

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# **PUBLIC BOARD MEETING**

Wednesday 20 November 2019 at 1.30pm at Great Ormond Street Hospital, Holborn, London WC1N 3JH

# **AGENDA**

| 19/095 | Apologies for absence To receive apologies for absence                                                                                                                                                                                                                               | (Oral)   |
|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| 19/096 | <b>Declarations of interests</b> To declare any new interests and consider any conflicts of interest specific to the meeting                                                                                                                                                         | (Item 1) |
| 19/097 | Minutes of the last Board meeting To approve the minutes of the Board meeting held on 18 September 2019                                                                                                                                                                              | (Item 2) |
| 19/098 | Matters arising To consider matters arising from the minutes of the last meeting                                                                                                                                                                                                     | (Oral)   |
| 19/099 | Chief Executive's report To receive the Chief Executive's report Andrew Dillon, Chief Executive                                                                                                                                                                                      | (Item 3) |
| 19/100 | Finance and workforce report To receive the report Ben Bennett, Director, Business Planning and Resources                                                                                                                                                                            | (Item 4) |
| 19/101 | Widening the evidence base: the use of broader data and applied analytics in guidance development To approve the proposals Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate / Alexia Tonnel, Director, Evidence Resources Directorate | (Item 5) |
| 19/102 | Response to consultation on the draft NICE Principles To approve the principles following the public consultation Andrew Dillon, Chief Executive                                                                                                                                     | (Item 6) |
| 19/103 | Indicator process guide update 2019 To approve the updates to the process guide following the public consultation Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate                                                                    | (Item 7) |

TITLE: BOARD AGENDA DATE: 20 November 2019

| 19/104 | NICE impact report: lung cancer To review the report Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate                             | (Item 8)  |
|--------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 19/105 | A new director post for Science, Evidence and Analytics To approve the proposals Professor Gillian Leng, Deputy Chief Executive and Director, Health and Social Care Directorate | (Item 9)  |
| 19/106 | NICE Charter To approve the amendments to the Charter following its annual review Jane Gizbert, Director, Communications                                                         | (Item 10) |
| 19/107 | Audit and Risk Committee To receive the unconfirmed minutes of the meeting held on 4 September 2019 Dr Rima Makarem, Chair, Audit and Risk Committee                             | (Item 11) |
| 19/108 | Board Chair and Vice Chair To appoint an interim Vice Chair Andrew Dillon, Chief Executive                                                                                       | (Item 12) |
| 19/109 | <b>Directors' reports for consideration</b> Health and Social Care Directorate                                                                                                   | (Item 13) |
|        | Directors' reports for information                                                                                                                                               |           |
| 19/110 | Centre for Guidelines                                                                                                                                                            | (Item 14) |
| 19/111 | Centre for Health Technology Evaluation                                                                                                                                          | (Item 15) |
| 19/112 | Communications Directorate                                                                                                                                                       | (Item 16) |
| 19/113 | Evidence Resources Directorate                                                                                                                                                   | (Item 17) |
| 19/114 | Any other business To consider any other business of an urgent nature                                                                                                            | (Oral)    |

**Date of the next meeting**To note the next public Board meeting will be held on 29 January 2020 at the All Nations Centre, Cardiff, CF14 3NY

TITLE: BOARD AGENDA DATE: 20 November 2019

# **Interests Register – Board and Senior Management Team**

# **Board Members**

| Name                | Role with NICE            | Description of interest                                                                                                                                                                                                                                                                                                                                | Interest<br>arose | Interest<br>ceased |
|---------------------|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|
| Sir David Haslam    | Chair                     | Patron of Cry-Sis.                                                                                                                                                                                                                                                                                                                                     | 1986              |                    |
|                     |                           | Visiting Professor in Primary Health Care.de Montfort University, Leicester.                                                                                                                                                                                                                                                                           | 2000              |                    |
|                     |                           | Professor of General Practice, University of Nicosia.                                                                                                                                                                                                                                                                                                  | 2014              |                    |
|                     |                           | Contributor to Practitioner Medical Publishing, for writing a monthly column in The Practitioner.                                                                                                                                                                                                                                                      | 1996              |                    |
|                     |                           | Chair - Kaleidoscope Health & Care Advisory Board.                                                                                                                                                                                                                                                                                                     | 2016              |                    |
|                     |                           | Adviser to Vopulus Ltd.                                                                                                                                                                                                                                                                                                                                | 2016              |                    |
|                     |                           | Member of Faculty of Healthcare Leadership Academy.                                                                                                                                                                                                                                                                                                    | 2016              |                    |
|                     |                           | Patron - The Louise Tebboth Foundation.                                                                                                                                                                                                                                                                                                                | 2017              |                    |
|                     |                           | Member of Board of Directors, State Health Services Organisation, Nicosia, Cyprus.                                                                                                                                                                                                                                                                     | 2018              |                    |
| Prof Sheena Asthana | Non-Executive<br>Director | Trustee of Change Grow Live (charity).                                                                                                                                                                                                                                                                                                                 | 2017              |                    |
|                     |                           | Member of the Advisory Committee on Resource Allocation (NHS England).                                                                                                                                                                                                                                                                                 | 2017              |                    |
|                     |                           | Professor of Health Policy, University of Plymouth                                                                                                                                                                                                                                                                                                     | 2004              |                    |
| Prof Martin R Cowie | Non-Executive<br>Director | Consultancy payments for the membership of Steering committee/DSMBs/Endpoint committees related to Global Clinical Trials or Registries: XATOA, COMPASS, COMMANDER-HF (Bayer); SHIFT, QUALIFY, OPTIMIZE (Servier); RELAX-Region Europe, PARALLAX, VERIFY (Novartis); COAST (Abbott); COAST-AHF (Neurotronik); FIRE1 system (FIRE1); SERVE-HF (ResMed). | 2016              |                    |
|                     |                           | Associate Editor honoraria from Heart (BMJ Publications) and Journal of the American College of Cardiology.                                                                                                                                                                                                                                            | 2016              |                    |

| Name                          | Role with NICE                                         | Description of interest                                                                                                                                                                                                         | Interest<br>arose | Interest<br>ceased |
|-------------------------------|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|
|                               |                                                        | Research grants to Imperial College London to support investigator-led research projects (ResMed; Bayer; Abbott; Boston Scientific; NIHR; British Heart Foundation).                                                            | 2016              |                    |
|                               |                                                        | Fellowships of the Royal College of Physicians of London and Edinburgh, and of the European Society of Cardiology, the Heart Failure Association of the European Society of Cardiology, and the American College of Cardiology. | 2016              |                    |
|                               |                                                        | Chair of the Digital Committee of the European Society of Cardiology, and Member of the Digital Committee of the British Cardiovascular Society.                                                                                | 2016              |                    |
|                               |                                                        | Member of the Advocacy Committee of the European Society of Cardiology.                                                                                                                                                         | 2016              |                    |
|                               |                                                        | Member of the Medical Advisory Board of the patient charity: the Pumping Marvellous Foundation.                                                                                                                                 | 2016              |                    |
|                               |                                                        | Trustee of the Atrial Fibrillation Association (patient charity).                                                                                                                                                               | 2019              |                    |
|                               |                                                        | Adviser, BMJ Best Practice.                                                                                                                                                                                                     | 2019              |                    |
| Elaine Inglesby-<br>Burke CBE | Non-Executive<br>Director                              | Chief Nursing Officer, Northern Care Alliance NHS Group (Salford Royal NHS Foundation Trust and Pennine Acute NHS Trust).                                                                                                       | 2004              |                    |
|                               |                                                        | Board Member – AQuA (Advancing Quality Alliance).                                                                                                                                                                               | 2012              |                    |
|                               |                                                        | Professional Advisor (Secondary Care) Governing Body – St Helens CCG.                                                                                                                                                           | 2014              | 2019               |
|                               |                                                        | Trustee – Willowbrook Hospice, Merseyside.                                                                                                                                                                                      | 2007              |                    |
| Prof Tim Irish                | Non-Executive Director and Senior Independent Director | Life science assets held in a blind trust and managed by an independent trustee                                                                                                                                                 | 2015              |                    |

| Name            | Role with NICE            | Description of interest                                                                                                                     | Interest<br>arose | Interest<br>ceased |
|-----------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|
|                 |                           | Professor of Practice, King's College London's School of Management / Business and a paid consultant to King's Commercialisation Institute. | 2017              |                    |
|                 |                           | Non-Executive Director, Life Sciences Hub Wales Ltd.                                                                                        | 2017              | 2019               |
|                 |                           | Chairman and Non-Executive Director, Quirem Medical BV Supervisory Board.                                                                   | 2015              |                    |
|                 |                           | Non-Executive Director, Fiagon AG.                                                                                                          | 2017              |                    |
|                 |                           | Non-Executive Director, eZono AG.                                                                                                           | 2018              |                    |
|                 |                           | Non-Executive Director, Feedback plc.                                                                                                       | 2017              |                    |
|                 |                           | Non-Executive Director, Styrene Systems Ltd.                                                                                                | 2017              | 2019               |
|                 |                           | Board Member, Pistoia Alliance Advisory Board.                                                                                              | 2017              | 2019               |
|                 |                           | Non-Executive Director, Pembrokeshire Retreats Ltd.                                                                                         | 2006              |                    |
|                 |                           | Non-Executive Director, ImaginAb Inc.                                                                                                       | 2019              |                    |
|                 |                           | Non-Executive Director, Rutherford Health Plc.                                                                                              | 2019              |                    |
| Or Rima Makarem | Non-Executive<br>Director | Audit Chair & Non-Executive Director, University College London Hospitals NHS Foundation Trust (UCLH).                                      | 2012              |                    |

| Name           | Role with NICE            | Description of interest                                                        | Interest<br>arose | Interest<br>ceased |
|----------------|---------------------------|--------------------------------------------------------------------------------|-------------------|--------------------|
|                |                           | Chair, National Travel Health Network & Centre (NaTHNaC).                      | 2015              |                    |
|                |                           | Trustee at UCLH Charity.                                                       | 2013              |                    |
|                |                           | Independent Council Member at St George's University of London.                | 2016              |                    |
|                |                           | Non-Executive Director and Audit Committee Chair, House of Commons Commission. | 2018              |                    |
|                |                           | Non-Executive Director, The Hillingdon Hospitals NHS Foundation Trust.         | 2019              | 2019               |
|                |                           | Lay Member, General Pharmaceutical Council.                                    | 2019              |                    |
| Tom Wright CBE | Non-Executive<br>Director | Chief Executive, Guide Dogs.                                                   | 2017              |                    |
|                |                           | Trustee, Doteveryone charity.                                                  | 2017              |                    |

# Senior management team

| Name                          | Role with NICE                                                      | Description of interest                                                                                     |      | Interest ceased |
|-------------------------------|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|------|-----------------|
| Sir Andrew Dillon Chief Execu |                                                                     | Trustee, Centre for Mental Health charity.                                                                  | 2011 |                 |
|                               |                                                                     | Visiting Professor at Imperial College London.                                                              | 2016 |                 |
| Ben Bennett                   | Director Business<br>Planning and<br>Resources                      | None.                                                                                                       |      |                 |
| Meindert Boysen               | Director<br>Centre for Health<br>Technology<br>Evaluation           | Member of the Board of Directors for the International Society for Pharmacoeconomics and Outcomes Research. | 2017 |                 |
|                               |                                                                     | Member of the International Advisory Panel for the Agency for Care Effectiveness (ACE) in Singapore.        | 2019 |                 |
| Paul Chrisp                   | Director<br>Centre for Guidelines                                   | Spouse works in medical communications offering services to a range of pharmaceutical companies.            | 2009 |                 |
| Jane Gizbert                  | Director<br>Communications                                          | Non-Executive Director Tavistock and Portman NHS Mental Health Trust.                                       | 2014 | 2019            |
| Prof Gillian Leng             | Deputy Chief<br>Executive and Health<br>and Social Care<br>Director | Honorary Librarian and Trustee at the Royal Society of Medicine.                                            | 2013 |                 |
|                               |                                                                     | Editor of the Cochrane EPOC Group.                                                                          | 2012 |                 |
|                               |                                                                     | Visiting Professor at the King's College London.                                                            | 2012 |                 |
|                               |                                                                     | Association Member BUPA.                                                                                    | 2013 | 2019            |
|                               |                                                                     | Chair - Guidelines International Network (GIN).                                                             | 2016 |                 |

| Name          | Role with NICE                 | Description of interest                                   | Interest<br>arose | Interest<br>ceased |
|---------------|--------------------------------|-----------------------------------------------------------|-------------------|--------------------|
|               |                                | Spouse is an Executive Director at Public Health England. | 2013              |                    |
| Alexia Tonnel | Director<br>Evidence Resources | None.                                                     |                   |                    |



# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Public Board Meeting held on 18 September 2019 in the Town Hall, Sheffield, S1 2HH

### Unconfirmed

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

Sir David Haslam Chair

Professor Angela Coulter Non-Executive Director Elaine Inglesby-Burke Non-Executive Director Dr Rima Makarem Non-Executive Director Tom Wright Non-Executive Director

# **Executive Directors**

Sir Andrew Dillon Chief Executive

Ben Bennett Business Planning and Resources Director Professor Gillian Leng Health and Social Care Director and Deputy

Chief Executive

Alexia Tonnel Evidence Resources Director

# Directors in attendance

Meindert Boysen Centre for Health Technology Evaluation Director

Paul Chrisp Centre for Guidelines Director
Jane Gizbert Communications Director

<u>In attendance</u>

Elaine Repton Corporate Governance & Risk Manager (minutes)

### 19/077 APOLOGIES FOR ABSENCE

 Apologies for absence were received from Professor Sheena Asthana, Professor Martin Cowie and Professor Tim Irish.

# 19/078 DECLARATIONS OF INTEREST

2. The declared interests were noted, and it was confirmed there were no conflicts of interest relevant to the meeting.

### 19/079 MINUTES OF THE LAST MEETING

3. The minutes of the Board meeting held on 17 July 2019 were agreed as a correct record.

# 19/080 MATTERS ARISING

- 4. The Board reviewed the actions arising from the public Board meeting held on 17 July 2019 and noted that:
  - 52% of staff appraisal forms had been completed and returned to the HR Team, although data in the staff survey showed 85% of respondents said they did have an appraisal last year. Ben Bennett advised the Board that there is likely to be significant underreporting in this data. The outstanding paperwork will continue to be requested from line managers. The Board noted that the planned move to an e-appraisal system next year (through the electronic staff record), will streamline the process and hopefully improve completion rates.
  - the Board's request to the Care Quality Commission (CQC) to consider incorporating NICE guidance into their key lines of enquiry where appropriate, had been fed back.

### 19/081 CHIEF EXECUTIVE'S REPORT

- 5. Andrew Dillon presented his report which provided an update on the main programme activities to the end of August and summarised the financial position at the end of July 2019. Performance against the main programme outputs showed medtech innovation briefings (MIBs) below target but there were no issues of concern to report and the year-end target was expected to be achieved.
- 6. The Board received the report.

# 19/082 FINANCE REPORT

- 7. Ben Bennett presented a report on the financial position at 31 July 2019 noting a current £0.8m underspend. The full-year forecast is a break-even position. Income from Technology Appraisals and Highly Specialised Technologies charges are on target which may result in a lower than anticipated transition funding requirement from the Department for Health and Social Care (DHSC).
- 8. The Board received the report.

# 19/083 NICE CONNECT: THE CASE FOR CHANGE AND TRANSFORMATION

9. Gill Leng presented the case for change and plans for a transformation programme delivered through NICE Connect, to achieve a future vision for NICE advice and guidance in a care pathway format, which is accessible to users whenever and wherever they need it and easy to integrate into other care

- systems. The project will require significant investment over the next 3-5 years and subsequent reports to the Board will provide details on resource planning.
- 10. Gill summarised the key drivers for change being feedback from users and system partners that NICE advice is difficult to find on different parts of the website; the range and volume of guidance is difficult to keep updated and the need to make better use of digital technologies. The Board welcomed this first written report on the project which set out the case for change and the extent of the transformation work required.
- 11. In response to a question about the issue of silo working in the current organisational structure, Gill advised that Connect has already initiated cross-team discussions within the expert groups working on the pilot projects. Multi-disciplinary teams are also meeting to work on a single content model and the management of stakeholder data.
- 12. The outcome of the diabetes pathways pilot was discussed. Gill reported that the committee had provided the ideas for the future presentation of information in a layered format with interconnecting points, and had highlighted that moving from separate guidelines to a single pathway was resource intensive. As a result of the pilot, the diabetes guideline is being updated and the pathway committee has been stood down.
- 13. In response to a question from the Board about adopting new technologies, including digital experience platforms to provide a broader feedback mechanism, Alexia Tonnel commented that this could be considered as part of the model for a stakeholder management platform for which software tools are starting to emerge in the market.
- 14. Sarah Cumbers, outgoing Transformation Programme Director, was thanked for her work in supporting the project to this stage.
- 15. The Board approved the purpose of the transformation and structure of the programme, and agreed that the funding and management of the programme be discussed in more detail at the October Board strategy meeting.

# 19/084 STAFF SURVEY 2019: REPORT AND ACTION PLAN

- 16. Ben Bennett presented the results of NICE's 2019 staff survey and an action plan to address areas identified for improvement. Overall the results were very positive and in the majority of categories were in line with last year's scores. The Board welcomed the positive outcome and discussed two specific issues concerning the usefulness of the annual appraisal system to staff and the handling of bullying and harassment cases.
- 17. Ben advised that the HR Team will look at the staff feedback to review whether appraisals are useful to improve how staff do their job. In relation to bullying and harassment, it was noted that whilst the number of cases was low, none had been upheld last year. It was recognised that cases are often complex however where there are elements of learning in a case, these are taken forward. The Board

noted that NICE had various mechanisms in place to support staff including the nomination of two freedom to speak up guardians and trained mental health first aiders. It was agreed that the development of a set of NICE values and behaviours will be helpful in setting expected levels of conduct. This work is currently underway.

18. The Board received the report.

# 19/085 NICE IMPACT REPORT: MATERNITY AND NEONATAL CARE

- 19. Gill Leng presented the impact report on how NICE's evidence-based guidance contributes to improvements in maternity and neonatal care.
- 20. The Board noted that the percentage of mothers who smoke at the time of birth had not reduced over the last three years. It was queried whether a joint campaign with Public Health England may help to achieve further improvement. Jane Gizbert advised that a launch of the report was planned to coincide with a minister's visit to the maternity wards of a hospital, thereby presenting an opportunity to showcase the report and raise more awareness of the risks associated with smoking in pregnancy.

**ACTION: Gill Leng / Jane Gizbert** 

- 21. The Board also expressed concern about valproate prescribing for women and girls aged 14 to 45. Data showed that fewer prescriptions were being given but there was room for further improvement. Gill confirmed that NICE guidance had been updated to align with advice provided by the Medicines and Healthcare products Regulatory Authority.
- 22. The Board received the report.

# 19/086 ANNUAL EQUALITY REPORT

- 23. Ben Bennett presented the annual equality report which demonstrated NICE's compliance with the public sector equality duty and provided an update on NICE's equality objectives. The report also included information on equality considerations within guidance published in 2018/19.
- 24. The Board received the report.

# 19/087 ANTIMICROBIAL RESISTANCE: DEVELOPING AND TESTING INNOVATIVE MODELS FOR THE EVALUATION AND PURCHASE OF ANTIMICROBIALS

25. Meindert Boysen presented the report and welcomed Professor Colm Leonard, a Consultant Clinical Adviser at NICE, to answer questions from the Board. The paper outlined the joint project between NICE, NHS England, the Department of Health and Social and the Association of the British Pharmaceutical Industry to develop and test a new model for the evaluation and purchase of antimicrobials, based primarily on a NICE-led health technology assessment (HTA) of their value

- to the NHS. A central project team has been established to test the feasibility of an adapted NICE technology appraisal evaluation framework, with two antimicrobial products selected for assessment in the pilot.
- 26. The Board discussed the challenges of a global reduction in the use of antibiotics, against the need to develop alternative, novel products. Research and development investment in antimicrobials is widely seen as unattractive due to the high costs and low financial returns. The paper outlined the project overview, governance arrangements, proposals for targeted stakeholder engagement and the commercial model, which will set out the approach to reimbursement and in due course the levels of payments for the selected antimicrobials.
- 27. The Board received the report.

### 19/088 STANDING ORDERS AND RESERVATION OF POWERS TO THE BOARD

- 28. The Board considered minor amendments to NICE's reservation of powers to the board to clarify that the Non-Executive Directors (NEDs) will exercise their power to appoint the chief executive and other executive members in a meeting solely of NEDs rather than at a board meeting. An accompanying amendment was proposed to the standing orders to set a quorum of 3 for these NED meetings.
- 29. The Board approved the amendments.

### 19/089 DIRECTOR'S REPORT FOR CONSIDERATION

30. Jane Gizbert highlighted the events and social media activity in her communications report. NICE's month on month media coverage statistics remain very good but the team have recognised there was an opportunity to further promote NICE through Instagram, an app with growing popularity among younger people. The Board suggested that the Communications Team consider how they could extend the current report on media coverage of NICE's work to include digital references.

**ACTION: Jane Gizbert** 

31. The Board noted the report and thanked Jane for the directorate's work.

## 19/090 - 19/093 DIRECTORS' REPORTS FOR INFORMATION

32. The Board received the Directors' Reports.

### 19/094 OTHER BUSINESS

33. The Chair reported that this was Professor Angela Coulter's last public board meeting before her term of office ends in November. The Board thanked Angela for her contribution to NICE during her appointment.

# **NEXT MEETING**

34. The next public meeting of the Board will be held at 1.30pm on Wednesday 20 November 2019 at Great Ormond Street Hospital, London, WC1N 3JH.

# National Institute for Health and Care Excellence Chief Executive's report

This report provides information on the outputs from our main programmes for the 7 months to the end of October and on our financial position for the 6 months 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 2019

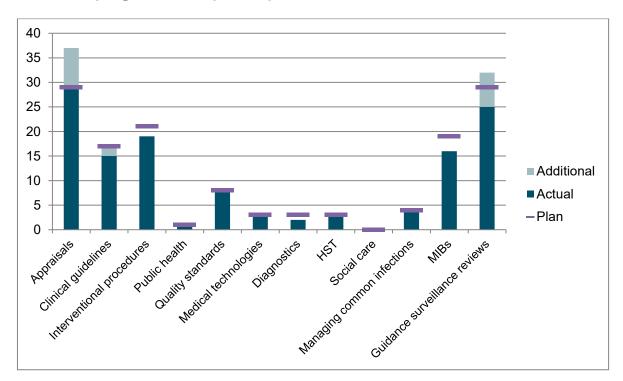
# Introduction

- 1. This report sets out the performance of the Institute against its business plan objectives and other priorities for the 7 months to the end of October 2019 and for income and expenditure to the end of September 2019 (month 6). This report notes the guidance published since the last public Board meeting in September and refers to business issues not covered elsewhere on the Board agenda.
- 2. The report also contains a report on the performance of the Science, Advice and Research programme in Appendix 5.
- The balanced scorecard, reporting more detail on aspects of our performance for the period April to September 2019, is set out at Appendix 6. There are no material variations to note on this report.

# **Performance**

- 4. The current position against a consolidated list of objectives in our 2019-20 business plan is set out in Appendix 1.
- 5. 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 October 2019 is set out in Chart 1.

Chart 1: Main programme outputs: April to October 2019



# download the data set for this chart

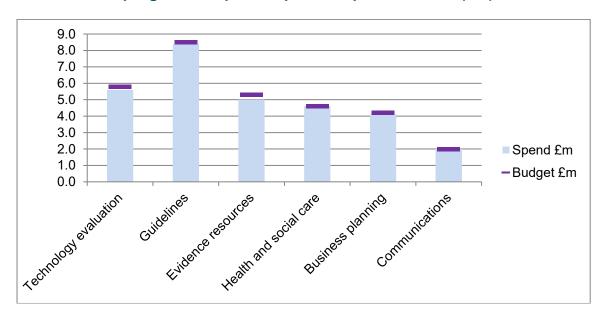
### Notes to Chart 1:

- a) HST refers to the highly specialised technologies programme (drugs for very rare conditions)
- b) MIBs (medtech innovation briefings) are reviews of new medical devices
- c) Guidance surveillance reviews provide the basis for decisions about whether to update current NICE guidance
- 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
- 6. 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.

# **Financial position (Month 6)**

7. The financial position for the 6 months from April 2019 to the end of September is an under spend of £1.3m (5%), against budget. This consists of an under spend of £0.5m on pay and £0.47m on non-pay budgets, supported by an over-recovery of £0.33m on income. The position of the main budgets is set out in Chart 2. Further information is available in the Business Planning and Resources Director's report, including a detailed report on the recovery of costs for the technology appraisal and highly specialised technologies programmes.

Chart 2: Main programme spend: April to September 2019 (£m)



## download the data set for this chart

# **Appendix 1: Business objectives for 2018-19**

In managing its business, NICE needs to take account of the objectives set out in its business plan, and the organisational and policy priorities for NICE set out by the Department of Health and Social Care. The table below consolidates and tracks progress with the main elements of these influences on our work in 2019-20.

| Deliver and support the adoption of accessible, up to date and adaptable advice, fully aligned to the needs of our users                                                                                                                     | Delivery date | Progress update                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Deliver guidance, standards, indicators and evidence products and services, in accordance with the schedule set out in the business plan and the balanced scorecard, including the planned increases in the technology evaluation programmes | Ongoing       | Details of the main programmes' performance against plan, including explanations for any variances are set out elsewhere in this report.                                                                                                                         |
| Subject to evaluation of the NICE Connect project pilot, develop a business case and programme plans for the next phase of the project                                                                                                       | • End of Q3   | A detailed report was considered by the<br>Board in September, setting out a business<br>case and plans for the next phase of work. A<br>vision and strategy for the guidelines<br>programme has been developed following<br>the October Board strategy meeting. |
| Undertake a review of the topic selection arrangements for the HST programme and methods guides for the technology evaluation programmes                                                                                                     | End of Q4     | The programme of work for the review has<br>been launched, with internal and external<br>planning meetings held, and a dedicated<br>page on the NICE website created.                                                                                            |
| Review and update the guidelines methods and process manual to determine the optimal development path and timeline for guideline development in the context of the NICE Connect project                                                      | • End of Q4   | Work is ongoing with other NICE teams and external guideline developers to identify priority areas for update to the methods and process manual. This will be reflected in the Connect methods, process and analytics expert group.                              |

|                                                                                                                                                                                                           | The expert group includes works prescribing pathways, surveillan wording of recommendations.                                                                                                   |                                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| Maintain and monitor performance of NICE Evidence Services<br>(CKS, HDAS, BNF microsites, Evidence Search, Medicines<br>Awareness Service), with investment in new features on a strictly<br>needed basis | Ongoing     All systems are performing in lin recent trends. Continued strong performance of the BNF microsi CKS service.                                                                      |                                              |
|                                                                                                                                                                                                           | We are establishing closer links<br>better align it with updates to gu<br>recommendations.                                                                                                     |                                              |
| Enable access to the new national core content and procure any additional content in line with Health Education England's (HEE) commissioning decisions                                                   | • Q1 • Complete.                                                                                                                                                                               |                                              |
| Support shared decision making within NICE through delivery of commitments in the action plan of the Shared Decision-Making Collaborative                                                                 | Ongoing     A meeting of the Shared Decision Collaborative was held in June a attended. A revised action plan developed following on from this                                                 | and was well<br>is being                     |
| Deliver a range of tools and support for the uptake of NICE guidance and standards, including adoption support products, endorsement statements, and shared learning examples                             | Ongoing     Tools and support have been deplanned. Further information is the Health and Social Care Directory. The need for adoption support public being reviewed as part of the NI project. | available in<br>ctor's report.<br>roducts is |
| Evaluate the most effective social and multimedia channels currently used to promote NICE's work                                                                                                          | Ongoing     An evaluation of our social medi underway and is expected to be wider distribution and discussion                                                                                  | ready for                                    |
| Evaluate the scope to improve the recruitment and retention of advisory committee members                                                                                                                 | End of Q2     New digital platforms have been promote opportunities for comm members, and ways of being more                                                                                   | ittee                                        |

|                                                                                                                                                                                                  |               | about recruitment are being explored in CHTE.                                                                                                                                                                                                                                                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Play an active, influential role in the national stewardship of the health and care system                                                                                                       | Delivery date | Progress update                                                                                                                                                                                                                                                                                                    |
| Work with NHS England and other health and care system partners to support the implementation of the NHS long term plan                                                                          | Ongoing       | We have mapped areas of NICE's work to<br>the implementation arrangements for the<br>Long-Term Plan and are working with NHS<br>England to ensure NICE guidance is<br>appropriately reflected. Progress is<br>monitored by the Senior Management<br>Team.                                                          |
| Explore with NHS England the options for a digital health technology evaluation workstream, building on the Evidence for Effectiveness standards                                                 | • End of Q2   | An internal project team has been established and there is a stakeholder Steering Group, chaired by the Programme Director, Evidence Resources.                                                                                                                                                                    |
|                                                                                                                                                                                                  |               | <ul> <li>An outline process has been developed for<br/>the evaluation pilot.</li> </ul>                                                                                                                                                                                                                            |
|                                                                                                                                                                                                  |               | <ul> <li>Four apps have been identified as pilot topics.</li> </ul>                                                                                                                                                                                                                                                |
| Subject to the UK's EU exit arrangements, design and put in place changes to our current technology appraisal process in order to secure consistency with UK regulatory arrangements             | • End of Q2   | Planning for EU Exit is complete and its status is being monitored pending confirmation of a final date for leaving the EU. The combined impact of EU Exit and impending changes to European device regulations on NICE's guidance recommendations for medical devices and diagnostics is being closely monitored. |
| Commission a bi-annual NICE reputation research project to assess<br>our key stakeholders' views of NICE and our work, and conduct<br>specific and targeted audience research on key issues that | End of Q2     | The final report on the findings of the research project findings was presented to the Board in August. The survey results are being shared with teams across NICE and                                                                                                                                             |

| contribute to meeting corporate business objectives and implementation of NICE guidance                                                                                                                              |               | plans are being developed to implement suggestions from the NICE Board. The findings are helping to inform business planning for 2020/21.                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Deliver a suite of activities to mark NICE's 20 <sup>th</sup> anniversary                                                                                                                                            | End of Q1     | Complete.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Take advantage of new data sources and digital technologies in developing and delivering our advice                                                                                                                  | Delivery date | Progress update                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Develop and establish a long term data analytics strategy for NICE together with a framework for the appropriate use of data analytics across NICE's programmes, and facilitating a national leadership in the field | • End of Q3   | <ul> <li>A 'Statement of Intent' has been developed, setting out how we aim to use data analytics in our future work. This has been subject to a 3-month consultation, and a report is being presented to the Board in November highlighting the feedback and setting out next steps.</li> <li>The implications of this work on methods and processes will be picked up by the methods, process and analytics Connect expert group.</li> </ul>                                                            |
| Identify digital investment priorities, and their sequencing, to align with the NICE Connect project transformation work, reviewing the roadmap quarterly                                                            | Ongoing       | <ul> <li>SMT has approved a proposal to merge the NICE IT and digital services teams. We are currently working with an external consultancy to design the target operating model for the integrated team and to refresh our technical strategy.</li> <li>We are currently procuring a strategic partner to support the development of our digital workplace and data management strategies and their implementation.</li> <li>Work to upgrade the Medicine Evidence Daily service has started.</li> </ul> |

| Manage and maintain the live digital services of NICE utilising user insight and strategic service goals to prioritise use of resource                                                        | Ongoing                | Usual activity of defect resolution and responding to change requests continues.                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Generate and manage effectively the resources needed to maintain our offer to the health and care system                                                                                      | Delivery date          | Progress update                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Deliver performance against plan for all budgets and achieve or exceed on non-Grant-in-Aid income targets                                                                                     | • End of March 2020    | <ul> <li>Current year end projections show that we expect to remain within the tolerance agreed with DHSC for the transition year to the full cost recovery for technology appraisal and highly specialised technologies.</li> <li>NICE Scientific Advice has generated a small surplus in income over the first 7 months and is on-track to achieve the 2019/20 income targets, which include a full contribution to NICE's overheads.</li> </ul> |
| Introduce charging for technology appraisal and highly specialised technologies and recover the target income for 2019/20                                                                     | • From 1<br>April 2019 | As above: charging systems are now fully operational. Income was slightly ahead of target for quarter 1, and projections at the end of quarter 2 show that we expect to remain within the tolerance agreed with DHSC for this first year.                                                                                                                                                                                                          |
| Deliver existing grant funded research projects to plan and timetable and secure a pipeline of new projects for 2020/21                                                                       | • End of March 2020    | Science Policy and Research income is on target for 2019/20. Several projects extend to future years (some to 2023), with funding for the next 2 years secured at comparable levels to this year. A new project is in the final stages of NICE governance approval with a start date of early 2020 expected. Existing projects are being delivered to plan.                                                                                        |
| Promote our capacity for knowledge sharing with international organisations interested in NICE's expertise and experience, including the re-use of NICE's published content outside of the UK | Ongoing                | The NICE International team received 27 new enquiries, and delivered 16 international engagements including a                                                                                                                                                                                                                                                                                                                                      |

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                      | week-long series of HTA workshops for the Ministries of Health in Uruguay, Brazil and Colombia (also attended by the Peruvian authorities) organised by the Department of International Trade Latin America. A further 22 enquiries are currently in progress or are yet to be confirmed. A press release and new web pages to re-launch NICE International went live on 5 November.  Revenue generated from content re-use (of published NICE guidance) services at the end of August was approximately £98,000, which is ahead of target for the year. |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Support the UK's ambition to enhance its position as a global life sciences destination                                                                                                                                                                                                                                                                                                                                                                                                  | Delivery date        | Progress update                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Make preparations to implement the commitments of the 2019     Voluntary Scheme for Branded Medicines Pricing and Access     related to NICE so that (i) all new active substances and drugs with     significant licence extensions will be appraised, except where there     is a clear rationale not to do so, by April 2020; (ii) NICE is able to     publish recommendations on non-cancer drugs within 90 days of     licensing to match the timescales for cancer drugs (ongoing) | • End of Q4/on-going | Planning meetings have been held with NHS England and NHS Improvement, and with the Department of Health and Social Care, to consider the timing of the expansion of the technology appraisal programme, and the ability to publish guidance for non-oncology drugs against the same 90 day target as oncology drugs.                                                                                                                                                                                                                                    |
| Deliver the actions set out for NICE in the Government's Life<br>Sciences Sector Deals and significantly increase the number of<br>evaluations of these health tech products conducted, giving greater<br>scope for considering different types of innovation, including digital<br>products.                                                                                                                                                                                            | Ongoing              | <ul> <li>Work is ongoing with NHS England and NHS Improvement on the development of a new Medtech funding mandate, with NICE as a key partner.</li> <li>Confirmation has been received from the Department of Health and Social Care that the expansion of the Medtech programmes will be funded. Discussions are ongoing with NHS England and NHS Improvement about</li> </ul>                                                                                                                                                                          |

|                                                                                                                                                                                                                              |               | the timing of the expansion of the Medtech programmes.                                                                                                                                                                                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Prepare a final case for establishing a not for profit organisation<br>delivering fee for service advisory and educational programmes,<br>aligned to NICE's public task                                                      | • End of Q3   | The Board agreed in June that the original proposal was not viable and to stand down planning for the proposed entity.                                                                                                                                                                   |
| Maintain a motivated, well-led and adaptable workforce                                                                                                                                                                       | Delivery date | Progress update                                                                                                                                                                                                                                                                          |
| Ensure that all staff have clear objectives supported by personal development plans                                                                                                                                          | End of Q1     | Each directorate has an individual business<br>plan and that is cascaded into individual<br>objectives which links to the annual<br>appraisal and informs personal development<br>plans.                                                                                                 |
| Actively manage staff engagement and morale with the objective of ensuring that the global job satisfaction index in the annual staff survey is maintained or improved from its 2018 level                                   | • End of Q1   | The annual staff survey achieved our<br>highest-ever completion rate of 85%. The<br>results are used to form organisational and<br>directorate action plans, supported by HR.<br>The results and organisational action plan<br>were presented to the Board at its<br>September meeting.  |
| Implement the actions set out in the workforce strategy, including mapping out career paths for key roles, including increasing opportunities for apprenticeships, and defining the behaviours expected of a manager at NICE | • End of Q2   | <ul> <li>We have introduced leadership and management apprenticeships at levels 3, 5 and 7 (MBA level) and are developing graduate opportunities in a range of areas.</li> <li>We will be introducing organisational values and behaviours for managers in the coming months.</li> </ul> |
| Work with the Department of Health and Social Care to secure the future London office accommodation, and begin planning for the move to take place in the summer of 2020                                                     | End of Q3     | Planning for the move to Stratford in<br>Summer 2020 is progressing. The steering<br>group with membership from all the tenants                                                                                                                                                          |

|   |                                                                                                                       |           | <ul> <li>is well established. A project manager has been appointed and is in post.</li> <li>Engagement with the leaseholder and other tenants on space configuration are well-advanced.</li> </ul> |
|---|-----------------------------------------------------------------------------------------------------------------------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| • | Develop and implement a programme of improvements for the Manchester office to ensure best use of the space available | End of Q2 | A paper was presented to SMT in August proposing that improvements should be made. External advice has been commissioned on the best way to make these improvements.                               |

# **Appendix 2: Extracts from the Directors' reports**

| Director                        | Featured section                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Section/<br>reference |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Health and social care          | We have written to all new regional directors in the 7 NHS England/Improvement (NHSE/I) regions to confirm our interest in working together to develop and shape local implementation plans and to introduce them to the relevant Field team representatives. The letters also offered a face to face meeting with Andrew Dillon and Gill Leng and most regions have responded positively. The regional offices of both NHS England and NHS Improvement in the North have referenced the use of NICE guidance and standards as part of their key lines of enquiry, which they will use to support and assure STP/ ICS 5-year plans.                                                                                                                                                 | Paras 11 and 12       |
| Guidelines                      | We are collaborating with NHS Digital to agree a standard digital specification for the CHA2DS2-VASc risk calculator the use of which is recommended in NICE's guideline on management of atrial fibrillation to assess stroke risk. The calculator has been codified by clinical system providers, and there is a risk of variation in the coding of clinical parameters. This work may form the basis of a future collaborative process when NICE recommends other risk calculators in its guidance.                                                                                                                                                                                                                                                                              | Para 9                |
| Health technology<br>evaluation | The programme continues to support the work of the Accelerated Access Collaborative in implementing the 3 pieces of diagnostics guidance that were selected as rapid uptake products. Diagnostics guidance, Myocardial infarction (acute): Early rule out using high-sensitivity troponin tests (Elecsys Troponin T high-sensitive, ARCHITECT STAT High Sensitive Troponin-I and AccuTnI+3 assays) (DG15), is being updated since its publication in October 2014 in response to discussions with the AAC. The purpose of the guidance update is to address several key questions such as evaluating new high sensitivity Troponin tests which have come to market since guidance was published, and an assessment of early rule out protocols now that more evidence is available. | Para 18               |

| Evidence resources       | Our directorate is supporting CHTE to explore with NHS England the options for a digital health technology evaluation workstream, building on the Evidence Standards for Digital Health Technologies published in 2018/19. Over the last two months, we have focused on supporting the following activities:                                                                                                                                                                                                                                                                                                                                                               | Para 7          |
|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
|                          | •Organising and presenting at NHS Expo on NICE's Evidence Standards Framework and activities in digital health;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                 |
|                          | •Chairing the September and October meetings of the External Steering Group for NICE's pilot Digital Health Evaluation Pilots;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                 |
|                          | •Attendance at NHSX's Al Mission Delivery Board and cross-regulatory working group; •Continued promotion of the use of NICE's Evidence Standards for Digital Health Technologies including hosting a table at an Innovate UK technology competition event.                                                                                                                                                                                                                                                                                                                                                                                                                 |                 |
| Communications           | Planning is in progress for the NICE Annual Conference taking place at the Hilton Deansgate, Manchester, on 11 November 2020. The conference programme has been drafted and is being reviewed by the events team, ahead of submission to SMT for approval. Plans are progressing for NICE to jointly-host the 2021 HTAi annual meeting in Manchester, along with Health Improvement Scotland, and the All Wales Toxicology and Therapeutics Centre. The HTAi secretariat is expected to make a decision on the conference venue by mid-November 2019. The events team hopes to start recruitment soon for a project manager to oversee planning and delivery of the event. | Paras 26 and 27 |
| Finance and<br>workforce | As part of the focus on increasing leadership confidence and capability across the organisation, 18 staff members are now on leadership and management development programmes funded through the apprenticeship levy. The courses are at levels 3, 5 and 7, and will provide managers with skills, knowledge, strategies and tools to make a positive difference to their performance, their team's performance, working relationships and results. The apprenticeships also aim to lift participants out of day-to-day management and look strategically at their area of responsibility and the wider organisational priorities.                                         | Para 52         |

# Appendix 3: Guidance development: variation against plan April - October 2019

| Programme                 | Delayed Topic                                                                  | Reason for variation                                                                                                                                                                                                                                                                                                                                               |
|---------------------------|--------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Clinical Guidelines       | 2 topics delayed                                                               | Diverticular Disease: Publication was delayed to November 2019 to align the guideline with the release of a related NHS England report.  Cannabis-based products for medicinal use: Publication scheduled for                                                                                                                                                      |
|                           |                                                                                | November 2019.                                                                                                                                                                                                                                                                                                                                                     |
|                           | 2 additional topics<br>published in 2019-20, that<br>were not planned for this | Surgical site infections: prevention and treatment: Originally planned for 2018-19. Published April 2019 (Q1 2019-20).                                                                                                                                                                                                                                             |
|                           | financial year                                                                 | Suspected neurological conditions: Originally planned for 2018-19. Published May 2019 (Q1 2019-20).                                                                                                                                                                                                                                                                |
| Interventional procedures | 2 topics delayed                                                               | Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues: The consultation period was extended from four weeks to eight weeks following feedback from stakeholders. This impacted all timings moving forward. Guidance due to publish in November 2019 (Q3 2019-20). |
|                           |                                                                                | Irreversible electroporation for primary liver cancer: The committee meeting was not quorate during August 2019 so this topic could not be discussed. The discussion was rescheduled. This impacted all timings moving forward. Guidance due to publish in November 2019 (Q3 2019-20).                                                                             |
| Medical technologies      | No variation against plan 2019-20                                              | -                                                                                                                                                                                                                                                                                                                                                                  |
| Public Health             | No variation against plan 2019-20                                              | -                                                                                                                                                                                                                                                                                                                                                                  |
| Quality Standards         | No variation against plan 2019-20                                              | -                                                                                                                                                                                                                                                                                                                                                                  |
| Diagnostics               | 1 topic delayed                                                                | Implantable cardiac monitors (BioMonitor 2-AF, Confirm Rx insertable cardiac monitor and Reveal LINQ Insertable Cardiac Monitoring System) to detect atrial fibrillation after cryptogenic stroke: The final guidance for this topic was originally                                                                                                                |

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| Programme             | Delayed Topic                                                                  | Reason for variation                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|--------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                       |                                                                                | scheduled to publish in September 2019. The committee requested additional analysis at the first committee meeting and no document was released for consultation following the first meeting. The third committee discussion was rescheduled from September to November 2019 to allow the NICE Decision Support Unit to complete an independent critique of the economic model. The earliest anticipated publication date is now March 2020 (Q4 2019-20). |
| Technology Appraisals | No variation against plan 2019-20                                              | -                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                       | 8 additional topics<br>published in 2019-20, that<br>were not planned for this | Cabozantinib for previously treated advanced hepatocellular carcinoma: Published as a terminated appraisal in May 2019 (Q1 2019-20).                                                                                                                                                                                                                                                                                                                      |
|                       | financial year                                                                 | Bosutinib for untreated chronic myeloid leukaemia: Published as a terminated appraisal in April 2019 (Q1 2019-20).                                                                                                                                                                                                                                                                                                                                        |
|                       |                                                                                | Brentuximab vedotin for untreated advanced Hodgkin lymphoma: Published as a terminated appraisal in August 2019 (Q2 2019-20).                                                                                                                                                                                                                                                                                                                             |
|                       |                                                                                | Lenalidomide with bortezomib and dexamethasone for untreated multiple myeloma: Published as a terminated appraisal in September 2019 (Q2 2019-20).                                                                                                                                                                                                                                                                                                        |
|                       |                                                                                | Pomalidomide with bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma: Published as a terminated appraisal in September 2019 (Q2 2019-20).                                                                                                                                                                                                                                                                                  |
|                       |                                                                                | Bezlotoxumab for preventing recurrent Clostridium difficile infection: Published as a terminated appraisal in September 2019 (Q2 2019-20).                                                                                                                                                                                                                                                                                                                |
|                       |                                                                                | Ramucirumab for treating unresectable hepatocellular carcinoma after sorafenib: Published as a terminated appraisal in October 2019 (Q3 2019-20).                                                                                                                                                                                                                                                                                                         |
|                       |                                                                                | Ibrutinib with rituximab for treating Waldenstrom's macroglobulinaemia: Published as a terminated appraisal in October 2019 (Q3 2019-20).                                                                                                                                                                                                                                                                                                                 |

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| Programme                                | Delayed Topic                               | Reason for variation                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------------------|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Highly Specialised<br>Technologies (HST) | 1 topic delayed                             | Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2: Appeal received following release of final draft guidance (FED), which was rejected at the scrutiny stage. Following the appeal NICE made the decision to review the FED. At its meeting on 29 August the committee concluded it can recommend cerliponase subject to a managed access agreement (MAA). An MAA is now being arranged and FED release is expected in November 2019. |
|                                          | 1 topic planned for 2019-20 published early | Voretigene neparvovec for treating inherited retinal dystrophies caused by RPE65 gene mutations. Originally planned to publish in December 2019. Guidance published early in October 2019 (Q3 2019-20).                                                                                                                                                                                                                                                 |
| Social Care                              | No variation against plan 2019-20           | -                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Managing Common Infections               | No variation against plan 2019-20           | -                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

# Appendix 4: Guidance published since the last Board meeting in September 2019

| Programme                  | Topic                                                                                               |  |
|----------------------------|-----------------------------------------------------------------------------------------------------|--|
| Clinical Guidelines        | Abortion care                                                                                       |  |
|                            | Twin and triplet pregnancy                                                                          |  |
|                            | End of life care for adults: service delivery                                                       |  |
| Interventional procedures  | Implant insertion for prominent ears                                                                |  |
|                            | High-intensity focused ultrasound for glaucoma                                                      |  |
|                            | Bioprosthetic plug insertion for anal fistula                                                       |  |
|                            | Midcarpal hemiarthroplasty for wrist arthritis                                                      |  |
| Medical technologies       | No publications                                                                                     |  |
| Diagnostics                | No publications                                                                                     |  |
| Public Health              | No publications                                                                                     |  |
| Managing Common Infections | Pneumonia (community-acquired): antimicrobial prescribing                                           |  |
|                            | Pneumonia (hospital-acquired): antimicrobial prescribing                                            |  |
|                            | Cellulitis and erysipelas: antimicrobial prescribing                                                |  |
|                            | Diabetic foot problems: prevention and management                                                   |  |
| Social care                | No publications                                                                                     |  |
| Quality Standards          | Suicide prevention                                                                                  |  |
| Technology Appraisals      | Lenalidomide with bortezomib and dexamethasone for untreated multiple myeloma                       |  |
|                            | Pomalidomide with bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma |  |
|                            | Bezlotoxumab for preventing recurrent Clostridium difficile infection                               |  |

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| Programme                             | Topic                                                                                                      |  |  |
|---------------------------------------|------------------------------------------------------------------------------------------------------------|--|--|
|                                       | Ramucirumab for treating unresectable hepatocellular carcinoma after sorafenib                             |  |  |
|                                       | Ibrutinib with rituximab for treating Waldenstrom's macroglobulinaemia                                     |  |  |
|                                       | Pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer |  |  |
|                                       | Sodium zirconium cyclosilicate for treating hyperkalaemia                                                  |  |  |
|                                       | Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease    |  |  |
|                                       | Lanadelumab for preventing recurrent attacks of hereditary angioedema                                      |  |  |
|                                       | Xeomin (botulinum neurotoxin type A) for treating chronic sialorrhoea                                      |  |  |
|                                       | Idelalisib for treating refractory follicular lymphoma                                                     |  |  |
| Highly Specialised Technologies (HST) | Voretigene neparvovec for treating inherited retinal dystrophies caused by RPE65 gene mutations            |  |  |
| Medtech Innovation<br>Briefings (MIB) | The V.A.C. Veraflo Therapy system for infected wounds                                                      |  |  |
|                                       | SuperNO2VA for the relief of upper airway obstruction in people with obstructive sleep apnoea              |  |  |
|                                       | UroShield for preventing catheter-associated urinary tract infections                                      |  |  |
|                                       | InterDry for intertrigo                                                                                    |  |  |
|                                       | Alpha-Stim AID for anxiety                                                                                 |  |  |
|                                       | superDimension Navigation System to help diagnostic sampling of peripheral lung lesions                    |  |  |
|                                       | MR-proADM test for use with clinical deterioration scores in cases of suspected infection                  |  |  |
| Guidance Surveillance<br>Reviews      | CG69 Respiratory tract infections (self-limiting): prescribing antibiotics (exception review)              |  |  |
|                                       | CG95 Chest pain of recent onset: assessment and diagnosis                                                  |  |  |
|                                       | CG176 Head injury: assessment and early management (exception review)                                      |  |  |

| Programme | Topic                                                                |
|-----------|----------------------------------------------------------------------|
|           | NG81 Glaucoma: diagnosis and management (exception review)           |
|           | PH29 Unintentional injuries: prevention strategies for under 15s     |
|           | PH30 Unintentional injuries in the home: interventions for under 15s |
|           | PH31 Unintentional injuries on the road: interventions for under 15s |

# **Key to recommendation types**

# Guidelines (clinical, social care and public health):

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

# **Interventional Procedures:**

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

# **Medical technologies:**

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

# **Diagnostics guidance:**

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

# Management of common infections:

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

# **Quality standards:**

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

# Technology appraisals and highly specialised technologies:

This guidance can 'recommend' the use of a new drug or other treatment, 'optimised use', in which the recommendation is positive for some but not all uses, or 'not recommend' routine use in the NHS. Research only use is also sometimes recommended. Positive recommendations are subject to a legal funding requirement.

# **Evidence summaries and medtech innovation briefings:**

Both publications provide information (but not guidance) about a particular topic.

## Surveillance reviews:

Provide the basis for decision about whether to update current NICE guidance.

# Appendix 5: Science, Advice and Research Programme progress report

# NICE Scientific Advice

- 1. NSA continues to build on the early successes of 2019/20, bringing in a range of new and interesting projects and focussing on greater stakeholder engagement, with on-going efforts to strengthen relationships within the UK research infrastructure. The team has developed a "concurrent" advice service, that can be utilised in the event of an EU exit, which allows NICE to provide scientific advice concurrently alongside the existing European advice services which NICE is currently part of. NSA is on track to recover all costs and make a full contribution to the NICE overheads.
- 2. For the period of September and October 2019, NICE Scientific Advice has initiated 20 individual advisory projects. This includes 2 projects where companies have sought advice from NICE directly (including one "concurrent" advice project as described above), 1 joint advice project with the Canadian HTA agency, CADTH, 4 projects where NICE has given advice through the European Network for HTA (EUnetHTA) Early Dialogue procedure, 1 Medtech Advice project via META pilot project and 2 META Tool consultations. NSA and University of Manchester have also initiated 10 projects supporting UK-based digital health technology companies as part of the Innovate UK Digital Health Technology Catalyst competition, with further discussions about supporting another 6 companies in early 2020. An additional 5 advisory projects have been confirmed with contracts in the process of being signed, as well as a further 16 ongoing enquiries for projects starting later in the year.
- 3. The NICE International team received 27 new enquiries, and delivered 16 international engagements, including a week-long series of HTA workshops for the Ministries of Health in Uruguay, Brazil and Colombia (also attended by the Peruvian authorities) organised by the Department of International Trade Latin America. Other international engagements included the provision of quality assurance advice on proposals for the work of the Prosperity fund in China and delivering tailored seminars to a number of delegations from Japan, Switzerland, India, Denmark, Indonesia and China. A further 22 enquiries are currently in progress or are yet to be confirmed, including a 3-day visit from the Brazilian Ministry of Health in November and a consultancy project providing advisory work on the proposals to create a HTA agency in Brazil. Work with the Centre for Guidelines on potential guideline contextualisation projects for Egypt, Saudi Arabia and Cyprus is also ongoing. The team have been working towards the relaunch of NICE international and published a press release and the new web pages on Tuesday 5 November.

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# Science Policy and Research

- 4. During September and October, strong progress has been made across the portfolio of research and science policy projects, with particularly high levels of activity on the Innovative Medicines Initiative (IMI) project "GetReal Initiative", where NICE has a leading role in establishing a real-world evidence think tank, which will gather international thought leaders and will discuss, assess and give recommendations on the opportunities and barriers to the generation, use and acceptability of real-world evidence in the context of European regulation and HTA.
- 5. We issued an updated <u>position statement</u> in October 2019, stating that NICE does not recommend the EQ-5D-5L value set for England. An accompanying <u>blog</u> explains the background and the rationale behind NICE's position. In brief, quality assurance and advice from 4 independent experts raised serious concerns about the quality of the data and the modelling that underpins the value set. EuroQol, the not-for-profit foundation that owns EQ-5D, has agreed to fund a new EQ-5D-5L valuation study for England. The study will be designed and run by academic experts, with support and advice from NICE, the Department of Health and Social Care, and NHS England. In the meantime, NICE continues to recommend the older EQ-5D-3L value set; this policy will be reviewed when the new study is complete.

# **EUnetHTA**

6. The EUnetHTA joint action has entered its fourth year. The project plan for the final deliverable from the NICE-led work package has been finalised and the data collection phase started. This final deliverable will evaluate changes in implementation between the current and previous joint action and will be finalised in May 2020. In addition, the NICE team is currently consulting on its fourth implementation report that describes 207 examples of use of EUnetHTA reports by partners. In March, NICE will host its final annual conference with partners in Budapest, Hungary to reflect on the achievements of the work package.

# **Appendix 6: Balanced Scorecard: April - September 2019**

#### **Delivering services and improvements**

| Outputs                                                                      | Measure                           | Target | Planned<br>To End Q2 | Actual<br>To End | Cumulative performance | RAG status |
|------------------------------------------------------------------------------|-----------------------------------|--------|----------------------|------------------|------------------------|------------|
|                                                                              |                                   |        |                      | Q2               |                        |            |
| Publish 3 public health<br>guidelines                                        | Publication within stated quarter | 80%    | 1                    | 1                | 100%                   | Green      |
| Publish 23 clinical guidelines                                               | Publication within stated quarter | 80%    | 14                   | 16               | 114%                   | Green      |
| Publish 6 managing common nections guidelines                                | Publication within stated quarter | 80%    | 3                    | 3                | 100%                   | Green      |
| Publish 1 social care<br>Juidelines                                          | Publication within stated quarter | 80%    | 0                    | 0                | 100%                   | Green      |
| Publish 78 technology appraisals or highly specialised technologies quidance | Publication within stated year    | 80%    | 28                   | 33               | 118%                   | Green      |
| Publish 32 interventional procedures guidance                                | Publication within stated quarter | 80%    | 18                   | 18               | 100%                   | Green      |
| Publish 6 diagnostics<br>Juidance                                            | Publication within stated quarter | 80%    | 3                    | 2                | 67%                    | Amber      |

#### Notes:

1 topic delayed.

• Implantable cardiac monitors (BioMonitor 2-AF, Confirm Rx insertable cardiac monitor and Reveal LINQ Insertable Cardiac Monitoring System) to detect atrial fibrillation after cryptogenic stroke

| mornioning dystern) to a | morning eyetern to detect data instituation after or yet eyet to be executed |     |   |   |      |       |  |  |  |
|--------------------------|------------------------------------------------------------------------------|-----|---|---|------|-------|--|--|--|
| Publish 7 medical        | Publication within stated year                                               | 80% | 3 | 3 | 100% | Green |  |  |  |
| technologies guidance    |                                                                              |     |   |   |      |       |  |  |  |
|                          |                                                                              |     |   |   |      |       |  |  |  |
|                          |                                                                              |     |   |   |      |       |  |  |  |

| Development and publication of guidance and evidence outputs (as specified in Business Plan) |                                |        |                      |                        |                        |            |  |  |
|----------------------------------------------------------------------------------------------|--------------------------------|--------|----------------------|------------------------|------------------------|------------|--|--|
| Outputs                                                                                      | Measure                        | Target | Planned<br>To End Q2 | Actual<br>To End<br>Q2 | Cumulative performance | RAG status |  |  |
| Publish 38 medtech innovation briefings (MIBs)                                               | Publication within stated year | 80%    | 19                   | 14                     | 74%                    | Amber      |  |  |

#### Notes:

5 briefings are delayed:

- Sonata System
- NGPod
- CMF OL1000 (Combined Magnetic Field)
- MR-Pro ADM
- superDimension Navigation System to help diagnostic sampling of peripheral lung lesions

| Deliver up to 38 commercial                                                                                  | Publication within stated year | 80% | 8 Managed                                                                         | 8 MAAs                                                               | 100% | Green |
|--------------------------------------------------------------------------------------------------------------|--------------------------------|-----|-----------------------------------------------------------------------------------|----------------------------------------------------------------------|------|-------|
| and up to 17 managed access                                                                                  |                                |     | Access                                                                            | published                                                            |      |       |
| briefings for NHS England to<br>support discussions with<br>companies, including 'Patient<br>Access Schemes' |                                |     | Agreements<br>(MAAs)<br>published                                                 | 21 PAS sent to NHS                                                   |      |       |
|                                                                                                              |                                |     | 19 Patient<br>Access<br>Scheme<br>(PAS) final<br>advice sent<br>to NHS<br>England | England  Additionally 11 Commercial Briefings sent to NHS England in |      |       |
|                                                                                                              |                                |     |                                                                                   | September<br>2019                                                    |      |       |

Note:

Commercial Liaison (PASLU) became responsible for developing commercial briefings for NHS England from September 2019.

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| Development and publication of guidance and evidence outputs (as specified in Business Plan) |                                                                      |        |                                                         |                                                        |                        |            |  |  |
|----------------------------------------------------------------------------------------------|----------------------------------------------------------------------|--------|---------------------------------------------------------|--------------------------------------------------------|------------------------|------------|--|--|
| Outputs                                                                                      | Measure                                                              | Target | Planned<br>To End Q2                                    | Actual<br>To End<br>Q2                                 | Cumulative performance | RAG status |  |  |
| Deliver up to 4 commissioning support programme topics to NHS England                        | Submission to NHS England<br>Clinical Panel within stated<br>quarter | 80%    | 4                                                       | 4                                                      | 100%                   | Green      |  |  |
| Manage portfolio of up to 3 evaluative commissioning projects for NHS England                | Submission to NHS England<br>Clinical Panel within stated<br>quarter | 80%    | Delivery of 3 reports, ongoing management of 2 projects | 3 reports delivered in this period.  1 project ongoing | 80%                    | Green      |  |  |

#### Notes:

One project has been suspended indefinitely due to the manufacturer's withdrawal of the product from the market. Potential new topics are being discussed with NHS England

| Publish 52 guidance surveillance reviews                             | Publication within stated quarter   | 80%  | 24 | 29 | 121% | Green |
|----------------------------------------------------------------------|-------------------------------------|------|----|----|------|-------|
| Deliver up to 4 evidence<br>summaries – antimicrobial<br>prescribing | Publish within year                 | 80%  | 0  | 0  | 100% | Green |
| Deliver up to 10 evidence reviews for NHSE specialised commissioning | Delivery to NHS England within year | 80%  | 0  | 2  | 200% | Green |
| Deliver 8 quick guides for social care                               | Publication within year             | 100% | 3  | 3  | 100% | Green |
| Deliver 16 quality standards                                         | Publication within stated quarter   | 80%  | 8  | 8  | 100% | Green |
| Deliver 1 indicator set                                              | Publication within year             | 100% | 1  | 1  | 100% | Green |
| Deliver 30 endorsement statements                                    | Publication within stated quarter   | 80%  | 14 | 13 | 93%  | Green |

| Development and publication of guidance and evidence outputs (as specified in Business Plan) |                                   |        |                      |                        |                        |            |  |  |
|----------------------------------------------------------------------------------------------|-----------------------------------|--------|----------------------|------------------------|------------------------|------------|--|--|
| Outputs                                                                                      | Measure                           | Target | Planned<br>To End Q2 | Actual<br>To End<br>Q2 | Cumulative performance | RAG status |  |  |
| Deliver 50 shared learning examples                                                          | Publication within stated quarter | 80%    | 20                   | 22                     | 110%                   | Green      |  |  |
| Publish 12 monthly updates of the BNF and BNF C content                                      | Publication within stated quarter | 80%    | 6                    | 6                      | 100%                   | Green      |  |  |
| Deliver a regular medicine awareness service (50 MAWs)                                       | Publication to regular schedule   | 90%    | 27                   | 27                     | 100%                   | Green      |  |  |
| Deliver update of 16 medicines optimisation key therapeutics topics                          | Publication within stated quarter | 80%    | 0                    | 16                     | 1600%                  | Green      |  |  |
| Deliver 24 medicines evidence commentaries                                                   | Publication within stated quarter | 80%    | 12                   | 10                     | 83%                    | Green      |  |  |
| Deliver 7 IAPT (Improving Access to Psychological Therapies) assessment briefings            | Publication within stated quarter | 80%    | 7                    | 6                      | 86%                    | Green      |  |  |

# **Adoption and impact**

| Provision of support products for the effective implementation of guidance                                                                          |                     |        |                         |                        |                        |       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------|-------------------------|------------------------|------------------------|-------|
| Outputs                                                                                                                                             | Measure             | Target | Planned<br>To End<br>Q2 | Actual<br>To End<br>Q2 | Cumulative performance | RAG   |
| Publish resource impact products to support all NICE guidelines, positively recommended technology appraisals, medical technologies and diagnostics | Provide within year | 90%    | 100%                    | 100%                   | 100%                   | Green |

| guidance at the point of guidance publication              |                                                                                                      |     |     |     |     |       |  |
|------------------------------------------------------------|------------------------------------------------------------------------------------------------------|-----|-----|-----|-----|-------|--|
| Maintaining and developing recognition of the role of NICE |                                                                                                      |     |     |     |     |       |  |
| Coverage of NICE in the media                              | % of positive coverage of NICE in<br>the media resulting from active<br>programme of media relations | 80% | 80% | 80% | 80% | Green |  |

# Operating efficiently

| Delivering programmes and ac                     | ctivities on budget                                                                                                                                                                       |                          |                                                                                                     |                                                                                                                                 |       |
|--------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|-------|
| Outputs                                          | Measure                                                                                                                                                                                   | Target                   | Planned To End Q2                                                                                   | Cumulative performance                                                                                                          | RAG   |
| Effective management of financial resources      | Revenue spend                                                                                                                                                                             | To operate within budget | 2019/20 budget for the period April – September 2019 was £24.9m.                                    | Net YTD spend was £23.6m. This was a net under spend of £1.3m and is mainly due to vacant posts and income being ahead of plan. | Green |
| Effective management of non-<br>exchequer income | Net income received from non-exchequer income sources (including Scientific Advice, Office for Market Access, research grants, knowledge transfer) measured against business plan targets | 90%                      | The business plan income target was to receive £2.8m year-to-date (YTD) from non-exchequer sources. | The year-to-date income recognised is £2.9m so we are currently ahead of target.                                                | Green |

| Maintaining and developing a ski  |                                                                                                                                                               | Torrect                   | Cumulativa               | DAC   |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------------|-------|
| Outputs                           | Measure                                                                                                                                                       | Target                    | Cumulative   performance | RAG   |
| Management of recruitment         | Proportion of posts appointed to within 4 months of first advertisement                                                                                       | 80%                       | 93.8%                    | Green |
| Management of sickness absence    | Quarterly sickness absence rate is lower than the average rate (3.33% as at January 2018) across the Specialist Health Authorities and other Statutory Bodies | 3.33%                     | 1.87%                    | Green |
| Staff satisfaction                | Proportion of staff reporting in staff survey that the Institute is a good, very good or excellent place to work (global job satisfaction index)              | 75%                       | 94%                      | Green |
| Staff involvement                 | Hold monthly staff meetings                                                                                                                                   | 80%                       | 100%                     | Green |
| Staff well-being                  | Implementation of NICE's quality standard for healthy workplaces: improving employee mental and physical health and wellbeing in respect of own staff         | 80% of quality statements | 83%                      | Green |
| Sustainable development           |                                                                                                                                                               |                           |                          |       |
| Recycled waste                    | % of total waste recycled                                                                                                                                     | 90%                       | 100%                     | Green |
| Improving stakeholder satisfactio | n                                                                                                                                                             |                           |                          |       |
| Improved satisfaction             | Complaints fully responded to in 20 working days                                                                                                              | 80%                       | 100%                     | Green |
| Improved satisfaction             | Enquiries fully responded to in 18 working days                                                                                                               | 90%                       | 77%                      | Amber |

Between October 2018 and March 2019 capacity within the enquiry handling team was significantly impacted by long term sickness and vacancies in key posts, including management capacity. During the same period the team saw significant campaigning activity on a number of high-profile topics. The remaining team members were also required to contribute to development of a new CRM system to manage the team's workload. This combination resulted in a backlog of enquiries. Following successful recruitment to vacant posts, the trend in performance since Q4 2018-19 is positive and continues to improve. We expect this improvement to continue through Q3 and Q4.

| Improved satisfaction | Number of Freedom of Information requests | 100% | 98% | Amber |
|-----------------------|-------------------------------------------|------|-----|-------|
|                       | responded to within 20 working days       |      |     |       |
|                       |                                           |      |     |       |

#### Notes:

One FOI was answered on day 21 due to delays in the team receiving the information and sign off.

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| Improved satisfaction         | Parliamentary Questions contribution provided within | 90% | 100%   | Green |
|-------------------------------|------------------------------------------------------|-----|--------|-------|
|                               | requested timeframe                                  |     |        |       |
| Ensuring stakeholders have    | Percentage of planned availability, not including    | 98% | 99.97% | Green |
| access to our websites as the | scheduled out of hours maintenance                   |     |        |       |
| main communication channel    |                                                      |     |        |       |

| Outputs                                                                                                         | Measure                          | Target |     |     | Cumulative performance | RAG   |
|-----------------------------------------------------------------------------------------------------------------|----------------------------------|--------|-----|-----|------------------------|-------|
| Interest in opportunities for lay people to sit on our advisory reflected by ratio of applications to positions | 2 to 1 (or greater) each quarter | 100%   | 2:1 | 8:1 | 400%                   | Green |

| Improving efficiency and speed of outputs |                                                                                                                                    |               |                        |       |  |
|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|---------------|------------------------|-------|--|
| Outputs                                   | Measure                                                                                                                            | Annual target | Cumulative performance | RAG   |  |
| Speed of production                       | % STAs for all new drugs issuing an ACD or FAD within 6 months of the product being first licensed in the UK                       | 90%           | 100%                   | Green |  |
| Speed of production                       | % of multiple technology appraisals from invitation to participate to ACD in 41 weeks, or where no ACD produced to FAD in 44 weeks | 85%           | N/A                    | N/A   |  |
| Notes:                                    |                                                                                                                                    |               |                        |       |  |
| No publications have been planne          | ed.                                                                                                                                |               |                        |       |  |
| Speed of production                       | % of Appeal Panel decisions received within 3 weeks of the hearing                                                                 | 80%           | N/A                    | N/A   |  |
| Notes:                                    |                                                                                                                                    |               |                        |       |  |
| No appeal decisions have been p           | lanned.                                                                                                                            |               |                        |       |  |

RAG Status - Key

Green

= Greater than or equal to annual target

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November 2019

# National Institute for Health and Care Excellence Finance and Workforce Report

This report gives details of the financial position as at 30 September 2019 and the current forecast outturn for 2019/20. The report also includes information on Technology Appraisal (TA) and Highly Specialised Technologies (HST) income generated through cost recovery charging and an update on workforce matters.

The Board is asked to review the report.

Ben Bennett

Director, Business Planning and Resources

November 2019

# Position as at 30 September 2019

# Summary

1. Table 1 summarises the financial position as at 30 September 2019. There is a full analysis in Appendix A.

Table 1: Year to Date Financial Position at 30 September 2019

| Area                       | Year to<br>date<br>budget<br>£m | Year to<br>date<br>expenditure<br>£m | Year to<br>date<br>income<br>£m | Year to<br>date<br>variance<br>£m |
|----------------------------|---------------------------------|--------------------------------------|---------------------------------|-----------------------------------|
| Guidance & Advice Centres  | 24.3                            | 24.2                                 | (0.6)                           | (0.7)                             |
| <b>Corporate Functions</b> | 6.7                             | 6.9                                  | (0.5)                           | (0.3)                             |
| Science Advice & Research* | (0.0)                           | 1.2                                  | (1.3)                           | (0.1)                             |
| Income (non grant-in-aid)  | (6.1)                           | 0.0                                  | (6.4)                           | (0.2)                             |
| Grand Total                | 24.9                            | 32.3                                 | (8.7)                           | (1.3)                             |

<sup>\*</sup>The full Income and expenditure position for the SAR Directorate is shown below in table 6

- 2. The table above shows a total underspend against budget of £1.3m (5%) at the end of September 2019.
- 3. Table 2 below gives an estimated outturn for 31 March 2020. The full-year forecast is an underspend of £0.5m (1%). This is a reduction from the current under spend position because of cost pressures expected later in the year relating to NICE Connect and preparations for relocating to a new office in London.

**Table 2: Estimated Outturn Financial Position at 30 September 2019** 

| Area                      | Estimated outturn (March 2020) Budget £m | Estimated<br>outturn<br>(March<br>2020)<br>Expenditure<br>£m | Estimated<br>outturn<br>(March<br>2020)<br>Income<br>£m | Estimated outturn (March 2020) Variance £m |
|---------------------------|------------------------------------------|--------------------------------------------------------------|---------------------------------------------------------|--------------------------------------------|
| Guidance & Advice Centres | 49.2                                     | 49.5                                                         | (1.1)                                                   | (8.0)                                      |
| Corporate Functions       | 13.8                                     | 14.9                                                         | (0.9)                                                   | 0.2                                        |
| Science Advice & Research | 0.0                                      | 2.5                                                          | (2.6)                                                   | (0.1)                                      |
| Income (non grant-in-aid) | (14.4)                                   | 0.0                                                          | (14.2)                                                  | 0.2                                        |
| Grand Total               | 48.6                                     | 66.9                                                         | (18.7)                                                  | (0.5)                                      |

4. The project to bring recruitment in house is progressing well and the new system is expected to be fully implemented in January 2020

#### Financial Position as at 30 September 2019

5. Table 3 summarises the year to date financial position as at 30 September 2019 split between pay, non-pay and income.

Table 3: Year to date Financial Position by spend category (September 2019)

| Type of cost       | Budget<br>£000's | Outturn<br>£000's | Variance<br>£000's |
|--------------------|------------------|-------------------|--------------------|
| Pay                | 19,234           | 18,732            | (502)              |
| Non-pay            | 14,034           | 13,567            | (467)              |
| Income             | (8,408)          | (8,742)           | (333)              |
| <b>Grand Total</b> | 24,860           | 23,557            | (1,303)            |

- 6. Table 3 above shows total net expenditure to 30 September 2019 was £23.6m against a budget of £24.9m, giving an underspend of £1.3m (5%). The underspend comprised of:
  - £502,000 pay underspend due to vacancies and staff turnover across the organisation.
  - £467,000 non-pay underspend relating to lower than expected depreciation, contractual expenditure in the MedTech Evaluation programme and Digital Services non-pay expenditure.
  - £333,000 income in excess of target due to TA and HST charging income being ahead of plan and increased intellectual property and copyright license income generated within the Evidence Resources Directorate.
- 7. Appendix A shows in detail the financial position and forecast outturn by centre and directorate. Directors receive detailed monthly reports on the budget performance of their directorates and the senior management team receive a finance report detailing the summary position and any issues on a bi-monthly basis.

#### Pay and resourcing

8. Pay expenditure to 30 September 2019 was £18.7m against an adjusted budget of £19.2m, resulting in an underspend of £0.5m. The distribution across the centres is shown in table 4:

Table 4: Year to date Pay Figures by Centre

| Centre / Directorate                    | Budget<br>£000 | Expenditure<br>£000 | Variance<br>£000 | Variance<br>% |
|-----------------------------------------|----------------|---------------------|------------------|---------------|
| Centre for Guidelines                   | 3,313          | 3,199               | (114)            | (3%)          |
| Centre for Health Technology Evaluation | 4,556          | 4,520               | (37)             | (1%)          |
| Health & Social Care                    | 4,197          | 4,146               | (51)             | (1%)          |
| Evidence Resources                      | 2,629          | 2,481               | (148)            | (6%)          |
| Science Advice and Research             | 1,142          | 1,067               | (75)             | (7%)          |
| Business Planning & Resources           | 1,543          | 1,553               | 10               | 1%            |
| Communications                          | 1,854          | 1,766               | (89)             | (5%)          |
| Grand Total                             | 19,234         | 18,732              | (502)            | (3%)          |

- 9. The pay budget is a part year effect budget as each year during budget setting teams' pay budgets are reduced in line with any current or expected vacant posts. This funding is used for new business developments and in year pressures. This financial year it also funded the NICE Connect project.
- 10. During September the total number of vacancies was 28 wte (a 4.1% vacancy rate). This has reduced from the 10% consistent vacancy rate in 2018/19 and the 5.2% rate in July. Current vacancies are mainly due to the timing delay between leavers and new starters. Table 5 below shows the number of new starters and leavers between 1 April 2019 and 30 September 2019.

Table 5: New Starters and Leavers, 1 April 2019 to 30 September 2019

| Month          | New<br>Starters<br>(Headcount) | Leavers<br>(Headcount) |
|----------------|--------------------------------|------------------------|
| April          | 9                              | 11                     |
| May            | 8                              | 7                      |
| June           | 13                             | 8                      |
| July           | 9                              | 9                      |
| August         | 12                             | 7                      |
| September      | 11                             | 11                     |
| Grand<br>Total | 62                             | 53                     |

11. There are currently 5 wte agency staff employed across the organisation with a total spend up to September 2019 of £165,000 (1% of total pay costs), this is an increase of 50% compared to the same period last year. The main reasons for this increase is the use of agency staff within the Business Planning and

Resources directorate due to staff shortages in facilities and additional resource for the London office move and NICE Connect. Some of these roles have now been recruited to substantively.

#### Non-pay

- 12. Non-pay budget under spends have contributed £0.5m to the current year to date underspend, this is mainly due to the following areas of under spend.
- 13. MedTech External Assessment Centre contracts of £107,000. This is due to lower than expected numbers of topics being run by the Observational Data Unit. This under spend is expected to increase between now and the end of the financial year, however, it is now likely that some of the variable element of the MedTech external assessment centre budget (£0.35m) will be utilised during 2019/20. This accumulated underspend will be used to offset the potential cost pressures relating to the London Office move and NICE Connect resource requirements mentioned in the forecast below.
- 14. A planned year to date underspend of £127,000 in the Digital Services non-pay budget. This will be used to fund digital development work in the latter part of the year to develop a new customer relationship management system, Microsoft Office 365 rollout and commitments relating to the NICE Connect project.
- 15. Facilities underspend of £110,000. This relates to lower than expected spend on external meeting room hire and prior year service charge credits for the Manchester Office.
- 16. Depreciation of £70,000. The depreciation underspend is expected to grow in the short-term but will reduce in the latter part of the year as we commit expenditure on capital purchases such as IT hardware and purchases associated with the London Office move. Depreciation is a non-cash allocation which means under spends on this budget cannot be allocated to expenditure elsewhere.

#### Income

- 17. Income at 30 September is £0.3m more than planned. Technology Appraisal and Highly Specialised Technologies charges, intellectual property and copyright license income are all ahead of plan and have exceeded their targets in the first 6 months of the year. £62,000 relates to funding received from NHS England for the pilot evaluation of digital health technologies. The funding is used to reimburse for CHTE staff time spent on the pilot.
- 18. Further details about Technology Appraisal income is included later in this report.

National Institute for Health and Care Excellence Finance and workforce report Date: 20 November 2019 Reference: 19/100 19. Table 6 below shows the financial position for the Science, Advice and Research Directorate split by pay, non-pay and income as at 30 September 2019 and the full year forecast outturn.

Table 6: Summary of Science, Advice and Research Directorate's Financial Position

| Spend Category     | Year to<br>Date<br>Budget<br>£000's | Year to<br>Date<br>Actual<br>£000's | Year to<br>Date<br>Variance<br>£000's | Estimated<br>outturn<br>(March<br>2020)<br>Budget<br>£000's | Estimated<br>outturn<br>(March<br>2020)<br>Outturn<br>£000's | Estimated outturn (March 2020) Variance £000's |
|--------------------|-------------------------------------|-------------------------------------|---------------------------------------|-------------------------------------------------------------|--------------------------------------------------------------|------------------------------------------------|
| Pay                | 1,142                               | 1,067                               | (75)                                  | 2,325                                                       | 2,194                                                        | (130)                                          |
| Non-Pay            | 184                                 | 150                                 | (33)                                  | 368                                                         | 338                                                          | (30)                                           |
| Income             | (1,343)                             | (1,325)                             | 18                                    | (2,671)                                                     | (2,575)                                                      | 96                                             |
| <b>Grand Total</b> | (18)                                | (108)                               | (90)                                  | 22                                                          | (43)                                                         | (65)                                           |

- 20. The year to date financial position shows a surplus of £90,000. There was a £75,000 underspend on pay due to vacancies, £33,000 underspend on non-pay and income is currently £18,000 in deficit. The marginal income deficit highlights that the directorate is still managing to deliver close to planned levels of income with lower related expenditure.
- 21. The current estimated outturn for March 2020 predicts that the income deficit will continue to build but this will be offset predominantly by vacancies within the two teams leaving an estimated outturn surplus of £65,000.

#### Forecast Outturn

- 22. The overall current full year forecast is an underspend of £0.5million. Non-recurrent underspends relating to vacancy savings and non-pay reductions are being used to offset costs relating to the NICE Connect transformation programme and potential cost pressures including potential costs arising from the London office move due to take place in 2020.
- 23. The summary financial position analysed by directorate is shown in Appendix A. The first is shown against Centre for Health Technology Evaluation (CHTE), where the total forecast underspend £0.3m is wholly attributable to the flexible element of the MedTech External Assessment Centre contract as mentioned above. Other non-recurrent pay underspends are being used to offset the likely increased pay costs within CHTE in the latter part of the year relating to Technology Appraisal expansion plans funded by cost recovery income.
- 24. It is still too early to predict with any certainty what the final income figure for Technology Appraisal and Highly Specialised Technologies charges will be in 2019/20. A forecast income figure of £4.5m is the best estimate at this stage

- based on the topics in the pipeline for the rest of the financial year. DHSC have agreed to cover the shortfall if required.
- 25. Evidence Resources is showing a £0.14m forecast underspend against budget. Vacancy underspends across the directorate will be used to offset planned non-pay relating to the CRM implementation and Office 365 and SharePoint configuration and support later in the financial year.
- 26. The resources required to support the NICE Connect transformation programme have been estimated at £0.45m for the current financial year, which will be fully funded by £0.46m budget allocated to the programme in 2019/20.
- 27. The final significant variation shown in Appendix A relates to potential cost pressures (£0.3m) which may materialise during the year. These include:
  - Investment is required to update the IT infrastructure and other technology, including implementing recommendations made by external consultants in relation to data management and storage.
  - A need to make provisions in the accounts towards the end of the financial year for potential costs and liabilities arising from the London office move.
- 28. There are currently no reserves in place to fund the above potential cost pressures if they materialise. However, the current forecast assumes that a number of non-recurrent underspends in teams (including the forecast underspend in CHTE noted above) will be sufficient to offset these potential costs.

# Mid-year review

29. The financial statements (statement of comprehensive net expenditure and statement of financial position) comparing the mid-year position from 2018/19 to 2019/20 are presented for review in Appendix 2.

Statement of Comprehensive Net Expenditure (Income and Expenditure Statement)

30. The statement of comprehensive net expenditure shows the income and expenditure for the first 6 months of the financial year. As shown in the financial positions section above, net expenditure during April to September 2019 was £23.6m. This is broadly in line with the same period in 2018/19 when net expenditure was £24.1m. Table 7 details the breakdown by pay, non-pay and income.

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Table 7: April to September net expenditure, 2018/19 and 2019/20

| April to September net expenditure | 2018/19<br>£m | 2019/20<br>£m | Variance<br>£m | Variance<br>% |
|------------------------------------|---------------|---------------|----------------|---------------|
| Pay                                | 17.5          | 18.8          | 1.3            | 7%            |
| Non-pay                            | 15.4          | 13.5          | (1.9)          | (12%)         |
| Income                             | (8.8)         | (8.8)         | 0.0            | 0%            |
| Total                              | 24.1          | 23.5          | (0.6)          | (2.5%)        |

31. Expenditure on pay is £1.3m higher due to an increase in staff numbers in the past 12 months. Table 8 below shows the increase in staff numbers by Centre/Directorate.

Table 8: Change in staff numbers over the past 12 months (September 2018 to September 2019)

| Centre / Directorate                    | 2018/19<br>(WTE at 30<br>September<br>2018) | 2019/20<br>(WTE at 30<br>September<br>2019) | WTE<br>Increase/<br>(Decrease) |
|-----------------------------------------|---------------------------------------------|---------------------------------------------|--------------------------------|
| Centre for Guidelines                   | 101                                         | 102                                         | 1                              |
| Centre for Health Technology Evaluation | 136                                         | 158                                         | 21                             |
| Health & Social Care                    | 122                                         | 128                                         | 7                              |
| Evidence Resources                      | 85                                          | 87                                          | 2                              |
| Science Advice and Research             | 39                                          | 32                                          | (7)                            |
| Business Planning & Resources           | 67                                          | 66                                          | (1)                            |
| Communications                          | 69                                          | 68                                          | (1)                            |
| Grand Total                             | 618                                         | 641                                         | 23                             |

- 32. The Centre for Health Technology Evaluation has shown the most significant increase in staffing with their whole time equivalent (WTE) increasing by 21, an increase of 15%, with analyst roles accounting for most of this increase. In addition, Health & Social Care staffing numbers have increased due to the creation of the Healthcare Data & Analytics team and NICE Connect.
- 33. Non-pay expenditure is £1.9m lower than last year and is largely due to a reduction in contract spending. Of this, £0.8m relates to a contract we had with the Royal College of Psychiatrists to develop Evidence Treatment Pathways for Mental Health, work which ended in March 2019. Additional reductions in contract spend including reducing the capacity of the Guideline Development Centres £0.2m) and Medical Technology External Assessment Centres (£0.3m). Other differences include spend on digital projects in the first half of last year being £0.3m higher, including building the HealthTech Connect database. Table 9 below highlights the key movement in non-pay spend in the past 12 months.

Table 9: Non-pay spend comparison

| Non-Pay Category     | Year to Date<br>Actual (as at<br>30<br>September<br>2018)<br>£000's | Year to Date<br>Actual (as<br>at 30<br>September<br>2019)<br>£000's | Increase/<br>(Decrease)<br>£000's |
|----------------------|---------------------------------------------------------------------|---------------------------------------------------------------------|-----------------------------------|
| Contracts            | 8,515                                                               | 6,600                                                               | (1,914)                           |
| Other                | 3,419                                                               | 3,379                                                               | (40)                              |
| IT                   | 687                                                                 | 684                                                                 | (3)                               |
| Facilities           | 2,002                                                               | 2,006                                                               | 5                                 |
| Travel & Subsistence | 811                                                                 | 897                                                                 | 87                                |
| Grand Total          | 15,433                                                              | 13,567                                                              | (1,866)                           |

34. There is no variance on the total income received, although there has been a change in the underlying make up of this. The position this year includes £1.45m from TA and HST charges. This is offset by a reduction in income from NHS England relating to Evidence Treatment Pathways noted above (£0.8m), the Commissioning Support Programme ending (£0.3m) and a reduction in topics in the Observational Data Unit (£0.3m).

#### Statement of Financial Position (Balance Sheet)

- 35. This statement shows the value of all our assets and liabilities at 30 September 2019. As well as physical (or fixed) assets it also shows amounts that were owed to us by debtors, set against our liabilities or amounts that we owed to creditors. The difference between assets and liabilities is the total net liabilities of £1.2m. This is owned by the taxpayer and therefore described as taxpayers' equity in the final section of the statement.
- 36. Overall our total net assets up to 30 September 2019 have decreased by £5.8m from the previous year for the following reasons:
  - Non-current assets are £0.3m less then prior year due to depreciation of existing assets and a low number of additions in the past 12 months;
  - Trade and other receivable balances are £1.0m more than prior year due to TA charging invoices now being raised and higher amounts of accrued grant income;
  - Cash and cash equivalents balance is £4.5m less than last year due to the timing of payments and receipts and careful cash management, only drawing down cash from DHSC as needed;
  - Trade and other payables are £2.1m more than prior year due to timing of invoice payments and increased deferred income due to the need to spread TA and HST income across the full timeline of the appraisal;

- Provisions for liabilities and charges are £0.1m lower than prior year as some previous provisions have been utilised or released.
- 37. The net effect of these movements results in the General Fund decrease of £5.8m.
- 38. As an NDPB we have an annual cash limit that we have a financial duty to operate within. As at 30 September we have drawn down £18m of cash from the exchequer, which represents 37% of our £48.5m limit for 2019/20. We manage our cash balances to ensure that we do not hold any significant funds beyond our short-term needs. Cash balances are likely to rise in the second half of the year due to retained non exchequer cash balances and increased non-exchequer funding received from TA cost recovery, Scientific Advice and other income generating teams.

# **Technology Appraisals and Highly Specialised Technologies Charging**

- 39. This report covers the position to 30 September 2019 which is the first 6 months of cost recovery charging regime for Technology Appraisal (TA) and Highly Specialised Technologies (HST). At 30 September 2019, 36 topics had started (that is, had their invitation to participate (ITP) notice) and are subject to charging; of these 31 were Single Technology Appraisals, 4 were Cancer Drugs Fund reviews and 1 was a Highly Specialised Technologies evaluation.
- 40. The planning assumption is that 78 topics will commence in each financial year. This is equivalent to an average of 6-7 topics starting per month. Therefore, the number of topics expected to have started by 30 September 2019 is 39. The actual number of topics started is 36, slightly lower than predicted, however, the income recognised to date is higher than forecast due to the timing and phasing of those invoices, with a higher than expected number of topics starting in April and May. It is expected that there will be peaks and troughs like this throughout the year, but this will be mitigated by the fact the income is recognised over the life of the appraisal (10-11 months) rather than when the invoice is raised.
- 41. The TA and HST income target for 2019/20 is £4.8m. The year to date income target is £1.3m and £1.45m of income has been recognised for the 36 topics that have started. These topics are expected to achieve £3.6m of income for 2019/20.
- 42. Chart 1 below shows that we are currently £0.15m ahead of target and the income recognised exceeds the forecast amount in each individual month so far. However, as topics do not start in linear fashion across the year the current full year forecast is £4.5m.

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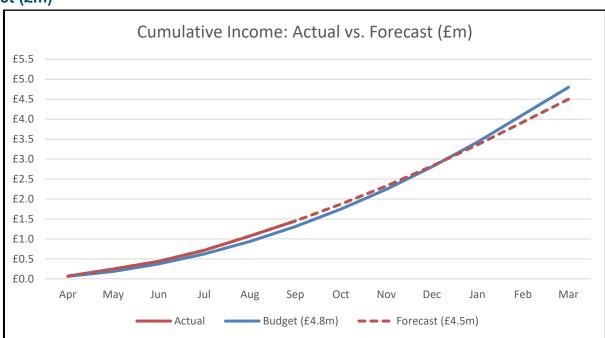


Chart 1: Cumulative income to date and full-year forecast compared to 2019-20 budget (£m)

#### Download the data set for this chart

- 43. At any point in time there are multiple TA and HST topics in the 'pipeline', some of which are in the scoping phase, some have been referred by DHSC but not yet had their ITP and others have started the appraisal process. At 30 September 2019, 79 topics had started the appraisal process and 36 of those are subject to charging (46%), with the balance of 43 relating to appraisals that began before 1 April 2019. As we move through 2019/20 the number and proportion of topics that have started and have been charged for will increase and conversely the number of topics that are residually funded by GIA will decrease.
- 44. It was agreed that small companies (as defined by the companies' act) will receive a 75% discount and have the option of paying in instalments. Our initial estimate was that around 10% of topics would be from a small company based on previous technology appraisals. Thus far only 1 of the 36 TA and HST topics that have started this year have been from a small company. In addition, 4 small companies have been invoiced for topics starting later in the year.
- 45. During this launch phase, the CHTE topic selection and finance teams have continued to maintain good communication with companies regarding charging and payment has usually been received promptly. Debt management procedures and consideration of pausing topics have not been required.

## Workforce

## Resourcing

- 46. The project to bring recruitment in house is progressing well. The HR team have appointed a new Recruitment assistant and are currently out to advert for a Recruitment adviser. The configuration of the new applicant tracking system is on track and will be used for a small number of recruitment campaigns to test the system before it is fully implemented in January 2020.
- 47. A new recruitment and selection policy is being developed to support the new in house service.

#### Culture

- 48. The Freedom to Speak Up Guardians role have been promoted across NICE, with drop in sessions taking place to raise awareness.
- 49. The 2019 NICE staff survey was presented at the September board meeting. Our HR and Organisation Development (OD) teams are now working with staff survey leads from each of the directorates to develop and implement action plans.

## Transformational Change

50. The HR team continue to be involved in NICE Connect. We will be establishing a People Expert Group in the new year and will be recruiting for a HR and OD Transformational Change Manager to be the key point of contact for this work.

# **Maximising Potential**

- 51. HR have delivered mini masterclasses on 'resolving issues at work' which updated managers skills related to informal grievances and disciplinary issues and 'management admin' which reminded managers of their responsibilities regarding pay sensitive changes and record keeping. Mini masterclasses have now been delivered on all revised HR policies to date. Following the delivery of the popular 'sickness absence' sessions before the end of 2019, the HR team will undertake a review of the success of these classes before running any further management training in 2020.
- 52. As part of the focus on increasing leadership confidence and capability across the organisation, 18 staff members are now on leadership and management development programmes funded through the apprenticeship levy. The courses are at levels 3, 5 and 7, and will provide managers with skills, knowledge, strategies and tools to make a positive difference to their performance, their team's performance, working relationships and results. The apprenticeships also

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#### Item 4

aim to lift participants out of day-to-day management and look strategically at their area of responsibility and the wider organisational priorities.

# **Appendix A: Summary of Financial Position**

The table below is a summary of the financial position per centre and directorate as at 30 September 2019 and gives an estimated outturn to March 2020.

| Centre / Directorate                                                                        | Year to<br>date<br>budget<br>£000's | Year to date actual £000's | Year to date variance £000's | Year to<br>date<br>variance<br>% | Estimated<br>outturn<br>(March<br>2020)<br>Budget<br>£000's | Estimated<br>outturn<br>(March<br>2020)<br>Outturn<br>£000's | Estimated outturn (March 2020) Variance £000's | Estimated<br>outturn<br>(March<br>2020)<br><i>Variance</i><br>% |
|---------------------------------------------------------------------------------------------|-------------------------------------|----------------------------|------------------------------|----------------------------------|-------------------------------------------------------------|--------------------------------------------------------------|------------------------------------------------|-----------------------------------------------------------------|
| Income from other<br>ALBS, Devolved<br>Administrations and<br>other miscellaneous<br>income | (4,837)                             | (4,905)                    | (68)                         | 1%                               | (9,570)                                                     | (9,697)                                                      | (127)                                          | 1%                                                              |
| Income from TA and HST cost recovery                                                        | (1,298)                             | (1,450)                    | (153)                        | 12%                              | (4,800)                                                     | (4,500)                                                      | 300                                            | (6%)                                                            |
| Centre for Guidelines                                                                       | 8,527                               | 8,408                      | (119)                        | (1%)                             | 17,353                                                      | 17,166                                                       | (186)                                          | (1%)                                                            |
| Centre for Health<br>Technology<br>Evaluation                                               | 5,815                               | 5,571                      | (244)                        | (4%)                             | 11,830                                                      | 11,564                                                       | (266)                                          | (2%)                                                            |
| Health & Social Care                                                                        | 4,614                               | 4,609                      | (6)                          | 0%                               | 9,254                                                       | 9,042                                                        | (212)                                          | (2%)                                                            |
| Evidence Resources                                                                          | 5,322                               | 4,989                      | (333)                        | (6%)                             | 10,757                                                      | 10,621                                                       | (136)                                          | (1%)                                                            |
| Science, Advice and<br>Research                                                             | (18)                                | (108)                      | (90)                         | n/a                              | 22                                                          | (43)                                                         | (65)                                           | n/a                                                             |
| Business Planning & Resources                                                               | 4,239                               | 4,125                      | (114)                        | (3%)                             | 8,570                                                       | 8,616                                                        | 46                                             | 1%                                                              |
| Communications                                                                              | 2,056                               | 1,964                      | (91)                         | (4%)                             | 4,120                                                       | 4,011                                                        | (109)                                          | (3%)                                                            |
| NICE Connect                                                                                | 115                                 | 100                        | (16)                         | (14%)                            | 463                                                         | 455                                                          | (9)                                            | (2%)                                                            |
| Potential cost pressures                                                                    | -                                   | -                          | -                            | -                                | 0                                                           | 300                                                          | 300                                            | n/a                                                             |
| Depreciation                                                                                | 325                                 | 255                        | (70)                         | (22%)                            | 650                                                         | 600                                                          | (50)                                           | (8%)                                                            |
| Grand total                                                                                 | 24,860                              | 23,557                     | (1,303)                      | (5%)                             | 48,648                                                      | 48,134                                                       | (514)                                          | (1%)                                                            |

# **Appendix B Financial Statements**

| Statement of comprehensive net expenditure for the period April to September (6 months) | 30 <sup>th</sup> Sept<br>2019 Total<br>£000 | 30 <sup>th</sup> Sept<br>2018 Total<br>£000 |
|-----------------------------------------------------------------------------------------|---------------------------------------------|---------------------------------------------|
| Total operating income                                                                  | (8,774)                                     | (8,775)                                     |
| Operating expenditure                                                                   |                                             |                                             |
| Staff costs                                                                             | 18,834                                      | 17,512                                      |
| Purchase of goods and services                                                          | 5,576                                       | 5,638                                       |
| Depreciation and impairment charges                                                     | 254                                         | 370                                         |
| Other operating expenditure                                                             | 7,667                                       | 9,376                                       |
| Total operating expenditure                                                             | 32,331                                      | 32,896                                      |
| Comprehensive net expenditure                                                           | 23,557                                      | 24,121                                      |

The above statement shows the income and expenditure incurred during months April - September in each financial year only to aid comparison.

| Statement of financial position as at 30 <sup>th</sup> September                        | 30 <sup>th</sup> Sept<br>2019 Total<br>£000 | 30 <sup>th</sup> Sept<br>2018 Total<br>£000 |
|-----------------------------------------------------------------------------------------|---------------------------------------------|---------------------------------------------|
| Non-current assets                                                                      |                                             |                                             |
| Property, plant and equipment                                                           | 1,313                                       | 1,571                                       |
| Intangible assets                                                                       | 107                                         | 100                                         |
| Total non-current assets                                                                | 1,420                                       | 1,671                                       |
| Current assets                                                                          |                                             |                                             |
| Trade and other receivables                                                             | 6,208                                       | 5,195                                       |
| Cash and cash equivalents                                                               | 1,064                                       | 5,580                                       |
| Total current assets                                                                    | 7,272                                       | 10,775                                      |
| Total assets                                                                            | 8,692                                       | 12,446                                      |
| Liabilities                                                                             |                                             |                                             |
| Trade and other payables                                                                | (8,979)                                     | (6,865)                                     |
| Provisions for liabilities and charges                                                  | (931)                                       | (1,009)                                     |
| Total liabilities                                                                       | (9,910)                                     | (7,874)                                     |
| Total assets less liabilities                                                           | (1,218)                                     | 4,572                                       |
| Taxpayers' equity                                                                       |                                             |                                             |
| General fund – segment 1 NICE                                                           | (2,030)                                     | 3,534                                       |
| General fund – segment 2 NICE Scientific Advice (balance brought forward at 31st March) | 812                                         | 1,038                                       |
| Total taxpayers' equity                                                                 | (1,218)                                     | 4,572                                       |

The above statement shows the statement of financial position (also known as the balance sheet) as at 30 September in each financial year. It is a snapshot at that particular date and is not necessarily representative of the financial position at other points of the financial year or the position reported in the annual accounts.

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November 2019

#### **National Institute for Health and Care Excellence**

# Widening the evidence base: the use of broader data and applied analytics in guidance development

This paper describes changes made to a statement of intent for the appropriate use of data analytics across NICE's programmes.

The Board is asked to discuss and agree the changes and the proposed next steps for the Data and Analytics transformation programme.

Professor Gillian Leng

Deputy Chief Executive and Director, Health and Social Care Directorate

Alexia Tonnel

Director, Evidence Resources Directorate

November 2019

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# Introduction

- NICE helps the health and social care system to deliver the best outcomes within
  the resources available. We do this through a diverse range of programmes
  which share the same core process, including identification, assessment and
  interpretation of evidence, presented as guidance recommendations, advice or
  information.
- 2. The recommendations we make and the information we provide all need to be kept up to date, requiring a periodic repeat of the guidance development process, or a variation of it.
- 3. Increases in the amount and breadth of data available, the development of new and efficient mechanisms for analysis, and advances in the way information is labelled, linked and shared, have the potential to significantly disrupt our traditional approaches to synthesising research evidence. At the same time, they offer opportunities to improve timeliness, relevance and efficiency.
- 4. This paper describes the feedback received on our 'statement of intent' signalling our ambition for the future use of data and analytics within NICE's guidance programmes and wider products.

# **Background**

Reference: 19/101

- 5. Following Board discussions in March and May 2018, recurrent funding was ring-fenced to support the establishment of a new Data and Analytics (DA) team. A cross-NICE steering group, comprising senior representatives from all relevant internal programmes, has also been in place since early 2018. It is responsible for high level oversight of NICE's activities associated with data and analytics and provides strategic support to the new team.
- 6. In January 2019 the Board considered a paper on the use of data analytics at NICE, which highlighted progress to date on how NICE is enhancing its capability to identify and use data and analytics in its work. This included the strategic focus to develop a framework for the appropriate use of data analytics across NICE's programmes.
- 7. Developing the framework, positioned as a 'statement of intent' (SoI) for the use of data and analytics, was prioritised as a crucial part of both internal transformation and external communication. The statement built on internal advice to guideline developers produced to support the updated guidelines manual published in October 2018.
- 8. The statement of intent covers four key areas:

- What kind of evidence does NICE currently use to develop guidance?
- What broader types of data are available?
- When and why should broader types of data be considered?
- Practical considerations associated with data analytics.
- 9. Technical detail on methodological considerations are not included in the statement and future detailed documentation on this topic will be developed at a later stage, aimed at a technical audience and embedded within NICE's future methods guides.
- 10. In May 2019 the Board approved making the statement of intent publicly available on our website and open to consultation comments from stakeholders for a period of three months (from June 13th September 13th, 2019).
- 11. The statement of intent was also discussed with appropriate existing groups with an interest in our developing work on data analytics; and we also held two faceto-face workshops, attended by a broad range of stakeholders from over 50 organisations.

#### Consultation feedback

- 12. A total of 111 responses were received from the online consultation, 93% of which were from the UK and 68% of which were submitted on behalf of organisations.
- 13. Other key statistics from the online consultation to note were:
  - a. 86% of respondents agreed or strongly agreed that the overall approach set out in the SoI was clear and understandable
  - b. 80% of respondents agreed or strongly agreed that the Sol took appropriate account of current and future trends
  - c. 39% of respondents felt that the SoI had gaps or omissions in the scope of ambition
  - d. 70% of respondents agreed or strongly agreed that NICE's ambition aligned appropriately with relevant external initiatives
  - e. 74% of respondents agreed or strongly agreed that the Sol appropriately set out the scope of the data NICE should be considering
  - f. 93% of the respondents were from the UK. Overall, 38% of responses were from individuals and 63% were on behalf of organisations. The

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majority of respondents (69%) indicated that they had heard about the consultation via direct communication from NICE (website – 19%; newsletter – 12%; direct email communication – 38%).

# Summary of changes made to the statement of intent

14. In response to the consultation the team has made a number of additions and clarifications to the statement of intent which are set out in Table 1. The final version of the statement will be published on the NICE website.

Table 1: Additions and clarifications made to the Statement of Intent

| Category               | Summary of comments                                                                                                                                                                                                                                                                                                                                                         | Action by NICE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Process considerations | Stakeholders noted a lack of clarity around the intersection between this work programme and the CHTE 2020 methods review. There were also queries as to what role external experts would play as either consultants on projects or in delivering complete pieces of analysis. Several stakeholders were interested in NICE's position on using international data sources. | Modified the Sol with an additional paragraph detailing the relationship with the CHTE methods review: "This statement of intent and the Centre for Health Technology Evaluation (CHTE) methods update are separate strands of work within NICE. However, we acknowledge that there is a significant degree of commonality, particularly in the areas of uncertainty, types of evidence and evidence generation. In light of this similarity our ambition will be that processes and methods are consistent across NICE where possible, but not homogeneous." |
| Data                   | Many respondents, particularly those from individual rather than organisational submissions, felt that the consideration of qualitative information, particularly from patients, guardians or carers, should be included within NICE's data and analytics strategy.                                                                                                         | Amended the Sol to include a reference to this.  A risk was logged in the risks table regarding the use of 'grey' literature due to its vulnerability to bias.                                                                                                                                                                                                                                                                                                                                                                                                |
|                        | Some respondents thought that the statement of intent document should include disease registries as a source of additional data.                                                                                                                                                                                                                                            | Amended the Sol to include a reference to these data sources.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|                        | Some respondents mentioned that genomic or biobank data could be a potential source of data that NICE may want to consider.                                                                                                                                                                                                                                                 | Amended the Sol to include a reference to these data sources.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

Reference: 19/101

|                           | Where no appropriate UK data sources exist, some respondents thought that NICE may wish to consider the use of non-UK sources of data. This might be for rare conditions or medical technology in use elsewhere but not yet in the UK.                                                                                                                                                                                                                             | Amended the draft Sol to explain we are open to non-UK sources if generalisable to a UK setting but such will require additional methodology and information governance considerations.                                                                                                              |
|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                           | Some respondents mentioned that apps, wearables and the 'internet of things' could be a potential source of data                                                                                                                                                                                                                                                                                                                                                   | Amended the Sol to include a reference to these types of technologies.                                                                                                                                                                                                                               |
|                           | Some respondents suggested that data from tertiary healthcare providers such as charities may be a potential source                                                                                                                                                                                                                                                                                                                                                | Amended the Sol to include a reference to this data source.                                                                                                                                                                                                                                          |
|                           | A common response was a suggestion to include phrasing that NICE remain open to new data sources becoming available                                                                                                                                                                                                                                                                                                                                                | Amended the Sol to include a reference to this data source.                                                                                                                                                                                                                                          |
|                           | Data from the community setting (e.g. community services dataset, maternity services, mental health services dataset) was mentioned by some respondents as being potentially useful additional sources of data                                                                                                                                                                                                                                                     | Amended the Sol to include a reference to this data source.                                                                                                                                                                                                                                          |
| External<br>Initiatives   | Health Data Research UK                                                                                                                                                                                                                                                                                                                                                                                                                                            | Amended the Sol to include a reference to this initiative.                                                                                                                                                                                                                                           |
|                           | Local Health Record Exemplars                                                                                                                                                                                                                                                                                                                                                                                                                                      | Amended the Sol to include a reference to this initiative.                                                                                                                                                                                                                                           |
|                           | Accelerated Access Collaborative                                                                                                                                                                                                                                                                                                                                                                                                                                   | Amended the Sol to include a reference to this initiative.                                                                                                                                                                                                                                           |
|                           | Academic Health Science Centres                                                                                                                                                                                                                                                                                                                                                                                                                                    | Amended the Sol to include a reference to this initiative.                                                                                                                                                                                                                                           |
| Transparency: publication | The principle remedy/mechanism to maintain transparency mentioned by respondents was the aim to publish as much detail describing the analysis and data handling as possible. Publication was seen as an important step in order for other parties to be able to replicate the analyses if desired.  Responses stressed the usefulness of posting code used as part of the analysis, but also information on meta-data, analysis plans and data cleaning processes | Amendments made to the Sol reflecting the ambition to publish as much detail as is appropriate to aid transparency.  Further details on the publication of code, data, analysis plans etc. as well as the use of reporting and ethical frameworks are to be addressed in a further methods document. |

|                                                                 | Although privacy concerns and/or commercial confidentiality will generally prevent the sharing of raw datasets to support reproducibility, there was support for NICE to explore this where otherwise feasible. |                                                                                                                                                            |
|-----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Transparency: Adhering to existing defined reporting frameworks | Several respondents also mentioned the use or adoption of a specific reporting or ethical standard to use as a framework.                                                                                       | As per amendments above. There are a number of ongoing projects, including some to which NICE is contributing, which aim to improve practice in this area. |

- 15. Other substantive feedback from respondents, from both the workshops and online submissions, sought more information about how the approach set out in the SoI would:
  - impact on existing NICE processes;
  - inform and complement the CHTE 2020 Methods Review and other processes and methods across NICE);
  - fit within the hierarchy of evidence;
  - deal with bias;
  - impact on data governance;
  - lead to an expansion of data sources used by NICE to include, for example - more qualitative data, data from disease registries and data provided by manufacturers on digital technologies, wearables and implantable devices
  - result in the publishing of a framework or code, updated processes and methods, analysis and other documents. [Publication of NICE's position was encouraged wherever possible].
- 16. A broader set of feedback themes about the impact on NICE and its role are captured in Appendix A.

# **Vision and Next Steps**

- 17. NICE intends to use a broader range of data and analytic methods in our guidance production process to improve, update and enhance our existing methods and processes at all stages of the guidance development process and across the broad range of guidance products that we produce.
- 18. We intend to update all of our process and methods for the identification, assessment and interpretation of data, setting out the full range of data sources that we will accept, the methods and analytical tools we will put in place to assess the quality and suitability of data providing advice, both internally and externally, on how to achieve this in a way that assesses any (potential) bias, ensures rigour, and minimises uncertainty.
- 19. We will work with the transformation structures and processes to support NICE Connect, using this as the mechanism to drive a new culture around the acceptance and use of data and analytics, ensuring we keep pace with external developments and drivers.
- 20. Specific priorities and activities planned between now and March are captured below. In undertaking these, we intend to improve and update our working practices, the quality, relevance and timeliness of our advice and recommendations and their impact on the health and care system.

# **Key Data and Analytics Team Priorities**

21. The Data and Analytics team will undertake work in the following areas:

#### Methods & Processes

- 22. Scope out the full range of methodological issues that need consideration from data processing to analysis and communication of findings. Define the programme to develop a methods framework for activities involving broader sources of data.
- 23. Define the programme to set a standards framework for best practice in conducting unbiased, high quality analyses of data to inform our own work and that of third parties, especially digital technology companies, who wish to submit evidence based on such (rather than traditional research).
- 24. Support the CHTE Methods review on all aspects of data analytics work within the 'exploring uncertainty' and 'types of evidence' strands of this review.
- 25. Develop a framework for prioritisation of projects, mapping out the end to end journey of guidance development and identifying where broader data exploitation may be appropriate for guidance in development over the next 12-18 months.

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#### Transparency

26. Investigate best practice in transparency, working with the Open Data Institute, ISPOR and others to develop clear guidance for project teams.

## Transformation and Delivery

- 27. Contribute to the different NICE Connect Expert Groups on the range of conjoint challenges and opportunities.
- 28. Establish what the organisational expectations are in terms of volume and timeliness of what Data and Analytics will deliver strategically to ensure the effective implementation of the aspirations set out in the Statement of Intent.
- 29. Consider what the optimum future NICE data function might include to fully serve organisational needs – i.e. Data and Analytics as a service. Consider the structure and expectations for the volume and scope of outputs for future financial years.
- 30. Define the role of NICE in a Learning-Health-System; establishing the concept for a minimal viable product for using real world information and insight on the experiences of practitioners and people using health and social care services to quickly identify and resolve issues which may need prompt and decisive action for operational and/or reputational reasons.

## Internal and External engagement

- 31. Develop the role of the 'Data Champions' so as to build the analytics community at NICE and improve communications to ensure greater visibility across NICE.
- 32. Continue to work with the Association of Professional healthcare Analysts [AphA]; HDR UK; NHSX and others to establish the cross-sector programme for professionalisation of data science.
- 33. Continued engagement with HDR UK on bringing NICE on-board as a potential user / senior customer of the Digital Innovation Hub programme.
- 34. Continue to define (the substance of) a strategic partnership with The Health Foundation.
- 35. Refresh and revamp the NHS Digital Partnership Agreement; including methods to streamline the DARS (data access) process.
- 36. Establish a clear external stakeholder management plan which seeks to both build on existing partnerships and establish further collaborative opportunities that support NICE's ambition.

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- 37. Establish an international strand to the portfolio so that:
  - in appropriate situations, non-UK data can be utilised for data exploitation (case study example is the Canadian data utilised for the guidance on cannabis-based medicinal products);
  - International networks and communities share best practice on health and social care data exploitation;
  - International considerations are included in the Methodological (and process) developments.

# **Risks and mitigation**

- 38. NICE will seek to mitigate key risks as we further develop our data and analytics work.
- 39. Future projects are likely to require internal staff to access individual level anonymised or pseudonymised data for the purposes of conducting analysis or providing quality assurance of externally commissioned work. This may require data to be held on site for practical reasons. NICE will need to confirm its position in relation to this and the boundaries of data governance.
- 40. The data and analytics team may require access to IT hardware and software sufficient to fulfil the intended function. This could include access to software with the capability to connect to external APIs, store and retrieve data at scale in a secure environment (e.g. a specialist server or virtual server with restricted access), and be interoperable with other software and databases.
- 41. Currently NICE does not hold significant amounts of data in its own right. Data that is held by the organisation is often difficult to digitise or translate into a machine-readable format. To obtain the maximum value from data, NICE may in future have to expand the scope of the data that it has access to and also work toward being able to store data in more accessible formats.
- 42. Where external expertise may be required for particular specialised methodologies, the data and analytics team will need to collaborate and seek input from external partners.

# Conclusion

Reference: 19/101

#### Issues for decision

- 43. The Board is asked to:
  - Approve the revisions to the statement of intent.

- Note the response to consultation.
- Approve the proposed next steps.
- Note the intention to provide an update on the programme to the Board in March 2020.

Reference: 19/101

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# Appendix 1: Broader feedback themes on the impact on NICE and its role

The following broader feedback themes were received about the impact of this activity on NICE's role, which the Board should note:

Project delivery timelines

What effect will the inclusion of additional sources of evidence have on the timely delivery of guidance? What steps will NICE need to take to ensure teams are able to deliver this work on time?

Effect of broader data sources on decision making

In what ways might the use of broader sources of data affect decision making in the process of guidance development?

Position on the use of international data sources

What is NICE's position on using international sources of data to support guidance development and how does it propose to ensure access to these sources?

Workforce skilling

How does NICE plan to ensure that it has a workforce with appropriate skills available to carry out its proposals in the use of data in guidance development and evaluation?

Role of NICE in defining terminology

Does NICE have an interest or a role in defining the use of consistent terminology around the use of broader sources of data in health and social care guidance development?

System-wide leadership

What role does NICE have in providing leadership across the Health and Social care system with respect to extending the use of data to support continuous improvement?

Leadership from NICE on data standards

Does NICE intend to contribute to setting standards in data content and quality in the health and social care sector?

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November 2019

## **National Institute for Health and Care Excellence**

# Response to consultation on the draft NICE Principles

This report summarises comments from the 2019 public consultation on the draft NICE Principles and presents an updated draft of the Principles to address these comments.

The Board is asked to approve the revised draft of the NICE Principles proposed by SMT (appendix A).

If the proposed draft is approved, it will succeed the Social Value Judgements (SVJ) as the working document for NICE advisory committees. The <u>latest edition of the SVJ</u> (published in 2008) will remain on our website for information and as an important underpinning document.

Andrew Dillon Chief Executive November 2019

#### Introduction

- In March 2018, the Board approved a proposal to develop a list of NICE
   Principles bringing together existing statements of the way we practice, in
   particular the principles set out in <u>NICE's Social Value Judgements (SVJ)</u>
   <u>document</u>. The aim was to provide a more accessible and up to date description
   of NICE's approach to its work, with appeal to multiple audiences.
- 2. In June 2018 the Board approved a draft version of the NICE Principles, which underwent a public consultation concluding in Q1 2019. We received comments from approximately 100 organisations and individuals.
- 3. This paper summarises the consultation comments and how we have addressed them in the updated draft. Appendix A contains the updated draft for the Board's consideration.

#### **Summary of consultation comments**

- 4. Though acknowledging that the consultation sets out the way NICE currently works, stakeholders had a number of concerns. There were 5 key overarching issues:
  - The origins of and rationale for the draft NICE Principles were unclear.
  - NICE's underpinning moral and ethical values were missing.
  - The draft Principles were too utilitarian, implying reduced willingness for departing from the standard cost-effectiveness threshold.
  - The draft Principles lacked commitment to reflect the values of society.
  - The interaction between the draft NICE Principles and the Charter, and the purpose and status of each document, was unclear.
- 5. There were also suggestions to add specific principles, or amend existing ones, to reinstate elements of the SVJ which have proved valuable for developing and defending NICE guidance. Stakeholders proposed that the NICE Principles should include:
  - NICE's commitment to reducing inequality.
  - A definition of how we assess value for money and an explanation of our 'thresholds'.
  - A clearer definition of innovation.
- 6. These concerns and suggestions have been addressed in an updated draft of the NICE Principles (appendix A), for review by the Board.

#### Overarching issues arising from consultation

The origins of and rationale for the NICE Principles were unclear

- 7. Stakeholders were not clear how NICE had developed the draft Principles. The ABPI and European Medicines Group suggested that the draft document "is no replacement for the 2008 SVJ ... NICE makes normative decisions with life and death consequences and these are obscured in this document ... It's as though the value judgements at the very heart of what NICE does have been whitewashed over, and its decisions can be an objective matter based on evidence." A publication in the Journal of the Royal Society of Medicine (Littlejohns et al. 2019) suggests that "the main casualties of this new approach are likely to be accountability, transparency, consistency, and public, political and professional understanding of the reasons for NICE's decisions."
- 8. **Action:** The NICE Principles document has been amended to clarify its origins and purpose, and to provide continuity with the SVJ, but with a focus on the key principles that are universal to all of our guidance and standards, and presented in a simpler and more accessible way than the SVJ. The NICE Principles document should be read in conjunction with our methods and process guides and our charter. The SVJ will remain on our website, watermarked as 'superseded', to provide stakeholders with the historical context and origins of the NICE Principles.

#### NICE's underpinning moral and ethical values were missing

- 9. The draft NICE Principles were perceived as too procedural, mainly because the underpinning moral and ethical values were missing. Internal and external stakeholders were particularly concerned about the omission of values of fairness and autonomy. One stakeholder commented that the draft NICE Principles document "is pitched on the principles governing NICE processes which, while important, are no substitute for principles that articulate the social and ethical goals that NICE is committed to help secure for the NHS."
- 10. Action: The moral principles that underpin the way we work have been added to the document's introduction (appendix A: paragraphs 4-6), with an explanation of the tension and balance between autonomy and fairness. That is, although NICE agree that individual choice is important, this should not mean that users of health and social care services as a whole are disadvantaged by guidance recommending interventions that are not clinically and/or cost effective.

The draft NICE Principles were too utilitarian, implying reduced scope for considering factors other than cost-effectiveness

- 11. Stakeholders thought that the draft NICE Principles did not adequately represent our decision-making process. Stakeholders referred to the Citizens Council's view that it is not satisfactory to make recommendations based solely on formulaic considerations (for example, the incremental cost-effectiveness ratio) and that NICE's judgements have to take account of other factors.
- 12. **Action:** The following statement, reflecting text in the SVJ, has been added to Principle 7: "NICE's recommendations should not be based solely on evidence of costs and benefit alone, and we must consider other factors when developing our guidance." This is supported by other additions to the document stating that the committee's reasoning must be clearly explained, with reference to all the factors that have been taken into account. Readers are directed to our methods manuals for further detail of our approach. The updated Principles document is also clearer about how we support personalised care and shared decision-making.

The draft Principles lacked a commitment from NICE to reflect the values of society

- 13. The 2017 NICE Charter made a commitment that NICE decisions will involve value judgements that reflect the values of society, and the 2008 SVJ states that "the NHS is funded from general taxation, and it is right that UK citizens have the opportunity to be involved in the decisions about how the NHS's limited resources should be allocated." Stakeholders noted that these commitments are missing from the 2018 Charter and the draft NICE principles. They recognised that the Citizens Council has been a key enabler of incorporating societal views in NICE's methods and asked for clarity on whether the Council will continue to operate.
- 14. **Action:** The Citizens Council has not met since 2015 and NICE is currently considering its future and what other options might exist for collecting information on societal values in the future.

The interaction between the draft NICE Principles and the Charter was unclear

- 15. Stakeholders highlighted that the draft NICE Principles and NICE Charter have overlapping content and questioned whether the documents serve different purposes.
- 16. **Action:** The NICE Principles document has been amended to clarify its purpose and the distinction from our Charter. This distinction will be made clear in our communications to stakeholders when the final version is published. That is, NICE is required by <u>law</u> to publish a <u>charter</u> explaining what we do and how we

do it - the <u>health and social care act</u> allows for our <u>Regulations</u> to make provisions requiring NICE to publish a charter. Our charter was first published in 2013, many years after the SVJ. Our charter is a statement of purpose, explaining our procedures and how we develop them. The Principles, and before them the SVJ, go beyond this. The Principles, taken together with our more detailed methods and process manuals, are intended to help NICE's advisory committees resolve uncertainty in the evidence available.

#### Consultation comments on specific principles

#### NICE's commitment to reducing inequality

- 17. Internal and external stakeholders were unanimous that the NICE Principles should include NICE's commitment to reducing inequality (i.e. reinstate Principle 8 of the SVJ) and be clear about when it is reasonable to make recommendations that differentiate between people with different characteristics (i.e. reinstate Principle 7 of the SVJ). It was not felt to be sufficient to refer to the equalities legislation and the NICE equality scheme because NICE intentionally goes beyond the legislation (for example, in considering socioeconomic inequality), and neither our equality scheme nor our methods guide explain situations where it is appropriate to make different recommendations for certain 'protected' groups.
- 18. Action: Two new principles have been added (appendix A: Principles 9 and 10)

#### How NICE defines value for money

- 19. The omission from the draft Principles of our specific approach to assessing value for money was interpreted by stakeholders as a deliberate decision to give NICE greater scope for departing from its standard threshold. A publication in the Journal of the Royal Society of Medicine (Littlejohns et al. 2019) expressed concern that this could be "either upwards to the benefit of industry or downwards for the sake of expenditure control".
- 20. **Action:** An existing principle has been expanded to explain that NICE's core method for assessing value for money is cost-effectiveness analysis and that our standard threshold is £20,000 to £30,000 (appendix A: Principle 7). It explains that some programmes use alternative methods that are better suited to the types of decision and evidence base under consideration, and that a different threshold is applied to Highly Specialised Technologies.

#### How NICE supports and defines innovation

21. The draft NICE Principles document defined innovation as interventions that are "good value for money and have plausible potential to substantially improve outcomes for patients". Stakeholders felt that this definition contradicted our

manuals and methods guides, which define innovation as the potential to make demonstrable and distinct substantial benefits that may not have been captured in the measurement of health gain. The definition of innovation in the draft NICE Principles may be viewed as too permissive and could be used to support demands for NICE to recommend treatments that have the potential to benefit patients but have a weak evidence base.

22. **Action**: A new Principle has been added (appendix A: Principle 8).

#### References

Littlejohns P, Chalkidou K, Culyer A et al. (2019) <u>National Institute for Health and Care Excellence, social values and healthcare priority setting</u>. Journal of the Royal Society of Medicine 112(5): 173-9

#### Issues for decision

- 23. The Board is asked to approve the revised draft of the NICE Principles proposed by SMT (appendix A).
- 24. If the proposed draft is approved, it will succeed the Social Value Judgements (SVJ) as the working document for NICE advisory committees. The latest edition of the SVJ (published in 2008) will remain on our website for information and as an important underpinning document.

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November 2019

#### Appendix A

## The principles that guide the development of NICE guidance and standards (post consultation draft)

#### Introduction

- In 2005, NICE published a guide setting out the social and scientific 'value judgements' that informed our approach to developing guidance. The <u>Social Value Judgements document</u> helped our advisory committees resolve uncertainty in the available evidence. It informed their judgement when developing guidance, by giving them a set of principles.
- 2. The Social Value Judgements were originally designed to support decision-making in guidance on new technologies. NICE's remit has grown significantly since then. We now produce guidance for local government and social care providers, which draws on a wider range of evidence. The original Social Value Judgements document remains relevant to our work, and much of what it contains is included in our methods and process manuals.
- 3. This document, which replaces the Social Value Judgements document, focuses on the key principles that are universal to all of our guidance and standards. Our independent advisory groups are expected to use it, along with our methods and process guides and the NICE charter, to inform their decisions. Our charter is a statement of purpose that describes who we are, what we do and how we do it. The NICE principles document, like the Social Value Judgements document before it, goes beyond that, to explain the morals, ethics and values that underpin our recommendations.
- 4. When making decisions, NICE and our committees strive to balance the need to achieve the most overall benefit for the greatest number of people, with the need to ensure fairness and respect for individual choice. NICE advisory committees have to make judgements about the fair and equitable distribution of scarce resources, often in the face of uncertain evidence. When making judgements about what health and social care services should provide, it is important to be able to explain what informs those judgements.
- 5. NICE guidance aims to meet population needs by identifying care that is high quality, good value, and provides the best outcomes for people using health and social care services within the budget available. An important part of high-quality care is enabling people to be equal partners in planning their care and making informed decisions about it. But in the best interests of the wider population, and because of limited resources, decisions have to be made about what options are publicly funded. This might be, for example, by focusing resources on

interventions that have been proven to be effective or cost effective. NICE believes that overall population needs are paramount in determining the fair allocation of resources. But it also recognises that in some circumstances, in the interests of fairness, the needs of particular groups may override those of the broader population.

- 6. NICE's advisory committees use their own discretion when developing guidance and standards. But their decisions are guided by the principles in this document, which are based in part on the following moral principles:
  - People have the right to make informed choices about the care they
    receive. But not everyone has the ability to make their own choices, and
    not everything people might want will necessarily be available.
  - Every intervention has the potential to cause harm and may not always benefit everyone. So it is important consider the balance of benefits and harms when deciding whether an intervention is appropriate.
  - Resources need to be allocated appropriately and fairly. They must provide the best outcomes for the finite resources available while balancing the needs of the overall population and of specific groups.

#### The principles that guide NICE's work

How we produce guidance

## Principle 1. Prepare guidance and standards on topics that reflect national priorities for health and care

- 7. NICE's remit covers health, public health and social care, as set out in the <u>Health</u> and <u>Social Care Act 2012</u>. To ensure our guidance and standards appropriately cover this breadth of topics, we have several processes to prioritise our work.
- 8. We welcome topic suggestions from a range of sources. These include people using services, health and social care professionals, manufacturers and commercial sponsors, and horizon scanning by the National Institute for Health Research. We work with the Department of Health and Social Care, Public Health England and NHS England and NHS Improvement to select and prioritise topics that reflect the ambitions and capacity of the health and care system. We do this using criteria that include several aspects of a disease, condition or care need. These include impact on health and wellbeing, variation in current service provision, uncertainty about best practice, the available evidence, and the potential to reduce health inequalities.

## Principle 2. Describe our approach in process and methods manuals, and review them regularly

- 9. NICE's guidance can have a significant impact on people's lives. So it is important that we are explicit about the approaches we use and allow others to comment on them. The <u>NICE (Constitution and Functions) Regulations 2013</u> require us to have, and consult on, procedures for giving advice or guidance, and making recommendations. The principles of the <u>NHS Constitution</u> also highlight the importance of transparency and accountability in our decision-making processes.
- 10. All our guidance and standards programmes have detailed process and methods manuals. These go through rigorous review, assessment and consultation before being published. They are updated regularly. We are required to follow our documented processes and methods and are accountable for the decisions that we make. Sometimes it is appropriate to depart from the documented processes and methods for particular recommendations. When this happens, we clearly explain our rationale in the guidance or standard, or in accompanying documents.

### Principle 3. Use independent advisory committees to develop recommendations

- 11. We use independent advisory committees to consider the evidence. This is to ensure that our recommendations are unbiased and objective, and that the evidence is interpreted in a way that is relevant to health and social care delivery in England. Even the best research evidence will never be complete and comprehensive, so it is essential that it is considered by a committee independent of NICE.
- 12. The credibility of NICE guidance depends on the committee making decisions using a process that is transparent and contestable. It is crucial that the reasons for the committee's decisions and reasoning are explained clearly. This includes explaining the available evidence, and how the contributions of experts and the views of people who responded to consultation have been taken into account.
- 13. Committees include people from the NHS, commissioners and providers of social care, local authorities, academia, relevant industries, organisations that represent people who use services and carers, and the general public. Committee members are selected for their knowledge and experience. They are each there in their own right and do not usually represent organisations they work in. All committee members, invited experts and any organisations nominating specialists or making written submissions, declare any relevant interests both annually and for each committee meeting they attend. They do this according to our policy on managing potential conflicts of interest.

## Principle 4. Take into account the advice and experience of people using services and their carers or advocates, health and social care professionals, commissioners, providers and the public

- 14. NICE needs to ensure that the process for developing guidance and standards involves people who will be affected by it, to ensure their needs and priorities are reflected. We build in these perspectives through the membership of our guidance development committees. If this isn't possible, we find experts to give testimony to the committee.
- 15. The people who work with us reflect the experiences of a wide range of people affected by the guideline. They don't base their views solely on personal experience. All interested groups, including health and social care professionals and voluntary and community sector organisations, are involved in defining the scope of our products, may be invited to submit evidence to the committee, and have the opportunity to comment on draft recommendations.
- 16. NICE's Public Involvement Programme supports people who use services, their families, carers and the public to take part in our work. It promotes their involvement regardless of disability, language, or other potential barriers.

## Principle 5. Offer people interested in the topic the opportunity to comment on and influence our recommendations

- 17. NICE recommendations are based on detailed consideration of the evidence by our committees, and it is important that a wider group of stakeholders are also consulted. This wide consultation helps ensure the validity of the final recommendations. The principles of the <a href="NHS Constitution">NHS Constitution</a> also require us to be accountable to the public, and to make decisions in a clear and transparent way.
- 18. All our guidance and standards are therefore developed using a process that takes into account the opinions and views of the people who will be affected by them. Consultations are open to voluntary and community sector organisations as well as health and social care professionals, NHS organisations, industry, social care businesses and local government. As part of the consultation stakeholders have an opportunity to comment on the potential impact of our guidance on health inequalities, as well as on the content of the recommendations. Our advisory committees consider and respond to comments and make amendments if appropriate.

#### What we take into account

#### Principle 6. Use evidence that is relevant, reliable and robust

- 19. NICE's guidance and standards are underpinned by evidence. So we need to ensure that this evidence is relevant, reliable and robust. To do this, we have processes to identify research evidence, determine whether it is relevant and assess its quality. We also work with data providers to ensure the information and data analytics that we use are high quality and robust.
- 20. For each piece of guidance, we consider whether the methodology used to produce the evidence is appropriate. We recognise the value of traditional 'hierarchies of evidence' but take a comprehensive approach to assessing the best evidence that is available to answer the questions we face. Our process and methods manuals set out the types of evidence that are generally appropriate for different types of question. This can include qualitative and quantitative evidence, from the literature or submitted by stakeholders. It can also include observational data and testimonies from experts.
- 21. Committees should not recommend an intervention if there is no evidence, or not enough evidence, on which to make a clear decision. But they may recommend using it in a research programme or alongside mandatory data collection, if this will provide more information about its effectiveness, safety or cost (see principle 11).

## Principle 7. Base our recommendations on an assessment of population benefits and value for money

- 22. When NICE was established, the directions from the Secretary of State for Health made clear that we should take into account both the costs and benefits of interventions in our recommendations and encourage the effective use of resources. This was restated in the Health and Social Care Act 2012, which requires us to have regard to the broad balance between the benefits and costs of providing health services of social care in England. We must also take account of our commitment under the <a href="NHS Constitution">NHS Constitution</a> to provide 'the best value for taxpayers' money and the most effective, fair and sustainable use of finite resources'.
- 23. If possible, NICE considers value for money by calculating the incremental cost-effectiveness ratio (ICER). This is based on an assessment of the intervention's costs and how much benefit it produces compared with the next best alternative. It is expressed as the 'cost (in £) per quality-adjusted life year (QALY) gained'. This takes into account the 'opportunity cost' of recommending one intervention instead of another, highlighting that there would have been other potential uses of the resource. It includes the needs of other people using services now or in the future who are not known and not represented. The primary consideration underpinning our guidance and standards is the overall population need. This

means that sometimes we do not recommend an intervention because it does not provide enough benefit to justify its cost. It also means that we cannot apply the 'rule of rescue', which refers to the desire to help an identifiable person whose life is in danger no matter how much it costs. Sometimes NICE uses other methods if they are more suitable for the evidence available, for example when looking at interventions in public health and social care.

- 24. Interventions with an ICER of less than £20,000 per QALY gained are generally considered to be cost effective. Our methods manuals explain when it might be acceptable to recommend an intervention with a higher cost-effectiveness estimate. A different threshold is applied for interventions that meet the criteria to be assessed as a 'highly specialised technology'.
- 25. NICE's recommendations should not be based on evidence of costs and benefit alone. We must take into account other factors when developing our guidance. We also recognise that decisions about a person's care are often sensitive to their preferences. We support personalised care and shared decision-making and provide information and tools to help with this in and alongside our guidance and standards.

What our guidance aims to achieve

### Principle 8. Support innovation in the provision and organisation of health and social care services

- 26. The importance of promoting innovation in the provision of health services and social care is set out in the <u>Health and Social Care Act 2012</u>. NICE aims to support this innovation by encouraging interventions that provide substantial distinctive benefits that may not be captured by measuring health gain (that is, the estimated QALYs gained).
- 27. Innovation does not necessarily lead to better outcomes than existing practice. And if innovations come at an additional cost, they may divert resources away from existing practices that are better value for money. To mitigate the risk of an innovative intervention not performing as expected NICE's committees can, in appropriate circumstances, recommend its use in the context of a managed access arrangement.

#### Principle 9. Aim to reduce health inequalities

28. The <u>Health and Social Care Act 2012</u> states that the Secretary of State, NHS England and NHS Improvement and clinical commissioning groups must give 'due regard' to reducing inequalities. This provides the context in which NICE's recommendations are implemented. So our guidance should support strategies that improve population health as a whole, while offering particular benefit to the most disadvantaged.

29. We think about equality in relation to the protected characteristics stated in the Equality Act 2010. We also take into account inequalities arising from socioeconomic factors and the circumstances of certain groups of people, such as looked-after children and people who are homeless. If possible, our guidance aims to reduce and not increase identified health inequalities. This may mean making recommendations for specific groups of people (see principle 10).

#### Types of recommendation

## Principle 10. Consider whether it is appropriate to make different recommendations for different groups of people

- 30. NICE's guidance aims to serve the interests of the population as a whole. But sometimes the available evidence shows differences in the effectiveness and cost effectiveness of an intervention for a particular group of people. Certain groups may also be at a disadvantage compared with others, including those covered by the Equalities Act 2010. In such cases, it may be appropriate for us to make recommendations for specific groups of people.
- 31.NICE may recommend an intervention for a specific group of people only if there is:
  - enough relevant evidence that the intervention is more effective or cost effective in the subgroup, or
  - a legal requirement to act in this way, or
  - other reasons relating to fairness for society as a whole.

## Principle 11. Propose new research questions and data collection to resolve uncertainties in the evidence

- 32. NICE examines the available evidence when it produces guidance. This often highlights unanswered questions. There may be uncertainties because there is no published evidence available, or the evidence is conflicting, insufficient or not robust. We make recommendations for research in areas for which resolving uncertainties could affect future recommendations. We liaise with the research community to ensure they are addressed.
- 33. We have processes and methods for committees to make recommendations for research. We share these recommendations with researchers and funders including the UK Research Councils, research charities, and industry. We work closely with the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC) to prioritise the recommendations.
- 34. If there are uncertainties about an intervention's effectiveness, safety or cost that can be addressed by collecting more data, committees may recommend using the intervention:

- only in a research programme, or
- if explicit conditions are met for collecting data to resolve the uncertainties, for example, through a managed access agreement.

This is helpful for interventions showing promise of being better than existing alternatives, but for which the evidence is limited.

What we do after making recommendations

## Principle 12. Publish and disseminate our recommendations and provide support to encourage their adoption

- 35. NICE's guidance and standards will not have any impact if they are not used by the health and care system. When implemented effectively, they can support local improvement initiatives, improve outcomes, reduce health inequalities and reduce variations in practice across the country.
- 36. The NICE (Constitution and Functions) Regulations 2013 require us to publish or disseminate our recommendations. Our implementation strategy supports adoption of these recommendations by:
  - producing guidance and standards that are fit for the audience's needs
  - ensuring relevant audiences know about our recommendations
  - motivating and encouraging improvement
  - highlighting practical support to improve local capability and opportunity
  - evaluating impact and uptake.

We work with strategic partners to reinforce NICE's recommendations in national and regional initiatives. We support personalised care, including shared decision-making, in all our work to help people implement our guidance and standards.

### Principle 13. Assess the need to update our recommendations in line with new evidence

- 37. NICE's guidance and standards need to be up to date to ensure people receive the best care and advice, and to be credible for health and social care professionals, commissioners and providers. The NICE (Constitution and Functions) Regulations 2013 require us to review and revise, as we consider appropriate, all our advice, guidance and information.
- 38. We regularly assess the need to update our guidance and standards. New evidence might change conclusions about the benefits and risks of an intervention, and so the extent to which it represents good value for money. We may review guidance if we find evidence that might change our recommendations, or if there are changes in the health and care system. We

normally consult with relevant organisations on a proposal about whether guidance needs updating and, if so, how to do the update.

#### Resources

- The 2008 edition of <u>social value judgements</u>: <u>principles for the</u> <u>development of NICE guidance</u>, which this document replaces
- The Citizens Council reports

The legislative and policy requirements that apply to NICE's guidance are set out in these documents:

- The <u>7 principles of public life</u> (also known as the 'Nolan principles')
- Care Act 2014
- Department of Health and Social Care's outcomes frameworks
- Equality Act 2010
- Health and Social Care Act 2012
- Human Rights Act 1998
- NHS Constitution
- NICE (Constitution and Functions) Regulations 2013
- NICE charter
- NICE Patient and Public Involvement Policy
- <u>Sustainable Development Unit's sustainable deve</u>lopment strategy

# National Institute for Health and Care Excellence Indicator process guide update

This report gives details of the updates made to the NICE indicator process guide.

The Board is asked to

- review and approve the updates to the process guide
- approve publication of the indicator process guide in December 2019.

Professor Gillian Leng

Deputy Chief Executive and Director, Health and Social Care Directorate

November 2019

National Institute for Health and Care Excellence Indicator process guide update Date: 20 November 2019 Reference: 19/103

#### **Background**

- The NICE indicator process guide is used by the NICE indicator advisory committee to develop indicators for a range of different purposes. Currently, indicators are predominantly developed for the Quality and Outcomes Framework (QOF) used in general practice and for commissioner level outcomes, presently reported at CCG level in two national measurement frameworks.
- 2. The QOF has been operating since 2004 and is still one of the largest pay for performance schemes in the world. In 2017/18 the QOF in England was worth over £680 million and provided about 8% of practice income (down from around 15-20% when the QOF was implemented).
- NICE's role in the QOF is to develop high quality evidence-based indicators derived from guidance and quality standards which are used to inform contract negotiations between NHS England and the BMA's General Practitioner Committee (GPC). The content of the QOF is determined through these negotiations.
- Changes to the QOF in England for 2019/20 included the addition of 13 indicators developed by NICE, the new indicators had around £120 million of incentives attached.
- 5. Commissioning level indicators developed by NICE are currently mainly reported at CCG level and used in the CCG Outcomes Indicator Set (CCG OIS) and the CCG Improvement and Assessment Framework (CCG IAF). The CCG frameworks do not have financial incentives attached; the aim of these frameworks is to allow benchmarking across CCGs. In the latest CCG OIS 36 of the 55 indicators were developed by NICE.
- 6. NICE indicators are underpinned by evidence-based guidance and have been through a rigorous process, which includes:
  - development by an independent expert committee (including GPs, hospital consultants, public health and social care practitioners, NHS commissioners and lay members.)
  - testing and piloting in partnership with NHS Digital
  - public consultation.
- 7. Those indicators not suitable for or not chosen for inclusion in specific national frameworks can be used to measure the quality of care in local quality improvement schemes.

#### Updating the process guide

- 8. The guide was scheduled for an update in 2018/19. The update was timed to allow NHS England and the BMA's GPC to undertake a review of the QOF in England. The QOF review published in July 2018.
- 9. The update was overseen by a steering group established in the summer of 2018. The steering group was chaired by Gill Leng and included membership from PHE, NHS England, the King's Fund and the chair and vice-chair of the NICE indicator advisory committee.
- 10. The update was informed by a stakeholder workshop held in August 2018. Over 20 external attendees attended with representation from NHS Improvement, NHS England, NHS Digital, CQC, Local Government Association, National Voices, PHE and the BMA's GPC.
- 11. Following this workshop, it was agreed that we should develop clear assessment criteria that can be used when developing or assuring indicators. These criteria were informed by contemporary literature alongside the outputs from the August 2018 workshop.

## Substantive changes to the indicator process guide - prior to consultation

Specific criteria for assessment

12. The draft guide included specific criteria for indicator assessment. The previous guide included similar elements as informal considerations but did not require indicator assessments to be published in this format. The criteria were informed by contemporary literature and a desire for decisions made by the committee to be more transparent and consistent. This was in preparation for supporting indicator development more widely across the system avoiding duplication of effort by allowing consistent assessment of indicators developed by external organisations. The criteria against which it has been agreed an indicator will be assessed are provided in table 1.

Table 1. Indicator assessment criteria

| Domain        | Criteria                                                                                                                    |
|---------------|-----------------------------------------------------------------------------------------------------------------------------|
| Importance    | The indicator reflects a specific priority area identified by NHS England or Public Health England.                         |
|               | The indicator relates to an area where there is known variation in practice.                                                |
|               | The indicator will lead to a meaningful improvement in outcomes.                                                            |
|               | The indicator addresses under or over-treatment.                                                                            |
| Evidence base | The indicator is derived from a high quality evidence base.                                                                 |
|               | The indicator aligns with the evidence base.                                                                                |
| Specification | The indicator has defined components necessary to construct the indicator, including numerator, denominator and exclusions. |
|               | The indicator has a minimum population level.                                                                               |
| Feasibility   | The indicator is repeatable.                                                                                                |
|               | The indicator is measuring what it is designed to measure.                                                                  |
|               | The indicator uses existing data fields or the burden of additional data collection is acceptable.                          |
| Acceptability | The indicator assesses performance that is attributable to or within the control of the audience.                           |
|               | The results of the indicator can be used to improve practice.                                                               |
| Risk          | The indicator has an acceptable risk of unintended consequences.                                                            |

#### Population size for use of the indicator

13. The draft guide stated that each indicator should reference the minimum population for which it is valid. The previous approach classified indicators as suitable at GP practice or CCG level. Stating the minimum population will ensure NICE indicators can respond to changing NHS structures, including primary care networks and integrated care systems, which might vary in size. This change will also identify when an indicator may be inappropriate for use because of small denominators that can be subject to random variation.

#### Variable testing regimens for indicators

14. The draft guide included levels of testing required for an indicator which can vary depending on the intended purpose and how much the indicator differs from existing indicators. This update was made to allow the more rapid development of high-quality indicators. The previous guide presented a more rigid approach to testing depending on the anticipated framework in which it would be used. Figure 1 illustrates the different levels of testing which may be used.

Judgement Improvement Increasing level of Piloting in around 30 Qualitative feedback Desktop review to Quantitative data GP practices with from a workshop of assess availability of analysis of relevant quantitative data experts, patients and existing data extraction and service users qualitative feedback Population level Comparatively minor Examples Pay-for-performance Local quality reporting on variation changes to existing indicator (QOF) in improvement in outcomes at indicator that is new clinical area commissioner level already in use

Figure 1. Illustrative example of how testing may be used

#### Assessment of third party indicators

15. The draft guide included an option for NICE to assess the validity of indicators developed by other organisations. For example, where another organisation has developed an indicator for an area identified as a priority, NICE could in future undertake an assessment of that indicator rather than undertake the full development process for an identical or similar indicator. This has been included to avoid system wide duplication of effort and reduce development time. The previous guide did not include this as an option.

#### Process for maintenance of indicators

16. The draft guide contained greater clarity on the process for maintenance of indicators that have been published, including assigning a review date at the point of development and repeating assessment against the criteria at the point of review. The indicator advisory committee will advise on actions required to ensure indicators continue to be valid or retirement. The previous guide did not include the requirement for review dates.

#### Consultation feedback and agreed response

- 17. A three-month public consultation on the amended guide took place from 16th April to 15th July 2019. Comments were received from 24 organisations and were supportive of the proposed changes.
- 18. Consultees were supportive of the substantive changes to the process guide set out in paragraphs 12 16 of this paper
- 19. Consultation comments have been summarised by key themes and where this has resulted in a change to the guide or an alternative response this is explained.

#### The NICE indicator programme - general

20. It was suggested it would be helpful to include how NICE indicators relate to or differ from indicators used in the QOF. The guide has therefore been amended to clarify this: "In England the content of the Quality and Outcomes Framework (QOF) is determined through negotiations between NHS England and the General Practitioners Committee (GPC) of the British Medical Association (BMA). NICE indicators are considered for inclusion in the QOF during these negotiations."

#### Who is involved in developing NICE indicators?

21. The inclusion of input from patients, carers, experts and service users was supported. Additional membership of the indicator advisory committee (IAC) was suggested across a number of specialist areas. The guide highlights that additional topic experts and co-opted members can be invited to attend the committee where required.

#### Process for developing indicators

22. Greater visibility of indicator progression was suggested to provide transparency and assurance to stakeholders and avoid duplication of effort across the system. In future, NICE will publish a log of indicators in development or under review on the website. The previous guide did not include this as a requirement.

National Institute for Health and Care Excellence Indicator process guide update Date: 20 November 2019 Reference: 19/103

- 23. We said that we would begin to publish information that explains why certain indicators do not progress to publication on the NICE indicator menu, including the outcome of the use of the assessment criteria. This will help to avoid system wide duplication of effort in development and use of indicators which do not meet the assessment criteria. It will also increase transparency of decision making. The previous guide did not include this as a requirement.
- 24. Clarification on those involved in providing qualitative feedback during piloting in general practice was requested. The guide has been amended to state that practice staff, patient and user feedback will be included as appropriate.
- 25. At the point of indicator review we will consider, depending on the indicator, whether consultation on retirement from the NICE menu is needed. This is in response for comment made. The previous guide did not include this.

#### Stakeholder involvement

- 26. There was some concern expressed about how the current process relies on people's awareness to check the NICE website or actively identify themselves as stakeholders. We will continue to work with the NICE communications team to make sure consultations are notified to a wide audience.
- 27. Greater transparency on how stakeholder comments submitted to NICE consultations are reviewed and presented to committee members was requested. We have updated the guide to include that line by line responses will be provided to comments received.

#### Conclusion

- 28. The Board is asked to:
  - review and approve the updates to the process guide
  - approve publication of the indicator process guide in December 2019.

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November 2019

National Institute for Health and Care Excellence

NICE impact report: lung cancer

This report gives details of how NICE's evidence-based guidance contributes to improvements in lung cancer care.

It provides information about NICE's communication activity in relation to the previous impact report on maternity and neonatal care.

The Board is asked to review the NICE impact lung cancer report and note the actions proposed by the system support for implementation team and the communication's activity.

Professor Gill Leng

Deputy Chief Executive and Director, Health and Social Care Directorate

November 2019

#### Introduction

The attached NICE impact report focuses on lung cancer and reviews the uptake
of NICE guidance in this area. It is the second impact report focusing on cancer
and covers: the prevention of lung cancer; recognition of lung cancer; diagnosis
and staging; treatment and patient experience.

#### **System support for implementation**

2. The system support for implementation team is currently reviewing the impact report and will consider how to address any implementation issues highlighted. Any proposed implementation and support activities will be presented to the Health and Social Care Senior Leadership Team as appropriate.

#### **Promoting NICE impact reports**

- 3. The latest NICE impact report on <u>maternity and neonatal care</u> was published on 26 September and promoted to key audiences and stakeholders.
- 4. The following is a summary of key activities and highlights from the communications and engagement activity to promote the impact report.

#### Working with partners and stakeholders

- 5. We engaged with ALBs, stakeholders involved in the impact report and professional bodies to help us highlight the report's key findings. Below are some examples of the communication activities carried out:
  - The Twins and Multiple Births Association (TAMBA) tweeted about the report to their 6,014 followers
  - Mumsnet tweeted to their 152,600 followers
  - The Nursing and Midwifery Council featured the report in their newsletter to employers
  - The Royal College of Obstetricians and Gynaecologists included a piece in their members' newsletter (circulation 9,200)
  - The Local Government Association put a piece in the Community Wellbeing Board Bulletin (circulation 6,039)
  - The Royal College of GPs tweeted to their 64,600 followers
  - NHS England and NHS Improvement featured the report in their Informed and CCG e-bulletins (circulations 7,000 and 4,000 respectively). This is the first time that impact reports have been covered in these publications.

Informed is a monthly bulletin for NHS and health and social care professionals. The CCG e-bulletin goes out weekly to CCG leaders and staff. These bulletins, and other relevant bulletins by NHS England and NHS Improvement, will be targeted for future impact reports.

- The Association of Child Psychotherapists included the report in their member newsletter (circulation 1,000)
- The Birth Trauma Association put out a Facebook post (8,250 followers)
   and a tweet (4,042 followers)
- The UK Newborn Screening Programme Centre included a news piece on their website and tweeted to their 3,881 followers
- The National Health Executive (NHE) published a <u>blog</u> by Professor Gill Leng which had been viewed 112 times by 10 October. NHE also tweeted it to their 14,600 followers.

#### **Newsletters**

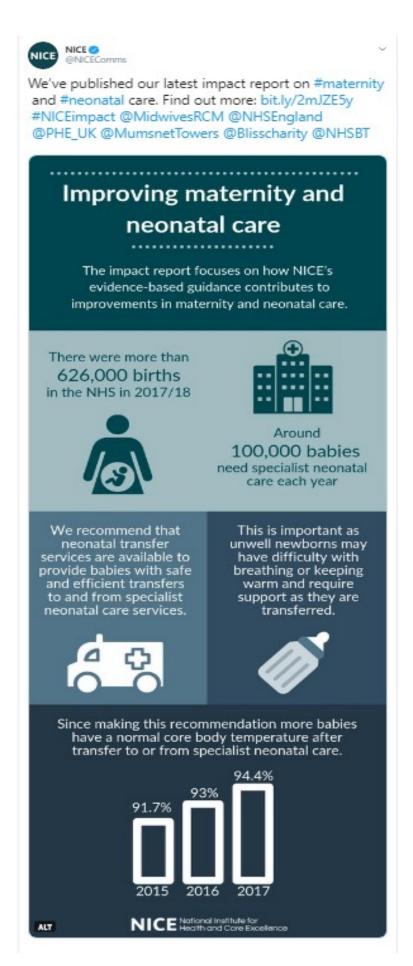
6. The impact report was featured in two of NICE's newsletters; NICE News (28,449 subscribers) and Update for Primary Care (12,750).

#### Social media

7. We promoted the impact report over a 5-day period on Twitter, Facebook and LinkedIn using a mix of infographics, quote graphics and images. By posting on 3 channels we reached a varied audience; professionals in health and care on Twitter and LinkedIn and the general public on Facebook.

#### Twitter:

8. On Twitter our 6 posts overall were viewed 46,342 times and received 410 clicks, likes, comments or shares.



9. Our first infographic post received the highest engagement rate of 1.67%. This is positive because Twitter usually gets, on average, 0.06% on an individual post. This post was retweeted by organisations including TAMBA and Maternity Outcomes Matter, and high-profile individual accounts including Yana Richens, Deputy Head of Maternity at NHS England and NHS Improvement.

#### LinkedIn:

10. Our 2 posts on LinkedIn led to 121 clicks through to the report. The engagement rate of 2.86% and 2.25% respectively was high. Around 2% is considered good.

#### Facebook:

11. Our 4 posts overall were viewed 4,346 times and received 57 clicks, likes, comments or shares. Our infographic and quote graphic received the highest engagement rates, 1.72% and 1.73% respectively, compared to two posts sharing stock images, 0.76% and 0.79%. This suggests that providing more information in the form of a graphic could help to engage the Facebook audience when promoting future impact reports.



#### Google Analytics

- 12. Google Analytics are featured in this report for the first time. They are a tool which tracks website activity such as session duration, pages per session and bounce rate, along with information on the source of the traffic.
- 13. Analysis of the online visits to the maternity and neonatal care impact report shows that we receive more visits to the HTML content (pages on our website) than the PDF (a link to a document added to the website) which was

downloaded 101 times. The HTML pages were clicked on 917 times. This is representative of activity across our site: users want to receive content in web format as opposed to PDFs or Microsoft Office documents. Producing content in web format also fulfils our obligations under the public sector accessibility regulations.

#### **Events**

14. NICE's events team continues to promote the impact reports at all relevant events, exhibitions and speaking engagements. Our maternity and neonatal care impact report will be promoted at the RCGP Annual Conference 24-25 October in Liverpool and Acute and General Medicine 2019 12-13 November in London.

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November 2019





## **NICE**impact lung cancer

Lung cancer is the **third most common** cancer in England and is the leading cause of cancer death. In 2017, there were almost 39,000 new cases of lung cancer and just over 28,000 related deaths. This report considers how NICE's evidence-based guidance can contribute to improvements in the care of people with lung cancer.

This report highlights progress made by the health and care system in implementing NICE guidance. We recognise that change can sometimes be challenging and may require pathway reconfiguration. Additional resources such as training and new equipment may also be required.

We work with partners including NHS England, Public Health England and NHS Improvement to support these changes, and we also look for opportunities to make savings by reducing ineffective practice

#### Prevention of lung cancer p4

Most lung cancers are associated with smoking. The number of people who smoke has been dropping over the last 4 decades, but more can be done to help people stop.

#### **Recognition of lung cancer** p6

NICE recommends public awareness campaigns to boost recognition of the signs and symptoms of lung cancer, including in those who have never smoked. Combined with faster referral this has led to more people being seen by a specialist within the recommended 2 weeks.

#### Diagnosis and staging p9

Advances in diagnostic capabilities has led to increased use of tumour markers and more pathological confirmations. This allows for more informed decisions around prognosis and targeted treatment options.

#### **Treatment** p11

More people are receiving treatment for lung cancer, with surgery rates for non-small-cell lung cancer (NSCLC) having doubled since 2009.

#### Patient experience p16

Survey results suggest that most people with lung cancer have a positive experience of care overall, but there is room for improvement. Improving communication and ensuring the availability of specialist nurses can help to achieve this.

#### Commentary p18

Professor Michael Peake reviews recent achievements and considers NICE's role in improving outcomes for people with lung cancer.

# Why focus on lung cancer?

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

NICE provides evidence-based guidance and advice to help improve health and social care services. The uptake of NICE guidance is influenced by close relationships with partners across health and care, such as NHS England, NHS Improvement and Public Health England (PHE).

Since the publication of NICE's first guideline on lung cancer in 2005, we have produced a <u>suite of lung cancer related</u> <u>guidance</u>, which aim to improve outcomes by focusing on survival rates and ensuring the most effective tests and treatments are used.

In England, overall <u>survival rates</u> for cancers are improving but there is still a marked difference between lung cancer and other cancers. Between 2012 and 2016 more than 95% of people with breast or prostate cancer survived more than 1 year after their diagnosis, compared to less than 40% of people with lung cancer. There is an even greater difference between 5-year survival rates. More than 85% of people with breast or prostate cancer survived more than 5 years but just over 15% of people with lung cancer survived this long. When <u>comparing</u> <u>with other countries in Europe</u>, England's long-term survival for people with lung cancer is poor, ranking 26th out of 29 countries.

The NHS Long Term Plan (LTP) focuses on the faster diagnosis of all cancer in order for people to have the best chance of curative treatment and improve long-term survival. This is set out with several milestones with the aim of diagnosing 75% of cancers at stage 1 or 2 by 2028.

We routinely collect data which give us information about the uptake of our guidance. To produce this report, we have worked with national partners to select data which tell us how NICE guidance might be making a difference in priority areas of lung cancer care. They also highlight areas where there is still room for improvement.

2 guidelines

2 quality standards

78
technology appraisals

10 interventional procedure guidance

diagnostics guidance

## Prevention of lung cancer

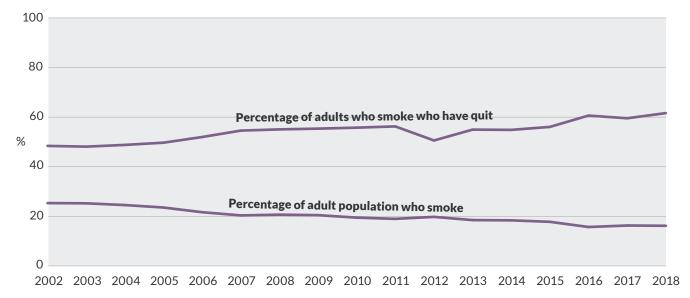
Over 80% of lung cancer cases are associated with **smoking** and **other risk factors**, such as air pollution, workplace exposure and ionising radiation. Stopping people from being exposed to these risk factors can help to prevent lung cancer.

#### Helping people to stop smoking

NICE's first public health guideline, published in 2006, was on brief interventions and referrals for people who smoke. Since then we've published a <u>suite of guidance and advice</u> covering interventions and strategies to prevent children and young people from taking up smoking, how to reduce harm from tobacco and how to help to help people who already smoke to quit. More recently we've published guidance on <u>outdoor air quality</u>, recommending a number of actions to reduce pollution from road traffic.

Smoking prevalence began to decline in the 1970s and has continued to do so. Smoking rates are highest among the most disadvantaged communities. In 2018, over a quarter of people in routine and manual occupations reported that they are current smokers, while just over 10% of people in professional and managerial roles smoked.

Smoking prevalence has continued to decline and more people who smoke have decided to quit



The Ottawa Model for Smoking Cessation has been implemented in 120 hospitals across Canada. It identifies the smoking status of all admitted patients, followed by brief advice, personalised bedside counselling, timely nicotine replacement therapy and/or pharmacotherapy, and follow-up after discharge.

It improves long-term quit rates by 11%. The Royal College of Physicians has modelled the impact of implementing the Ottawa Model for Smoking Cessation intervention within the NHS, and the NHS Long Term Plan has adopted this model. The NICE quality standard on smoking: supporting people to stop states that healthcare practitioners should ask people if they smoke and offer advice on how to stop for those who do smoke. In 2016, 73% of people seen in secondary care were asked if they smoked by a healthcare practitioner, according to an audit report on smoking cessation from the British Thoracic Society (BTS). However, only 28% of people who smoked were asked if they'd like to quit and only 6% of people who smoked received advice on how to stop.

The picture in primary care is more promising. Data from NHS Digital's **Quality and Outcomes Framework (QOF)** show a steady increase in offers of support and treatment to current smokers. In 2018, almost 90% of smokers aged 15 or over who are registered with a GP had a record of an offer of support or treatment.

To support people to quit smoking the quality standard also says that people should be offered a referral to an evidence-based smoking cessation service. These services increase the likelihood that someone will quit smoking. In 2018 just over a third of all people who set a quit date through NHS stop smoking services successfully quit, as confirmed with carbon monoxide validation. This quit rate has remained steady over the last 4 years.

#### **Reducing air pollution**

Air pollution is associated with around 8% of all lung cancers. Outdoor air pollution is a mixture of man-made pollutants, such as vehicle fumes, and natural substances like wind-blown dust. The International Agency for Research on Cancer (IARC) has linked tiny particles in the air to lung cancer, though it is not yet fully understood how these particles cause cancer.

The NHS Long Term Plan (LTP) outlines plans to reduce air pollution produced by the NHS, aiming for a 20% reduction in business mileage and fleet air pollutant emissions by 2023/24. The LTP adds that the overall reduction in air pollution is the responsibility of local government.

NICE's <u>guideline</u> and <u>quality standard</u> on outdoor air pollution cover road-traffic related air pollution and its links to ill health. They make recommendations that will improve air quality through reduced emissions and initiatives such as clean air zones, with the aim of preventing a range of health conditions and deaths.

## Recognition of lung cancer

Early detection of lung cancer is key to improving outcomes. This can be achieved through improved public awareness and quick referral to specialist care when lung cancer is suspected.

Symptoms of lung cancer can be vague and may be mistaken for other illnesses, such as chest infections. Delayed detection of lung cancer means that the disease has had more time to progress and is often at an advanced stage at the time of diagnosis. National Cancer Registration and Analysis Service (NCRAS) data show that almost half of all lung cancers are stage 4 at diagnosis, whereas the majority of breast and prostate cancers are stage 1 or 2 at diagnosis. Late diagnosis, where curative treatment is not possible, is a contributing factor to poor survival rates for people with lung cancer.

Lung cancer is often diagnosed at a later stage than other common cancers like breast and prostate cancer



The late diagnosis of lung cancer can be a result of several factors, including a lack of awareness and recognition of symptoms, how quickly people visit a doctor and the speed at which cancer is suspected and then diagnosed. NICE's guidelines and quality standards on <a href="suspected cancer">suspected cancer</a> and <a href="lung cancer">lung cancer</a> have been developed to address these issues. They state that people should be made aware of lung cancer through coordinated public awareness campaigns and outline the criteria for referring people for relevant investigations or onto a suspected cancer pathway.

Implementation of these recommendations will raise public awareness of the signs and symptoms of lung cancer, which could encourage and empower people to seek advice from a healthcare professional. In addition, increasing primary care awareness and clear referral criteria can reduce the time from when lung cancer is first suspected by a clinician to the relevant investigations being undertaken, reducing the likelihood of late stage diagnosis.

The NHS Long Term Plan (LTP) has committed to extending a programme of lung health checks, which have produced strong results in Liverpool and Manchester by boosting the proportion of cancers detected at stage 1 and 2. NICE welcomes evidence arising from this programme.

#### Public awareness campaigns

To increase the number of lung cancers that are diagnosed at an earlier stage, NICE recommends that the public should be better informed on the signs and symptoms that are characteristic of lung cancer.



Public awareness campaigns have been shown to increase early stage cancer diagnoses



Results from the Be Clear on Cancer campaign show how successful public awareness campaigns can be. The campaign, led by Public Health England working in partnership with the Department of Health and Social Care, NHS England and Cancer Research UK, was set up in 2010 to promote awareness and early diagnosis of lung cancer. An estimated 700 additional cancers were diagnosed in the months surrounding campaign activity, compared to the same period in the previous year, and around 400 more people had their cancer diagnosed at an earlier stage.

#### Referral to a specialist

As well as increased public awareness of lung cancer, fast referral to a specialist for relevant investigations is also key to increasing diagnoses made at an earlier stage of disease. To ensure that people with any cancer are seen at the earliest opportunity, NICE developed a guideline on <a href="suspected">suspected</a> cancer: recognition and referral. The guideline includes a section on the signs and symptoms of lung cancer which healthcare professionals should look out for to trigger an urgent referral to a specialist.

Data from NHS England's <u>Cancer Waiting Times annual report</u> show that the proportion of people with suspected lung cancer seen by a specialist within 2 weeks, following an urgent GP referral, has remained at around 96% for the last 3 years. This exceeds the operational standard of 93% set by NHS England.

As lung cancer staging is a key part of guiding treatment and prognosis, it is very important to have valid, complete staging data. NICE has developed an indicator on the proportion of lung cancer cases for which a stage at diagnosis is recorded. This fed into the development of a CCG outcome indicator, designed to encourage staging of lung cancer at the time of decision to treat. The percentage of people diagnosed with lung cancer who have a valid stage recorded at the time of decision to treat has increased over recent years, from 86% in 2013 to 94% in 2017.

A NICE shared learning example reports how one GP implemented the NICE guideline on suspected cancer: recognition and referral in their area. They set up an implementation group that identified implementation barriers such as the cost of increased referrals and worked with the CCG to ensure sustained funding. By engaging with other GP practices, cancer pathways were re-designed, referral forms were standardised, and plans to enhance patient engagement were set.

An associated outcome reported by the <u>National Cancer</u>

<u>Patient Experience Survey</u> (CPES) is how many times people saw their GP about the health problem caused by cancer, before they were referred to a specialist.

Over the last 4 surveys around a third of people with lung cancer could recall being referred to a specialist after just 1 GP appointment. This is lower than in the 'all cancer' population, where 43% of people recalled seeing their GP once before referral. In 2018 the proportion of people with lung cancer who recalled seeing their GP 5 or more times before referral was almost 8% compared with 6% for the 'all cancer' population.

To support GPs in recognising cancer symptoms, NICE has endorsed an online cancer education platform called **GatewayC**. Using recommendations from our guideline on **suspected cancer: recognition and referral**, the interactive platform aims to improve cancer outcomes by facilitating earlier and faster diagnosis through supporting clinical decision making in primary care.

#### Recognition of lung cancer in never-smokers

In the UK it is estimated that nearly <u>6,000 people who have</u> <u>never smoked</u> die of lung cancer every year, making it the eighth most common cause of cancer-related death. While causes can be partly attributed to environmental factors such as air pollution, identifying the cause of the cancer in individuals can be difficult.

Never-smokers generally refers to people who have smoked less than the equivalent of 100 cigarettes in their lifetime.

'I had a bad back and it wasn't getting any better so I went to see the GP, where he told me he was checking for cancer. This surprised me as I have never smoked. After 3 months of tests and scans, I was told that I had a tumour in my lung. I then had a lung biopsy and an MRI scan. Upon receiving results of the biopsy, my oncologist immediately started me on gefitinib, as it targets the EGFR mutation that I had tested positive for. While I was very satisfied with the people and the care I received, I wish they had implemented a faster diagnosis process. Greater Manchester have now instituted a faster 1-month diagnosis pathway and are in the process of rolling it out.' Male, diagnosed at stage IV

The latest Roy Castle awareness campaign Like Me, challenges the misconception that only certain people get lung cancer. The campaign highlights that lung cancer can affect anyone, which can lead to late diagnosis and increased mortality rates.

## Diagnosis and staging

Minimising the number of steps in a diagnosis and staging pathway and completing them efficiently will reduce delays in care. NICE's guideline on lung cancer makes a number of recommendations that optimise the diagnostic pathway and allow flexibility for managing a range of people that may present with symptoms of lung cancer.

#### Pathological confirmation and staging

NICE's <u>guideline</u> and <u>quality standard</u> on lung cancer state that, when taking samples in people with suspected lung cancer, they should be adequate to permit pathological diagnosis, including tumour subtyping and assessment of predictive markers. A predictive cancer marker is anything present in or produced by cancer cells or other cells of the body in response to cancer. They can provide information on how aggressive the cancer is and whether it could be treated with a targeted therapy. Obtaining a pathological diagnosis and assessment of predictive markers ensures that the most appropriate treatment regimen is offered.

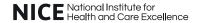
Data from the Royal College of Physicians' National Lung Cancer Audit (NLCA) show that pathological confirmation rates in all stages of lung cancer dropped in 2014. They have since shown improvement but still remain below the 2013 rate.

Tumours grow when, instead of repairing or self-destructing, mutated cells continue to multiply. Samples of the cancerous cells can be biopsied and used for pathological analysis to provide detail on the type of mutation. This is known as pathological diagnosis.

Cancer stage refers to how much the cancer has developed by growing and spreading. Stage I lung cancer is small and hasn't spread, while stage IV has usually spread to the other lung, or other parts of the body such as the liver, bones or brain. Accurate assessment of stage often involves various scans and other tests, such as an endobronchial ultrasound, a technique used to visualise the airway.

## Pathological confirmation rates of lung cancer





Performance status (PS) is a measure of how well a person is able to carry on ordinary daily activities while living with cancer and provides an estimate of what treatments a person may be able to tolerate. Someone whose PS is 0 or 1 can carry out most of their usual daily activities without help, whereas someone with a PS of 4 is usually confined to a bed or chair and needs help with all daily activities.

The latest report from the NLCA, published in May 2019, reports pathological confirmation rates in people with early stage lung cancer only. This is because some clinicians feel that people who have late stage lung cancer are unlikely to tolerate or benefit from an invasive biopsy. Similarly, NICE recommends that pathological diagnosis should only be performed without unacceptable risk to the person. In 2017, the pathological confirmation rate for people with stage I-II lung cancer who had a performance status of 0-1 was 89% in England.

To enable increased pathological diagnosis rates, the <a href="NHS Long Term Plan">NHS Long Term Plan</a> (LTP) details plans to increase capacity in diagnostic services by investing in new equipment and staff.

#### Multidisciplinary team meetings

Multidisciplinary team meetings (MDTs) are key to the effective diagnosis and staging of lung cancer. Bringing together a breadth of experience and knowledge from a range of healthcare professionals to form an MDT allows for rapid decisions around patient assessment and appropriate treatment. Lung cancer MDTs will often include a chest physician, radiologist, pathologist, specialist nurse, oncologist, surgeon and members of a palliative care team.



Recent years have seen an increase in the proportion of people with lung cancer that are being discussed at multidisciplinary team meetings

NICE recommends that the care of all people with suspected lung cancer should be discussed at a lung cancer multidisciplinary team (MDT) meeting. Data from the NLCA show that, in 2017, 87% of people with lung cancer were discussed at an MDT meeting. This is an increase from 82% in the 2015 audit.

## **Treatment**

Treatment for lung cancer includes surgery, chemotherapy, radiotherapy, immunotherapy and other targeted therapy drugs. People may be offered one or more different treatments depending on the stage and type of lung cancer as well as their general health.

Non-small-cell lung cancer (NSCLC) is the most common type of lung cancer, accounting for 87% of cases. NSCLCs can be broken down into 2 major sub-types: adenocarcinoma (sometimes referred to as non-squamous) and squamous cell carcinoma. With recent advances in scientific evidence, treatment for these subtypes is becoming increasingly different, with the identification of mutations in tumours being of particular importance in adenocarcinomas.

Small cell lung cancer (SCLC) is less common, accounting for around 12% of lung cancers. SCLC is an aggressive cancer which spreads at an early stage and so is nearly always advanced at the time of diagnosis, leading to limited curative-intent treatment options.

#### **Surgery**

Surgery for NSCLC has proven to be effective, with <u>National</u> <u>Cancer Registration and Analysis Service</u> (NCRAS) data showing that 45% of people with NSCLC were still alive 5 years post-surgery. Five-year survival rates for people with NSCLC who do not have surgery was 3%.

Over the last 10 years, surgery rates in NSCLC have doubled, from around 9% in 2006 to over 18% in 2017, exceeding the target of 17% set by the National Lung Cancer Audit (NLCA).

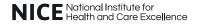
NICE recommends that people with non-small-cell lung cancer (NSCLC), who are well enough and for whom treatment with curative intent is suitable, should be offered a lobectomy (either open or thoracoscopic). It is encouraging that data from the National Lung Cancer Audit show that surgery rates for people with stage I-II lung cancer and a good performance status have increased from almost 52% in 2015 to almost 61% in 2017, though there does appear to be significant regional variation.

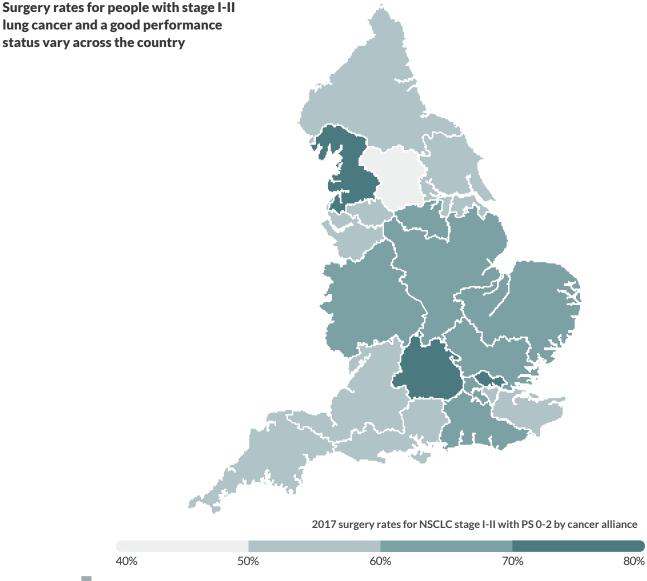
Adenocarcinoma is a cancer that starts in glandular cells, for example, ones that secrete mucus. These are often found in alveoli, the tiny air sacs in the lung.

Squamous cell carcinoma is a cancer that starts in squamous cells, which are thin, flat cells that line the airways.

An open lobectomy (thoracotomy) is the removal of a lobe of the lung through a cut made around the side of the chest.

A thoracoscopic lobectomy is keyhole surgery, where a lobe of the lung is removed using several small incisions, guided by a camera. This is normally more suitable for smaller tumours.







Overall surgery rates for NSCLC are increasing, but there is variation across the country

### **Chemoradiotherapy for NSCLC**

For more advanced NSCLC, surgery or radiotherapy alone is often not appropriate as the cancer has spread too far for it to be possible or effective. Even for more advanced cancers that have not spread too far, the curative potential of radiotherapy alone is low. A chemotherapy regimen is often added to radiotherapy to control small clusters of cancer cells that have spread to other parts of the body. Additionally, many chemotherapy agents make the cancer more sensitive to the radiotherapy.

NICE recommends that chemoradiotherapy should be considered for people with stage II or III NSCLC when surgery isn't suitable or is declined.

Chemoradiotherapy for people with stage III NSCLC is steadily increasing. The National Lung Cancer Audit reports that 34% of people with stage IIIA NSCLC and good performance status received treatment with chemotherapy and either radical radiotherapy or surgery in 2017.

### Chemotherapy, radiotherapy and chemoradiotherapy

Chemotherapy is a whole-body treatment where drugs are used to kill cancer cells by disrupting their growth. For early stage cancer, it can be used to shrink a tumour before surgery, making it easier to remove or it can be used after surgery to reduce the risk of the cancer coming back.

For people with advanced lung cancer, chemotherapy can be used to stop the cancer from spreading further and help people live longer.

Radiotherapy uses high energy x-rays to destroy cancer cells to stop them growing and spreading.

Radiotherapy can be used in early stage NSCLC for people who cannot have surgery.

It can also be used after surgery if it was not possible to remove all the cancerous tissue. In late stage lung cancer, radiotherapy can be used to manage symptoms.

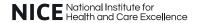
Chemoradiotherapy is a combination of chemotherapy and radiotherapy. This is generally offered to people with stage II or III NSCLC who are reasonably well as it can be difficult to tolerate the side effects of both treatments.

#### Systemic anti-cancer treatment for NSCLC

Systemic anti-cancer treatments (SACT) include all treatments that are administered to the whole body, for example chemotherapy, immunotherapy and other medicines that disrupt the behaviour of the cancer cells. These treatments are more often used to treat advanced NSCLC. Clinical trials have demonstrated that people with advanced and incurable NSCLC can benefit from SACT, delivered to improve quality of life and to extend survival.

NICE has produced a number of recommendations relating to the treatment of NSCLC using targeted SACT and in March 2019 we published 2 algorithms for the treatment of squamous and non-squamous stage IIIB and IV NSCLC.

Baseline data from the NLCA show rates of SACT for people with advanced stage lung cancer (IIIB-IV) who have a good performance status are increasing, from almost 63% in 2016 to 66% 2017.

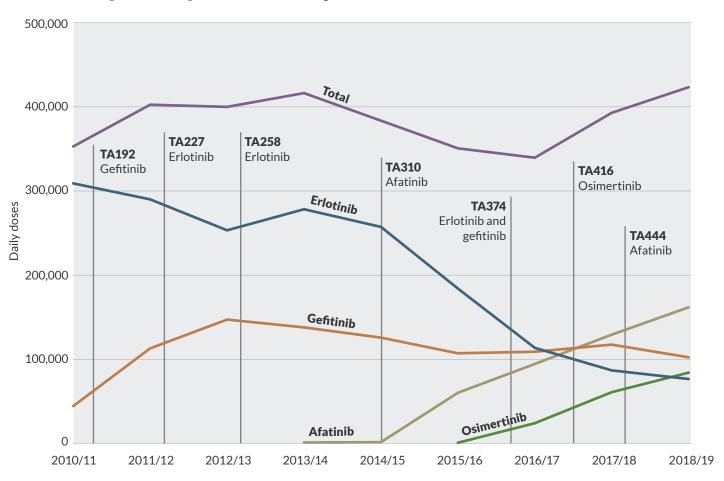


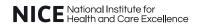
The <u>Innovation scorecard estimates report</u> is produced by NICE and published by NHS Digital. The report shows the trend in prescribing of NICE recommended first-generation (gefitinib and erlotinib) and second-generation (afatinib and osimertinib) tyrosine kinase inhibitors, which are indicated for the targeted treatment of adults with locally advanced or metastatic epidermal growth factor receptor (EGFR) mutation-positive NSCLC.

Prescribing data indicates that the second-generation medicines have become a more popular treatment choice once available. Emerging evidence suggests that the second-generation medicines may be better in terms of prolonging progression free survival.

For the last 2 years, approximately 1,700 people in England received treatment each year with one of the EGFR targeted medicines.

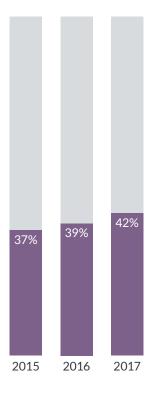
#### **Prescribing of EGFR targeted medicines**





## Rates of multi-modality treatment for people with SCLC are increasing

% with stage I-III SCLC with PS 0-2 who received multi-modality treatment with chemotherapy and radical radiotherapy or surgery



#### **Treatment for small cell lung cancer**

Around 30% of small cell lung cancer (SCLC) cases are detected at stage I-III. For those detected early enough, treatment with curative intent is an option. NICE recommends that twice-daily radiotherapy with concurrent chemotherapy should be offered to people with limited-stage disease SCLC. NICE also says that surgery should be considered in people with early-stage SCLC.

The NLCA shows that treatment with curative intent for people with SCLC has increased. In 2017, 42% of people with stage I–III SCLC with a performance status of 0–2 received treatment with chemotherapy and radical radiotherapy or occasionally surgery, which is a year on year increase since 2015.

For SCLCs that are detected at a late stage, chemotherapy and radiotherapy can be used to improve quality of life and chances of medium-term survival.

NICE recommends that people with limited-stage SCLC should be offered 4 to 6 cycles of cisplatin-based combination chemotherapy and that people with extensive-stage SCLC should be offered a platinum-based combination chemotherapy.

Data from the NCLA show that the proportion of people with SCLC who receive chemotherapy has remained steady for the last few years at around 70%, which meets the NLCA's audit standard.

## **Changes in commissioning**

Stereotactic ablative radiotherapy (SABR) is a type of radiotherapy used to treat cancers by directing narrow beams of radiation at the cancer from different angles. The tumour gets a high dose of radiation and the surrounding healthy tissues get a low dose, reducing the risk of damage to healthy tissue.

Oligometastatic disease occurs when cancer cells from the original (primary) tumour travel and form a small number of new (metastatic) tumours.

SABR is not routinely commissioned for the treatment of oligometastatic disease and was selected by NHS England for the Commissioning

through Evaluation (CtE), which is part of its Evaluative Commissioning Programme.

CtE enables a limited number of patients to access treatments that are not funded by the NHS but show significant promise for the future, while new clinical and patient experience data are collected. NICE is commissioned by NHS England to oversee individual CtE schemes. The updated policy which will contain a summary of the results of the CtE scheme will be published on the NHS England Specialised Commissioning document library once a decision has been made.

## **Patient experience**

The NHS Constitution highlights the importance of people being at the heart of everything the NHS does. People should be treated with compassion, dignity and respect and involved in decisions about their care and treatment. These key themes are reflected in NICE's guideline and quality standard on patient experience in adult NHS services.

#### **Specialist nurse**

Having a named specialist nurse who is easy to contact for information, advice and support can help people feel reassured that they are well informed and involved as much as they want to be in decisions about their care. The NICE guideline on the diagnosis and management of lung cancer recommends that a lung cancer clinical nurse specialist (CNS) is available at all stages of care.

Lung cancer CNS are nurses who have completed an accredited programme of study in lung cancer. They are a core member of the multidisciplinary team (MDT), contributing to decisions around assessment and care planning. They coordinate the patient pathway and often act as the key worker for patients referred to the team. Recent studies have shown that lung cancer CNS assessments are associated with higher rates of anti-cancer therapies.



In recent years, more people with lung cancer have been seen by a nurse specialist but this number remains lower than expected

According to the National Lung Cancer Audit (NLCA), the proportion of people seen by a lung cancer CNS has increased, from 55% in 2008 to 70% in 2017 and the National Cancer Patient Experience Survey (CPES) reports that, in 2018, 90% of people with lung cancer were given the name of a lung cancer CNS. The CPES also reports that more than three quarters of people with lung cancer found their CNS easy to contact.

Lung cancer clinical nurse specialists account for a low proportion of the overall cancer nurse specialist workforce Workforce data collected by <u>Macmillan</u> show that there has been a general increase in cancer CNSs. While the total number of lung cancer CNSs has increased, given its prevalence as the third most common cancer, it would be expected that the proportion <u>specialising in lung cancer</u> would be greater than 11%.



#### **Communication**

People with lung cancer face an increasing amount of new and complex information at a time when their ability to process and understand it can be impaired by the stress of their illness.

'Everything was made clear but I was too scared to think straight and was unable to take it all on board. I couldn't make an informed decision because of the terror I felt at dying and just went along with what I was advised to do. This, obviously, as I'm still here was the right thing to do.' Shirley, diagnosed at stage IV NICE recommends that people with lung cancer should be given accurate and easy-to-understand information and that they should have tests and treatment options explained, including potential survival benefits, side effects and effect on symptoms.

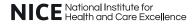
Compared to other cancers, people with lung cancer were less likely to be given written information that is easy to understand

Lung cancer

The latest CPES report shows that people with lung cancer are less likely to say that they were given easily understood, written information on their cancer compared with people with most other cancer types. Results for all other areas of communication that the cancer patient experience survey asks about are comparable between lung cancer and all other cancer types.

Given written information about the type of cancer that was easy to understand

| Cancer average                                   | 65%                             |     |
|--------------------------------------------------|---------------------------------|-----|
| Treatment options explained before the treatment | nent started                    |     |
| Lung cancer                                      |                                 | 88% |
| Cancer average                                   |                                 | 87% |
| Possible side effects of treatment(s) explained  | in a way the patient understood |     |
| Lung cancer                                      |                                 | 94% |
| Cancer average                                   |                                 | 93% |



Professor Michael Peake is Clinical Director for the Centre for Cancer Outcomes and Honorary Professor of Respiratory Medicine at the University of Leicester.

## **Commentary**

Professor Michael Peake, September 2019

In England the average 5-year survival rate for people diagnosed with lung cancer between 1991 and 1993 was 5% but varied by Area Health Authority between 2% and 8.5%. The latest figures from the Office for National Statistics show that 5-year survival had tripled for people diagnosed in 2011 to 14% for males and 17.5% for females.

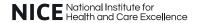
Before the National Cancer Plan and the NICE guidelines were published, cancer care was fragmented. The first NICE guideline on lung cancer was published in 2005, the same year that full data collection in the National Lung Cancer Audit (NLCA) began. Since then there has been the universal adoption of MDT working and a steady increase in the proportion of people receiving any active anti-cancer treatment, namely surgery, chemotherapy or radiotherapy. Of these the most important explanation of the improvement in 5-year survival is likely to be the more than doubling of the number of people undergoing surgical resection of their cancers. The quality of surgery has also improved over that period, with significant falls in peri-operative mortality, to some of the lowest levels reported internationally, despite surgery being carried out on older, less fit patients. That has been achieved by a doubling of the number of specialist thoracic surgeons since 2005.



Outcomes for people with lung cancer are improving but there is still work to be done to reduce regional variation and ensure adequate staffing levels

This has all been accompanied by much better diagnostic and staging techniques and the unprecedented increase in knowledge of the basic science and emergence of personalised medicine, based on advances in molecular pathology.

The development of NICE's referral guidelines for GPs and the rapid referral pathways, combined with all the work on public and primary care awareness, have been associated with an increase in the proportion of people diagnosed at stages I and II from 19.5% in 2012 to 28% in 2017. Evidence of the effectiveness of lung cancer screening is now strong and the emergence of screening programmes in England is likely to have a major long-term impact on survival and mortality rates.



However, as is well demonstrated by the NLCA, wide variation in treatment and survival rates remain between different areas of the country. Apart from the limitations of current treatments, the main barrier to further progress in England is a shortfall in workforce, particularly in radiology, pathology and oncology, although there are many examples where, with better organisation and design of services, improvements in both the timeliness and quality of care can be achieved within current resources. The aim should be to achieve universal and timely access to optimal care delivered by specialist teams as described in NICE guidance, which would result in further improvement in outcomes, both in terms of survival and quality of life, for people with lung cancer.

We would like to thank Professor Michael Peake, Clinical Director for the Centre for Cancer Outcomes. We would also like to thank Professor Chris Harrison, Medical Director (Strategy) at The Christie NHS Foundation Trust and all those who contributed to the report by providing us with their experiences of lung cancer care.

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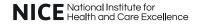
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## National Institute for Health and Care Excellence

## A new director post for Science, Evidence and Analytics

This report gives details of a proposed new director role and associated changes in related roles. The new post will increase capacity in the senior management team in an area of strategic importance for NICE.

The Board is asked to approve the creation of new director post and the associated changes.

Professor Gillian Leng

Deputy Chief Executive and Director, Health and Social Care Directorate

November 2019

Page 1 of 4

Reference: 19/105

#### Introduction

- 1. The purpose of this paper is to approve the creation of a new director post and the associated changes in related roles.
- 2. The rationale for this new post is to increase capacity in the senior management team in an area of strategic importance for NICE. This is important because it will:
  - Manage an important new cross-cutting function that will provide greater efficiency and cross Institute working.
  - Contribute additional capacity to support the NICE Connect transformation, in an important area for the future.
- 3. The new post will provide leadership for methods, data analysis and research by bringing together a range of important related functions. This is core to our business, and for the future development required for NICE Connect. This additional capacity will also provide more stability and support during the transition to a new Chief Executive. The job description is attached.

### **Financial implications**

4. There are direct financial implications of funding a new director post on the Executive Senior Manager (ESM) pay scale. The exact salary level will be confirmed with the Department of Health and Social Care's (DHSC) Remuneration Committee. In addition, part funding for one senior post, which will no longer be supported by an external income source will be required. There are no other new staff associated with the post, but there will be ongoing related costs such as travel, general expenses and attendance at Board meetings. Provision will be made in the 2020-21 budget for these costs.

### **Key issues and recommendations**

- 5. The key issues in the creation of this new post, other than financial considerations, are the impact on affected staff. All staff affected are aware of the proposals and agree to the proposed changes, therefore there is no requirement for a formal management of change process. The changes are summarised in the table below, which will take effect when the new director comes into post.
- 6. In addition to changes in line management and responsibilities, a new job title is being proposed for the director of evidence resources. This will become the director for digital, information and technology, reflecting the change in focus of the role.

National Institute for Health and Care Excellence A new director post for Science, Evidence and Analytics Date: 20 November 2019 Reference: 19/105

| Post affected                                       | Impact of the change                                                                                                                                                                                                       |
|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Programme director for information resources        | The post and the associated team (35 WTE) will transfer from the director of evidence resources to the new director. Following the transfer, the post holder's temporary management of the data analytics team will cease. |
| Programme director for science, policy and research | The post and the associated team (20 WTE) will transfer from the Chief Executive to the new director. The part funding of this post by NSA will gradually cease once the post has been transferred.                        |
| Associate director for data analytics               | The post and the associated team (5 WTE) will transfer from the programme director for information resources to the new director.                                                                                          |
| Director for NICE scientific advice (SA)            | The post and the associated team will transfer from the Chief Executive to the director of the Centre for Health Technology Evaluation (CHTE).                                                                             |
| Director of evidence resources                      | The post is renamed as the director for digital, information and technology (DIT). This reflects the loss of the evidence functions, and the recent addition of the business IT team.                                      |
| Director for CHTE                                   | Additional line management responsibility following transfer of NICE SA.                                                                                                                                                   |
| Chief Executive                                     | Additional line management responsibility following creation of the new director post, offset by loss of responsibility for NICE SA and the programme director for science, policy and research.                           |

### **Next steps**

Reference: 19/105

- 7. The next steps in taking forward the creation of a new director post are as follows:
  - Review by the NICE Remuneration Committee (RemCom) on November 28.
  - Review by the DHSC RemCom on December 12, which requires a business case to be submitted 10 working days beforehand. The NICE sponsor team is aware of the proposal and is supportive.
  - Post advertised in early January, with a view to interviews taking place by the end of February.

## **Actions required by the Board**

8. The Board is asked to approve the creation of new director post and the associated changes.

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November 2019



#### **Director for Science, Evidence and Analytics**

#### **Job Description**

#### **Job Summary**

The Director for Science, Evidence and Analytics is responsible for ensuring that NICE uses the best available evidence in its guidance to support health and care decision makers across health and care. The postholder will be taking on the responsibility for developing NICE's use of real world data, and for building it into our routine assessment of evidence, as well as continuing to develop the science, policy, research, and evidence service functions at NICE. He or she will take forward the approach NICE has set out in a Statement of Intent about our future use of data, and work with our guidance centres to develop appropriate methods and processes. He or she will provide strategic leadership with external stakeholders, nationally and internationally, to determine where and when real world data should form part of the assessment of new technologies, building on the Evidence Standards Framework for digital products. The director will also take responsibility for developing new ways in which NICE can make further use of the evidence it receives to support guidance development. He or she will be tasked with strengthening the academic outputs NICE could develop from the evidence it receives. Together these various responsibilities provide the postholder with a key role in the development and use of science, evidence and analytics at NICE, providing an opportunity to support the development of responsive, up to date, relevant guidance. She or he will make a full contribution to the development of NICE's strategy and policy both as a member of the Senior Management Team and at the Board.

Accountable to: Chief Executive

Accountable for: Programme director for Information Resources

Programme director for Science, policy and research

Associate director for data analytics

**Resources:** £5.0m per annum and 60 WTE staff



#### Main Responsibilities

#### **Data analytics**

- Lead a central management, advice and support function across NICE to embed and improve the use of healthcare data and analytics in NICE's guidance development functions, ensuring the organisation takes full advantage of the opportunities offered by the use of real world data.
- 2. Manage a team that acts as a central point of contact for staff with a data and analysis role, to ensure alignment of vision, purpose and methods across NICE.
- 3. Build on the ambition set out in the Statement of Intent and, working closely with colleagues in guidance programmes, embed new approaches using data analytics into NICE's standard methods and processes.
- 4. Organise a programme of training and development on the role of data analytics across NICE, to build capacity and capability in relevant staff.
- 5. Provide strategic leadership for NICE on the use of data analytics, working with partners across universities, healthcare and medical technology industries.
- 6. Oversee contracts with external partners to support complex data analysis, and lead NICE's external reference group in this area.
- 7. Support the development of evidence surveillance systems to ensure that this process is as efficient as possible, and aligns research questions, data collection, assessment of research evidence and guidance updating.
- 8. Engage with director colleagues to review and remodel the approach to developing and delivering NICE guidance to take account of real world data, machine learning and new digital platforms.

#### Science and research

- 9. Lead a team with responsibility for identifying a programme of research through an internal Research Advisory Group to support the development of NICE methodologies, including the analysis of real world data.
- 10. Encourage partners to commission research relevant to our work, including the analysis of real world data. This involves close working with the DHSC Research and Development Committee, the Medical Research Council (MRC) and the National Institute for Health Research (NIHR).
- 11. Support the uptake of research questions developed during guidance development by liaising with relevant funding bodies, including researchers, funders, charities and policy organisations, to ensure this informs the updating of guidance.
- 12. Develop and maintain NICE's research governance infrastructure. The programme collaborates with and influences external policy partners and the research community to define and develop research projects of strategic importance to NICE.
- 13. Lead on key external engagement with a number of regulatory and policy bodies including the MHRA and on NICE's collaboration with institutions and agencies outside the UK, which face common methodological challenges.



#### Information functions

- 14. Take responsibility for a team that manages and develops the Institute's information functions, including an internal service to inform guidance development and surveillance.
- 15. Provide strategic leadership for NICE Evidence Services and for NICE's work to procure and enable access to a wide range of evidence resources for the NHS, including the National Core Content
- 16. Ensure that methods and processes for identifying and prioritising content for inclusion in the NICE Evidence Search are maintained and developed.
- 17. Lead a programme of regular engagement with key stakeholders, in part through established Reference Groups, to ensure all developments are aligned with external priorities.
- 18. Oversee the strategic development of information functions, to ensure they take full advantage of opportunities offered by new technologies including artificial intelligence.

#### Wider corporate activity

- 19. Ensure that accountable staff are motivated, encouraged to deliver to their full potential, and have the opportunity for a meaningful assessment of their work through agreed and annually reviewed objectives.
- 20. Ensure that budgets for which the post holder has delegated responsibility are managed in accordance with standing orders and standing financial instructions and secure value for money.
- 21. Contribute to the development of NICE's strategy and policy through membership of the Senior Management Team and at the Board.
- 22. Participate in the Institute's programme of speaking engagements nationally and internationally.

#### **Terms and Conditions of Appointment**

**Terms:** Salary will be set through the DHSC Pay framework for

Executive and Senior Managers in Arm's Length Bodies or the NHS Consultant medical and dental terms and

conditions of service

Salary: Subject to review

**Annual Leave:** From 27 days to 33 days per annum dependent on NHS

Service plus 8 bank holidays per annum



**Pension:** Optional NHS Superannuation Scheme

#### **Equality & Diversity**

All NICE employees must have respect for every individual, treating everyone with dignity, courtesy, fairness and consideration, and welcoming and accepting differences between people. It is the responsibility of every employee to work towards the elimination of all discrimination and prejudice.

#### **Health & Safety**

All NICE employees have a statutory duty of care for their own personal safety and that of others who may be affected by their acts or omissions. Employees are required to co-operate with management to enable NICE to meet its own legal duties.

#### Governance

All NICE employees are responsible for making themselves fully aware of and committed to all NICE Policies, Procedures and Initiatives relating their employment at the work that they undertake.

This job description does not purport to cover all aspects of the job holder's duties but is intended to be indicative of the main areas of responsibility

#### Person specification

#### Essential skills, knowledge and experience

Experience and understanding of the development and use of data across the healthcare system.

Knowledge and experience of data analytics in a relevant sector or discipline

A clear vision for the way NICE can successfully apply the use of real world data in its guidance development processes.

Good communication and influencing skills, the ability to think and plan strategically and to lead an area of work with high impact and complexity.

Demonstrable ability to inspire and motivate staff, develop and coach teams and harness the strengths and talent of employees in delivering against challenging expectations.

The ability to command the respect of leaders in the field of data analytics and in the life sciences industries, with a track record of building credibility and strong relationships with a diverse range of stakeholders.

#### Desirable skills, knowledge and experience

Board level experience in health, social care or the wider public sector.



A working understanding of the methods and processes used in the development of evidence-based health and care practice guidance and standards, together with a general understanding of the science which is driving current and potential near-future innovation in the health and care services.

A general understanding of the organisation of the health and care system and the political, economic and industrial contexts in which NICE exists.

Working knowledge of the application of economic evaluation in the preparation of guidance and standards for the health and care sector.

# National Institute for Health and Care Excellence NICE Charter - updates for 2019

This report gives details of proposed updates for the NICE Charter.

The Board is asked to consider the updated NICE Charter detailed in Annex 1, and to approve this for publication on the NICE website.

Jane Gizbert

Director, Communications

November 2019

Page 1 of 2

Reference: 19/106

#### 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 who we are, what we do and how we work.
- The Department of Health requested that the Charter should be updated every three years, and as such it was updated and approved by the Board in November 2016.
- 3. At that time, the Board requested to review the Charter on an annual basis.

## Proposed updates and changes to the NICE Charter for 2019

- 4. An updated version of the NICE Charter can be seen in Annex 1 of this paper. Changes being suggested to the Charter for 2019 are:
  - The addition of a new paragraph on the NICE principles, outlining the 13 principles (paragraph 11)
  - Updating of paragraphs 13 and 14 in reference to our use of QALYs
  - Updating of paragraph 23 on the role of the Commercial Liaison Team
  - Addition of more information to paragraph 25, outlining how our guidance is used in relation to the Heath and Social Care Act 2012
  - The updating of 'Putting our guidance into practice' section, removing information on online educational tools and removal of a paragraph on cost saving resources
- 5. The current version of the Charter, published in 2018, is available on the NICE website at www.nice.org.uk/about/who-we-are or on request.

#### **Decision**

- 6. The Board is asked to consider the updated Charter and approve for publication on the NICE website.
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November 2019

National Institute for Health and Care Excellence NICE Charter Date: 20 November 2019 Reference: 19/106

## National Institute for Health and Care Excellence NICE Charter 2019

#### 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 in England. NICE guidance, standards and other resources help health and public health professionals, and social care practitioners, to deliver the best possible care within the resources available.
- 2. NICE works closely with local and national organisations including NHS England and NHS Improvement, the Care Quality Commission, Public Health England 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. They recommend the most effective ways to prevent and manage specific conditions and to improve health and manage medicines in different settings. Our guidelines make recommendations on effective social care interventions and services for adults and children, and outline ways to improve the health of communities. In addition, our guidelines recommend the most effective ways to provide integrated health and social care services that meet the needs of patients and people who use services. Alongside other initiatives in the health and care services, we are seeking ways to incorporate environmental sustainability into our guidance.
- 4. Our recommendations about the use of new medicines, medical technologies and diagnostics identify the most clinically- and cost-effective treatments available. We work collaboratively with the life sciences industry 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. We also prepare advice on new health technologies in Medtech Innovation Briefings.
- 5. NICE quality standards are a key component of the drive to promote 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 enables the NHS, local government and social care providers to make the best use of resources by setting out the case for investment and disinvestment through our guidance programmes and other advice. Our position is to work with system partners to realise the benefits of 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.
- 8. 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.
- 9. 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 and the Clinical Knowledge Summaries, on behalf of the health service These resources can be accessed from NICE Evidence via the NICE website.
- 10. 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.

#### The principles that guide NICE's work

- 11. NICE guidance and quality standards are developed to a high standard and in accordance with a set of core principles that underpin all of our work and how it is produced. We are internationally recognised for the rigorous processes we use to produce our recommendations, and for the quality and accuracy of our products.
  - **Principle 1**. We prepare guidance and standards on topics that reflect national priorities for health and care.

**Principle 2.** We describe our approach in process and methods manuals and review them regularly.

**Principle 3**. We use independent advisory committees to develop recommendations.

**Principle 4**. We take into account the advice and experience of people using services and their carers or advocates, health and social care professionals, commissioners, providers and the public.

**Principle 5**. We offer people interested in the topic the opportunity to comment on and influence our recommendations.

**Principle 6**. We use evidence that is relevant, reliable and robust.

**Principle 7**. We base our recommendations on an assessment of population benefits and value for money.

**Principle 8**. We support innovation in the provision and organisation of health and social care.

**Principle 9**. We aim to reduce health inequalities.

**Principle 10**. We consider whether it is appropriate to make different recommendations for different groups of people.

**Principle 11**. We propose new research questions and data collection to resolve uncertainties in the evidence.

**Principle 12**. We publish and disseminate our recommendations and provide support to encourage their adoption.

**Principle 13**. We assess the need to update our recommendations in line with new evidence.

#### A methodological approach

- 12. All our independent advisory committees take a rigorous and structured approach to guidance development, based on set processes and methods that are published on our website. We keep our methods and processes up to date by regularly reviewing them and consulting on changes with our stakeholders.
- 13. Our independent advisory committees typically assess value for money by calculating the additional 'Quality Adjusted Life Years' (QALYs) that new treatments and other health technologies offer compared to standard practice. QALYs show the benefits that a treatment provides in terms of length of life, and quality of life, over the life of the patient. They are calculated by estimating

- the number of years a new treatment will provide benefit and, using fractions of a scale of 0-1, what change in quality of life it will provide.
- 14. The number of extra QALYs a new treatment brings is then set against the cost of the new treatment to get a 'cost per QALY.' We usually recommend new treatments up to £20,000 per QALY but in special cases we can recommend up to £30,000 per QALY. For treatments that extend life at the end of life, we can go as high as £50,000 per QALY. For treatments for very rare conditions NICE uses a different threshold range of between £100,000 and £300,000 per QALY.

#### How we involve people

- 15. We take into account the opinions and views of the people who will be affected by our work, including patients, carers and members of the public, as well as healthcare professionals, social care practitioners, NHS organisations, industry, social care businesses and local government.
- 16. Our consultation process enables 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 experts such as surgeons and midwives, health economists and social workers, as well as patients or carers or other members of the public.
- 17. 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 companies to ensure that evidence they submit on the effectiveness of their products is the most appropriate to enable an evaluation to be undertaken.
- 18. We value the input of patients, carers and the general public in our work. By involving them, 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 life sciences industry

19. 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 elsewhere in the world. For these reasons we regard the relationship we have with industry and individual companies as having equal importance with our other stakeholders and we will continue to work with the industry associations and companies in this country and abroad to build mutual respect and trust.

- 20. NICE digital services hosts *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.
- 21. HealthTech Connect is also hosted by NICE and provides a service to companies, NHS England and the Academic Health Science Networks by allowing emerging medical device, diagnostic and digital products to be identified for NICE guidance.
- 22. 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 their pathway to market.
- 23. Our fee-for-service Scientific Advice programme engages life sciences companies to help them understand the evidence requirements of NICE's advisory committees. Our Commercial Liaison Team (CLT) supports the development of commercial agreements, entered into by NHS England.
- 24. We work in partnership with NHS England to operate the Cancer Drugs Fund. The Fund provides a fast-track route for access to cancer treatments that require a further period of evidence-collection, before a final decision can be made about their routine use. It also allows speedier access to clinically- and cost-effective treatments that have been recommended by NICE, with treatments becoming available within the NHS before final NICE guidance is published.

#### How our guidance is used

25. 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 clinical commissioning groups, NHS England and local authorities are required to fund and resource medicines and treatments recommended through these programmes. The legal status of this mandatory funding is reinforced in the NHS Constitution and the Health and Social Care Act 2012. The NHS Constitution 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. The Health and Social Care Act 2012 also states that the Secretary of State and the NHS Commissioning Board (now NHS England and NHS Improvement) should have regard to the quality standards prepared by NICE as part of their duty to secure continuous improvement in the quality of services.

- 26. Nevertheless, health and social care professionals are actively encouraged to follow the recommendations in other guidance 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.
- 27. 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 work with partners at a national level to help local organisations by providing a programme of implementation support to put our guidance into practice locally.
- 28. Our guidance is relevant to charities, voluntary and community organisations, residential care homes, private sector employers, patients, carers, service users and the public 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.
- 29. We measure the use of NICE guidance and publish impact reports showing how our recommendations have been used in practice to improve outcomes in priority areas. Our impact reports are based on publicly available data and other sources which contain information about the uptake of our work.

#### Communicating about our guidance, standards and other resources

- 30. 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.
- 31. 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 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 direct enquiries from health and care professionals, patient groups, charities, parliamentarians and members of the public.

#### Access to our guidance

32. We use a number of innovative ways to help all users access all of our products including NICE Pathways and NICE Evidence. Website improvements and new

- digital developments are user-led and strive to maintain high standards of accessibility.
- 33. 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.

#### Putting our guidance and standards into practice

- 34. 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.
- 35. 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 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.
- 36. 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.



#### **AUDIT & RISK COMMITTEE**

Unconfirmed minutes of the meeting held on 4 September 2019 at the NICE London office, and via V/C to the Manchester office

#### **Present**

Dr Rima Makarem Non-Executive Director (chair)

Elaine Inglesby-Burke Non-Executive Director

In attendance

Andrew Dillon Chief Executive

David Coombs Associate Director - Corporate Office
Barney Wilkinson Associate Director - Procurement and IT
Catherine Wilkinson Deputy Director - Business Planning and

Resources

Fiona Glen Programme Director – Centre for Guidelines (for

item 4.2)

Elaine Repton Corporate Governance & Risk Manager (minutes)

Ashish Vyas Financial Accountant (observer)
Niki Parker Government Internal Audit Agency

Andrew Jackson National Audit Office (NAO)
Andrew Ferguson National Audit Office (NAO)

Hassan Rohimun Ernst & Young (EY)

Jane Newton NICE Sponsor Team Lead, DHSC

#### Apologies for absence

 Apologies for absence were received from Sheena Asthana, Tom Wright and Ben Bennett

#### **Declaration of interest**

There were no declarations of interest relevant to this meeting.

#### Minutes of the last meeting

3. The minutes of the meeting held on 19 June 2019 were agreed as a correct record.

#### **Action Log**

4. The committee reviewed the action log noting that all the actions were closed with the exception of a report on assurance mapping which will be presented in November.

#### **RISK MANAGEMENT**

#### Strategic risks 2018-21

The committee reviewed the strategic risks 2018-21 which had recently been updated by the Senior Management Team. It was noted that the NICE Connect project was listed as a mitigation against several of the strategic risks but that NICE Connect had not yet been approved by the Board and was a high rated risk itself within the business risk register. Andrew Dillon stated that NICE Connect was a major project for NICE and a key risk but a project that had been in the planning for over 12 months, with a detailed 'case for change' paper being presented to the Board in September. It was acknowledged that the DHSC funding allocation to NICE for 2020/21 had not been agreed but NICE Connect was a strategic priority which would be funded, subject to Board approval, and that consideration would have to be given to ceasing some activities, if need be, to ensure it will be fully resourced.

#### Business risks 2019/20

- The committee reviewed the 2019/20 risk register noting the latest updates from the Senior Management Team. Two amendments were highlighted, firstly a reduction in the risk rating from red to amber for income recovery from the TA and HST programmes, in light of the experience to date of payments being received on time.
- 7. Secondly, a change in focus of the EU Exit risk from 'NICE failing to plan adequately for the UK's exit from the EU' to 'a no-deal exit from the EU having an adverse impact on NICE including EU relationship-sensitive income, timelines and income from TA/HST charging'. This was due to the potential for there to be implications from matters that are outside of NICE's control. It was also agreed to increase the target risk rating from green to amber.

**ACTION: ER** 

8. The committee considered whether a new risk should be added following the announcement that the chief executive will be standing down at the end of March, at the same time as arrangements are underway to appoint a new chair of NICE. It was agreed that it would be sensible to add this risk to the register.

**ACTION: ER** 

 Andrew Jackson pointed out that when an Accounting Officer leaves before the annual report and accounts are signed, they must prepare a letter of assurance for their successor to support the new appointee's signature of the documents.

**ACTION: AD/BB** 

10. The committee supported the amendments to the 2019/20 risk register.

#### Risk discussion - Centre for Guidelines maintaining consistency & quality

- 11. Fiona Glen presented an overview of the guideline development framework and the supporting policies and procedures, to demonstrate how the Centre for Guidelines ensures consistency and quality across all its committees.
- 12. The chair asked how the Centre receives assurance that all the committees are equitable in terms of the skills and capability of the chair and expertise of the committee members. Fiona advised that the chair appointments are supported by the involvement of a non-executive director on the recruitment panel and all

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proposed appointments are reviewed by the SMT before being confirmed. There are also built in checks throughout the guideline development process including support for the chair from the programme director, project teams and the commissioning and technical teams to ensure there is a good composition of members, a balance of views expressed and no one is allowed to dominate discussions at the meeting. Other events take place to support chairs including an annual meeting of all the chairs.

- 13. Concern was expressed when there is only one applicant for a chair's role and the individual is inexperienced. Fiona advised that in some cases an inexperienced chair will be appointed and in others the application may be declined based on the views of the panel and the specific requirements for the respective committee. It was noted that a great deal of effort goes into selecting the right candidate for a chair position and the committee was assured that there is support available to assist them, where needed.
- 14. The committee thanked Fiona for her attendance.

#### **INTERNAL AUDIT**

#### Internal audit progress report

- 15. Niki Parker presented a progress report of the 2019/20 internal audit plan confirming that there were no issues of concern to bring to the committee's attention.
- 16. David Coombs advised that NICE was currently completing the Data Security and Protection (DSP) toolkit for 2019/20 which is possibly going to require a piece of assurance work on completion as directed by NHS Digital. Further guidance was expected to be published soon, but the committee was asked to note that it might be necessary to request internal audit to include additional days in the plan to cover this piece of work.
- 17. The report was noted.

#### **Financial Reconciliations**

- 18. The committee welcomed the findings of the internal audit review of financial reconciliations and congratulated the team on a substantial assurance level with only two minor recommendations.
- 19. The internal audit report was noted.

#### **EU Exit**

- 20. The committee reviewed the findings of the EU exit internal audit which received a moderate assurance rating with four medium actions for improvement. All four actions were agreed by management.
- 21. The internal audit report was noted.

#### **EXTERNAL AUDIT**

#### NAO wider work in the health and care sector

22. Andrew Ferguson updated the committee on the NAO's recent work and publications within the wider health and care sector. The report was noted.

#### **CONTRACTS & IT**

#### Waiver report - April to August 2019

23. The report on contract waivers from Standing Orders and the Standing Financial Instructions was reviewed. The report was noted.

#### Phishing exercise

- 24. Barney Wilkinson reported on the results of an exercise in which simulated phishing emails were sent to staff during the last three months aimed at raising their awareness of potential cyber security threats and requesting them to complete a short training exercise if they failed to recognise the risk by proceeding to open attachments and click on links.
- 25. The committee welcomed the report.

#### **FINANCE**

#### Financial accounting performance

- 26. Catherine Wilkinson presented the financial accounting performance report as at 31 July 2019 confirming a satisfactory financial position in most areas, including TA charging where there have been no delays in receiving payments.
- 27. Catherine advised that despite different approaches, including speaking directly with the NHS England's Director of Financial Control, there were still administrative challenges with their payment process. Jane Newton confirmed that the Sponsor Team had also spoken to colleagues at the DHSC to try and resolve the matter. The table of NHS England funded programmes in 2019/20 showed that only one of the nine work programmes had so far received a purchase order for payment. The committee noted this was not having an adverse impact on cashflow at present but the position would continue to be monitored.
- 28. Jane Newton queried the basis for deciding when salary overpayments are recovered or written off. Catherine advised that the circumstances of the overpayment were reviewed before a judgement was reached. Where appropriate, monthly repayments are considered to avoid anyone experiencing financial hardship.
- 29. The report was noted.

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#### CORPORATE OFFICE

#### Use of the NICE Seal

30. The NICE seal had not been used since the last meeting.

#### **Annual Complaints Report 2018/19**

- 31. David Coombs presented the annual complaints report for 2018/19 detailing the seven complaints considered under NICE's general complaints procedure. No complaints were escalated to the Parliamentary and Health Service Ombudsman's office.
- 32. The report was noted.

#### Internal audit recommendations log

- 33. Progress in addressing the outstanding audit actions was reviewed. Some actions were now closed in agreement of the internal auditor.
- 34. From the 2018/19 plan, the counter-fraud actions had been addressed with the exception of a staff training module which was in hand. It was noted that the new non-staff travel and subsistence system went live on 28 August 2019, which will allow management information reports to be produced in the last quarter of the year and thereafter.
- 35. The progress update was noted.

#### Counter fraud functional standard return

- 36. The committee reviewed the submissions made to the Cabinet Office demonstrating NICE's compliance with the counter fraud function standard. Further work will be taking place, building on the initial action plan and risk assessment. The submission will be RAG rated during September/October and a response will be sent to the Business Planning and Resources Director (as Accountable Individual) in November.
- 37. It was noted that independent assurance of the submissions has not been requested at present but this was something to be aware of in the future. As discussed above, it could have an impact on NICE's internal audit planning.
- 38. The functional standard return was noted.

#### Committee annual plan 2019/20

39. The committee noted its annual work plan for 2019/20.

#### **OTHER BUSINESS**

40. There were no further items of business raised.

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#### **FUTURE MEETING DATES**

- 41. The Committee confirmed its meetings in 2019/20 would take place at 2.00pm on:
  - 28 November 2019 (Thursday)
  - 18 December 2019 (NEDs meeting and training session)
  - 22 January 2020
  - 22 April 2020
  - 17 June 2020 (at 9.30am)
  - 9 September 2020
  - 25 November 2020

The meeting closed at 3.20pm.

## National Institute for Health and Care Excellence Board Chair and Vice Chair

Sir David Haslam's term of office as NICE Chair ends on 31 December 2019 and the process to appoint his successor is underway. Due to the general election on 12 December, the final stages of the appointment process are now unlikely to be completed until January. The Department for Health and Social Care has therefore appointed Tim Irish, NICE's current Vice Chair, as interim Chair from 1 January 2020 for a period of 3 months or until a new Chair is appointed, whichever is sooner.

It is therefore necessary for the Board to appoint an interim Vice Chair for this period, who would deputise for the interim Chair as required and also undertake the Vice Chair's role in the technology appraisal and highly specialised technologies appeals process.

Following consultation with Board members, the Chair is recommending that Dr Rima Makarem is appointed as the interim Vice Chair for the period that Tim Irish is interim Chair. It is proposed that Dr Makarem continues her existing responsibilities as Senior Independent Director and chair of the Audit and Risk Committee during this period – this would though be reviewed should Dr Makarem be required to cover for the interim Chair for a substantial period of time.

#### The Board is asked to:

• appoint Dr Rima Makarem to the role of interim Vice Chair in addition to her existing responsibilities for the period that Tim Irish is interim Chair.

**Andrew Dillon** 

Chief Executive

November 2019

# National Institute for Health and Care Excellence Directors' progress reports

The next 5 items provide reports on the progress of the individual centres and directorates listed below. These reports give an overview of the performance of each centre or directorate and provide an update on any issues of note.

Professor Gillian Leng, Director, Health and Social Care Directorate (Item 13)

Jane Gizbert, Director, Communications (Item 14)

Dr Paul Chrisp, Centre for Guidelines (Item 15)

Meindert Boysen, Director, Centre for Health Technology Evaluation (Item 16)

Alexia Tonnel, Director, Evidence Resources Directorate (Item 17)

November 2019

National Institute for Health and Care Excellence Directors' progress reports Date: 20 November 2019 Reference: 19/109 – 19/113

# National Institute for Health and Care Excellence Health and Social Care Directorate progress report

- 1. This report sets out the performance of the Health and Social Care Directorate against our business plan objectives for September and October 2019. A summary is also provided for areas of work that have seen significant progress and are of note for the Board.
- 2. The Chief Executive's Report details the delivery of quality standards.

## **Performance**

3. The directorate has achieved its business plan deliverables and progress is set out below. Key publications for this reporting period are detailed in Appendix 1.

Deliver and support the adoption of accessible, up to date and adaptable advice, fully aligned to the needs of our users

## Public Involvement Programme

- 4. The ratio of applications to vacancies for lay members on committees during the reporting period was 6.4:1, with the target being 2:1 or greater (121 applications were received for 19 vacancies).
- 5. Nine patient experts were identified to give testimony at committee meetings and at NICE's Scientific Advice meetings, and 4 people have been co-opted as specialist committee members onto Quality Standards Advisory Committees.

# National strategic engagement

- 6. In May, the directorate presented to the Board a plan for strategic engagement during 2019/20 which included a set of deliverables and metrics for engagement at a national and regional/local level. The metrics are on track except for 2 (supporting mental health strategic clinical networks to understand and use NICE guidance and standards and engagement with regional networks of principal social workers for adult services). Activity for these increased in the reporting period with over 80% of the targets achieved by 31 October, and both metrics are anticipated to be on track by the end of Quarter 3. Highlights from our engagement activities have been detailed below.
- 7. The Department of Health and Social Care's (DHSC) consultation on Advancing our health: prevention in the 2020s set out proposals to tackle the causes of preventable ill health in England. In our response, we supported approaches

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- based on available evidence, highlighted relevant partnership working on quality and detailed a range of appropriate NICE resources including guidelines, quality standards and the Impact report. We also highlighted areas where NICE's expertise could further support the DHSC in their new approach to prevention.
- 8. Public Health England (PHE) arranged a national workshop in October which we supported. The workshop aimed to explore how our recently published guidelines on antimicrobial prescribing are being used and identify the barriers and enablers to effective implementation.
- 9. We have worked with a range of national social work organisations to develop a campaign to raise awareness of NICE guidance and standards and show how they can be used to improve social work practice. Resources for social workers were shared with national organisations and Principal Social Worker networks in September and accompanying meetings with the networks are now taking place.
- 10. Two national webinars were held with the Social Care Institute for Excellence (SCIE) during September and October. One webinar focused on our strengths and asset-based guidance for social workers, while the second on covert medicines administration was designed for registered managers of care homes and home care. Both webinars were successful with participant numbers ranging from 120 to 190.

## Regional and local strategic engagement

- 11. We have written to all new regional directors in the 7 NHS England/Improvement (NHSE/I) regions to confirm our interest in working together to develop and shape local implementation plans and to introduce them to the relevant Field team representatives. The letters also offered a face to face meeting with Andrew Dillon and Gill Leng and most regions have responded positively.
- 12. Both regional offices of NHS England and NHS Improvement in the North have referenced the use of NICE guidance and standards as part of their key lines of enquiry, which they will use to support and assure STP/ ICS 5-year plans.
- 13. In social care, our activity has focussed on engagement with Principal Social Worker networks across each region during this reporting period. While this has taken longer than anticipated, responses are encouraging and some good examples of the networks using NICE guidance have been presented.
- 14. Working in partnership with the Lead for Community Healthcare in Wales, we developed a set of principles for managing medicines in the home care sector. A further set of guiding principles referring to NICE guidance and quality standards on managing medicines in the community has now been agreed and endorsed by NICE, Care Inspectorate Wales, the Royal Pharmaceutical Society and Social Care Wales.

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- 15. We are working with the North West Association of Directors of Adult Social Services (ADASS) branch network to design "NICE into the process" of sector-led improvement. Each of the 23 local authorities will have a peer review based on their use of NICE to support strategies and manage risk every 2-3 years.
- 16. The 33 social care commissioners in London (through ADASS network) have developed a new set of metrics for the quality assurance of learning disability and mental health service providers. They will go live in April 2020 and are based on NICE quality standards. They build on the success of the metrics developed last year for services for older people.

#### NICE Connect

## Engagement and communication

- 17. The NICE Connect external engagement group met in September and considered and how our transformation aligns at a strategic level with work in partner organisations. Opportunities for joint working were discussed, which included options for funding and potential secondments into NICE. We also considered Health Education England's new national discovery system and the Artificial Intelligence lab at NHS X.
- 18. Engagement with our staff on NICE content also took place during September, which included a content transformation workshop and a content Hackathon. The Hackathon took a new approach, which enabled staff to take significant time out and to explore an issue outside their usual teams. It was very positively received. Two teams of cross-organisational subject matter experts undertook the task, which culminated in a presentation to SMT of ideas that that could enhance our content for users. These ideas will now be explored by the content expert group and consideration will be given to using the Hackathon approach more broadly across the organisation. Presentations on NICE Connect have also been made to the Interventional Procedures Advisory Committee and the Guideline Methodology Group.

#### Resource and governance

- 19. Recruitment has taken place for the post of Transformation Programme Director and the successful applicant will commence in January 2020.
- 20. The Connect Steering Group, Content Expert Group and Data Management Expert Group are fully operational. A further 4 expert groups (technology; people; user insight and methods; processes & analytics) have SMT leads agreed and terms of reference in place. It is anticipated that these groups will be operational before the end of the financial year.

National Institute for Health and Care Excellence Health and Social Care Directorate progress report Date: 20 November 2019 Reference: 19/109 21. Alternative funding routes for the Transformation Programme are under consideration. Early benefits of the Connect change, for external users and for staff, are being discussed at the Connect Steering Group.

# Notable issues and developments

22. This section includes significant developments or issues that occurred in the reporting period.

## Quality Improvement

23. Following a successful round table event in June 2019, jointly led by NICE, a new National Quality Improvement Framework for health is being developed. This work is being taken forward by the new National Director of Improvement, and supporting guidance, standards and resources from NICE have been highlighted for inclusion. This will help embed the use of NICE guidance in future quality improvement initiatives.

## **Quality Standards**

- 24. Professor Bee Wee, Chair of the Quality Standards Advisory Committee 1, stepped down in September. Dr Gita Bhutani, Vice-Chair of the committee, has been appointed to the role until July 2020.
- 25. The quality standard (QS) on physical activity attracted significant media attention through its development. Further opportunities have been taken to promote this quality standard since its publication. A factsheet promoting the QS was developed for use at the National Institute for Health Research physical activity themed review launch event in July. Together with the Communications team, we are also supporting the Richmond Group and Sport England with their national physical activity campaign which references a range of NICE's guidance and standards, through social media. NICE also supported PHE's North West Physical Activity Network Event, which highlighted the breadth of NICE's resources. Many attendees reported being made aware of QS for the first time.

#### **Indicators**

26. An academic paper<sup>1</sup> published by NICE staff and GP academics from the University of Cambridge and the University of Edinburgh won the RCGP Research Paper of the Year 2019 in the Health Service Research Category. The paper was presented at the RCGP conference in Liverpool on 24 October.

<sup>&</sup>lt;sup>1</sup> Minchin, Roland, Richardson, Rowark and Guthrie (2018). Quality of Care in the United Kingdom after the Removal of Financial Incentives, NEJM: 379 948-57

27. We are part of a national advisory group tasked with undertaking a review of the current commissioning arrangements for vaccination and immunisation in England. The group has published <u>interim findings</u>, which have been published prior to commencing contract negotiations with the BMA's General Practitioners' Committee and the Pharmaceutical Services Negotiating Committee.

## What Good Looks Like (WGLL)

28. The Association of Directors of Public Health (ADPH) and PHE have been developing a series of publications that set out the guiding principles of 'what good quality looks like' for population health programmes in local systems. The initial 10 WGLL guides have now been published in draft format. We have worked with ADPH and PHE to reference NICE guidelines and quality standards across these guides.

## Involved and Informed: Good Community Medicines Support

29. Involved & Informed: good community medicines support is a multi-agency initiative launched in July led by NICE which promotes key messages from our community medicines management guideline and quality standards. Actions from NICE guidance were promoted by our wide range of social care and health partner organisations during September and October, which included a publication by the Royal College of General Practitioners and Royal Pharmaceutical Society on 'top tips' for GPs and Pharmacists.

# **Adoption and Impact**

30. We are working with the Accelerated Access Collaborative (AAC) to support 7 technologies that have been designated as rapid uptake products (RUPs). The AAC RUP subgroups bring together NICE, Academic Health Science Networks and NHS and industry bodies to develop a bespoke approach to support the uptake of the technologies. The technologies have been identified as having potential to help 500,000 patients to access new treatments and save the NHS £30 million. An adoption toolkit for high sensitivity troponin and a consensus statement for cladribine has been produced collaboratively. We have facilitated stakeholder meetings for PCSK9 inhibitors and developed a range of shared learning examples and a resource for endorsement across the 7 products.

# Support for Implementation

31. To date, over 20 members of the directorate have gained the 'Basic Certificate in Quality and Safety' from the Institute for Healthcare Improvement. This internationally recognised qualification from a world leading organisation comprises 13 modules covering the essentials of healthcare quality, safety, the triple aim for population health, and leadership. This enabled staff to gain a

National Institute for Health and Care Excellence Health and Social Care Directorate progress report Date: 20 November 2019 Reference: 19/109 thorough understanding of the Model for Improvement, now used by many NHS trusts to drive quality improvement and implementation of NICE guidance. This enables improved expertise and credibility and helps shape our implementation support offer to the external system.

## Fellows & Scholars Programme

32. We recently sought applicants for up to 10 Fellows and 10 Scholars for the programmes commencing in 2020. The closing date for applications was 28 October and the response has been positive with 21 fellowship and 25 scholarship applications received.

## Medicines and Technologies (M&T) Programme Product Review

33. A review is being undertaken of the M&T programme's product portfolio, which comprises 23 different outputs funded through grant in aid. To date, the review has included internal and external stakeholder engagement through 75 interviews and 3 focus groups within the programme, audience insights team, field team and NICE Associates. A series of recommendations on the future published output from the programme will be presented to SMT at the end of November.

## Resource Impact Assessment (RIA) for Social Care

34. A cost model has been developed in partnership with ADASS in England and service commissioners and providers which aims to support a better understanding of the costs of providing home care services. After a pilot period earlier this year, the model was launched for use in London in September. One local authority has asked their providers to complete the model to allow them to benchmark all providers' costs with a view to setting a standard hourly rate across the borough. This gives consistency across providers and offers a transparent way to set a price for the commissioner. It also allows a transparent sustainable price to be set to enable continuity of service provision. The model is being considered for any upcoming tender exercise for contracts, to give greater clarity on the different costs submitted by potential providers.

#### **Shared-Decision Aids**

35. NICE develops patient decision aids to help support joint decision-making in practice between health professionals and patients, their family members or carers. We have published a suite of decision aids using a new design format on the surgical and non-surgical options for managing urinary incontinence and pelvic organ prolapse. They will enable every woman who is considering surgery for urinary incontinence or pelvic organ prolapse to have the best available evidence to inform them of the benefits and risks of each type of procedure. The decision aids featured in news reports on NICE's guidelines.

National Institute for Health and Care Excellence Health and Social Care Directorate progress report Date: 20 November 2019 Reference: 19/109 36. We have also developed a decision aid on inhalers for asthma highlighting to people the environmental impact of different types of inhaler. This is the first decision aid of its type launched in the UK. Additional decision aids have been published on; decisions about decompressive hemicraniectomy in stroke, bisphosphonates for treating osteoporosis, lifestyle options and medicine choice for controlling blood pressure and choosing between medical and surgical abortion.

### Public Involvement

- 37. We have co-produced proposals for improving the use of patient evidence and the engagement of patient experts in technology appraisals. The proposals were developed with patient organisations and our lay members through a working group, workshops and a targeted consultation exercise. Members of the working group contributed to the final report, which includes recommendations for NICE to consider as part of the technology appraisals methods and process reviews.
- 40. We contributed to an international meeting on Early Dialogues, a piece of work being undertaken as part of the Health Technology Assessment International (HTAi) PARADIGM initiative. Early Dialogues is similar to NICE's work in Scientific Advice and aims to strengthen patient involvement in key research studies ahead of health technology assessment. The work provided an opportunity to share NICE's growing experience of engagement with patients at an early stage and advise on the benefits of doing so.

# **Appendix 1: Publications - September and October 2019**

The table below provides a list of guidance and advice produced in the reporting period.

| Product title                                                                                                                                                                                      | Product type                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
|                                                                                                                                                                                                    |                                                   |
| Myocardial infarction (acute): Early rule out using high-<br>sensitivity troponin tests (Elecsys Troponin T high-<br>sensitive, ARCHITECT STAT High Sensitive Troponin-<br>I and AccuTnI+3 assays) | Adoption support resource – insights from the NHS |
| Falls Management Exercise (FaME) programme implementation toolkit                                                                                                                                  | Endorsement statement                             |
| HeartFlow                                                                                                                                                                                          | Endorsement statement                             |
| Guiding Principles for Medicines Support in the  Domiciliary Care Sector                                                                                                                           | Endorsement statement                             |
| Midwifery Unit Standards                                                                                                                                                                           | Endorsement statement                             |
| High blood pressure in pregnancy decision aid and graphic                                                                                                                                          | Endorsement statement                             |
| Core skills in musculoskeletal care                                                                                                                                                                | Endorsement statement                             |
| Multiple Antenatal Care Pathway                                                                                                                                                                    | Endorsement statement                             |
| Minddistrict for adults with depression                                                                                                                                                            | IAPT assessment briefing                          |
| Regul8 for adults with irritable bowel syndrome                                                                                                                                                    | IAPT assessment briefing                          |
| Polypharmacy and shared decision-making: development of a conversation guide                                                                                                                       | Medicines Evidence<br>Commentary (MEC)            |
| New MHRA drug safety advice: June 2019 to August 2019 [included in the medicines awareness weekly email]                                                                                           | Medicines Evidence<br>Commentary (MEC)            |
| Gastrointestinal disease: observational study and randomised trial give conflicting evidence on                                                                                                    | Medicines Evidence<br>Commentary (MEC)            |

Reference: 19/109

| Product title                                                                                                                                           | Product type                                        |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--|
| association between long-term PPI use and increased risk of death                                                                                       |                                                     |  |
| Gabapentin and pregabalin associated with increased risks of suicidal behaviour, injuries, unintentional overdose, and road traffic incidents           | Medicines Evidence<br>Commentary (MEC)              |  |
| Connect with Pharmacy: a web based intervention to reduce hospital readmissions for older people                                                        | Medicines Evidence<br>Commentary (MEC)              |  |
| Vitiligo: systematic review and meta-analysis investigates topical calcineurin inhibitors                                                               | Medicines Evidence<br>Commentary (MEC)              |  |
| Antibiotic prescribing for respiratory tract infections in children: study finds antibiotic-seeking behaviour by parents does not influence prescribing | Medicines Evidence<br>Commentary (MEC)              |  |
| <u>Lipid-modifying drugs</u> (update)                                                                                                                   | Medicines optimisation key therapeutic topics (KTT) |  |
| Asthma: medicines safety priorities (update)                                                                                                            | Medicines optimisation key therapeutic topics (KTT) |  |
| Hypnotics (update)                                                                                                                                      | Medicines optimisation key therapeutic topics (KTT) |  |
| Antipsychotics in people living with dementia (update)                                                                                                  | Medicines optimisation key therapeutic topics (KTT) |  |
| Antimicrobial stewardship: prescribing antibiotics (update)                                                                                             | Medicines optimisation key therapeutic topics (KTT) |  |
| Type 2 diabetes mellitus: medicines optimisation priorities (update)                                                                                    | Medicines optimisation key therapeutic topics (KTT) |  |
| Wound care products (update)                                                                                                                            | Medicines optimisation key therapeutic topics (KTT) |  |
| Anticoagulants, including direct-acting oral anticoagulants (DOACs) (update)                                                                            | Medicines optimisation key therapeutic topics (KTT) |  |
| Acute kidney injury (AKI): use of medicines in people with or at increased risk of AKI (update)                                                         | Medicines optimisation key therapeutic topics (KTT) |  |

| Product title                                                                                                                                                         | Product type                                        |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--|
| Multimorbidity and polypharmacy (update)                                                                                                                              | Medicines optimisation key therapeutic topics (KTT) |  |
| Psychotropic medicines in people with learning disabilities whose behaviour challenges (update)                                                                       | Medicines optimisation key therapeutic topics (KTT) |  |
| Safer insulin prescribing (update)                                                                                                                                    | Medicines optimisation key therapeutic topics (KTT) |  |
| Medicines optimisation in chronic pain (update)                                                                                                                       | Medicines optimisation key therapeutic topics (KTT) |  |
| Chemotherapy dose standardisation (update)                                                                                                                            | Medicines optimisation key therapeutic topics (KTT) |  |
| Shared decision making (update)                                                                                                                                       | Medicines optimisation key therapeutic topics (KTT) |  |
| Suicide prevention: optimising medicines and reducing access to medicines as a means of suicide (update)                                                              | Medicines optimisation key therapeutic topics (KTT) |  |
| NICE Impact Report – Maternity and neonatal care                                                                                                                      | NICE Impact Report –<br>Maternity and neonatal care |  |
| Abortion before 14 weeks: choosing between medical or surgical abortion                                                                                               | Shared decision making product                      |  |
| Abortion from 14 weeks up to 24 weeks: choosing between medical or surgical abortion                                                                                  | Shared decision making product                      |  |
| Improving care for older people with co-existing mental disorders and alcohol misuse                                                                                  | Shared learning example                             |  |
| Safe prescribing of high-risk drugs                                                                                                                                   | Shared learning example                             |  |
| Implementation of NICE TA393/394 in a tertiary Lipid Clinic - the first three years' experience                                                                       | Shared Learning example                             |  |
| Innovative Medicines Optimisation Clinic for PCSK9 inhibitors & Statin Intolerance                                                                                    | Shared Learning example                             |  |
| Applying the principles of PINCER to learn from patient medicines safety incidents to improve the prescribing and monitoring of oral methotrexate in general practice | Shared Learning example                             |  |

| Product title                                                                                                                             | Product type            |
|-------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| Benzodiazepine/Hypnotics de-prescribing                                                                                                   | Shared Learning example |
| Tackling the overtreatment of type 2 diabetes in frail older people through individualising care in East Sussex: a pharmacist led project | Shared Learning example |
| Reducing the risk of violent and aggressive behaviours                                                                                    | Social care quick guide |
| Assessment and diagnosis of autism: what to expect                                                                                        | Social care quick guide |

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November 2019

# National Institute for Health and Care Excellence Centre for Guidelines progress report

 This report sets out the performance of the Centre for Guidelines against our business plan objectives during September and October 2019. It also highlights recognition from the Guidelines International Network, and collaborative work with the Centre for Health Technology Evaluation, ONS, Cochrane and NHS Digital.

## **Performance**

- 2. Seven guidelines were published during September and October 2019; three clinical guidelines and four antimicrobial guidelines. No public health or social care guidelines were scheduled for publication during this period.
- 3. Seven surveillance reviews were published during this reporting period, of which three were exceptional reviews. All other deliverables are on track.
- 4. The 2019-20 campaign to distribute the print version of BNF78 and BNFC 2019 to eligible prescribers has started. The print copies of the BNF and the BNFC were received from the printers in Germany within the agreed timeline.

# Notable issues and developments

- 5. NICE has received an award in recognition for its long-standing support and contribution to guideline development at the 2019 Guidelines International Network (GIN) conference. Five members of the team attended the 2019 GIN conference to present an invited plenary session and a range of oral and poster presentations.
- 6. The team is working with colleagues in the Centre for Health Technology Evaluation to consider options for a cross-organisational approach to health economic modelling to inform the update to the Type 2 diabetes guideline.
- 7. Collaboration continues with ONS to explore an automated method to identify related recommendations across multiple guidelines; development of an algorithm to link related recommendations has begun. This will facilitate the consistency and speed of surveillance and updating.
- 8. In September, members of the team met with the senior editorial team at the Cochrane Central Executive and Cochrane UK to explore opportunities for making more efficient use of Cochrane reviews to inform NICE guidelines.

National Institute for Health and Care Excellence Centre for Guidelines progress report Date: 20 November 2019 Reference: 19/110 9. We are collaborating with NHS Digital to agree a standard digital specification for the CHA2DS2-VASc risk calculator the use of which is recommended in NICE's guideline on management of atrial fibrillation to assess stroke risk. The calculator has been codified by clinical system providers, and there is a risk of variation in the coding of clinical parameters. This work may form the basis of a future collaborative process when NICE recommends other risk calculators in its guidance.

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November 2019

# 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 Heath Technology Evaluation (CHTE) against our objectives during September and October 2019. It also highlights key developments in the centre during that period.

# **Notable developments**

- 2. Notable developments in the Centre since the report to the September 2019 meeting of the board are as follows:
  - Publication of the 600th piece of Technology Appraisal guidance
  - Conclusion of discussions between NHS England and NHS Improvement and Vertex Pharmaceuticals resulting in a commercial and managed access agreement to make Orkambi, Symkevi and Kalydeco available to NHS patients in England, including a commitment from the company that they will engage in future NICE technology appraisals.
  - Judicial review proceedings regarding the evaluation of cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2 have been discontinued after the company and NHS England and NHS Improvement reached a commercial agreement.

# **Performance**

#### Centre Coordination Team

- 3. During September and October CCT have coordinated recruitments for 15 positions within CHTE. These vacancies have been created by staff leaving, maternity cover and the creation of new roles through the expansion of the TA/HST teams.
- 4. In September and October 4 committee recruitments have completed, with 14 posts filled successfully and 1 provisional offer made. Alongside this, 8 campaigns are currently in progress across 8 committees for a total of 44 posts (43 professional and 1 lay).

#### Commercial Liaison

5. The Commercial Liaison team, which encompasses PASLU, is project managing four joint workstreams with the NHS England and NHS Improvement commercial team in areas that have been agreed to be high priority: budget impact test

timelines, information sharing, transactability, and early triage. In addition, the team has been working on presenting a set of internal process driven checkpoints, closely aligned with the NICE technology appraisal process, designed to give a clear steer on the process for development of a commercial proposition. This will facilitate improved operational coordination of activities and constructive engagement between stakeholders and will be operational at the beginning of Q4 2019/20.

- 6. The commercial liaison team took on full responsibility for the delivery of commercial briefing notes to NHSE&I at the start of September 2019, with 11 briefing notes delivered by the end of September. These briefings represent the impact of the new operational approach of the team and we are characterising the demand for the briefing notes as part of our broader work with NHSE&I.
- 7. The commercial liaison team continues to issue PAS advice to NHS England and NHS Improvement and had issued 21 pieces of PAS advice by the end of September.
- 8. Between April and October 34 topics have been subject to the budget impact test process at the committee submission stage. Thirty-one of these have been completed; 15 topics met the budget impact test at this stage and 16 did not.

## Managed Access

- 9. A paper was submitted to SMT providing an overview of the Managed Access function highlighting key successes: over 40,000 patients have access to treatments via managed access arrangements; further additional data collection has helped to address uncertainties when topics are reviewed; the option to make a recommendation for managed access has helped committees to make decisions that enable patient access to promising new treatments. Further development work will focus on: standardising NICE's approach to managed access; leveraging NICE's Data and Analytics programme to enhance data collection possibilities and focussing on ensuring successful exits from existing arrangements.
- 10. We anticipate up to 17 Managed Access Agreements (MAA) will be developed in 2019/20. Since April 2019, 13 new MAAs have been finalised and associated guidance published.
- 11. Three pilots of the EUnetHTA Register Evaluation and Quality Standards Tool (REQueST) have been commissioned via the EAC Operations Group to establish whether the tool will provide information required for due diligence work prior to the conclusion of a data collection agreement.

- 12. The Stereotactic ablative radiotherapy (SABR) for hepatocellular carcinoma report was submitted to NHS England. Preliminary discussions around the feasibility of a new CtE scheme with NHS England and NHS Improvement are underway.
- 13. The managed access team is coordinating active data collection arrangements for 27 CDF, 4 HST and 2 TA topics. Data collection has completed for 6 CDF topics in so far in 2019/20, with 1 CDF topic having guidance withdrawn due to withdrawal of its marketing authorisation. Data collection for a further 3 CDF topics, plus 1 HST and 1 TA topic will end before 31 March 2020, which will see these topics re-appraised for a final commissioning decision.

## NICE Office for Market Access (OMA)

14. The Office for Market Access (OMA) delivered further engagements (EAMS, multi-stakeholder and knowledge transfer) in September and October 2019. The pipeline of engagements for 2019/20 remains healthy and the programme is on track to achieve cost recovery.

## Accelerated Access Collaborative Secretariat (AACS)

15. The AACS is continuing to support the AAC Delivery Unit at NHS England & Improvement with delivery of the expanded remit of the AAC. This work includes providing technical resource to assist with develop of metrics to demonstrate the impact of the AAC, supporting the development of a single system-wide horizon scanning approach, and supporting the rollout of the Artificial Intelligence Fund. The AACS continues to provide governance support for existing and new structures in the AAC and has established internal governance structures to coordinate NICE's contributions to the AAC's work.

# Diagnostics Assessment Programme

- 16. The programme remains on track to publish 5 pieces of diagnostics guidance within the 2019/20 business year. 8 pieces of guidance are currently in development.
- 17. The final guidance for the assessment of <u>digital implantable cardiac monitors to</u> <u>detect atrial fibrillation after cryptogenic stroke</u> will publish later than planned. The third committee discussion planned for September 2019 was rescheduled until November 2019 following consultation. In response to feedback from stakeholders, the NICE Decision support Unit (DSU) have been commissioned to provide an independent critique of the economic model provided by the External Assessment Group (EAG) to be considered at the committee meeting in November 2019. If no significant changes to the recommendations are made, the earliest possible publication date for the final guidance is March 2020.

18. The programme continues to support the work of the Accelerated Access Collaborative in implementing the 3 pieces of diagnostics guidance that were selected as rapid uptake products. Diagnostics guidance, Myocardial infarction (acute): Early rule out using high-sensitivity troponin tests (Elecsys Troponin T high-sensitive, ARCHITECT STAT High Sensitive Troponin-I and AccuTnI+3 assays) (DG15), is being updated since its publication in October 2014 in response to discussions with the AAC. The purpose of the guidance update is to address several key questions such as evaluating new high sensitivity Troponin tests which have come to market since guidance was published, and an assessment of early rule out protocols now that more evidence is available.

## Interventional Procedures Programme

- 19. The Interventional Procedures Programme was scheduled to publish six guidance publications from September to October 2019. The August Committee Meeting was not quorate and therefore scheduled discussions could not take place. This impacted guidance production. Four guidance publications took place from September to October 2019.
- 20.IPAC has considered the most recent evidence base on "Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues". This was an update of IPG196. Guidance publication is due to take place during November 2019.
- 21. There are currently 3 vacancies (out of 25) for IPAC committee members with other committee members nearing the end of their term. This represents unusually high turnover of committee members and recruitment to the positions has been problematic because of a lack of applicants. However, the risks have been managed by the IP team and recruitment is in progress at shortlisting stage.

# Medical Technologies Evaluation Programme

- 22. The programme remains on target to publish 7 pieces of guidance in 2019/20. Guidance is currently being developed on 8 technologies.
- 23. The 4 digital health technologies pilot topics have now commenced.
- 24. The programme published 7 MedTech innovation briefings in July and August with briefings in development on 12 more technologies. We remain on target to publish 34 MIB's in 2019/20.

### HealthTech Connect

25. HealthTech Connect is continuing to make good progress. Over 450 companies have registered, and over 120 technologies have been submitted.

26. Approximately 20% of all submitted technologies have been selected by NICE (for Medtech innovation briefing +/- NICE guidance). 66% of technologies have been selected for support by a number of different organisations including the AHSN network, NIHR, and Department for International Trade.

## Technology Appraisals and Highly Specialised Technologies

- 27. In September the TA programme published its 600th piece of guidance 'Pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer'. In early October the HST programme published its 11th piece of guidance 'Voretigene neparvovec for treating inherited retinal dystrophies caused by RPE65 gene mutations'. Voretigene neparvovec was recommended for routine commissioning and this was the first HST topic to receive a positive recommendation at its first committee discussion.
- 28. Currently over 40% of topics following the new STA process are achieving a 'straight to final guidance' decision. The 2019/20 business plan indicates that NICE would publish 78 technology appraisals and highly specialised technologies. At the time of writing the report, 35 pieces of final guidance have published and it is currently anticipated that a 77 pieces of guidance will publish in the 2019/20 business year; 1 lower than the business plan forecast.

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November 2019

# National Institute for Health and Care Excellence Communications Directorate progress report

- 1. This report sets out the performance of the Communications Directorate against the directorate's business plan objectives during September and October 2019. The business plan objectives are listed at the end of the report.
- 2. These Communications Directorate business objectives are closely aligned to the NICE strategic objectives.
- 3. 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.

## **Performance**

## Communications support and strategic advice

- 4. During September and October, the external communications team carried out a programme of targeted promotion of the NICE Fellows and Scholars scheme, in order to raise awareness of the recruitment drive for new applicants. A campaign of social media posts including vox pop videos with previous and current fellows and scholars and stakeholder communications activities led to increased traffic to both programmes' website landing pages, with them receiving 8,081 views in September October, compared to 1,958 in July August. Applications for the 2020 intake of fellows and scholars have now closed. Overall, NICE received 45 applications, which is one more than last year.
- 5. The team also worked with departments across NICE to draft responses to three national consultations: a Department of Health and Social Care (DHSC) consultation on ill-health prevention in the 2020s; a Department for Work and Pensions/DHSC consultation on ill-health-related job loss; and a Social Work England consultation on the process for carrying out and recording continuing professional development (CPD). Each response gave NICE the opportunity to promote forthcoming guidelines and quality standards in these areas.
- 6. Support and advice were provided to Mirella Marlow, CHTE Programme Director, in advance of her participation as speaker and panellist at the All Party Parliamentary Group on Access to Medicines and Medical Devices' meeting on 'Medical device regulation in a post-Brexit landscape.'

- 7. We have created a <u>new web page</u> to help recruit more GPs to our committees. The new page gives an insight into the experience of a number of GPs who have worked with us recently and will be used in ongoing communication and promotional activities.
- 8. We have also created a new area of the website to support <a href="NICE international">NICE international</a>'s re-launch. We are working on promotional brochures to distribute at events and have ensured all staff are fully briefed on the services through new intranet content and updates in Your Week@NICE.
- 9. Work on curated content for commissioners continues with a new <u>STP resource</u> on respiratory conditions.
- 10. We have developed an internal communications plan to help embed the new freedom to speak up guardians and have begun to implement the internal communications strategy for the London office move.

## Audience insights

- 11. We are continuing to disseminate the reputation research findings, attending directorate meetings and publishing the results on NICE space.
- 12. Our involvement in the shared decision making project group has led to the audience insights team reviewing information gathered to date on the shared decision making tools NICE currently produces, whilst also setting up an approach to conduct further research with internal stakeholders.
- 13. Our broader support of user insight work across NICE continues. This includes running user interviews as part of digital services' operational productivity work on the planning system for NICE Connect. The team is also conducting and reporting on a survey commissioned by Evidence Services about the NICE Electronic and Print Content Framework Agreement.

# Editorial and publishing

- 14. In September and October, we prepared 208 documents for digital publication.
- 15. We prepared and published:
  - 6 new and 10 updated guidelines
  - 16 new and 4 updated guidance documents (diagnostics, medical technologies, technology appraisals, interventional procedures and highly specialised technologies)
  - 1 new and 2 updated quality standards

- 7 new and 16 updated advice products
- 1 update to corporate documents (NICE style guide updated September)
- 19 new and 3 updated information for the public
- 107 evidence documents (16 html/converted documents and 91 downloadable documents)
- 51 tools and resources (11 html/converted and 40 downloadable documents)

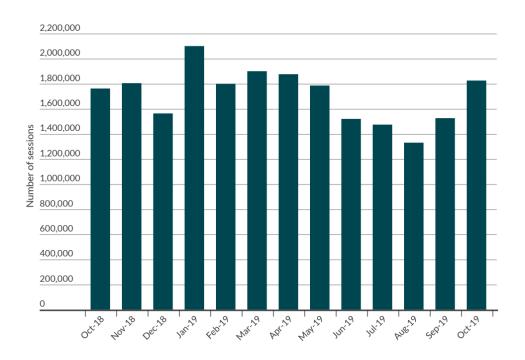
16. In terms of NICE Pathways, in September and October we:

- Published 3 new pathways
- Fully updated 2 pathways
- Updated 25 pathways to take account of new guidance or advice (for example, adding new health technology guidance)
- Updated a further 35 pathways to add related pathway links or as maintenance updates.
- 17. In summary, there are now 265 live pathways, which consists of 2,243 guidance, advice and CKS products.
- 18. Working with colleagues in the corporate communications team, we have continued to provide one-to-one and team training sessions across NICE on accessible content development. The team is also examining and changing Word templates to ensure NICE's products are accessible.
- 19. Following feedback about the difficulty of finding decision aids on the website, we have adapted the search function to encompass these products and improve their visibility. Since the change, downloads for the top 5 decision aids (for hypertension (NG136), asthma (NG80), CVD prevention (CG181), atrial fibrillation (CG180) and type 2 diabetes (NG28)) increased by 8.5% over a three-week period.

## Website performance

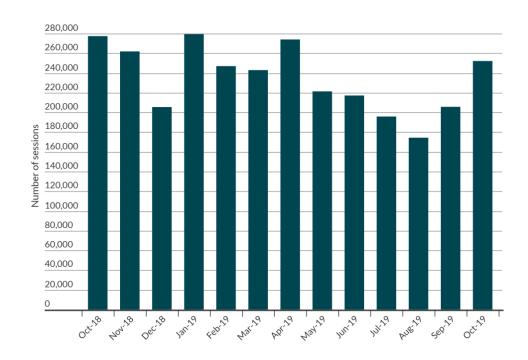
- 20. The most popular news stories in September and October included our guidance on Prostate Artery Embolisation (PAE) as a treatment for men with an enlarged prostate, viewed 4,505 times; our antimicrobial prescribing guidance recommending the use of paracetamol to relieve a sore throat rather than antibiotics, viewed 4,296 times; and our patient decision aid encouraging the use of green asthma inhalers, viewed 3,542 times.
- 21. There was a total of 3.4 million sessions on the NICE website in this reporting period which continues the year on year upwards trend.

Chart 1: Number of sessions on nice.org - September - October 2019



## Download the data set for this chart

Chart 2: Number of sessions on Pathways September - October 2019



## Download the data set for this chart

## **Enquiries**

- 22. During September and October, we responded to 1,572 enquiries which included 20 MP letters, 25 Freedom of Information (FOI) requests, and 15 parliamentary questions (PQs).
- 23. Topics covered by the PQs and MP correspondence were wide ranging but our appraisals of Orkambi for cystic fibrosis and Erenumab for migraine featured prominently.
- 24. FOIs included routine requests for IT contract information and also a number of more complex requests relating to guidance development information such as the Sativex cost effectiveness model for the treatment of spasticity in people with MS, and a number of requests for information redacted from technology appraisal guidance documents.
- 25. For public enquiries Erenumab for migraine was by far the most queried topic for this reporting period with 96 enquiries received in total. Enquirers were unhappy with the FAD that did not recommend the drug. Cannabis-based medicinal products continued to generate enquiries and fertility problems also remains a popular topic for enquiries from member of the public wishing to access services. We received a number of enquiries on the update to the hypertension in adults guideline, particularly where it has affected the type 2 diabetes guideline.

#### **Events**

- 26. Planning is in progress for the NICE Annual Conference taking place at the Hilton Deansgate, Manchester, on 11 November 2020. The conference programme has been drafted and is being reviewed by the events team, ahead of submission to SMT for approval.
- 27. Plans are progressing for NICE to jointly-host the 2021 HTAi annual meeting in Manchester, along with Health Improvement Scotland, and the All Wales Toxicology and Therapeutics Centre. The HTAi secretariat is expected to make a decision on the conference venue by mid-November 2019. The events team hopes to start recruitment soon for a project manager to oversee planning and delivery of the event.
- 28. The first corporate webinar on the new Zoom platform is due to be delivered on 21 November. The webinar is an invitation-only event for patient groups to find out more about the technologies' guidance methods review underway in CHTE. Almost 400 representatives from patient organisations were invited on 30 October. By 5 November, 113 had confirmed their attendance.

- 29. NICE took an exhibition stand to seven conferences during September and October: NHS Expo, Public Health England, Royal College of Midwives, Healthwatch England, Community Care Live London, British Association of Social Workers and the Royal College of GPs.
- 30. Staff delivered 16 speaking engagements in September-October, including Gill Leng who spoke at the Public Health England Annual Conference on 'The challenges of rigour: scientific evidence for 'real world' public health'. She explained how the NICE Connect project might help to overcome some of these challenges. Nick Crabb, Programme Director scientific advice and research, presented at the 3rd Annual Gene Therapy for Rare Disorders Europe conference. Helen Knight, Programme Director technology appraisals and highly specialised technologies, spoke at the 1st Joint DIA-EUROPE Workshop in Basel, Switzerland on 'ATMPs, Innovative Gene and Cell Therapies in the EU pricing and a reimbursement perspective'. Sarada Chunduri-Shoesmith, Associate Director system support, gave a keynote address on auditing practice and delivering service improvement based on NICE guidance at the National Clinical Audit Event. London.

## Media

- 31. Sentiment percentages for media coverage in September and October were as follows:
  - Positive 68.5%
  - Neutral 16%
  - Negative 15.5%
- 32. Our higher-than-normal proportion of neutral coverage was largely due to the decision in Scotland to approve Orkambi for cystic fibrosis patients, prior to its approval for use in England. This was featured extensively on a variety of channels, with NICE mentioned only in passing, without any negative or positive sentiment.
- 33. Subsequently, following the successful negotiations to make Orkambi available for patients in England, NICE featured in a Sunday Express <u>opinion piece by Secretary of State for Health, Matt Hancock</u>, in which he described the key role NICE plays in ensuring that new medicines represent value for money for the benefit of all patients. Another key driver for positive media coverage during this period was our announcement on 11 September that a <u>treatment for Batten disease</u>, a rare inherited condition affecting children, had been recommended. It was featured in the print and online versions of the Daily Telegraph and Daily

- <u>Mail</u>, printed in the Daily Express, and shared on <u>BBC Online</u> and extensively in local and regional news outlets and trade publications.
- 34. Coverage of our decision to <u>not approve erenumab</u>, a drug for preventing <u>migraine</u>, for use on the <u>NHS</u> and our decision to <u>not approve atezolizumab</u>, an <u>immunotherapy drug for breast cancer</u>, led to negative news coverage in this period. This was picked up in print and online versions of the <u>Daily Mail</u>, as well as the <u>Independent</u> and <u>BBC Online</u>, and extensively in local and regional news outlets.

## Social media and podcasts

- 35. Since the last reporting period we have seen an 18.6% increase in followers on Instagram with a total now of more than 2,701 followers. LinkedIn continues to be our second most popular channel with 42,256 followers and posts accumulating 637 likes, shares or comments over the last 2 months. Our posts on Twitter are continuing to get wide coverage overall receiving around 1,400,000 impressions (number of times posts are seen) over this 2-month period.
- 36. In September October 2019 we released 2 new NICE Talks podcast episodes looking at breast cancer and prostate cancer. Together these episodes have received 1,975 plays.

# Notable issues and developments

37. During the pre-election period we will limit our media and engagement activities. NICE will continue to publish all draft and final guidance, quality standards and advice products as planned, but we will not promote them by press releases or through our social media channels. We won't produce our corporate newsletters Update for Primary Care or NICE News during this period, and we are cancelling most of our external speaking engagements.

# Communication directorate objectives 2019-2020:

- 38. Ensure guidance and related products from NICE are of the highest quality and that the publishing and editorial function continues to deliver outputs of the highest standard during the NICE transformation programme.
- 39. Design and deliver a rolling programme of audience research that supports and informs the corporate business objectives.
- 40. Deliver a programme of strategic communication activities which promote NICE's work and support the uptake of NICE's offer.

- 41. Contribute communication expertise to the Connect (pathways) project and lead the communications and audience insights work to deliver the proof of concept phase.
- 42. Ensure communications is centralised and coordinated in the directorate by taking an integrated approach to planning and delivering communications.
- 43. Shape and manage our resources in order to support NICE and its strategic objectives effectively and efficiently.
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November 2019

# National Institute for Health and Care Excellence Evidence Resources progress report

- This report sets out the performance of the Evidence Resources directorate against our business plan objectives during September and October 2019. It also highlights the usage performance of the NICE Evidence suite of on-line services at the end of October 2019.
- 2. The Evidence Resources Directorate is responsible for the following key functions and services:
  - We provide a high-quality information service to NICE centres and directorates;
  - We manage third party access and re-use of NICE content, including internationally;
  - We support the Centre for Health Technology Evaluation (CHTE) with their digital health evaluation programme;
  - We support NICE's digital transformation activities and maintain all NICE's live digital services;
  - We manage the provision of NICE Evidence Services.

# **Performance**

3. Performance against the Evidence Resources objectives for 2019/20 is summarised in this section.

### Information Services

- 4. Following re-organisation of the Information Resources teams, which brought together all our information specialist professionals into a single information services function, reporting and governance structures have been reviewed and implemented.
- 5. A key objective of the directorate is to deliver efficient and high-quality information services to the NICE centres and directorates. In the last 2 months, alongside undertaking searches to support guidance development, work has focused on strategic developments, including:
  - On-going support to the CHTE 2020 programme, specifically to the topic selection and guidance process workstreams;

 Continuing a range of research projects to improve the efficiency of the searching and sifting processes, including exploring the use of machine learning technologies.

### Content re-use

6. A key objective of the team is to articulate and promote NICE's value propositions associated with the re-use of NICE content outside of the UK. In the last two months, the team signed five content and 1 syndication licences. The total income invoiced year to date is £98,000.

## **Digital Health**

- 7. Our directorate is supporting CHTE to explore with NHS England the options for a digital health technology evaluation workstream, building on the Evidence Standards for Digital Health Technologies published in 2018/19. Over the last two months, we have focused on supporting the following activities:
  - Organising and presenting at NHS Expo on NICE's Evidence Standards Framework and activities in digital health;
  - Chairing the September and October meetings of the External Steering Group for NICE's pilot Digital Health Evaluation Pilots;
  - Attendance at NHSX's Al Mission Delivery Board and cross-regulatory working group;
  - Continued promotion of the use of NICE's Evidence Standards for Digital Health Technologies including hosting a table at an Innovate UK technology competition event.

# **Data Analytics**

- 8. At the end of September 2019, the Data and Analytics team formerly managed as part of the Health and Social Care directorate was moved to the Evidence Resources directorate, to be led by the Programme Director for Information Services. Key achievements of the team in the last two months include
  - Managing the external consultation to NICE's statement of intent around the broader use of data and applied analytics in guidance development, conducting a series of stakeholder workshop events and summarising the outcome of these in preparation for the NICE November Board meeting.
  - Building the team with two new Data Scientists that started in this period (one of whom is working jointly with CHTE) and recruitment of a further health economist data scientist who will be based in the Centre for Guidelines.

 Representing NICE's data and analytic interests at key strategic external meetings/events including HDRUK, Better Care, Validate AI.

## **Digital Services**

## Strategic planning

- 9. The first objective of the Digital Services (DS) team for 2019/20 is to identify digital investment priorities, and their sequencing, to align with the NICE Connect project transformation work, reviewing the roadmap quarterly. Over the last two months activity has focused on:
  - Procuring a consultancy to support a short piece of work to inform our Target Operating Model and integrated technology and digital strategy. This consultancy began in October and will conclude in December, providing options and considerations for fully integrating Digital Services and NICE IT from April 2020;
  - Starting procurement of a strategic partner to support the development of a data management and records management strategy for NICE and to work with our internal team on the roll out of Office 365 and move towards a digital workplace;
  - Procuring a training provider to provide NICE-wide training on Microsoft Teams;
  - Ongoing work to support the shaping and next steps of NICE Connect including scoping and planning for resource and expert input relating our content transformation work and overall programme delivery.

#### Delivery of strategic digital services projects

- 10. Our second objective is to deploy our digital expertise to deliver business-led strategic projects in line with an agreed roadmap. Over the last two months activity has focused on:
  - The Evidence Management platform (delivering web tools for searching evidence, systematic review needs and building an evidence surveillance capability): we have commenced development of functionality to support the rollout to collaborating centres in the first half of 2020;
  - Ongoing work to support configuration of a new identity management solution to replace our current in-house 'NICE Accounts' solution;
  - Operational Productivity: A multi-disciplinary team from across NICE has been gathering information on our current processes and data management practices associated with stakeholder contacts and planning

information. This will inform our plans to replace our legacy Contact Database and Planning Tools.

### Live services maintenance and improvements

- 11. Our third objective is to manage and maintain the live digital services of NICE utilising user insight and strategic service goals to prioritise use of resource:
  - NICE Digital Services operated within the service levels (99.7%) agreed with DHSC for availability (uptime) with 99.87% average performance in the last two months;
  - In the last 2 months, 47 defects were closed. In the same period, 4
     Change Control Requests were completed.
- 12. Significant live service work has been undertaken to improve the accessibility of our services and meet incoming public sector accessibility legislation.
- 13. We have begun work to upgrade the platform for our Medicines Awareness Service.

### **Cross-cutting updates**

- 14. Recruitment: We have welcomed three new staff members to the team following recent recruitment campaigns. One Tier 2 application is ongoing, and we are opening new developer vacancies to offer progression and development for team members.
- 15. The team is predominantly made up of permanent staff members. To support capacity in some priority areas of our NICE Connect and live service work we are in the process of appointing 5 specialists who will be on short term contracts until end March 2020 to support targeted areas of work.
- 16. Talent management update: To support the delivery of our technical strategy we are engaging with our existing cloud network providers. Technical training will be delivered as part of our ongoing technical strategy and Digital Services/IT integration plans. Usage of our internal online training tool continues to increase as team members complete courses targeted to their development.
- 17. External collaborations: On the 29th October NICE together with FCI, HL7 UK, BCS and NHS Digital co-hosted a workshop entitled Mobilising Computable Biomedical Knowledge. This workshop brought together key stakeholders from across the system and represents the beginning of a movement within the UK to think about the ways health and care knowledge (such as guidelines) need to be standardised to enable them to efficiently and safely move between IT systems and into the hands of decision makers across the health and care system. This

workshop will be written up for the BMJ and as part of The Learning Healthcare Project. Future workshops are now being planned.

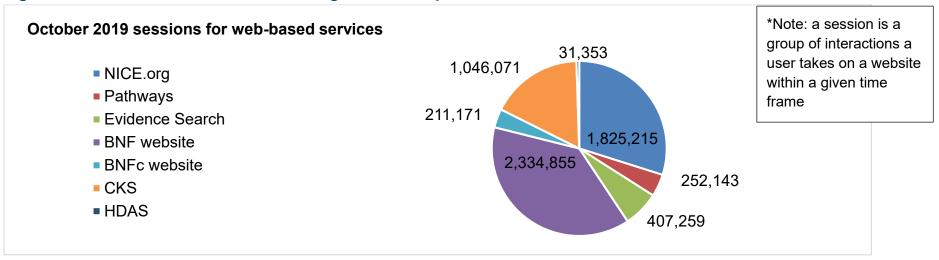
#### NICE Evidence Services

- 18. A core objective of the directorate is to maintain and monitor the performance of NICE Evidence Services which include CKS, HDAS, the BNF microsites, Evidence Search, and the Medicines Awareness Service. Over the last two months, negotiation has continued on the England-wide licence to access the Cochrane library as the current licence ends in April 2020. An agreement for the next three years has now been reached, subject to contract. Work to upgrade the technology and infrastructure that supports the medicines awareness service has now started and will be completed by the end of the financial year.
- 19. To provide these services, a key objective of the team is to enable access to the new National Core Content collection and to procure any additional content in line with Health Education England's (HEE) commissioning decisions. We have met with HEE to agree how we can use analytics and surveys to explore the search behaviour and search needs of advanced searchers in relation to the HDAS service, to ensure this service remains relevant and fit for purpose.

## Performance statistics for NICE Evidence Services

20. Figure 1 below summarises the position of all NICE's digital services at the end of October 2019, contrasting the relative size of the externally facing services of NICE, measured in number of 'sessions'. In October NICE digital services received altogether over 6 million sessions which represented an extra million sessions from the previous month (an 18% increase) and a very similar growth year-on-year. Overall NICE digital services have grown more than a quarter in the last 12 months.

Figure 1 and table 1: Overview of NICE's digital services performance as of October 2019



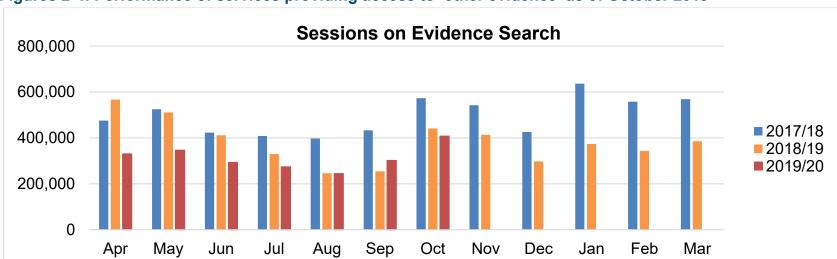
## download the data set for these charts

| Total sessions* in October 2019 across NICE web-based services                         | 6,108,067  |
|----------------------------------------------------------------------------------------|------------|
| % year-on-year variance                                                                | 17%        |
| % month-on-month variance                                                              | 18%        |
| Total sessions for the full year ending in October 2019 across NICE web-based services | 62,951,958 |
| % year-on-year variance                                                                | 27%        |

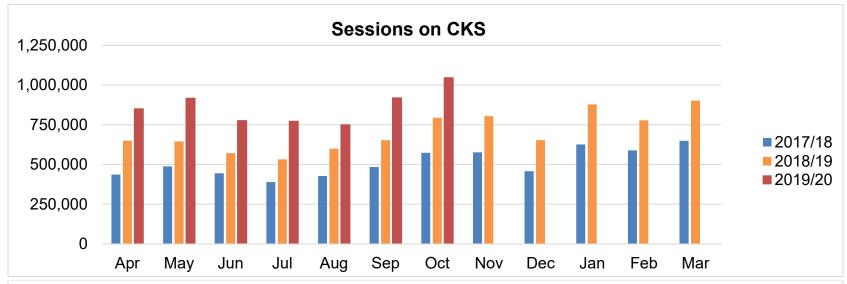
National Institute for Health and Care Excellence Evidence Resources Directorate progress report Date: 20 November 2019

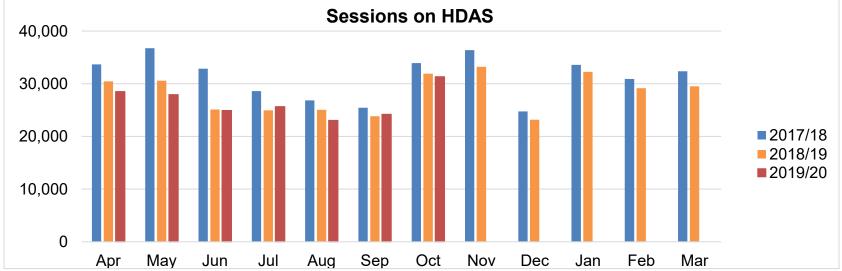
Date: 20 November 2019 Reference: 19/113

- 21. Figures 2-4 below detail the performance of the 3 services which provide access to evidence beyond that produced by NICE: Evidence Search, Clinical Knowledge Summaries (CKS) and HDAS.
  - October was a good month for CKS since this service has grown year-on-year by a third and it received over 1 million monthly sessions for the first time.
  - In October, Evidence Search and HDAS' performances dropped again with 8% and 2% respectively fewer sessions than in the previous year. We continue to monitor these services closely.



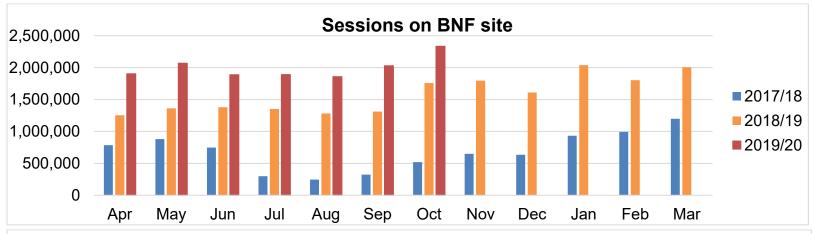
Figures 2-4: Performance of services providing access to 'other evidence' as of October 2019

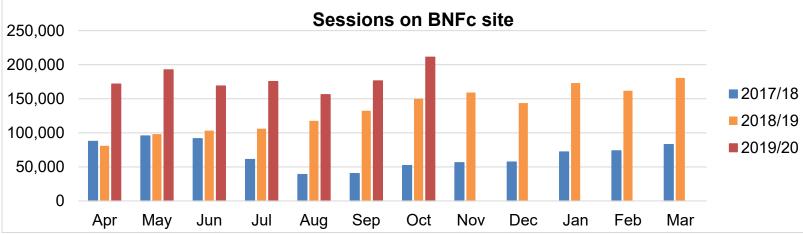




22. Figures 5-6 illustrate the performance of our BNF and BNFc microsites. These services continue to perform strongly growing year-on-year by 33% and 41% respectively.

Figures 5-6: Performance of services providing access to BNF content as of October 2019





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