>
</tr>
<tr>
<td>Mental health problems in people with learning disabilities: prevention, assessment and management (NG54)</td>
<td>September 2016</td>
<td></td>
</tr>
<tr>
<td>Public Health and Social Care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral health for adults in care homes (NG48)</td>
<td>July 2016</td>
<td></td>
</tr>
<tr>
<td>Transition between inpatient mental health settings and community and care home settings (NG53)</td>
<td>August 2016</td>
<td></td>
</tr>
<tr>
<td>Harmful sexual behaviour among children and</td>
<td>September 2016</td>
<td></td>
</tr>
<tr>
<td>Guidance title</td>
<td>Publication date</td>
<td>Notes</td>
</tr>
<tr>
<td>--------------------------------------------------------------------</td>
<td>------------------</td>
<td>-------</td>
</tr>
<tr>
<td>young people (NG55)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surveillance reviews</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CG126 Stable angina: management</td>
<td>April 2016</td>
<td></td>
</tr>
<tr>
<td>CG101 Chronic Obstructive Pulmonary Disease</td>
<td>April 2016</td>
<td></td>
</tr>
<tr>
<td>CG100 Alcohol use</td>
<td>April 2016</td>
<td></td>
</tr>
<tr>
<td>CG130 Hyperglycaemia In acute coronary Syndrome</td>
<td>July 2016</td>
<td></td>
</tr>
<tr>
<td>CG54 Urinary tract infection in children</td>
<td>July 2016</td>
<td></td>
</tr>
<tr>
<td>CG51 Drug misuse</td>
<td>July 2016</td>
<td></td>
</tr>
<tr>
<td>CG57 Atopic eczema in children</td>
<td>July 2016</td>
<td></td>
</tr>
<tr>
<td>CG140 Opioids in palliative care</td>
<td>July 2016</td>
<td></td>
</tr>
<tr>
<td>CG142 Autism spectrum disorder in adults; diagnosis and management</td>
<td>July 2016</td>
<td></td>
</tr>
<tr>
<td>CG138 Patient experience in adult NHS services: improving the experience of care for people using adult NHS services</td>
<td>August 2016</td>
<td></td>
</tr>
<tr>
<td>CG141 Acute upper gastrointestinal bleeding in over 16s: management</td>
<td>August 2016</td>
<td></td>
</tr>
<tr>
<td>CG143 Sickle cell disease: managing acute painful episodes in hospital</td>
<td>August 2016</td>
<td></td>
</tr>
<tr>
<td>CG170 Autism spectrum disorder in under 19s; support and management</td>
<td>September 2016</td>
<td></td>
</tr>
<tr>
<td>CG128 Autism spectrum disorder in under 19s; recognition, referral and diagnosis</td>
<td>September 2016</td>
<td></td>
</tr>
<tr>
<td>CG167 STEMI</td>
<td>September 2016</td>
<td></td>
</tr>
<tr>
<td>CG94 Unstable angina and NSTEMI: early management</td>
<td>September 2016</td>
<td></td>
</tr>
<tr>
<td>CG133 Self harm: Longer term management</td>
<td>September 2016</td>
<td></td>
</tr>
<tr>
<td>CG16 Self harm in over 8’s: Short term management and prevention of reoccurrence</td>
<td>September 2016</td>
<td></td>
</tr>
<tr>
<td>CG175 Prostate cancer: diagnosis and management</td>
<td>October 2016</td>
<td></td>
</tr>
<tr>
<td>CG127 Hypertension in adults: diagnosis and management</td>
<td>October 2016</td>
<td></td>
</tr>
</tbody>
</table>
National Institute for Health and Care Excellence

Centre for Health Technology Evaluation progress report

1. This report sets out the performance of the Centre for Health Technology Evaluation (CHTE) against our business plan objectives during September - October 2016.

2. CHTE have worked with colleagues in NHS England to develop and release a joint 12 week public consultation on changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE’s technology appraisal and highly specialised technologies programmes. The consultation started on 13 October 2016 and is scheduled to close on 13 January 2016. NICE and NHSE have arranged to hold 4 webinars and 2 face to face events with stakeholders to discuss the proposed changes in more detail.

3. The technology appraisal programme has now held 3 additional committee meetings in 2016/17 to consider Cancer Drugs Fund (CDF) transition topics. To date, the committee has considered 9 drug-indication pairings, and will discuss the remaining at the next CDF transition committee meeting on 29 November 2016.

4. NICE Scientific Advice has been working closely with NICE Digital Services in the development of the Medtech Early Technical Assessment (META) Tool. The latest version of the tool is currently undergoing testing with several SMEs who are in the product development cycle, to help further refine its structure and content. Our partner, Greater Manchester Academic Health Science Centre, and the Health Technology Cooperative, Devices for Dignity, will also provide feedback on facilitation of the META Tool and the educational training/materials. Following this, a final specification for the tool and a business model for commercial development will be produced. NICE Scientific Advice expects to launch the META Tool in April 2017.
## Performance

**Table 1 performance update for September - October 2016**

<table>
<thead>
<tr>
<th>Objective</th>
<th>Actions</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish 50 technology appraisals guidance (including up to 15 CDF reconsiderations)</td>
<td>11 published pieces of guidance</td>
<td>14 pieces of TA guidance were originally planned to publish in Sept and Oct 2016. 2 pieces of guidance went straight to FAD and, therefore, published earlier than anticipated. An appeal has been lodged for one guidance topic.</td>
</tr>
<tr>
<td>Publish 35 interventional procedures guidance</td>
<td>2 published pieces of guidance</td>
<td>Unable to publish four pieces of guidance during September 2016 due to other topics needing to be discussed at the July meeting. Discussions have now taken place at the September Interventional Procedures Advisory Committee Meeting and they are now due to be published in November/December 2016.</td>
</tr>
<tr>
<td>Publish 6 diagnostics guidance</td>
<td>No guidance published since last meeting</td>
<td>The diagnostics programme was not scheduled to publish any guidance in September or October. 5 pieces of guidance are scheduled to be published in this business year. This has changed from 6 pieces of guidance since the last board report; an NIHR external assessment group report needed further work and resubmission timeframes mean that that projected publication of resultant guidance will now fall in 2017/18.</td>
</tr>
<tr>
<td>Publish 3 highly specialised technologies guidance</td>
<td>No guidance published since last meeting</td>
<td>Two pieces of guidance were due to publish in October 2016. One guidance topic been delayed until November 2016 due to additional discussion needing to take place. The second topic is currently suspended and is awaiting new timelines.</td>
</tr>
<tr>
<td>Task</td>
<td>Progress</td>
<td>Notes</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>---------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Publish 7 medical technologies guidance</td>
<td>No guidance published since last meeting</td>
<td>Unable to publish 1 piece of guidance during October 2016. Unfortunately the August Committee meeting had to be cancelled as it was not quorate. All topics due to be considered at the August Committee meeting are still projected to publish within the financial year. 1 guidance topic planned for publication this financial year has been delayed due to awaiting the availability of key evidence and it is now planned to publish in 2017-18.</td>
</tr>
<tr>
<td>Publish 40 Medtech Innovation Briefings (MIBs)</td>
<td>6 published MIBs</td>
<td>Currently on plan to publish 36-40 MIBs.</td>
</tr>
<tr>
<td>Submit advice to ministers on 12 Patient Access Schemes</td>
<td>7 Patient Access Schemes submitted</td>
<td></td>
</tr>
<tr>
<td>Deliver up to 14 Commissioning Support Documents (CSDs)</td>
<td>No CSDs outputs</td>
<td>Due to the delay in receipt of the signed Memorandum of Understanding from NHS England and the delay in issuing the subsequent Purchase Order, we are rescheduling the timelines for CSD outputs in conjunction with NHS England.</td>
</tr>
<tr>
<td>Effective management of Scientific Advice income generated activity</td>
<td>9 Completed/Live advice projects</td>
<td>NICE Scientific Advice anticipates full recovery of all programme costs and contributions to NICE’s overhead costs. 8 pending advice projects due to start &amp; complete in 2016/17 2 seminars and a patient event scheduled before the end of 2016/17</td>
</tr>
<tr>
<td></td>
<td>Hosted 2 educational seminars</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Participated in 10 external events</td>
<td></td>
</tr>
</tbody>
</table>
**Key developments and issues**

**EUnetHTA**

5. The European network for Health Technology Assessment (EU netHTA) Joint Action 3 started on June 1 to run for 4 years. As part of its contribution to EU netHTA, NICE is leading work package 7 “National Implementation and Impact”. Work has started on research describing HTA and reimbursement processes for pharmaceuticals and medical technologies across the countries of the EU netHTA partners (covering the EU, Norway and Switzerland). Its objective is to identify ways in which EU netHTA partners will be able to engage in HTA cooperation within their routine working processes. NICE has also been interviewing EU netHTA partners about their experience of using previous EU netHTA assessments and engaging in cooperative working. This work will be used to inform development of proposals for a sustainable model of HTA cooperation within the EU.
Commissioning Support Programme

6. The majority of the team to develop the new NICE Health Technology advice output, commissioning support documents for NHS England, is now in place. Methods and processes for this new programme will be developed in collaboration with NHS England in the next few months and the programme will formally start on 1 February 2017.

Strategic Technology Appraisals Review

7. The abbreviated technology appraisal process (for technologies with similar or better efficacy at similar or lower costs) has completed its public consultation phase. This process was due to be implemented from January 2017, but will now be integrated with the proposed fast track technology appraisal process, currently out for consultation, with implementation in April 2017.

Science Policy and Research

8. The outcomes of an exploratory research project designed to catalogue key decision factors that contribute to Technology Appraisal decision making and develop prototype visualisation tools to display the complex set of evidence and inputs used has led to further work to explore the way in which visualisation tools can help facilitate advisory committee discussions and decision making. The overall objective of this work is to facilitate a more structured approach to decision making and provide a tool for enhanced communication of complex decision outcomes to external stakeholders. The project is being undertaken in conjunction with the Digital Services team and aligns with the current internal changes occurring as a consequence of the Transforming Guidance Development programme (TGD).

The Office for Market Access (OMA)

9. The Office for Market Access (OMA) has received over 400 enquiries since launch in October 2015.

10. The first cost recovery multi-stakeholder engagement meeting is being held in November 2016 after the completion of two successful pilots earlier this year. This meeting will be held under the ‘safe harbour’ principles underpinning all of the services that OMA develop.

Scientific Advice

11. NICE SA has recently joined forces with the US Food and Drug Administration (FDA) Payer Communication Task Force (PCTF) to assist companies developing medical devices and diagnostics to generate relevant evidence to
facilitate market access. Medtech companies seeking advice through the FDAs Centre for Devices & Radiological Health (CDRH) pre-submission program are now able to invite NICE Scientific Advice to participate in the process. NICE Scientific Advice will provide advice on the company’s proposals for evidence generation in parallel to the FDA’s regulatory advice and views from American payer organisations.

Interventional Procedures Programme

12. Representatives from the Interventional Procedures programme met with senior NHS policymakers from England and the devolved administrations in September 2016 to discuss the arrangements for NICE’s Interventional Procedures programme in England, Wales, Scotland and Northern Ireland. These arrangements were previously outlined in the Health Service Circular 2003/011 (The interventional procedures programme: working with the National Institute for Clinical Excellence to promote safe clinical innovation). As this circular is no longer current, the need for this event was noted by the Board when the Interventional Procedures Programme Manual was approved for publication last year. It was a very successful meeting, with attendees re-enforcing the need for a UK-wide approach for the review of the safety and efficacy of new surgical procedures and highlighting the importance of the NICE Interventional Procedures Programme.

13. The group discussed and agreed amendments to the original Circular to make it applicable to current conditions across the 4 nations. Each jurisdiction also agreed to reinforce to its providers and commissioners, the need to have due regard to the document (where applicable).

14. It was also decided to hold a “4 nations meeting” on an annual basis, to identify any further actions that might be needed to ensure advice from the Interventional Procedures Programme was being applied appropriately.
## Risks

Table 2 Risks identified September – October 2016: key controls and ratings

<table>
<thead>
<tr>
<th>Risk</th>
<th>Key controls</th>
<th>Risk rating now</th>
<th>Risk rating year end</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTEP: Committee capacity will be insufficient to schedule notified topics for selection and routing, leading to delays in starting guidance development (MTG or DG) on selected topics.</td>
<td>Efficiency measures being implemented including removing the need for external expert advisers to be in attendance for selection and routing decision-making.</td>
<td>Amber</td>
<td>Green</td>
</tr>
<tr>
<td>Technology Appraisals: Currently carrying 18 vacancies within the team which poses the risk of not being able to produce all the required guidance outputs as per 2016/17 business plan targets.</td>
<td>Working with HR and Finance (NICE 2020 group) to identify and prioritise recruitment arrangements across the programme.</td>
<td>Red</td>
<td>Red</td>
</tr>
</tbody>
</table>
## Appendix 1 guidance published since April 2016

<table>
<thead>
<tr>
<th>Guidance title</th>
<th>Publication date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology Appraisals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TA416; Lung cancer (non-small-cell, EGFR and T790M positive, metastatic) - osimertinib (after EGFR-TKI) – STA</td>
<td>October 2016</td>
<td>Recommended within the CDF</td>
</tr>
<tr>
<td>TA415; Rheumatoid arthritis - certolizumab pegol (after TNF inhibitor) – STA</td>
<td>October 2016</td>
<td>Optimised</td>
</tr>
<tr>
<td>TA414; Melanoma (BRAF V600, unresectable, untreated, metastatic) - cobimetinib (with vemurafenib) – STA</td>
<td>October 2016</td>
<td>Not recommended</td>
</tr>
<tr>
<td>TA413; Hepatitis C (chronic) - elbasvir-grazoprevir – STA</td>
<td>October 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td>TA412; Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases - STA</td>
<td>September 2016</td>
<td>Optimised</td>
</tr>
<tr>
<td>TA411; Necitumumab for untreated advanced or metastatic squamous non-small-cell lung cancer - STA</td>
<td>September 2016</td>
<td>Not recommended</td>
</tr>
<tr>
<td>TA410; Talimogene laherparepvec for treating unresectable metastatic melanoma - STA</td>
<td>September 2016</td>
<td>Optimised</td>
</tr>
<tr>
<td>TA409; Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion - STA</td>
<td>September 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td>TA408; Pegasparagase for treating acute lymphoblastic leukaemia - STA</td>
<td>September 2016</td>
<td>Optimised</td>
</tr>
<tr>
<td>TA407; Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors - STA</td>
<td>September 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td>TA406; Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer - STA</td>
<td>September 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td>TA405; Trifluridine–tipiracil for previously treated metastatic colorectal cancer - STA</td>
<td>August 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td>TA404; Degarelix for treating advanced hormone-dependent prostate cancer - STA</td>
<td>August 2016</td>
<td>Optimised</td>
</tr>
<tr>
<td>TA403; Ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer - STA</td>
<td>August 2016</td>
<td>Not recommended</td>
</tr>
<tr>
<td>TA402; Pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin – CDF rapid reconsideration</td>
<td>August 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Will now move from the CDF into baseline commissioning</td>
</tr>
<tr>
<td>TA401; Bosutinib for previously treated chronic myeloid leukaemia – CDF rapid reconsideration</td>
<td>August 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Will now move from the CDF into baseline commissioning</td>
</tr>
<tr>
<td>TA400; Nivolumab in combination with ipilimumab for treating advanced melanoma - STA</td>
<td>July 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td>TA399; Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts - STA</td>
<td>July 2016</td>
<td>Not recommended</td>
</tr>
<tr>
<td>TA398; Lumacaftor–ivacaftor for treating cystic fibrosis homozygous for the F508del mutation – STA</td>
<td>July 2016</td>
<td>Not recommended</td>
</tr>
<tr>
<td>TA397; Belimumab for treating active autoantibody-positive systemic lupus erythematosus – STA</td>
<td>June 2016</td>
<td>Optimised</td>
</tr>
<tr>
<td>TA396; Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma – STA</td>
<td>June 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td>TA395; Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer – STA</td>
<td>June 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td>TA394; Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia - STA</td>
<td>June 2016</td>
<td>Optimised</td>
</tr>
<tr>
<td>TA393; Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia - STA</td>
<td>June 2016</td>
<td>Optimised</td>
</tr>
<tr>
<td>TA392; Adalimumab for treating moderate to severe hidradenitis suppurativa - STA</td>
<td>June 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td>TA391; Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel - STA</td>
<td>May 2016</td>
<td>Recommended</td>
</tr>
<tr>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>TA390; Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes - MTA</td>
<td>May 2016</td>
<td>Optimised</td>
</tr>
<tr>
<td>TA389; Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer - MTA</td>
<td>April 2016</td>
<td>Various</td>
</tr>
<tr>
<td>TA388; Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction - STA</td>
<td>April 2016</td>
<td>Optimised</td>
</tr>
<tr>
<td>TA387; Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated - STA</td>
<td>April 2016</td>
<td>Recommended</td>
</tr>
</tbody>
</table>

Interventional procedures

<table>
<thead>
<tr>
<th>IPG566 - Single incision sub-urethral short tape insertion for stress urinary incontinence in women (formerly TVT Secur)</th>
<th>Oct 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPG565 - Miniature lens system implantation for advanced age-related macular degeneration</td>
<td>Sept 2016</td>
</tr>
<tr>
<td>IPG564 - Extracorporeal carbon dioxide removal for acute respiratory failure</td>
<td>August 2016</td>
</tr>
<tr>
<td>IPG563</td>
<td>Percutaneous endoscopic laser balloon pulmonary vein isolation for atrial fibrillation</td>
</tr>
<tr>
<td>-------</td>
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</tr>
<tr>
<td>IPG562</td>
<td>Ultrasound-guided percutaneous radiofrequency ablation for benign thyroid nodules</td>
</tr>
<tr>
<td>IPG561</td>
<td>Transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting</td>
</tr>
<tr>
<td>IPG560</td>
<td>Microstructural scaffold (patch) insertion without autologous cell implantation for repairing symptomatic chondral knee defects</td>
</tr>
<tr>
<td>IPG559</td>
<td>Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine</td>
</tr>
<tr>
<td>IPG558</td>
<td>Biodegradable subacromial spacer insertion for rotator cuff tears</td>
</tr>
<tr>
<td>IPG557</td>
<td>Endovenous mechanochemical ablation for varicose veins</td>
</tr>
<tr>
<td>IPG556</td>
<td>Percutaneous transforaminal endoscopic lumbar discectomy for sciatica</td>
</tr>
<tr>
<td>IPG555</td>
<td>Percutaneous interlaminar endoscopic lumbar discectomy for sciatica</td>
</tr>
<tr>
<td>IPG554</td>
<td>Balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension</td>
</tr>
<tr>
<td>IPG553</td>
<td>Microwave ablation for treating liver metastases</td>
</tr>
<tr>
<td>Diagnostics</td>
<td></td>
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<td>-------------</td>
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</tr>
<tr>
<td>DG23 PIGF-based testing to help diagnose suspected pre-eclampsia (Triage PIGF test, Elecsys immunoassay sFlt-1/PIGF ratio, DELFIA Xpress PIGF 1-2-3 test, and BRAHMS sFlt-1 Kryptor/BRAHMS PIGF plus Kryptor PE ratio)</td>
<td>May 2016</td>
</tr>
<tr>
<td>DG24 ImmunoCAP ISAC 112 and Microtest for multiplex allergen testing</td>
<td>May 2016</td>
</tr>
<tr>
<td>Highly Specialised Technologies</td>
<td></td>
</tr>
<tr>
<td>HST3; Ataluren for treating Duchenne muscular dystrophy with a nonsense mutation in the dystrophin gene</td>
<td>July 2016</td>
</tr>
<tr>
<td>Medical technologies</td>
<td></td>
</tr>
<tr>
<td>MTG29 GreenLight XPS for treating benign prostatic hyperplasia</td>
<td>June 2016</td>
</tr>
</tbody>
</table>
National Institute for Health and Care Excellence

Communications directorate progress report

1. This report sets out the performance of the Communications directorate against our business plan objectives during September and October 2016. These Communications Directorate business objectives are closely aligned to the NICE strategic objectives.

2. The Communications Directorate is responsible for ensuring NICE’s stakeholders know about how NICE’s work can help to improve quality and change practice in health and social care. We help to protect and enhance the reputation of NICE through daily contact with the public, media, parliamentarians and other key groups. And we contribute to ensuring NICE content meets users’ needs and is easily accessible through our website and other channels.
### Table 1 Performance update for September and October 2016

<table>
<thead>
<tr>
<th>Objective</th>
<th>Actions</th>
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</table>
| **1. CONTENT**  
Curate and facilitate high quality content in the outputs from the communication directorate and across NICE (in order to help NICE achieve its high level objective to publish guidance, standards and indicators). | Provide expertise and training to enable teams across NICE to produce quality content. | **Guidance and supporting products**  
In addition to the usual supporting documents for the guideline on mental health problems in people with learning disabilities, the publishing team produced an easy read version explaining the care that people should expect.  
We are collaborating with CHTE teams on new processes for quicker, more efficient working and developing templates for shorter documents.  
**Supporting shared decision making**  
Throughout October we have been working with colleagues in the Public Involvement Programme on proposals for how NICE can support the Shared Decision Making Collaborative’s consensus statement and action plan. We are looking for the most effective options within resources available.  
**Training**  
We ran 2 standard Writing for NICE workshops, and a workshop for the quality standards team focussed on writing concise, informative reports for the committees. |
<table>
<thead>
<tr>
<th>Objective</th>
<th>Actions</th>
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<tbody>
<tr>
<td>Provide communications expertise into the digital transformation project.</td>
<td>We have continued to update and maintain quality statements in the Knowledge Base. With the Centre for Guidelines and Digital Services, we are looking at the benefits and implications of using a system like MagicApp to author guidelines. MagicApp is a flexible and dynamic authoring system that uses structured data, and contains the evidence, rationale for making recommendations and the recommendations themselves.</td>
<td></td>
</tr>
<tr>
<td>Create clear brand guidelines which establish the voice and personality of NICE and govern every aspect of communication from NICE</td>
<td>The External Engagement team is leading a project working jointly with Digital Services to refresh the NICE brand and visual identity. Initial work is underway researching and devising options for the corporate colour palette. Once new corporate colours have been chosen, we will implement the new colour palette across all of NICE’s communications channels and brand assets including the website, intranet, newsletters, Powerpoint etc. A new set of brand guidelines will support the roll-out of the new colour palette, and staff will be updated in the coming months prior to the changes being made. The NICE logo itself will not be changed.</td>
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<tr>
<td>Objective</td>
<td>Actions</td>
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<tr>
<td>Ensure website content is up to date and accurate and deliver a rolling programme of improvements.</td>
<td>New web content</td>
<td>A number of new sections have been created on the website including new information for organisations wishing to re-use our content. Web pages have also been created to support the launch of 2 new quick guides for social care audiences on home care and on oral health in care homes. We also added links to the guides from NICE Pathways. We are continuing our review and update of the overview pages for CHTE guidance. <strong>Top tasks project</strong> We carried out a survey with a wide range of stakeholders to identify the 'top tasks' carried out on the website. 270 responses were received and the results validate qualitative insights that finding guidance is the top task (70%). Finding the recommendations, finding evidence, downloading and printing guidance, and looking at updates also featured highly. Full analysis and a report will be prepared in November.</td>
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<td>Objective</td>
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<tr>
<td>Maintain 100% of guidance in NICE Pathways and continue the programme of continuous improvement.</td>
<td>We continue to maintain 100% of guidance in NICE Pathways. In September and October, we published 3 new pathways, fully updated 9 pathways to bring them into line with current structure and standards, updated 20 pathways to take account of new guidance (for example, adding new health technology guidance), and updated a further 46 pathways to add related pathway links or as maintenance updates.</td>
<td></td>
</tr>
<tr>
<td>Use new online software package such as ‘Shorthand’ to present our new guidance to media and other stakeholders</td>
<td>Through Shorthand, we highlighted NICE’s guidance on domestic violence using the ‘be a lover not a fighter’ shared learning award finalist as a case study.</td>
<td></td>
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<tr>
<td>2 ENGAGEMENT</td>
<td>Lead a project to develop a customer relationship management (CRM) system that can be used across the organisation</td>
<td>Work is underway to update the CRM and develop new functionality to support more proactive stakeholder engagement. A specification is being finalised and a tender process is planned.</td>
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<td>Create a structured and coordinated approach for working with and listening to stakeholders</td>
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<tr>
<td>Develop an internal speaking engagement grid to help improve coordination of senior NICE representatives’ speaking</td>
<td>Speaking engagements are mapped through a grid. We are considering ways to improve intelligence about speaking activities.</td>
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<tr>
<td>commitments</td>
<td>Develop a new interactive online newsletter with content tailored for key audiences</td>
<td>We are currently examining audience analytics for newsletters to help inform both future content and digital platforms for newsletters. NICE News is opened by 28% of the 19,000 recipients (government average of 23%). More than 9% click on a link compared to 3.5% across government.</td>
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<td></td>
<td>Develop personalisation functionality on the NICE website (working with the digital services team) that allows visitors to tailor content to their needs</td>
<td>The discovery phase for the personalisation project is underway.</td>
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<td></td>
<td>Make greater use of social media including creating a Facebook presence and using Twitter to interact directly with audiences</td>
<td>The NICE Facebook page has been active for 3 months. It has gained nearly 800 likes in this time. Our posts reach, on average, 10,000 people a month and receive nearly 2,500 engagements.</td>
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<td></td>
<td></td>
<td>Our follower numbers on Twitter continue to grow. We now have over 110,000 people following the account, up by 3% since the last report. Our tweets were seen over 2.9 million times in September-October, also up by 3% since the previous 2-month period. Our profile page was visited over 28,000</td>
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<td>Objective</td>
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<tr>
<td></td>
<td></td>
<td>times and we were mentioned by users over 2,400 times; this was a slight decrease since the previous two month period. We are continuing to audit our follower activity to ensure we post content at times they are most likely to engage. Top tweets were on our involvement in the Shared Decision Making Collaborative and promotion of our guidance on World Sepsis Day.</td>
</tr>
<tr>
<td></td>
<td>Develop an guidance/issues grid that allows senior management and non-executive members to see ‘at-a glance’ scheduled guidance and the related strategic issues</td>
<td>This working document is updated weekly with forthcoming scheduled guidance, events, and a news diary from the health arms' length bodies.</td>
</tr>
<tr>
<td></td>
<td>Further develop a system to capture audience insights (including Twitter and Website analytics) and provide regular reports to senior management</td>
<td>We are currently developing a tender document to monitor and evaluate media and social media activity relevant to NICE.</td>
</tr>
<tr>
<td>3. ADOPTION and IMPACT</td>
<td>Develop protocol for using graphics and images to help explain guidance and related products</td>
<td>This is being considered within our branding refresh and as part of our social media guidelines.</td>
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Promote NICE's work and help users make the most of our products by providing...
<table>
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<th>Objective</th>
<th>Actions</th>
<th>Update</th>
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<tr>
<td>practical tools and support, using innovative and targeted marketing techniques. Contribute to demonstration of impact though regular evaluation</td>
<td>Develop new online guidance summaries which are short, concise and use infographics and multimedia techniques</td>
<td>Two quick guides on social care topics, home care, and oral health in care homes, were launched in October. Feedback on the guides has been positive and analytics so far indicate people are spending longer reading the online guides than other pages of the website. We are looking producing additional quick guides for other social care topics and as well as for other guidance topics</td>
</tr>
<tr>
<td>Bring content to life by reusing case studies, shared learning examples and other material.</td>
<td></td>
<td>Content across social media and within news and features pages is repurposed and reused to explain and illustrate NICE's work.</td>
</tr>
<tr>
<td>Use a variety of evaluation techniques to assess the impact of our work and to regularly gauge the views of our stakeholders</td>
<td></td>
<td>In September we launched a user survey to capture feedback on the quality of responses sent by the enquiry handling team. 73 responses received so far. 82% rated the information in the response as helpful or very helpful, 87% were satisfied or very satisfied with the response time, 91% thought the response was very easy or easy to understand and 86% said we met or exceeded their expectations of using the enquiry service overall.</td>
</tr>
<tr>
<td>4. PRODUCTIVITY To be effective and efficient and to work better with less</td>
<td>Use HR-developed Workforce Planning Tool to analyse current structure, define future needs and ensure our plans support the achievement of wider corporate objectives</td>
<td>Review of our current structure and future needs to support our objectives has been a core part of planning for the management of change proposals that will be consulted on in</td>
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National Institute for Health and Care Excellence
Communications Directorate Progress Report
Date: 16 November 2016
Ref: 16/107
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<th>Objective</th>
<th>Actions</th>
<th>Update</th>
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<tbody>
<tr>
<td></td>
<td>Develop and begin to roll out efficiencies and cost savings plan that will support the communication needs of the organisation in 2016-2017 and beyond.</td>
<td>We are currently consulting with staff on proposals to make reductions in the external relations and corporate communications team to deliver savings. The publishing team are reviewing the work they do and making changes to take account of the removal of 4 fixed term posts from April 2017.</td>
</tr>
<tr>
<td></td>
<td>Identify efficiencies within the Comms team by reusing content and procuring software that reduces time and effort in editing copy</td>
<td>In September the publishing team introduced an add-in to Word (PerfectIt) that automates some editing tasks. We have set it up to take account of NICE house style. Feedback so far is that it is saving time and improving accuracy.</td>
</tr>
</tbody>
</table>
Other issues

Cancer Drugs Fund

3. Our announcement of the first new drug we recommended to go into the Cancer Drugs Fund (Osimertinib for lung cancer) received a lot of positive coverage. We issued a press release and worked with the Roy Castle Foundation to issue a supportive statement. The Press Association wrote an article which was syndicated online at the Guardian, Mirror and several regional outlets. We also received coverage across national online and print outlets including the Daily Mail, Telegraph, Huffington Post, PMLive and Pharma Times.

Regional Stakeholder Events

4. In September and October the External Engagement Team ran four regional stakeholder roundtable events, each one targeted at a difference NICE audience as follows:

<table>
<thead>
<tr>
<th>Sector</th>
<th>Location</th>
<th>Date</th>
<th>Attendees</th>
<th>Invited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health</td>
<td>Birmingham</td>
<td>20th Sept</td>
<td>25</td>
<td>250</td>
</tr>
<tr>
<td>Integration</td>
<td>Manchester</td>
<td>19th Oct</td>
<td>25</td>
<td>250</td>
</tr>
<tr>
<td>The NHS</td>
<td>London</td>
<td>24th Oct</td>
<td>30</td>
<td>300</td>
</tr>
<tr>
<td>Social Care</td>
<td>Bristol</td>
<td>26th Oct</td>
<td>21</td>
<td>1800</td>
</tr>
</tbody>
</table>

5. We directly invited named stakeholders to attend, plus used our website, twitter and sector newsletters/bulletins (for example Public Health England bulletin and SCIE newsletter) to promote wider attendance at the events.

6. The events featured short presentations from senior NICE staff about our strategy and outputs in each sector, and then attendees took part in 90 minute facilitated roundtable discussions where we asked them key questions.

7. All four events featured lively table discussions and debates, and we captured feedback and insight on our audiences' views toward NICE's work and suggestions for how we could improve our interaction with each audience group.

8. We will be writing up reports from all four events, summarising key issues arising and recommendations for change.
Enquiry handling

9. During September and October we responded to 1736 enquiries. We responded to 13 MP letters and 12 Parliamentary Questions. Nivolumab remains a popular topic in relation to two indications for lung cancer and one for renal cell cancer. There is an ongoing campaign and petition regarding lung cancer which is attracting twitter attention and generating enquiries.

10. We also responded to 22 requests made under the Freedom of Information Act. Information requested varied widely from our expenditure on software to the number of Technology Appraisals and Highly Specialised Technologies suspended and/or not able to be published in financial years from 1999 to 2016 because of company non-submission.

Employee engagement

11. The October edition of NICEnet, ‘a unique perspective’ has been well received by staff. It’s been downloaded 614 times by 412 people. The new digital format is proving popular with people spending longer reading this edition. The average time spent is almost 8 rather than 5 minutes. The most popular feature was the interview with Gill Leng on our change programme.

12. Employee engagement through our intranet, NICE Space continues to grow. There are now 26 active blog streams (up from 20 in July) and there have been more than 250 posts since the site launched.

13. We have supported employee communication and engagement for the Management of Change programmes with new resource areas on NICE Space and regular updates for staff.
### Table 2 Risks identified during September and October: key controls and ratings

<table>
<thead>
<tr>
<th>Risk</th>
<th>Key controls</th>
<th>Risk rating now</th>
<th>Risk rating year end</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to seek feedback from stakeholders in how we work and communicate with them</td>
<td>Regional stakeholder events with key sector stakeholders Use of analytics to monitor and evaluate audience use of products and their views on NICE’s outputs</td>
<td>Green</td>
<td>Green</td>
</tr>
<tr>
<td>Proposals for management of change in the directorate fail to offer efficiency savings or present a viable structure for supporting NICE in the future</td>
<td>Working with SMT, and colleagues in HR, 2020 Group and staff to carefully consider business needs and areas for potential efficiencies</td>
<td>Amber</td>
<td>Green</td>
</tr>
</tbody>
</table>
Appendix 1 Website statistics

14. Statistics for NICE website and Pathways:

- In September and October there were more than 2.5 million sessions on the website and in about 76% of these sessions there was a 'meaningful interaction' such as downloading, sharing a page, following a link etc. Pathways had close to 490k sessions with a meaningful interaction rate of 57%.

- The News section on the website attracted 70,805 new visitors, a slight increase on the previous two months and 40,273 returning visitors.

- The most read news story in September and October was new thresholds for diagnosis of diabetes in pregnancy with 3,445 views over the two months. This story is from February 2015 and is consistently in our top ten most read stories..

- New drugs for diabetes, osimertinib for lung cancer, multimorbidity, harmful sexual behaviour and the TA/HST consultation stories all received more than 2,000 views each over the two months.
National Institute for Health and Care Excellence

Evidence Resources progress report

1. The Evidence Resources directorate comprises three teams which provide a range of functions to NICE:

   - The Digital Services team delivers NICE’s digital transformation programme and maintains all NICE’s digital services.
   - The Information Resources team provides access to high quality evidence and information to support guidance development and other NICE programmes. It also supports the provision of evidence content to NICE Evidence Services and it commissions key items of content made available to the NHS via the NICE Evidence Services.
   - The Intellectual Property (IP) and Content Business Management team manages the range of activities involved in granting permissions to use NICE’s IP and content.

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

3. This report sets out the performance of the Evidence Resources directorate against our business plan objectives during September and October 2016. It also highlights performance against agreed metrics and provides an update on the risks managed within the directorate.

Performance

4. The directorate is making good progress towards completing its agreed objectives for the year. Progress in September and October 2016 is summarised in the table below.
Table 1 Performance update for September and October 2016

<table>
<thead>
<tr>
<th>Objective</th>
<th>Actions</th>
<th>Update</th>
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<tbody>
<tr>
<td><strong>Evidence Information Services</strong></td>
<td>Deliver and continue to improve the suite of digital evidence services and evidence awareness products that constitute the NICE Evidence Services.</td>
<td>• Maintain and continually improve the components services of NICE Evidence Services including introducing new Types of Information (TOI) for Evidence Search and launching the upgraded HDAS federated search service.</td>
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<td>• Manage transition to a smaller portfolio of evidence awareness services.</td>
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<tr>
<td>Put in place arrangements to collaborate with key stakeholder organisations on the provision of evidence services to their users.</td>
<td>Continue to develop NICE’s partnership with Health Education England, by advancing the role of Evidence Services in forming a sustainable, long term bedrock of continuing professional development resources.</td>
<td>HEE and NICE gave a joint presentation at the Chartered Institute for Library and Information Professionals’ (CILIP) Health Libraries Group conference on progress with resource discovery activity and HDAS.</td>
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<td></td>
<td>Continue to explore arrangements for information sharing and interoperability of content with providers of social care and public health information. This includes collaboration around suitable vocabularies and information standards.</td>
<td>Meeting held by strategic leads at HEE and NICE to explore the future of knowledge delivery. This will be followed up by a workshop.</td>
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<td></td>
<td>Identify opportunities for syndicating suitable NICE Evidence Services across the sector.</td>
<td>Agreed use of virtual meeting tools with NHS Digital to create a forum for taxonomists across ALBs. Initial list of invitees collated.</td>
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<td></td>
<td></td>
<td>No further progress this period.</td>
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</table>

**Guidance Information Services**

<table>
<thead>
<tr>
<th>Develop information services capacity and support for new programmes of work</th>
<th>Develop information services support and identify capacity for new programmes of work including the cancer drugs fund (CDF), rapid evidence summaries (up to 12 per year) and commissioning support documents (up to 25 per year).</th>
<th>Completed for CDF and rapid evidence summaries in Q1.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Determine and implement any change to requirements for information services support as a result of the Accelerated Access Review.</td>
<td>Ongoing – Review now published and implications for NICE are being considered.</td>
</tr>
</tbody>
</table>
### Evidence Resources Directorate Progress Report

**Date:** 16 November 2016  
**Ref:** 16/108

<table>
<thead>
<tr>
<th><strong>ITEM 13</strong></th>
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| • Sponsor and provide expert stakeholder input to the evidence management project (part of the guidance development project), with specific focus on the reference management, literature sifting and document supply functions.  
• Ongoing – the project is now in the development phase. |
| **Explore new methods and approaches, and where suitable, deliver service improvement in the provision of Information Services across NICE.**  
• Continue to monitor the delivery of savings from using the Royal Society of Medicine's (RSM) document delivery service.  
• Continue to monitor the delivery of savings from requesting copyright cleared journal articles under the new NHS CLA (Copyright Licensing Agency) Licence Plus.  
• Savings as expected. No action needed.  
• Savings as expected. No action needed. |

### Digital Services

| **Deliver digital service projects in line with the agreed investment priorities for 2016/17 and NICE’s business plan objectives.**  
• Support the establishment and prioritisation of projects using the NICE project lifecycle and deliver agreed projects for the relevant strands of the NICE Digital Strategy.  
• As mentioned above, HDAS has now been launched and the AIMS procurement work completed.  
• Evidence Management Document Supply project is in the final phase of development and on target to launch later this month.  
• BNF Feed has had a ‘soft launch’ with communications out to stakeholders to publicise more widely later this month.  
• Work is in progress in collaboration with the Communications team to revise the corporate branding for the NICE website and digital services.  
• Scientific Advice have commenced user testing on the MedTech tool which will provide a consultancy service to companies taking new medical technologies to market. |

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National Institute for Health and Care Excellence  
Evidence Resources Directorate Progress Report  
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| Maintain operational service delivery and implement service improvements based on user insights and service performance against key performance indicators. | • Maintain the NICE Digital Services to agreed service levels (in terms of service availability and time to defect resolution).  

• Refresh digital services performance indicators in line with business priorities and user insights.  

• Continue to translate data and observations about the performance of NICE Digital Services into actionable improvement proposals.  

• In response to the above, continuously improve NICE Digital Services in line with agreed investment priorities. | • NICE Digital Services continue to fall within the generic agreed service levels for availability. Plans are in place to further improve the resilience and stability of the services through a programme of operational stability improvements.  

• A programme of refreshing the current NICE performance dashboards has been agreed and is now in progress.  

• An initial draft process for managing insights emerging from the NICE Digital Service performance dashboards has been developed. Further work is in train to ensure this interfaces effectively with the user experience and design processes.  

• 83 defects were closed during this period with 48 remaining open.  

• 39 CCRs were completed during this period with 46 remaining open. | • Recruitment of 2 new User Experience Research Analysts to complete team of 6. Workshop to be held in November to agree needs from the improved UX team and capability. Plan to be drafted in November.  

• Recruitment of a Data Architect to the Information Architecture & Search team. |

| Continue to build capacity and capability across the Digital Services teams. | • Develop NICE’s user experience (UX) testing capability and capacity.  

• Develop semantic capability to support our products and platforms. |
<table>
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<tr>
<th>Item 13</th>
<th>Evidence Resources Directorate Progress Report</th>
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<tbody>
<tr>
<td>Date: 16 November 2016</td>
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</table>

- Develop a ‘content’ model to represent the relationships between NICE products and their components.
- Initiated enhancements to the Knowledge Base platform to ensure concepts and components of content can be uniquely identified and managed.
- Product taxonomy developed and implemented across existing digital systems.
- Continuing process and modelling work to improve version control and the communication of updates to consumers of content.
- This is being investigated alongside updating other tools and software used in Digital Services to enable better collaborative working and more automated reporting on work in progress.
- Complete.

- Put in place an agile project management tool that enables risks and issues within projects to be managed effectively.
- Improve the resilience of NICE Digital Services and ensure an effective tested disaster recovery capability is in place as part of the new hosting arrangements.
- Complete.

- Continue to improve the productivity and effectiveness of the NICE Digital Services teams.
- Continue to reduce the end to end delivery time of small changes to NICE Digital Services ensuring shorter cycles of improvement and learning.
- Improvements to the Change Management process for handling continuous improvement to digital services has reduced the backlog of Change Requests (CRs) handled monthly by 25%; in effect, although numbers of CRs raised is remaining constant at 16 per month, we are fixing more CRs, more quickly and thus reducing the backlog.
- Ensure resources are effectively deployed on projects. This includes improving scheduling of suitable resource across the project portfolio and more closely monitoring project 'burn charts' against plan.

- Robust process for benefits forecasting and tracking put in place to support new digital services implementation and ensure investment is realised.

- Recruit permanent staff in line with budget assumptions. Monitor success of recruitment and adjust budget assumptions accordingly.

- Implement the new hosting solutions across all NICE Digital Services.

- A new resource tracking tool has been implemented which enables us to schedule each person against ongoing work. A cross-department working group meets weekly to focus on resourcing and ensure that the needs of both the immediate and longer-term future can be met to resource our projects and live services effectively.

- Work commenced to focus on the project ‘Concept’ stage to ensure the business value proposition is robust and justifies ongoing investment in developing the proposed digital service.

- 2 new staff have been recruited to support User Experience design and research and 1 new Data Architect as noted above.

- No leavers in the period.

- Complete.

Promote collaboration on digital initiatives and content strategy across ALBs and with academic establishments and other external stakeholders

- Support NHS Digital in the development and adoption of common standards, taxonomies and language across ALBs.

- Maintain an ongoing relationship with the nhs.uk project and promote joint working on digital initiatives including where appropriate local collaboration in Manchester.

External collaboration work has focused on the following activities:

- Development of an early concept of 'guidance as a platform', exploring new means of engaging and collaborating with local health systems around the use of our products.

- Approval from SMT to develop a data science strategy for NICE. Data science seeks to extract knowledge or insights from large data sets in various forms.
Promote the further understanding of strategic developments in evidence management and their applications for NICE.

Promote the distribution of NICE content through the most effective channels for users and decision makers including through decision support and other third party systems.

We are working closely with UCL (EPPI) to develop improvements in the evidence management processes and integrate them into the Transforming Guidance Programme, e.g. improved sifting of evidence and data extraction.

We continue to strengthen external collaboration with Cochrane Collaboration, MagicApp and UCL in our evidence and guidance development to align our programmes of work. Greater understanding and alignment was realised at the Cochrane Colloquium in Seoul.

### IP and Content Business Management

Develop a strategic plan to grow the commercial activity over the next 10 years. This should explore, for example, offering advice, digital protocols, assessments or a subscription service to other countries.

- Identify and evaluate the options for increasing income from non-Grant-in-Aid sources, inside the UK and beyond.
- Evaluate the options for the most effective vehicle for delivering this activity, by June 2016.
- Prepare business cases for each element of the programme by December 2016.

Since these objectives were agreed, the responsibility for completing the agreed action has changed as follows:

- The donor-funded International Decision Support Initiative work transferred to Imperial College in September 2016.
- The business model options for how to develop Scientific Advice activities are being pursued by the Scientific Affairs team in the Centre for Health Technology Evaluations.
- The remaining international engagement and content re-use activities are covered below.
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| Actively pursue revenue generation opportunities associated with the use and re-use of NICE content and quality assurance. | • Formalise the establishment of the business development team in Evidence Resources.  
• Act as a coordination desk for enquiries associated with use and reuse of NICE content and quality assurance.  
• Develop a robust framework and the necessary tools to support a range of products and services associated with the use and re-use of NICE content and quality assurance. This will include a pricing model, licenses and marketing material.  
• Grow revenue stream associated with the use and re-use of NICE content to at least double the size of the revenue stream compared with 2015/16.  
• Continue to log and, where suitable, re-direct enquiries associated with the other commercial opportunities available to NICE. |
| Continue to encourage the use of NICE content through the use of the NICE Syndication service. | • Update the NICE’s Syndication offering in line with other use and re-use of content services of NICE.  
• Continue to promote the use of NICE content by other ALBs using the NICE Syndication service. |
| Complete. | • Complete. |
| | • The NICE UK Open Content Licence was launched on the 17th October. The NICE Content Assurance Service which is a proofing and editing service for third parties has been formalised. International services, licences and the accompanying pricing model are in development.  
• 2015/16 income was £46,000. The 2016/17 income to date is £47,617. The introduction of the NICE UK Open Content Licence is creating a shortfall for the second half of the year which needs to be offset with new international revenues.  
• Ongoing. |
| | • The syndication licence is being updated to reflect the NICE UK Open Content Licence and International Licences.  
• No further progress this period. |
### Directorate wide

| Subject to the release of budget for this programme of work, support the implementation of the National Information Board (NIB) ‘Framework for Action’ and specifically contribute to the development of a framework for the assessment of digital applications. | Provide joint leadership, alongside Public Health England, to a multi-agency working group also involving NHS England and NHS Digital.  
Secure the resources necessary for NICE to be able to make a meaningful contribution to the work. Subject to adequate resourcing, agree a programme of work with key partners for 2016/17 and deliver against the agreed work plan.  
Contribute expertise to the development of proposals to assess the effectiveness of digital applications to include an evidence guide and the development of a new evidence evaluation process for digital health technologies. | The formal leadership of the programme transferred to NHS Digital in June 2016.  
The programme of work of NICE is agreed as part of a series of investment justifications (IJ). IJ1 approved for Q2. IJ2 was agreed in principle and submitted to cover for Q3 and Q4.  
CHTE will be piloting the development of Health App Briefings during Q3 and Q4. |
|---|---|---|
| Implement the first year of a three year strategy to manage the reduction in the Department of Health’s Grant-In-Aid funding and plan for a balanced budget in 2017-18. | Establish how to deliver the saving target allocated to the Evidence Resources directorate.  
Conduct management of change exercises with consultations to complete by the end of the summer in accordance with a schedule agreed and monitored by the SMT.  
Review and renegotiate supplier contracts in line with savings target and schedule agreed and monitored by the SMT. | Completed Q1.  
Completed during September 2016. Two staff at risk of redundancy have been redeployed into fixed term contracts and a third has been redeployed into a permanent post.  
Negotiation with suppliers is in progress. |
5. The performance of the NICE Evidence Services is measured monthly against the following metrics.

- The first metric is ‘sessions’ to the site, which is the number of visits to a website within a date range.
- 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 the ‘% of returns within 10 days’ is provided, 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.

6. Key developments in the last two months can be observed in Figure 1 below and include:

- October was a strong month in terms of growth for key services.
- The drop in sessions in HDAS is due to the new website going live on 17th October.
- The percentage of meaningful interactions and returning sessions seems stable apart from HDAS (probably due to the new website going live).
- The services with the highest percentage of loyal visitors (returning within 10 days) were NICE’s apps (BNF with 85%, BNFc with 80% and Guidance with 52%) followed by CKS (54%).

7. The reporting for NICE Apps follows the same performance reporting model. Performance from the last two months is available in Figure 2 below.
Figure 1 NICE Evidence Services performance over time

**Evidence Search**
- 400,431 sessions
- 74% meaningful interactions
- 21% of sessions returning within 10 days

**BNF**
- 530,204 sessions
- 38% meaningful interactions
- 33% of sessions returning within 10 days

**BNFc**
- 66,589 sessions
- 44% meaningful interactions
- 45% of sessions returning within 10 days
Figure 2 NICE apps performance over time

**BNF**
- 444,565 sessions
- 76% meaningful interactions
- 85% of sessions returning within 10 days

**BNFc**
- 96,217 sessions
- 74% meaningful interactions
- 80% of sessions returning within 10 days

**Guidance**
- 49,339 sessions
- 52% of sessions returning within 10 days
Risks

8. There are 5 risks in the high level risk register associated with the Evidence Resource directorate. None was identified during this reporting period and the risk rating for these 5 risks remained the same over the period.

9. Progress is being made with putting in place the controls to mitigate a risk to the pursuit of revenue generation opportunities associated with the use and re-use of NICE content and quality assurance, including internationally. The current risk is captured as: ‘NICE dilutes its new income generation opportunities by making unconnected agreements about the provision of products and services to 3rd parties’. As reported in Table 1, progress is being made with aligning business propositions associated with IP and content reuse across NICE and with developing corresponding licensing material. A new IP and Content Management group now meets monthly involving a cross-section of NICE staff.

10. A new NICE digital product failed to pass a Department of Health (DH) ‘digital service assessment’ gateway in September 2016. This led to new actions being taken to mitigate this risk: ‘Delays in obtaining DH & Government Digital Services approvals for projects and continuous improvement activity negatively impacts on digital project delivery and internal/external commitments’. These new actions include improving the scheduling and recording of user engagement and UX activity and improving the preparation of the service assessment meeting itself including better reflecting how NICE’s overall digital services structure supports individual projects (unlike for projects being delivered by an external agency). The failed service assessment will be re-sat before the end of Q3.

11. The risk associated with the delivery of the NIB app assessment work is increasing as further change to the governance of the cross-agency programme have been introduced. The risk is mitigated for NICE as follows: NICE is pushing for clarity on which agency is to provide cross-agency programme leadership and management function. We have submitted and seeking the sign off of NICE’s second investment justification to cover NICE’s related costs in Q3 and Q4. Finally work will start in November to pilot the development of a couple of Health App Briefings by March 2016 which will demonstrate the contribution from NICE.
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
AUDIT and RISK COMMITTEE

Unconfirmed minutes of the meeting held on 13 October 2016 in London and VC to Manchester

Present
Jonathan Tross, Non Executive Director (Chair)
Linda Seymour, Non Executive Director
Bill Mumford, Non Executive Director
Tim Irish, Non Executive Director

In attendance
Andrew Dillon, Chief Executive
Ben Bennett, Business Planning and Resources Director
David Coombs, Associate Director Corporate Office
Natalie Sargent, Head of Financial Accounting, Finance
Barney Wilkinson, Associate Director Procurement & IT
Catherine Wilkinson, Associate Director Finance & Estates
Julian Lewis, Governance Manager
Andrew Jackson, NAO
Mark Wilson, NAO
Jeremy Nolan, DH
Wajid Shafiq, DH
Christine Carson, Programme Director - NICE Centre for Guidelines (for agenda item only)

APOLOGIES FOR ABSENCE
None

DECLARATIONS OF INTEREST
1. Tim Irish was formally welcomed as a new committee member, as well as new NAO colleagues Andrew Jackson and Mark Wilson.
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, in particular
   • That Chris Carson will be addressing the Committee later in the meeting,
   • The new format of the Directors Report to cover any relevant risk issues,
   • The new process is in place for tracking audit recommendations.
5. In relation to the action point on MOUs the Committee noted that these were somewhat of a miscellany and suggested (although not a priority) that they might be reviewed at some stage to establish which are important (e.g. the developing relationship with NHSE and those that are dormant.

Action: BW

RISK MANAGEMENT

Centre for Guidelines

6. Chris Carson provided background information on guideline production for those new to NICE and then talked about the risks facing the Centre.

7. The Centre will at any time be working on 65 guideline slots, incorporating Social Care and Public Health guidance, which is currently being transferred into the Centre. Early in the year, a new contract started which replaced the previous four external contracts for supporting guideline production. The risks of moving from 4 contracts to 1 were managed by a series of steering committees and integration over a period of time, a staged approach over the course of the year. The move to the new structure under RCOG management had gone well with only two redundancies and maintenance of continuity of work, including in the subject area previously based in Cardiff, with the help of home working.

8. The Management of Change (MOC) programme currently taking place in the directorate is bringing together all the guidelines into one directorate. The MOC is a risk, as a change in the number of staff but also the methods of working. It requires lots of planning to ensure it is ‘business as usual’ during the changes. Some of the controls put in place to manage the risks are:

   - The Director and an Associate Director to work exclusively on the MOC, which leaves other senior staff free as ‘business as usual’.
   - Staff morale is managed on 1:2:1 basis.
   - Key players meet regularly, with weekly meetings in some instances.
   - The MOC will be introduced in phases.

9. The products of the directorate are changing. Over time the weight of the portfolio will change from guidelines to updates. This will mean that the directorate is more efficient whilst maintaining output.

10. The professionals on the committees are changing – it is more difficult for staff to be released from their practices/employment to sit on NICE committees. However the Centre continues to make sure that what we publish is credible and usable, and relevant to the people who are going to use it.

11. The Committee noted the calm and managed approach to the risks identified, taking considerable assurance from how it is managed.
Risk Register

12. Julian Lewis presented the paper.

13. In relation to the overview statement of risk, the Committee noted that the tensions within the system are becoming more acute with financial pressures and are shifting. It also noted the significant risk of Brexit on licensing, and that Tech Appraisals recharging is also linked to Brexit. This should be covered within the risk register.

14. The Committee requested that the overarching statement of risk be refreshed at some point, and that affordability and relationship and reputational issues with Pharma and public interest groups should be included. On the more detailed risk register, the Committee reiterated their view that governance continuity risks should be included as well as the impact of Brexit and the difficulties in recruitment to GDG committees in terms of employers’ willingness to release professionals’ time (in particular for nurses and midwives). They noted that NICE would continue to have international activities, that in relation to item 13 the line of risk and action did not match easily to the stated objective, and in relation to item 15 on guidance to help the service make savings a paper was coming to the Board in November. In relation to staffing risks arising from the MOC process, the Committee also noted that the HR/2020 report will be discussed at the October board meeting.

Action: JL/AD

Risk Management Policy

15. The Committee discussed the policy. They endorsed the risk appetite statement and suggested that consideration be given to adding a fourth item on the need to comply with government financial and other regulatory control requirements while accepting the need for proportionality in the face of constraints being placed on NICE. They found the guidance for staff in Appendix A helpful and noted the expectation that further action to mitigate risk should have a completion date.

Action: BB

16. The Committee suggested that the risk appetite definition be shared with the Board, perhaps as part of the minutes of this meeting.

Action: AD

INTERNAL AUDIT

Audit Plan

17. The plan was formally noted.

Progress report

18. Jeremy Nolan presented the report. Work was slightly behind schedule but it is anticipated that the reports on Payroll, Strategic Financial Management and
Risk Assurance will be taken to the next meeting, with Contract Management and Technology Appraisal to follow at the March meeting.

19. The Committee noted the report and reminded auditor colleagues that it is helpful to receive reports spread evenly throughout the year.

Key Financial Controls audit

20. The Committee reviewed the report of the internal audit on Key Financial Controls and confirmed they were content with the management judgement not to implement the low rated recommendation on the creation of purchase orders.

CONTRACT WAIVERS

DSU Waiver

21. Barney Wilkinson presented the waiver. The Committee noted, as they had before, the impact of a limited market for providers of evidence analysis support. They took assurance from the fact that NICE periodically review whether the service is still required and that we are satisfied with the value received. In this case the Committee also took assurance on costs being driven down.

Waivers report

22. Barney Wilkinson presented the report, which was noted. The Committee noted that the need for a particular support system was reviewed and challenged periodically.

AUDIT RECOMMENDATIONS LOG

23. The Committee discussed the report. They welcomed the new more structured format and expressed appreciation of its development. They suggested that items that are substantially complete and which have been incorporated into ‘business as usual’, be marked as complete and removed from the log. It further suggested that reasons for completion date changes be included. In some cases there would be good reason why external events had altered the need for action; for example the foreign exchange recommendations, although rated red, had been largely overtaken by the decision to transfer the work of NICE International where the exchange exposure lay.

Action: JL

USE OF SEAL

24. The seal was not used.
INFORMATION GOVERNANCE ANNUAL REPORT

25. Julian Lewis present the report, highlighting that there is an issue with NHS Digital releasing information to NICE and to others. The biggest challenge is the different risk levels between the two organisations.

26. The Committee noted that staff refreshers are to continue throughout the year and expressed their appreciation that there have been no data breaches this year.

ANY OTHER BUSINESS

27. Andrew Dillon thanked Jonathan Tross for his many years of service as chair and for providing appropriate challenge. The Committee recorded that this was Jonathan’s last meeting and that his successor is yet to be appointed.

28. Jonathan Tross thanked David Hunter and Linda Seymour in particular, as well as other committee attendees for their support. He further added that he enjoyed his time as chair of the ARC and the emphasis that it had been possible to place on business issues and risks as well as on the formal control framework. He expressed appreciation on behalf of the Committee for the support and engagement they had received from the CEO, the excellent support from the team under Ben Bennett and from auditors.

29. The chair recorded that it was also Linda Seymour’s and David Hunter’s last meeting. The Chair thanked them for their contribution and wished Tim Irish and those yet to be appointed well.

30. There was no other business.

PRIVATE DISCUSSION

31. As normal the Committee briefly reviewed progress with auditors without officers present. The discussion noted the continuity challenge (arising from the appointment process outside NICE’s control) that at the next meeting only one member, Tim Irish himself recently appointed, would remain from the current committee.

Future meeting dates

25 January 2017  10:30am
26 April 2017  2pm
21 June 2017  2pm
25 October 2017  2pm