Department
of Health

REPORT OF THE TRIENNIAL REVIEW OF

THE NATIONAL INSTITUTE FOR HEALTH AND CARE

EXCELLENCE

Title: Report of the Triennial Review of the National Institute for Health and Care Excellence	

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Executive Summary

The National Institute for Health and Care Excellence (NICE) is a national advisory body established by the Health and Social Care Act 2012 as an executive non-departmental public body. Its role is to provide guidance and support to providers and commissioners to help improve outcomes for people using the NHS, public health and social care services.

NICE's aim is to be the principal UK source of evidence to support health, public health and social care practice, commissioning and local decision-making, including practical support to help put recommendations into practice. NICE does this by producing recommendations about effective and cost effective practice in a range of forms, together with services to support their implementation.

The health and care system faces a number of significant challenges, including demographics, constrained resources, public expectation and new technologies. NICE will need to be committed to supporting the NHS, public health and social care, and organisations in the wider public and voluntary sector to respond to these challenges, making the best use of their resources by setting out the case for investment and disinvestment through their guidance programmes and other advice. From identifying specific recommendations that can save money, to advice on reconfiguration to support disinvestment from ineffective services NICE will need to work collaboratively with the Department of Health, NHS England and Public Health England, and other national partners, on their plans for a clear and compelling long-term vision for the future of health and care services, and ensure that NICE's advice and guidance forms an integral part of their plans for change.

This Triennial Review was announced through a Written Ministerial Statement on 30 October 2014. Triennial Reviews are part of the Public Bodies Reform work to provide a robust challenge to the continuing need for public bodies and to review their control and governance arrangements. Stage one of the review considered whether the functions undertaken by NICE are necessary and, if so, whether they could be better delivered through another organisational structure. Stage two moved on to an assessment of the NICE's impact, communications and relationships, efficiency and governance. The review process included gathering evidence from stakeholders, interviews and analysis of written material. This is the first Triennial Review of NICE.

The Accelerated Access Review into Innovative Medicines and Medical Technology

On 20th November 2014, the Minister for Life Sciences announced the Accelerated Access Review into Innovative Medicines and Medical Technology (the 'Accelerated Access Review'), which will consider how our healthcare and regulatory systems can best respond and adapt to the new landscape of innovation. The Review is expected to conclude before the end of 2015. It is not specifically reviewing NICE but will consider the pathways for the development, assessment and adoption of innovative medicines and medical technologies, and so this will include how NICE appraises and approves medicines and medical devices.

The Triennial Review Team worked closely with the Accelerated Access Review Team to avoid overlap and duplication of effort between these reviews. As such, the Triennial Review did not consider the methodologies and processes used by NICE in any depth, neither did it consider NICE's role in promoting and disseminating innovations as these are within the scope of the Accelerated Access Review. However, some of the issues raised by the NICE Triennial Review will be considered in greater detail in the Accelerated Access Review and the Triennial Review Team has shared any relevant material obtained as part of the Triennial Review process.

Main findings

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

The recommendations below are listed in the order in which they appear in the report, not in any order of priority or importance. NICE should seek to implement recommendations within nine - twelve months where possible and unless agreed otherwise, and have an agreed plan with the Department for longer-term proposals.

Stage one of the review concluded that the functions were necessary and that the current form is most appropriate. However, there is one recommendation covering issues around commercialisation and possible advantages in a change of status for non-statutory functions:

Recommendation 1: That the functions of NICE continue.

Recommendation 2: that NICE works with the Department and the Cabinet Office Commercial Models team to i) explore opportunities for greater expansion of NICE International and NICE Scientific Advice and ii) to consider whether these functions could be delivered more effectively through a different model or change of sector and, if this is appropriate, develop an agreed way forward in 2015/16.

Recommendation 3: That NICE retains its status as an NDPB.

Stage Two of the review looked at performance, communication and engagement, efficiency and governance issues. There are a further 11 high-level recommendations, broken down into specific areas where appropriate:

Recommendation 4: The health and care system is operating in a time of unprecedented financial constraints and NICE should play an integral role in supporting it to achieve its objectives and make best use of resources. It should do this by:

  o Working with the Department and NHS England to develop and publish a set of key performance indicators that reflect strategic objectives and assess the impact of the organisation, which are supported by appropriate input, output, or other performance targets [in 2015/16].

  o Working with other health and care leaders; especially NHS England, Public Health England and Care Quality Commission (CQC), to align the approach to implementation of NICE guidance and recommendations in order to support organisations in implementation activity [by the end of 2015].

Recommendation 5: DH should consider the clinical and cost effectiveness appraisals currently conducted within the health and care system, including (but not limited to) the Cancer Drugs Fund (CDF) and the Joint Commission on

Vaccinations and Immunisation (JCVI), with a view to establishing whether NICE should be the single expert body with responsibility for such appraisals [by April 2016].

Recommendation 6: Following the findings of the Accelerated Access Review, the Department of Health and NICE, with input from NHS England, should consider what changes to NICE's methods and processes are necessary to enable the health and care system make best use of the resources available [by July 2016].

Recommendation 7: In order to work effectively in an evolving health and care system, NICE should increase its profile, work more flexibly and further develop relationships across the sector by; analysing awareness of its profile across the stakeholder landscape, including with patients, service users, their families and carers and in social care, developing actions to increase awareness of its role and functions. [by April 2016].

Recommendation 8: NICE should continue to work with patient groups to make its approach to supporting patients more transparent and identifying where it can provide more support to those participating in the work of NICE [throughout 2015/16].

Recommendation 9: NICE should continue to improve communications and engagement work with social care stakeholders, including exploring whether alternative approaches to developing products would better fit the audience's needs [throughout 2015/16].

Recommendation 10: NICE should work with the Medicines and Healthcare Products Regulatory Agency (MHRA) to review the partnership agreement and consider publicising both the agreement and steps taken to ensure the principles are put into practice throughout all levels of the organisations. [by April 2016].

Recommendation 11: NICE should work with NHS England to identify systems and processes, with associated metrics where appropriate, to secure the application of commitment in the Partnership Agreement to using NICE guidance in the centralised and devolved commissioning arrangements [by July 2016].

Recommendation 12: NICE should work to further enhance relationships with organisations across health and care, clarifying areas where roles and responsibilities could be made clearer to stakeholders in 2015/16.

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

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

o Ensure that the arrangements for operating and quality controlling the work of the independent advisory committees are robust and transparent, publishing these arrangements where feasible [by July 2016].

Recommendation 14: In order to explore opportunities for further efficiencies:

o The Accelerated Access Review should consider the advantages and disadvantages arising from charging industry for health technology appraisals and medical devices and diagnostics evaluations.

o NICE should investigate the possibility of benchmarking functions with international comparators. [By July 2016].

Next Steps

NICE, working with the sponsor team in the Department of Health, should produce a plan to take forward these recommendations during 2015/16. The sponsor team should monitor progress and ensure that the Department of Health is actively engaged in decisions taken.

Acknowledgements

The review team would like to thank everyone who contributed to the review process, including all those who completed the call for evidence questionnaire or agreed to be

interviewed. Particular thanks go to Andrew Dillon, Gillian Leng, Ben Bennett and Alana Christopher at NICE.

1. Introduction and background

The aims of Triennial Reviews

1.1   It is best practice that an Arm's Length Body (ALB) should only be set up, or remain in existence, where the model can be clearly evidenced as the most appropriate and cost-effective way of delivering the function in question.

1.2   In April 2011, the Cabinet Office announced that all Non-Departmental Public Bodies (NDPBs) still in existence following the first stage of public bodies reform would have to undergo a substantive review once in a three year cycle. Triennial Reviews (TRs) have two main stages:

- **Stage one** tests the continuing need for the body, both in terms of the functions it performs and the model and approach in which they are delivered.

- **Stage two** considers the body's governance, performance and capability as well as exploring opportunities for efficiencies.

1.3   The health and social care system reforms, set out in the Health and Social Care Act 2012 and the Care Act 2014, resulted in the devolution of functions and powers away from the Department of Health (DH) to ALBs and local health and care organisations. As steward of this evolving system, the DH is using TRs to provide assurance that the system, and the ALBs within it, is fit for purpose.

1.4   Although the Cabinet Office requirement for government departments to undertake TRs applies only to NDPBs, the DH is including its Executive Agencies and Special Health Authorities within this process, with the reviews playing a key role in supporting effective stewardship and oversight of the Department's ALBs.   These TRs of Executive Agencies and Special Health Authorities are conducted in line with Cabinet Office guidance ("Guidance on Reviews of Non-Departmental Public Bodies", revised in 2014) so far as is appropriate and relevant.   This guidance states that all reviews should be conducted in line with the following principles:

Challenge Reviews must be challenging. They should take a first principles approach to whether the function of a body is still needed, and if it is, what is the

best form for delivery of that function. Reviews should not just seek to evidence the status quo. They should be robust and rigorous and provide evidence for all recommendations. They must consider issues of efficiency, including the potential for efficiency savings, and make relevant recommendations. They should consider the performance of the body, and whether it could provide better value for money, including in terms of the body's contribution to economic growth. A description of how the review will be structured to meet this aim should be set out clearly in the Terms of Reference, which will be agreed between the Department and Cabinet Office.

Proportionality Reviews must not be overly bureaucratic and should be appropriate for the size and nature of the NDPB being reviewed. Where appropriate, reviews of similar bodies should be combined or clustered to ensure the maximum benefit in terms of streamlining the review process, identifying synergies across departments and NDPBs, and considering efficiency.

Contextual Reviews should not be undertaken in silos, but should wherever possible be integrated with other departmental policy initiatives, efficiency reviews or landscape reviews, and seek to look across departmental boundaries to cluster reviews of bodies to further enable informed discussions about potential efficiencies. Departments should consider the potential for integration when building their Triennial Review timetable the Cabinet Office will assist departments in doing this.

Pace Reviews must be completed quickly to minimise the disruption to the NDPB's business and reduce uncertainty about its future. Reviews should normally take no more than six months. Timetables, including start and completion dates, for individual reviews will be agreed with the Cabinet Office at the beginning of each review.

Inclusivity Reviews must be open and inclusive. The NDPB being reviewed must be engaged and consulted at both Executive and Non-Executive level. Users and stakeholders must have the opportunity to comment and contribute. Parliament must be informed about the commencement and conclusions of reviews. Departmental Select Committees must be given the opportunity to input.

Transparency All reviews must be announced formally, both to Parliament and to the public. All review reports must be published once clearance has been given by the Minister for the Cabinet Office. The results of reviews must be announced to Parliament.

About the Triennial Review of NICE

Context

1.5   The Department of Health was exempt from the first round of Triennial Reviews due to the changes taking place in the health and care sector following the Health and Social Care Act 2012. This is, therefore, the first Triennial Review of NICE.

1.6   This review took place following the announcement of the Accelerated Access into Innovative Medicines and Medical Technology Review, announced on 20th November 2014 by George Freeman, Minister for Life Sciences. The Accelerated Access Review is due to conclude at the end of 2015 and will examine:

- how new approaches to the development of medicines, diagnostic and devices, based on precision medicine and emerging technologies, could speed up access to innovative products for NHS patients.

- how more collaborative work between companies, regulatory and evaluation bodies could ensure that innovative products can be assessed more quickly, using better data.

- how charities and patient groups can play a greater role so that NHS patients can get access to cutting-edge treatments.

- what more can be done to promote the rapid adoption of important medical innovations into clinical practice.

1.7   The Triennial Review Team worked closely with the Accelerated Access Team to avoid overlap and duplication of effort between these reviews. Therefore, this review of NICE has not considered some elements of NICE's work in any detail.   For example, we did not review: how NICE appraises new drugs and technologies or how NICE supports and drives medical innovation. Some of the issues raised by the NICE

Triennial Review will be considered in greater detail in the Accelerated Access review and the Triennial Review Team shared any relevant material obtained as part of the Triennial Review process.

Process

1.8   The review commenced on 30th October 2014 with the laying of a Written Ministerial Statement (see Annex A). This review was conducted in accordance with the principle and processes set out in the Cabinet Office 'Triennial Reviews: Guidance on Reviews of Non-Departmental Public Bodies'.

1.9   This Review was led by a small, Department of Health team, which was independent of the DH Sponsor Team, sitting within the Chief Operating Officer's Directorate. The Review was conducted under the direction of an impartial Senior Review Sponsor. Details of the review team can be found at Annex B.

1.10 The review was overseen by a Project Board, chaired by the SRS. The review was also subject to scrutiny by a Challenge Group, which was chaired by a DH Non-executive board member. The Challenge Group also looked at the Triennial Reviews of the Medicines and Healthcare Products Regulatory Agency (MHRA); the Commission on Human Medicines and the British Pharmacopoeia Commission and made links between these reviews where appropriate. The project Board and Challenge Group met four times during the course of the review. Terms of reference for the Project Board and Challenge Group can be found at Annex C.

Stakeholder Engagement

1.11 Stakeholder engagement was a key element of the evidence gathering process. The review team sought to obtain views from a wide range of stakeholders to pick up key themes emerging from a variety of viewpoints. The full list of stakeholder responses is provided at Annex D.

1.12 Evidence was gathered through a variety of ways:

- A public call for evidence announced on the Department of Health and NICE websites and open between 1 December 2014 and 9 January 2015. This received 56 responses.
- A total of 37 stakeholder interviews (including NICE staff, experts in the health and care system, industry representatives, patients and charitable groups, and international bodies).
- Three workshops to which stakeholders were invited to book seats and which captured the views of 24 individuals, some of whom also responded to the Call for Evidence.
- Meetings with relevant experts in NICE, DH, HM Treasury and Cabinet Office, to discuss the details of specific issues (e.g., financial controls, efficiency savings).
- Analysis of other published material (Annex E provides a list of the key papers used).

1.13 The Minister also wrote to the Health Select Committee to inform them of the review and invite any comments.

1.14 This review is based on qualitative evidence drawn from these discussions and from the responses provided to the call for evidence. By its nature, this type of review draws from the opinions and views of stakeholders with extensive knowledge and understanding of NICE, but who bring their own particular concerns and interpretations to what they have observed or experienced. The largest proportion of responses to the call for evidence came from the pharmaceutical and life science industry stakeholders and we also received responses from charities, health and care organisations and professionals and academics. A breakdown of responses to the call for evidence survey by sector can be found at Annex F.

1.15 We have drawn on the wealth of comments we have received to reach our conclusions.

Estimated costs of the review

1.16 The review team started planning the reviews of NICE in late-September 2014 with this report being cleared for publication by June 2015. The estimated direct costs of

the reviews based on six months duration are set out in the table below. There were no travel or other costs as interviews either took place in London or via telephone or video-conference. This estimate does not take account of indirect costs, such as the time contributed by NICE staff.

Table 1: Estimated cost of the Triennial Review of NICE.

Role	Proportion of time spent on review	Estimated cost
SRS	0.1	£7,250
Lead Reviewer	0.7	£29,254
Senior Executive Office Assistant Reviewer	0.8	£20,782
Higher Executive Officer Assistant Reviewer	0.4	£5,631
Volunteers	0.3	£7,793
Total estimated cost		**£70,710**

About NICE

The history of NICE

1.17 The National Institute for <u>Clinical</u> Excellence was established in 1999 by the National Institute for Clinical Excellence (Establishment and Constitution) Order 1999 and the National Institute for Clinical Excellence Regulations 1999 as a Special Health Authority. Its role was to provide authoritative, independent advice on different health-related interventions and pathways of care; increase fairness in access to treatments;

to be a national source of robust clinical guidance and to speed up the uptake of cost-effective treatments in the NHS. In April 2005, it joined with the Health Development Agency to become the National Institute for Health and Clinical Excellence and began providing public health guidance.

1.18 NICE International was set up in 2008 and contributes to better health around the world through the more effective and equitable use of resources.

1.19   Following the Health and Social Care Act 2012, the National Institute for Health and Care Excellence (NICE) was established in primary legislation as an Executive Non-Departmental Public Body operating under direction from the Secretary of State for Health. This change of status also extended its remit into adult and children's social care to help promote the integration of NHS, public health and social care.

1.20 As an Executive NDPB, NICE operates at arm's length from the Department of Health.

What is NICE's aim and how does it achieve this?

1.21 NICE's aim is to be the principal UK source of evidence and advice to support health, public health and social care practice, commissioning and local decision-making, including practical support to help put recommendations into practice. It provides advice to the health and care system on what interventions and forms of practice are effective and cost-effective.

1.22 NICE's work programme is set out in its business plan and agreed with the Department of Health and with NHS England. More detail on NICE's work programmes can be found in Stage One of the Triennial Review.

1.23 These programmes are supported by implementation support materials and activities, and are complemented by NICE Evidence Services, a suite of on-line evidence resources for all health and social care professionals.

1.24 NICE guidance is available to health and care professionals, patients and service users to make sure that the care they provide and receive is of the best possible quality and offers the best value for money. NICE guidance is for the NHS, local authorities, the third sector, and anyone with a responsibility for commissioning or

providing healthcare and public or social care. NICE also supports these groups in putting its guidance into practice.

1.25 How NICE works with DH is set out in a framework agreement[1] through which standards on accountability, governance, partnership working, risk management and transparency are determined. The framework agreement is reviewed every three years (or sooner, on the request of either party).

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[1] https://www.nice.org.uk/Media/Default/About/Who-we-are/NICE-and-Dept-of-Health-Framework-Agreement-March-2014.pd

2.   Context and future challenges

2.1   The health and care system faces considerable challenges over the next few years: people are living longer with increasing multiple and complex needs; expectations of what the health and care system should deliver are increasing; society is changing and the pace of innovation in the field of medical technologies and medicines is increasing. These factors lead to increased demand for both health and social care, yet public finances are constrained and are likely to remain so for the foreseeable future. It is vital that the health and care system operates effectively and makes best use of all available resources.

2.2   We should not underestimate the scale of the challenge, however this creates an opportunity for the system to do things differently; play a more active role in supporting growth in the UK, reducing direct costs to taxpayers caused by ill health, champion UK strengths in technology and life sciences, maintain the UK as a world-class location for clinical research and developing the life sciences sector, reduce barriers to innovation and make the most of UK health-related expertise.

2.3   These challenges and opportunities are recognised by both the Five Year Forward View (FYFV) and the Care Act 2014, which support health and care services in becoming more integrated, organised around the patient pathway with networks of care being developed across organisational boundaries.

2.4   NICE's decisions and products have a significant impact on the system at many levels and impact on both the public and private sector; for example private healthcare providers implement NICE guidance and many of the social care providers are independent providers. In the public sector, commissioners must fund new technologies once approved by NICE, which can have a significant financial impact, and NICE's guidelines set out the most cost-effective processes, practices, which can support the system in delivering an effective service. Therefore, it is crucial that NICE performs highly, both now and in the future and plays a lead role in responding to these opportunities and in supporting the system to make best use of its resources. In order to do this it needs to look to the future and develop robust strategies to respond to, or help to manage, future scenarios.

2.5   The complexity of both the health and care system and the changes that are needed to make the vision set out in the FYFV a reality make the adoption of NICE guidance challenging.   Resolving these issues requires a whole system approach rather than NICE acting in isolation.   Therefore, it is important that NICE continues to work collaboratively across the system, building on its established evidential approach to support the system to make best use of its resources and to improve health and care outcomes. It will need to continue being responsive to the local needs of the NHS and local government as well as supporting the innovation and growth agenda. It will also need to be willing to change in order to ensure alignment with the NHS's ability to fund those treatments which offer the best possible.

2.6 NICE is already aware of these challenges and has a number of initiatives in place to build relationships across the system. This review makes several recommendations to support further change.

3.   Findings on the function and form of NICE

3.1   This section of the review focuses on whether the functions currently undertaken by NICE should continue based on their contribution to the core business of government and the health and care system. Proposed improvements to how NICE's functions are delivered are set out in stage two of the report starting at page 40.

What are the functions of NICE?

3.2   NICE is a statutory body, as set out in the Health and Social Care Act 2012[2], and the NHS must have regard to NICE guidance. NICE was set up to reduce variation in the availability and quality of NHS treatments and care and now also provides guidance and quality standards to the NHS, public health and social care. In effect, NICE provides analysis and decisions on effectiveness and cost effectiveness that informs priorities, allows the NHS to make choices for the health and care service. Through use of these services and products the health and care system is able to identify and address poor quality care and be more responsive to patient, service user and family concerns and complaints.

3.3   NICE carries out a range of functions and delivers a number of products for the health and care system and for patients, service users and the public.

3.4   These functions aim to benefit the NHS, public health and social care services, as well as the users of these services. Most of these functions are set out in legislation and are therefore statutory.

Functions

3.5   NICE's legislative framework describes its general functions and provides that its work is commissioned by Ministers or by NHS England. NICE's work programmes are

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[2] The Health and Social Care Act 2012

normally set by Ministers and NHS England several years in advance and the development of individual pieces of guidance can take between 6 months to 2 years. Decisions on which topics to refer to NICE's work programmes, and their relative priority, are taken following a consultation with stakeholders, in particular DH and NHS England, and are based on NICE's capacity, the quality of evidence that is already available and the urgency of the topic.

3.6   NICE's functions can be summarised as follows:

- **Guidelines for health, public health and social care.** NICE guidelines make evidence-based recommendations on a wide range of topics, from preventing and managing specific conditions, improving health and managing medicines in different settings, to providing social care to adults and children, and planning broader services and interventions to improve the health of communities. They aim to promote integrated care where appropriate, for example, by covering transitions between children's and adult services and between health and social care. Providing evidence-based recommendations for health was one of the original statutory functions as set out in the original establishment order. Subsequent legislation expanded NICE's remit to include public health (in 2005) and social care (in 2013)[3]. Guidelines are relevant to charities, voluntary and community organisations, residential care homes and private sector employers as well as the NHS and local government. Guidelines aim to help improve outcomes for people using the NHS and other public health and social care services.

- **Technology appraisals**. NICE assess the clinical and cost-effectiveness of health technologies, such as new pharmaceutical and biopharmaceutical products, but also include procedures, devices and diagnostic agents. The NHS is legally obliged to fund and resource medicines and treatments recommended in NICE's technology appraisals with the intent that all NHS

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[3] The Health and Social Care Act 2012

patients have equitable access to the most clinically and cost-effective treatments that are available. Appraisal of technologies is a statutory function specified in the legislation that originally established NICE[4].

- **Highly Specialised Technology Evaluations**. NICE makes recommendations on the use of new and existing highly specialised medicines and treatments within the NHS in England. The highly specialised technologies programme only considers drugs for very rare conditions. The NHS is legally obliged to fund and resource medicines and treatments recommended in NICE's highly specialised technologies guidance with the intent that all NHS patients have equitable access to these treatments. Highly specialised technology evaluations are a statutory function specified in the regulations that establish NICE's constitution and functions.

- **Medical and diagnostics guidance.** Through assessing whether technologies offer advantages to patients and the NHS, this guidance is made available so that the NHS is able to adopt clinically and cost effective technologies rapidly and consistently.

- **Interventional procedures guidance.** NICE makes recommendations to the NHS on whether interventional procedures, such as laser treatments for eye problems or deep brain stimulation for chronic pain are effective and safe enough for use.

- **Quality Standards**. Legislation[3] requires NICE to provide quality standards which are concise sets of statements, with accompanying metrics. They are derived from the best available evidence, particularly NICE's own guidance and, where this does not exist, from other evidence sources accredited by

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[3] Health and Social Care Act 2012
[4] The National Institute for Clinical Excellence (Establishment and Constitution) Order 1999

NICE. Quality standards:

- o provide a means by which health, public health and social care practitioners are able to make decisions about care based on the latest evidence and best practice.
- o offer people receiving health and social care services, their families and carers and the public a route to find information about the quality of services and care they should expect from their health and social care provider.
- o deliver a way for service providers to quickly and easily examine the performance of their organisation and assess improvement in standards of care they provide, and
- o allow commissioners to be confident that the services they are purchasing are high quality and cost effective and focused on driving up quality.

- **Quality and Outcomes Framework (QOF).** NICE undertakes the development of an annual menu of potential indicators for inclusion in the clinical component of the QOF, the quality element of the contract the NHS has with General Practitioners. Development of these indicators provides a mechanism for healthcare leaders and system users to hold primary care providers to account for the outcomes they achieve. NICE also recommends whether existing indicators should continue or be retired.

- **Clinical Commissioning Group Outcomes Indicator Set (CCGOIS).** Working with the NHS England, as well as with professional and patient groups, NICE has developed a framework for measuring health outcomes and the quality of care (including patient reported outcomes and patient experience) achieved by clinical commissioning groups (CCGs). Development of these indicators provides a mechanism for healthcare leaders and system users to hold primary care providers to account for the outcomes they achieve. This is a statutory requirement as set out in the Health and Social Care Act 2012.

- **Evidence for Health and Social Care.** A unique index of authoritative, evidence-based information on health and social care from hundreds of trustworthy and accredited sources as part of this service.

- **Evidence resources.** NICE also provides access to information content purchased on behalf of the NHS. This includes access to a range of bibliographic databases such as MEDLINE and professional journals. NICE Evidence Services are for everyone working in health and social care that makes decisions about treatments, interventions or the use of resources and aim to help professionals make better and quicker evidence-based decisions. While NICE Evidence Services are designed primarily for professionals and practitioners, patients, service users and the wider public are also able to search most of the content.

- **British National Formulary (BNF)** and **British National Formulary for Children (BNFC)**. Published jointly by the Royal Pharmaceutical Society and the British Medical Association. For a number of years, NICE has been responsible for providing NHS access to these publications, including recently through the use of smartphone apps. The BNF and BNFC aim to provide prescribers, pharmacists, and other healthcare professionals with sound up-to-date information about the use of medicines to support clinical decision making.

- **Medicines and prescribing support.** NICE provides information on new pharmaceutical products and information about the use of particular products outside the scope of their licensed indications. This includes medicines practice guidelines to support best practice in medicines management, including practical advice on developing and maintaining local medicines formularies, and guidance, advice and support for delivering quality, safety and efficiency in the use of medicines.

3.7   NICE also provides a number of other services:

- **Fellows and Scholars programme**. NICE aims to foster a network of health and social care professionals committed to improving the quality of patient care within their local health and professional communities, as well as supporting the core values that underpin NICE's work.

- **NICE International.** Helps to raise standards of healthcare around the world

by providing advice and support to encourage the use of clinically and cost effective treatments. NICE International - which operates on a full cost recovery flexible charging (sensitive to the constraints of individual funding sources) fee-for-service basis - also carries out important research activities such as generating case studies, preparing tools to help data analysis and encouraging shared learning through international meetings. Funding for country-specific projects may be obtained directly from the client country or from donor agencies such as the World Bank and the UK's Department for International Development.

- **Scientific Advice.** NICE provides a full cost recovery fee-based consultancy service to developers of medicines, devices, diagnostics and orphan designation products to help manufacturers generate evidence to inform future NICE evaluations and to enable market access.

3.8   Possibly because the remit of NICE is so extensive, there is often confusion around the organisation's role. For example, many people believe NICE to be a regulator but NICE does not regulate drugs and technologies.

NICE does not:

- Regulate drugs or healthcare products; this is done by the MHRA.

- Consider the safety of healthcare technologies, other than in the context of assessing the effectiveness and cost-effectiveness of practice and interventions.

- Set prices, rather it considers the cost-effectiveness of practice and interventions based on evidence.

- Assess the effectiveness of all drugs and technologies. NICE conducts assessments on a subset of health technologies. These are agreed with NHS England and the Department of Health.

- Assess vaccinations or immunisations. This is done by the Joint Committee for Vaccination and Immunisation.

3.9   NICE's strategic objectives and priorities can be found at: www.nice.org.uk/about/who-we-are/Corporate-publications.

Are the functions of NICE still necessary?

3.10   In general, the weight of information received about NICE and its functions related to the technical and medicine appraisals and evidence functions. However, the review team received sufficient information across the piece to draw appropriate conclusions.

3.11   The review team considered each of NICE's functions separately, taking into account the value to stakeholders, the cost to the taxpayer and the benefit to the health and care system and concluded that all the functions are necessary and should continue.

3.12   The evidence heard from stakeholders was especially compelling as it demonstrated that all of the functions that NICE carries out are highly valued. Many stressed that if the organisation itself was abolished then the need for these functions would still exist.

3.13   NICE's role in the health and care system was described by a number of stakeholders as being vital in contributing to parity of care; supporting best practice and encouraging consistent uptake of evidence-based interventions and treatments in the NHS. Where medicines and technologies were not reviewed by NICE, stakeholders described a highly fragmented and duplicative system.

3.14   Responses to the call for evidence survey and face-to-face interactions frequently mentioned the strength of the NICE brand, which is recognised across England, the United Kingdom and internationally. This brand is trusted and credible for its rigorous and evidence based approach to carrying out these functions.

3.15   The review team noted that stakeholders occasionally expressed uncertainty about the full range of functions that NICE carries out and the extent of the organisation's authority and role. An example is confusion around the difference between NICE's role in assessing the effectiveness and value for money of drugs and medical technology and devices and the Medicines and Healthcare Products Regulatory Agency's (MHRA) role in assessing the safety, efficacy and quality of medicines and healthcare products and devices.

3.16 We also heard views on the need for clarity on NICE's role in the system relating to some areas where there are a number of players. The example given most often was that of quality, where NICE provides quality standards and where other bodies and groups, such as CQC, health think tanks and academic institutions also develop and deliver quality improvement metrics, initiatives and guidance. Generally it was felt that clarification on who leads on quality was needed.

3.17 The majority of responses submitted through face-to-face interactions and through the call for evidence survey welcomed NICE's approach to working with stakeholders, including partnership working to deliver some of NICE's functions. However, the review team found that issues around the extent, methods and impact of engagement were raised by some stakeholders and opportunities to improve collaboration, communications and transparency were identified.

3.18 Equally, there were suggestions from stakeholders on how NICE could deliver its functions in a way that improved its performance or could contribute to reduced spend across the system. These views are explored in chapters 5 and 6.

Conclusions on the functions of NICE

3.19 The review team has concluded that, based on evidence from stakeholders, the core functions that NICE carries out are necessary and that dropping any or all of these functions would have a negative impact on the health and care system and on the quality of care received by service users. Non-statutory functions, such as NICE International, are also regarded as useful and relevant by stakeholders. Therefore, it would not be appropriate to abolish the organisation as this would simply require NICE's functions to be moved elsewhere. That does not mean that all functions must necessarily stay within NICE and options are considered at paragraph 3.21.

3.20 We found there are opportunities to improve delivery of the functions and services currently delivered by NICE to improve their effectiveness. These opportunities for improvement are described in Chapters 5 and 6.

> **Recommendation 1: That the functions of NICE continue.**

Is a Non-Departmental Public Body (NDPB) the most efficient and effective way to deliver NICE's functions?

Current status

3.21 NICE is an Executive NDPB; key characteristics of an NDPB are described at Annex G.

3.22 As an Executive NDPB, NICE is sponsored by the Department of Health. Sponsorship of an Executive NDPB requires a sponsor team to be established within the department, which not only represents the Minister in providing appropriate oversight and scrutiny of the body, but also provides ongoing support and assistance to the NDPB. This provides NICE with a number of benefits and opportunities. For example:

(a) Part of the DH sponsorship team's role is to keep NICE informed of developments in the Department and emerging Government policy and initiatives that are relevant or of interest to NICE. This degree of openness and transparency is enabled by NICE being a public body.

(b) The sponsorship team also aims to represent NICE, its challenges and its work in a balanced way to Ministers, to colleagues within DH and across Whitehall.

(c) The sponsorship team is able to facilitate and/or advise NICE when its work involves engaging with other government bodies or new stakeholders whether within the health and care system or within DH.

Alternative delivery models

3.23 The review team considered whether any of the functions that NICE delivers had potential to be delivered through an alternative organisational delivery model.

3.24 In considering alternative delivery models, we looked for evidence that any recommended changes would deliver net benefits compared to NICE's current delivery model. The assessment was not simply about whether functions could be delivered

differently but considered how well each model would support NICE's core aims and functions, including the requirements set out in legislation. Any changes to the delivery model should deliver benefits, such as reduced costs or improvements in the quality of service provision. Changes should also ensure that:

- NICE's Board has full governance accountability and operation control to lead, manage and improve the organisation.
- Ministers are able to fulfil their statutory responsibilities for NICE (including the ability to define the overall purpose, hold the organisation to account and intervene in extreme circumstances if necessary to protect the public interest).
- NICE is an appropriate vehicle for the management of public money, providing sufficient transparency, controls, and assurance to the Department of Health Ministers responsible for NICE as a whole.

3.25 Therefore, given the scale and significance of the functions that NICE carries out, the optimum delivery model will achieve an appropriate balance between the statutory responsibilities of Ministers and the independence of the organisation as well as promoting the safety of patients, service users and their families. In order to achieve this balance it will meet the following four criteria:

1) Allow effective delivery of all NICE's core functions, as currently set out in legislation.
2) Ensure that NICE can carry out its technical functions and make decisions independently of government influence, and with political impartiality.
3) Have credibility with the health and care sector, the relevant industries and the public.
4) Allow NICE to innovate and collaborate with stakeholders across the sector and industry and to continue to contribute to development of government policy (by both central and local government).

3.26 The review team considered options both outside of Government and within Government. The alternative delivery model options outside of central government were:

(a) Transferring the ENDPB's functions to local government

(b) Outsourcing the functions to the private sector / converting the existing organisation into a corporation or company

(c) Moving the functions or the organisation itself into another sector – such as the voluntary and charitable or academic sector

3.27 The alternative delivery model options within central government considered by the review team were:

(d) Bringing the functions of the NDPB in-house

(e) Merging the existing NDPB with another public body

(f) Delivering the functions of the NDPB instead via an Executive Agency

(g) Retaining the status quo (i.e. continued delivery by the existing NDPB)

3.28 The review team noted that some of the evidence gathered by the review has demonstrated a lack of understanding of the status of NICE. There is an incorrect assumption that it should be independent of Government if it is to make impartial decisions, whereas NDPBs are by definition at arm's length from, not independent of, Government. It is also important to recognise that any change to the delivery model could have a significant impact on the ability of NICE to maintain business as usual and so has to be able to demonstrate significant advantages over the status quo.

Analysis of alternative delivery models

Transferring NICE's functions to local government

3.29 NICE's functions cover public health and social care, both of which fall under the remit of local government. More than 2,000 experts engage with NICE processes giving NICE the expertise that makes it resilient and respected. NICE is an expert organisation and its much-praised rigorous and evidence based approach requires expert health knowledge. It is unlikely that the local government structure would be able to support an expert organisation of this size and spread of functions. It is also unlikely that the local government structure would be in a position to support functions

that relate to the NHS and industry and it is doubtful that such a positioning would maintain NICE's current credibility with stakeholders.

3.30 The review team found that moving NICE into local government would not be appropriate.

Moving NICE into the private sector or converting NICE into a public corporation or company

3.31 NICE is well respected, credible and trusted by the public, clinicians and other stakeholders, in part due to its impartiality and independence. The review found that a key concern for stakeholders was that NICE continues to operate with impartiality and independence. This requires both a degree of separation from the Department and Ministers and from any perception that commercial pressure or other influences might impact on decisions.

3.32 These very characteristics of trust and credibility could give the organisation commercial potential and a head start as a private company, while outsourcing functions might offer opportunities to deliver greater efficiencies and provide increased control for Ministers.

3.33 One of the disadvantages to converting NICE into a public corporation or company is the potential to damage credibility and trust. This could result in any potential savings, benefits or profits being diminished as stakeholders lose faith. In addition, a public corporation model does not appear feasible due to the fundamental requirement for a public corporation to cover 50% of its operating costs from selling goods and services.

3.34 While outsourcing functions might offer opportunities to deliver greater efficiencies and provide increased control for Ministers, the same issues of a loss of credibility and trust arise, making this option unattractive. In addition, it is likely that there would be reductions in effectiveness and flexibility caused by the contractual relationship with Government. Stakeholders were largely resistant to this proposal.

3.35 The review team found that converting NICE into the private sector or changing its status to that of a private company would not be appropriate.

3.36 However, this does not mean that there are not opportunities for greater commercialisation of activity in non-statutory functions, especially where they are operated on a cost recovery basis, for example, NICE International, or already charge for services – such as NICE Scientific Advice. These were not studied in depth as part of this review and we recommend that action should be taken to explore this area in more detail to assess feasibility and scope. This is picked up in recommendation 2 below.

Move into the charitable or academic sector

3.37 The review team heard from stakeholders who felt that some of NICE's functions could be delivered by the academic sector (e.g. NICE Scientific Advice) or charitable sector (e.g. NICE International). We considered whether one, some or all of NICE's functions could be delivered on contract by another organisation in either of these sectors. As with the option for the private sector above, it is possible there would be a reduction in effectiveness and flexibility caused by the contractual relationship with Government, a loss of credibility with stakeholders and the level of expertise in the relevant areas. Although this model could potentially provide NICE with greater independence, rather than the autonomy it currently has, it could undermine Ministers' ability to meet statutory requirements and influence the necessary areas. In addition, stakeholders are likely to be resistant to a move away from the status quo.

3.38 The review does not recommend that NICE as whole moves into the charitable or academic sector. However, we considered that NICE International and NICE Scientific Advice might benefit from more independence and a change of sector and these should be explored with advice from the Cabinet Office.

> **Recommendation 2:** that NICE works with the Department and the Cabinet Office Commercial Models team to i) explore opportunities for greater expansion of NICE International and NICE Scientific Advice and ii) to consider whether these functions could be delivered more effectively through a different model or change of sector and, if this is appropriate, develop an agreed way forward by December 2015.

Bring functions within the Department

3.39 Integrating NICE into its sponsor department, DH, has significant practical downsides. It would mean bringing a number of expert functions, such as health technology assessments and development of guidance and quality standards, including the associated headcount and overheads, into a relatively, small policy department. It would be unpopular with industry stakeholders, who would perceive a loss of independence and impartiality and who were clear that these functions should sit at arm's length from Ministers.

3.40 Therefore, the review does not recommend that these functions are brought any closer into central government than they are currently.

Delivering the functions of NICE via an Executive Agency or other body (e.g. Special Health Authority)

3.41 An Executive Agency operates a step closer to Government than an NDPB (indeed, Executive Agencies have no separate legal personality from their parent department). This model therefore has many of the same disadvantages as bringing NICE's functions in-house and the review does not recommend it for the same reasons.

3.42 Special Health Authorities are health authorities that provide a health service to the whole of England, not just to a local community and are relevant to the NHS. NICE changed its status from that of a Special Health Authority to an NDPB in 2012 to take into account its expanded role covering social care. Being established under statute and accountable to Parliament rather than Government, being an NDPB allows more financial independence since the government is obliged to provide funding to meet statutory obligations. Therefore it would not be appropriate to revert back to a Special Health Authority.

3.43 This review does not recommend delivery of NICE's functions via an executive agency or Special Health Authority.

Merge with another body

3.44 Some stakeholders suggested that it might be feasible to merge NICE with another public body. Where respondents provided an example of a suitable body to merge with, they cited the MHRA due to the perceived overlap (MHRA needs evidence to prove the safety and efficacy of a drug, medical device or other technology whereas NICE requires evidence to prove the clinical and cost effectiveness of the technology). However, it should be noted that NICE's functions are much wider than assessing technologies and so the overlap in functions is relatively small. Any merger would risk a perceived conflict of safety and cost decisions that would damage the regard that both organisations are held in. Keeping the economic evaluation and regulatory functions separate is in line with several other countries which recognise the same concerns (e.g. Germany, Netherlands, Sweden, Denmark, Canada, Thailand, Ireland, Scotland, and Northern Ireland).

3.45 On this basis, the review found that merging NICE with the MHRA would not be appropriate.

Continuing delivery by the existing NDPB

3.46 There were two schools of thought from stakeholders as to how the 2012 change of delivery model from a Special Health Authority to an NDPB had impacted on NICE's ability to carry out its functions. The majority of those responding to the call for evidence survey felt that changing NICE's delivery model has made no tangible difference how it operates, while a minority felt that NICE is now more susceptible to government pressures, which has introduced delays and inefficiencies. Either way, there is little appetite from stakeholders for a change to NICE's organisational form, provided NICE's independence is retained.

3.47 Of the stakeholders consulted, most felt that NICE should remain an NDPB due to the impartiality and independence this allows. Many stakeholders expressed strong views on the possibility of conflicts of interest or a lack of impartiality resulting from a move to the private or voluntary and charitable sector. In general, stakeholders who responded to the call for evidence survey were not aware of any other organisations or models that could carry out the functions currently conducted by NICE, other than those explored above.

3.48 Therefore, the review team have concluded that the Executive NDPB model remains the most appropriate delivery model for NICE within central government, given the need for independence and impartiality in maintaining credibility and trust with stakeholders and customers and provided the three tests for being an NDPB are met.

Does NICE pass the three tests for being an NDPB?

3.49 The presumption is that if a 'public function' is needed then it should be undertaken by a body that is democratically accountable at either national or local level, and that such a body should only exist 'at arm's length' from Government (rather than any closer) if it meets one of three tests:

1. It performs a technical function (which needs external expertise to be delivered).
2. It performs a function which needs to be, and be seen to be, delivered with absolute political impartiality (such as certain regulatory or funding functions).
3. It performs a function which needs to be delivered independently of Ministers to establish facts and/or figures with integrity.

3.50 The review has concluded that the work of NICE does pass all three tests, as set out below.

Test	Result	Rationale
Does NICE perform a technical function (which needs external expertise to be delivered)?	✓	NICE does perform a technical function in appraising the effectiveness and cost-effectiveness of interventions and practice for NHS and care systems.
Does NICE perform a function which needs to be, and be seen to be, delivered with absolute political impartiality (such as certain regulatory or funding functions)?	✓	The setting of quality standards, providing of guidelines and appraising evidence across the health and care system must be seen to be done impartially and is essential to the credibility of NICE. The majority of stakeholders welcomed the impartiality that being at arm's length from government status gave to NICE and expressed the belief that this impartiality was essential to maintaining

		the trust of industry and sector bodies.
Does NICE perform a function which needs to be delivered independently of Ministers to establish facts and/or figures with integrity?	✓	The setting of quality standards, providing of guidelines and appraising evidence across the health and care system must be seen to be done impartially and is essential to the credibility of NICE. The majority of stakeholders welcomed the impartiality that being at arm's length from government status gave to NICE and expressed the belief that this impartiality was essential to maintaining the trust of industry and sector bodies.

3.51 The setting of standards and the collection and analysis of facts and figures to support NICE's work and individual research/assessment projects must be carried out independently and any facts and figures that they produce must hold up to peer review and independent scrutiny. The majority of stakeholders responding to the call for evidence survey believed that it was necessary that NICE was at arm's length from Government and welcomed the independence this brings.

Conclusions on delivery model for NICE

3.52 NICE has a wide-ranging and valuable set of functions. Some of these functions cannot easily be moved into a different form if NICE's autonomy and impartiality are to be retained. However, for other functions there may be benefits in operating differently and this should be explored to better understand the advantages and disadvantages involved.

3.53 While moving NICE into the private, academic or charitable sector might offer some opportunities to deliver further efficiencies, these are likely to be relatively small when set against the need for NICE to be able to retain its credibility with stakeholders and the likely disruption, risks and costs associated with a change in delivery model. But, there are possible advantages to moving individual functions, and, as above, these should be explored for a better understanding.

3.54 The majority of evidence received has supported NICE remaining as an Executive NDPB. It has also identified some areas in which NICE can improve delivery such as improving collaboration and engagement. These will be explored in detail in Chapter 6.

3.55 We also considered the three functions against the Cabinet Office tests for whether an arms-length body is appropriate. We found that it fulfils those tests. Therefore, this review recommends that NICE retains its NDPB status.

> **Recommendation 3: That NICE retains its status as an NDPB.**

4. Introduction to stage two

4.1 As the recommendation of stage one is that NICE should be maintained in its current form, this Review now moves on to stage two and considers the NICE's adherence with the principles of good corporate governance and any potential to improve performance or deliver efficiencies.

4.2 No organisation is perfect and Triennial Reviews seek to identify where the organisation can improve, both in the present and for the future. **Chapter 5** considers NICE's performance including its ability to identify and meet the challenges set out briefly in chapter 2. It also considered the constraints NICE is operating under and how it might support the system to make best use of resources in the future.

4.3 NICE is a key player in the health and care system and in order to deliver effectively it must communicate well and collaborate across the health and care sector and with industry and other stakeholders. **Chapter 6** assesses how well NICE communicates and collaborates currently, and where it needs to improve for the future if it is to communicate and engage effectively, build relationships and effectively support the health and care system in meeting its objectives.

4.4 Good corporate governance is central to the effective operation of all public bodies. As part of the review process, therefore, as an Arm's Length Body of the Department of Health, the governance arrangements in place within NICE were reviewed and assessed against the principles and policies set out in the Cabinet Office guidance. These reflect best practice in the public and private sectors and, in particular, draw from the principles and approach set out in the Corporate Governance in Central Government Departments: Code of Good Practice. An assessment of the governance arrangements within NICE can be found at **chapter 7**.

4.5 Efficiency is a key driver in the Triennial Review programme of work and is at the forefront of reviews. There is now a more explicit focus on examining efficiency and effectiveness of public bodies. Whilst this is primarily considered here in **chapter 8**, efficiency has also been addressed in stage one when considering the appropriateness of the delivery model.

5. Optimising the future impact of NICE

KEY MESSAGES

- Despite operating under a number of constraints, NICE is a high performing organisation that is trusted for its evidence-based approach.

- Looking ahead to identify changes, their likely impact and potential responses will support NICE in meeting future challenges.

- Being able to articulate NICE's contribution to improving outcomes in health and care is crucial in demonstrating value.

- NICE's processes and methodologies will need to evolve in order to ensure it is fully aligned with the health and care system.

- System overlaps, such as duplicated cost-evaluations, undermine NICE's role and lead to increased cost, delays and inconsistencies.

- Changes to the way that NICE operates may offer opportunities to help the NHS make best use of limited resources.

Context

5.1   Chapter 2 sets out the context that NICE is working in and the challenges it faces in the future. This chapter considers the key issues identified by the review process and where there are opportunities to improve performance and optimise impact in order to meet these challenges. The review team recognises that NICE is already taking action to address many of these issues.

5.2   This chapter also looks at constraints that may impact on current and future performance and considers how NICE can support the health and care sector in making the most of the limited resources likely to be available in the future.

NICE's performance and impact

5.3   NICE's decisions and products have a significant impact on the system at many levels. For example, the NHS must fund new technologies once approved by NICE which can have a significant financial impact, and NICE's guidelines set out the most cost-effective interventions and practice, which can support the system in delivering an effective service. Therefore, it is crucial that NICE performs highly.

5.4   It was clear from our engagement with stakeholders that most highly valued both NICE's functions and its method of operating. NICE is trusted, robust and open in its approach and has made a positive impact on the health and care system. NICE's products and approach are of international repute and its methodologies considered 'gold-standard' by international stakeholders.

5.5   However, some stakeholders, from across all stakeholder groups, suggested that there were areas where NICE could improve its performance and identified constraints that impinge on NICE's ability to deliver effectively.

Strategic planning and horizon scanning

5.6   NICE is operating in a changing environment. The Five Year Forward View and the Care Act 2014 sets out some of the changes needed to the health and care system; medicines and medical technologies are evolving rapidly and stakeholder and public expectations are growing.

5.7   To support the health and care system in delivering its objectives, NICE will need to be looking ahead to identify changes and challenges and their impact in order to be ready to meet them. These are often not issues that NICE can address by itself and will require open engagement across the health system and beyond.

5.8   The Board and Senior Management Team have covered this theme at meetings and away-days. However, this is not always visible to stakeholders, which affects their

perception of NICE's ability to think strategically and adapt accordingly. Recommendations relating to this issue are covered in chapter 7.

5.9   An example which came up often was around the use of healthcare 'apps'. Software apps have the potential to significantly reduce demands on the health system by supporting patients in monitoring themselves (e.g., heart rate, blood pressure, blood sugar) or supporting clinicians in remotely monitoring patients. Use of apps in this way is already developing but is inhibited by a lack of certainty over safety, accuracy and cost-effectiveness.   Stakeholders perceive NICE to be slow in responding to this emerging market and the benefits it might offer. NICE should ensure it is doing enough in this area and should also do more to publicise its work.

Performance Measurement

5.10   Key Performance Indicators should reflect and support the strategic priorities of an organisation. They help organisations understand how well they are performing in relation to their strategic goals and objectives. Below this, an organisation might use a number of further targets or measures.   There are a wide variety of types of performance indicators but some core examples are:

- **cost**: the money spent to acquire the resources;

- **input**: the resources (staff, materials and premises) employed to provide the service;

- **output**: the service provided, for example, in terms of tasks completed;

- **outcome**: the impact and value of the service delivery.

5.11   NICE uses performance targets and publishes these in the annual business and strategic plan[5]. The targets for 2014-15 are provided at Annex H.

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[5] https://www.nice.org.uk/about/who-we-are/corporate-publications

5.12 These performance indicators are largely related to process or output. They are predominantly measured as a particular number, or percentage, of actions or products within a particular timescale. Such targets are helpful but do not provide a full picture of performance and the value of the activities measured.

5.13 A range of different measures would provide a broader picture of performance and would measure the impact that NICE has. In particular, a number of outcome measures should reflect NICE's core aim of improving outcomes for people using the NHS and other public health and social care services and strategic objectives. For example; as well as measuring the number of guidelines it produces, NICE should also measure the take up of recommendations and compliance with guidelines in a way that provides tangible measures of success. This is a very challenging ask as such measures are not always entirely within the control of NICE. However, NICE's actions should be able to influence and support the desired outcome. NICE should work with the Department and NHS England to develop a series of measures that assess its effectiveness in delivering its aims.

Alignment

5.14 While NICE is currently considered a high performing organisation, its processes and methodologies will need to evolve to meet the challenges of the future. Some of these challenges were set out in chapter 2 and include:

- **Financial constraints**: the health and care system has seen a reduction in the levels of funding available and this is likely to continue

- **Patterns of disease**: multi-morbidities and non-communicable diseases, are becoming more prevalent and require different methods of treatment.

- **Technological advances:** medicines and medical technologies are changing and evolving rapidly with developments in stratified and personalised medicines, mobile health (m-health) and electronic health (e-health).

- **Integration and emerging new models of care**: as set out in the Five Year Forward View and Care Act 2014.

5.15 NICE's processes and methodologies will need to evolve in order to ensure NICE is aligned with these changes and able to support the health and care sector and the innovation and growth agenda. For example;

- increasing innovations in medical technologies and digital health care, such as apps, may mean that current timescales on appraisals are too lengthy;

- the increase of personalised and stratified medicines and multi-morbidities mean that assessments may need to be more flexible; and

- constrained finances will require closer examination of how affordable technologies are.

5.16 In addition, we heard from social care and mental health stakeholders that they perceive NICE to be overly reliant on randomised control trials (RCTs). While RCTs are considered the most robust and reliable form of evidence available, they are not readily available in every area that NICE assesses and may be of limited use. NICE includes other sources of evidence in its assessments as it can be more applicable or robust in certain areas, but a failure to make this known sufficiently reduces NICE's credibility.

Implementation

5.17 NICE has a small team responsible for supporting implementation of its guidance. The team provides strategic advice and context to help senior management teams in NHS, public health and social care organisations work with NICE guidance, sharing best practice and offering advice.

5.18 This resource is appreciated but implementation of NICE's guidance is patchy. This can result in guidelines not being implemented and the most cost-effective treatments and processes not being followed. Many stakeholders expressed their view that this could be improved if NICE did more to support, incentivise or monitor implementation.

5.19 There were three main views on NICE's role regarding implementation:

- NICE should do more to support implementation; including increasing the size of the current team and doing more hands on implementation support.

- NICE should have the power to incentivise or enforce implementation; monitoring to make sure implementation happens.

- Implementation is a system-wide issue and NICE should work with other organisations to improve take up.

5.20 In a time of limited financial resources it is important that the most effective and cost-effective practice is implemented consistently to reduce wastage and improve outcomes. However, the review team considers that this is not a role for NICE to deliver alone. Instead NICE should work with other health and care system leaders to influence players in the system, align the approach to implementation and share the responsibility of ensuring that organisations are supported to implement NICE guidance and recommendations.

Constraints

5.21 NICE is operating under a number of constraints.

The health and care system

5.22 The health and care system has many players, some new following the implementation of the 2012 Health and Social Care Act. Stakeholders perceived that there is little clarity around system roles and responsibilities and that this not only acts as a barrier to NICE achieving its aims but also results in duplication and waste and reduces innovation.

5.23 NICE has a pivotal role in promoting integration across the system and supporting the introduction and diffusion of innovative and cost-effective practice. In order to do this it needs to work collaboratively to promote system engagement; this is explored in more detail in chapter 6.

5.24 Stakeholders from several different groups (industry, the health and care sector, patient groups and charities) recognised, and were concerned by what they perceived as duplication or overlap of responsibilities in the health system. The main area for concern is cost-assessments at a national or local level, such as the Cancer Drugs Fund (CDF) or CCG level cost-effectiveness assessments.

Economic evaluations at a national level

5.25 The CDF was set up in 2010 to provide additional money to enable patients to access cancer drugs that would not otherwise have been routinely available from the NHS. Stakeholders believe the CDF to be unnecessary, a waste of resource and lacking stability. There was a consensus among those who contributed evidence to the review that it undermines the purpose of NICE and that NICE should administer the evaluations for cancer drugs.

5.26 NHS England conducts other evaluations, such as for specialised commissioning and medicines for rare diseases. Stakeholders report that this too is unhelpful. NICE is known for its open approach and NHS England's decision-making process suffers by comparison. There have been instances where NICE and NHS England have planned to review the same drugs and technologies in parallel. The different processes, requirements and formats are unhelpful as they result in inconsistences, increased bureaucracy, increased cost and a delay in patients being able to access the medicines and technologies they need.

5.27 The Joint Commission for Vaccinations and Immunisation (JCVI) also conducts economic assessments. This was less visible to stakeholders but those who did raise the overlap between NICE and the JCVI pointed out the operational delivery element that JCVI undertakes as a legitimate reason for the overlap of functions, nevertheless, there is a feeling that this overlap should also be reconsidered.

Economic evaluation at a local level

5.28 CCGs, Commissioning Support Units (CSUs) and other NHS organisations can conduct economic evaluations on drugs, effectively conducting a reassessment,

usually to establish the budgetary implications of NICE decisions. These often happen 'under the radar' and are delivered informally. Stakeholders feel these multiple approaches lead to a disjointed, wasteful and often inconsistent system that creates unnecessary hurdles, delays patient access and wastes resources.

5.29 Overall, there is a potentially strong case for having one expert organisation conduct all appraisals (national and local) of clinical and cost effectiveness on health interventions, drugs and vaccinations / immunisations for the health and care system.

Supporting the system to make best use of resources

5.30 In a challenging financial climate it is all the more important that NICE supports the health and care system to make the best use of resources.

5.31 NICE is currently developing proposals setting out how it can better support the health and care sector with decommissioning services and healthcare processes that are less effective in order to make space for more cost-effective or innovative services. There may be opportunities to go further in this area, and not only advise on which services to decommission, but also consider whether the health service can afford the new technologies.

5.32 There are other ways that NICE can reflect the resource environment facing the health and care system. For example, there has been debate around whether the Quality Adjusted Life Year (QALY) threshold is the right one. A study by York University[6] suggested that the current threshold is too high and that when NICE recommends the purchasing of drugs at higher prices, funds are diverted from other services. Setting the threshold at a lower price would ensure that only the most cost effective drugs are approved for use in the NHS. However, a reduced QALY threshold may lead to a

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[6] http://www.journalslibrary.nihr.ac.uk/hta/volume-19/issue-14#abstract

reduced number of new treatments making their way into the NHS as prices would be unlikely to drop simply because the threshold is set lower.

5.33 NICE could also consider the service it provides. Currently, it provides a 'gold-standard' service. Offering a more adaptable albeit less rigorous service could mean that NICE could reduce its costs, carry out more appraisals and/or deliver appraisals more quickly. This could result in more technologies being approved for use in the NHS.

5.34 Addressing these issues will require NICE to have the right capability and capacity if they are to adopt the right methodology for the right products and to support the health and care system.

5.35 These issues are outside of the scope of the Triennial Review. However, this does not mean that such matters should not be considered and we recommend that the Department of Health, NHS England, Public Health England and NICE explore these issues following the completion of the Accelerated Access Review, which will consider some of these areas, for example, affordability of NICE recommendations.

Recommendation 4: The health and care system is operating in a time of unprecedented financial constraint and NICE should play an integral role in supporting it to achieve its objectives and make best use of resources. It should do this by:

- Working with the Department and NHS England to develop and publish a set of key performance indicators that reflect strategic objectives and assess the impact of the organisation, and which are supported by appropriate input, output, or other performance targets. [in 2015/16]
- Working with other health and care leaders; especially NHS England, Public Health England and CQC, to align the approach to implementation of NICE guidance and recommendations in order to support organisations in implementation activity. [by end 2015]

Recommendation 5: DH should consider the clinical and cost effectiveness appraisals currently conducted within the health and care system, including (but not limited to) the Cancer Drugs Fund and the Joint Commission on Vaccinations and Immunisation with a view to establishing whether NICE should be the single expert body with responsibility for such appraisals [by April 2016].

Recommendation 6: following the findings of the Accelerated Access Review, the Department of Health and NICE, with input from NHS England, should consider what changes to NICE's methods and processes are necessary to enable the health and care system to make best use of the resources available [by July 2016]

6. Communications, engagement and relationships

KEY MESSAGES

- NICE engages extensively across a wide range of stakeholders who appreciate efforts in this area.

- Adopting a more flexible approach to stakeholder communications and engagement will help NICE better understand and meet the needs of each target audience.

- Increasing NICE's profile, especially with patients, service users and their families and carers and in social care, will maximise opportunities for service user engagement.

- In a system with many players, strong and clearly articulated relationships are important if the health and care system is to reduce duplication, promote co-production and minimise wastage.

Context

6.1   NICE is a key player in the health and care system and in order to deliver effectively it must communicate well, influence effectively and collaborate across the health and care sector and with industry and other stakeholders. With new models of care emerging and traditional structures dissolving, NICE will need to be able to adapt in order to communicate, influence and engage effectively, build relationships and effectively support the health and care system in meeting its objectives. This chapter considers how well NICE is currently engaging across the sector and where changes might need to be made to meet future requirements.

NICE's profile

6.2   The review found that although most stakeholders who responded to the call for evidence or face to face engagement had a good understanding of the functions they were immediately involved with, very few were aware of the full range of functions that NICE delivers. This was especially apparent in the social care sector and with the public. Stakeholders commented that the more they understand about NICE's remit, the more effective they found NICE to be and the more they were prepared to engage with its agenda.

Engaging patients, service users and the wider public

6.3 NICE does a great deal to involve patients, service users, their families and carers in its work through:

- the Public Involvement programme; a team within NICE that develops and supports patient, carer and public involvement;

- the Citizen's Council; a panel of 30 members of the public which provides NICE with a public perspective on overarching moral and ethical issues that NICE has to take account of when producing guidance; and,

- through inviting the public to comment on drafts of guidance or join a committee or working group.

6.4   NICE also attends the Patients Involved in NICE programme, a group comprising over 80 patient organisations that acts as a critical friend and partner in developing and shaping ideas on aspects of NICE's work. This group is not organised or sponsored by NICE.

6.5   NICE seeks feedback from lay members of committees and other members of the public involved in NICE's work through mechanisms such as exit surveys and evaluation forms. Despite positive feedback these approaches are not always successful. Some stakeholders reported that NICE's overly-academic approach made it difficult for organisations to find patients who were suitable to sit on committees and

groups to input into the decision-making process. Overall, there was a sense from stakeholders that patients felt second-best, that their input was not valued as highly as that of clinicians or specialist stakeholders and that NICE could do more to support patients who do get involved.

6.6   Several stakeholders referenced the relatively new Patient and Clinician Engagement stage that the Scottish Medicines Consortium (SMC) has introduced, which is intended to give patient groups and clinicians a stronger voice in SMC decision making as an example of good practice.

Relationships with industry

6.7   Industry stakeholders were generally positive about NICE's efforts to improve communications and engagement.

6.8   However, as before, there is still more to be done. There was a perception that the success of collaboration and engagement depended on the individual contacts and that the approach from NICE was not always consistent.

6.9   Several reported a lack of consistency in engaging with NICE, with some teams building excellent relationships through being open and transparent while others were less good. Many stakeholders would like better collaboration throughout the process of technology assessments, believing that more engagement early on improves transparency.

Engagement with the wider health and care system

6.10   The health and care system has many key bodies, some relatively new having been established in the 2012 Health and Social Care Act. This makes it all the more important that NICE's relationships within the sector are robust so that its impact is maximised. Weak or unstructured relationships can have an adverse effect on what NICE is able to achieve. With changes to established models of care emerging this relationship building and engagement is likely to become both more important and more complex in future years.

6.11 NICE goes to a great deal of effort to communicate and engage across the health and care sector but this is not always regarded as successful and it was felt improvement was needed.

Engagement with Social Care

6.12 Providers of social care services are diverse with the vast majority of social care now delivered in the independent and private sector rather than the public sector. Also, services are not just delivered in care homes but a big part of the delivery is via domiciliary care in people's homes. The diverse nature of the social care provision means there are big challenges for NICE in getting across its messages to the sector and influencing the various players in implementing NICE guidance and recommendations. Social care stakeholders reported that knowledge of NICE in this sector was low and that NICE does not yet communicate effectively with this audience. NICE recognises this as a challenge, partly due to the sheer size and diversity of the sector and because this is a relatively new area for NICE, which took on responsibility for social care in 2013. However it is important for NICE to impact on the social care sector if we are going to see improvement in the level of care across the health and care system.

6.13 While most social care stakeholders appreciated NICE's efforts to improve the level of communication, there were criticisms of NICE's approach to developing products for this group. It was felt that NICE's academic and evidence-based methodology, while suitable for health-related products, was not appropriate for social care. The solid evidence base available in health is missing in social care, the structures are different, meaning that the social care workforce finds it more difficult to be actively involved with NICE, and communications require a different approach. This means that NICE needs to be more flexible in how it communicates with, and develops products for, this sector to meet its needs.

6.14 NICE is well aware of these issues and is working with stakeholders to develop better engagement.

MHRA

6.15 Relationships with regulators were largely considered effective. However, we heard a repeated message that NICE and MHRA need to be more joined up and work together more effectively.

6.16 Examples of this disconnect can be found in a 2013 report from the Committee of Public Accounts, which raised concerns about information from clinical trials being provided by industry to the MHRA but not being routinely shared with NICE or with doctors and researchers.

6.17 Communications between NICE and MHRA have been improving since these issues arose and last year the two organisations signed a Partnership Agreement, which will be reviewed annually. However, while relationships between senior staff in each organisation are considered good, communication and engagement is less effective at lower levels and working relationships are not always visible to stakeholders.

Health and care organisations

6.18 Many stakeholders reported a lack of clarity surrounding the roles and responsibilities of bodies in the system, which acted as a barrier to NICE's work, resulting in duplication, delays and waste of resources.

6.19 Three areas were specifically mentioned:

- relationships between NICE and NHS England and Public Health England, where it was felt that the areas of co-operation and demarcation of responsibilities could be clearer. More co-branding and co-production would be welcomed;

- relationships with the NHS Trust Development Agency and Monitor, where closer working would help NICE to better understand the impact of their work on the sector;

- routes of engagement with CCGs and local government, where NICE could do more to explain its role and build relationships and seek input.

6.20 Primary care stakeholders also suggested relationships between general practitioners and NICE were patchy and that greater engagement with the end-users of NICE clinical guidelines would greatly improve awareness, understanding and impact.

6.21 NICE has partnership agreements and memoranda of understanding with a number of arm's length bodies and organisations in the system. These set out the nature and extent of the working relationships between the bodies but are often written from an internal perspective. There is an opportunity to revisit these with the relevant organisations to identify areas that need to be strengthened or amended with the external perspective and stakeholders in mind.

International engagement

6.22 The review asked international stakeholders for their views on NICE. We found that NICE's international reputation was very high, with many countries considering them world-leading both in their approach and relationships with industry. Informal relationships between NICE and equivalent/similar international bodies were largely positive, although NICE's willingness to engage formally in international committees was raised as a concern by one or two. Other UK nations also considered there could be improvements to the formal engagement between organisations, with one suggesting that NICE appeared unwilling to adapt or consider new methodologies.

Conclusions

6.23 NICE has strong and robust relationships with stakeholders but there are areas where communications and relationships can be improved if NICE is to continue to engage effectively and maximise its influence across the system, especially as changes to the way services are delivered evolve and are implemented.

Recommendation 7: In order to work effectively in an evolving health and care system, NICE should increase its profile, work more flexibly and further develop relationships across the system by: analysing awareness of its profile across the stakeholder landscape, including with patients, service users, their families and carers and in social care, and developing actions to increase awareness of its role and functions [by April 2016].

Recommendation 8: NICE should continue to work with patient groups to make its approach to supporting patients more transparent, identifying where it can provide more support to those participating in the work of NICE [throughout 2015/16].

Recommendation 9: NICE should continue to improve communications and engagement work with social care stakeholders, including exploring whether alternative approaches to developing products would better fit the audience's needs [throughout 2015/16].

Recommendation 10: NICE should work with the MHRA to review the partnership agreement and consider publicising both the agreement and steps taken to ensure the principles are put into practice throughout all levels of the organisations [by April 2016].

Recommendation 11: NICE should work with NHS England to identify systems and processes, with associated metrics where appropriate, to secure the application of commitment in the Partnership Agreement to using NICE guidance in the centralised and devolved commissioning arrangements [by July 2016].

Recommendation 12: NICE should work to further enhance relationships with organisations across health and care, clarifying areas where roles and responsibilities could be made clearer to stakeholders.

7.   Governance and accountability

KEY MESSAGES

- NICE complies with the principles set out in the good corporate guidance.

- The board would benefit from additional commercial and health economic expertise and a more explicit strategic and forward looking approach.

- Action should be taken to ensure the transparency and consistency of the expert and advisory groups and committees

Context

7.1   Good corporate governance is central to the effective and efficient running of all public bodies. This chapter outlines the findings of the review team in relation to:

i.   NICE's performance against the principles set out in the 'Guidance on principles of Good Corporate Governance in Executive NDPBs[7].'

ii.   NICE's governance of advisory committees which are set up to develop evidence-based guidance

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[7] https://www.gov.uk/government/publications/public-bodies-information-and-guidance

NICE and the principles of good corporate governance

7.2   Every arm's length body needs clear arrangements for overseeing its strategic direction, performance monitoring and review. The variety of organisations means that one solution will not fit all and departments, in discussion with the arm's length body, are able to decide on the precise structure of governance arrangements as long as the key principles are met. Such arrangements are then normally outlined in the Framework Document[8].

7.3   A recent report by the House of Commons, Public Administration Select Committee[9] noted the increase in the Cabinet Office's interest in public bodies, and the exercise of oversight and control by sponsor departments.

7.4   Cabinet Office guidance states that Triennial Reviews must assess the controls, processes and safeguards in place against the principles and supporting provisions set out in the Code of Good Corporate Governance. The Cabinet Office publishes a range of guidance on governance issues for public bodies[10].

7.5   The full assessment for each principle is detailed at Annex I and is based on analysis of the review team with input from NICE.

7.6   Overall NICE is fully compliant with all of the principles. However, the review noted some areas which require attention and recommend that NICE and the Department address these in the near future. The sections below highlight particular issues in relation to the various principles and make a number of recommendations.

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[8] https://www.nice.org.uk/Media/Default/About/Who-we-are/NICE-and-Dept-of-Health-Framework-Agreement-March-2014.pd

[9] *Who's accountable? Relationships between Government and arm's-length bodies* - House of Commons, Public Administration Select Committee, First Report of Session 2014–15

[10] www.gov.uk/government/publications/public-bodies-information-and-guidance

Accountability

7.7 NICE complies with all statutory accountability requirements. The Chief Executive is formally appointed as the Accounting Officer, with the role and responsibilities clearly set out in a draft Framework Agreement[11] between NICE and the Department. The responsibilities of the CEO as Accounting Officer are set out in the Standing Orders.

7.8 The Secretary of State appoints the Chair and all other non-executive board members. The relevant departmental minister holds an annual accountability meeting to review the performance and strategic development of NICE.

7.9 The Permanent Secretary has appointed a Senior Departmental Sponsor (SDS, at Director General level) to provide regular senior level contact between the Department and NICE. In this role the SDS supports the Permanent Secretary in holding NICE to account and providing assurance on performance. The SDS has quarterly accountability meetings with the Chief Executive and is responsible for agreeing NICE's annual business plan and priorities.

7.10 The SDS uses the quarterly accountability meetings to assess performance and can escalate any concerns to the Permanent Secretary if necessary. If NICE were to fail to comply with any requirement to address performance issues the Secretary of State would be able to make arrangements for another body to exercise the functions on his behalf.

7.11 This process sets out clear lines of accountability for the Chief Executive. However, the Chief Executive (as Accounting Officer) will also be accountable to the Permanent Secretary (as Principal Accounting Officer), and also directly to the Secretary of State and Parliament, for the Agency's performance and use of public funds.

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[11] https://www.nice.org.uk/Media/Default/About/Who-we-are/NICE-and-Dept-of-Health-Framework-Agreement-March-2014.pd

Role of the sponsor department

7.12 In addition to the SDS who holds quarterly meetings with NICE, there is a Departmental sponsor team which has regular contact with NICE and attends regular board meetings as an observer. The sponsor team is supported by sponsorship standards and a sponsor guide, and all sponsors receive induction.

7.13 The framework agreement[12] between the department and NICE sets out clear accountability arrangements and the roles and responsibilities of senior parties in both organisations and is reviewed every three years (or sooner, on the request of either party).

7.14 It was clear from the evidence provided to the review team that NICE value the senior departmental sponsor relationship, which provides opportunities for NICE to influence departmental strategy setting. Board members reported feeling supported by the Department and the sponsor team, and both NICE and the Department provided evidence to demonstrate that the ongoing relationship was sufficiently robust, supportive and challenging.

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

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

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

7.17 NICE's board provides leadership and strategic direction for the organisation and is made up of non-executive and executive members. The joint board is collectively

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[12] https://www.nice.org.uk/Media/Default/About/Who-we-are/NICE-and-Dept-of-Health-Framework-Agreement-March-2014.pd

accountable, through the Chair, to the Secretary of State for the strategic direction of NICE, for ensuring a sound system of internal control through its governance structures and for putting in place arrangements for securing assurance about the effectiveness of that system.

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

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

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

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

7.22   We also asked stakeholders whether NICE could improve its performance in any specific areas. In relation to the board, there were suggestions that stakeholders did not see the board as actively identifying and responding to future changes in the health

and care landscape and how it might impact NICE. The review team looked at minutes of board meetings and found that these issues were discussed, nonetheless, the perception remains and this is an area that NICE will want to be aware of in the future.

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

7.24 NICE holds monthly board meetings, six of which are held in public. Meetings consider reports on strategic issues facing NICE and its performance against business targets. In addition, the board reviews finance reports, the business plan, project-specific papers on major developments, reports from all directors on activity within their departments and reports from board committees, such as the Audit and Risk Committee.

The senior management team

7.25 Day to day running of the organisation is carried out by the senior management team, led by the CEO, Sir Andrew Dillon, supported by the Deputy CEO and five directors. The CEO is appointed by the NICE board with the appointment being approved by the Secretary of State.

7.26 The CEO is directly accountable to Parliament and the public for ensuring proper stewardship of public funds and assets, plus has an accountability line to the DH's Principal Accounting Officer. The CEO is also held to account by the NICE Chair for the day-to-day operation and management of NICE and for ensuring the organisation meets the standards required (in terms of governance, decision-making and financial management) set out in Managing Public Money.

7.27 All executive directors are appointed on a permanent basis under a contract of service at an agreed annual salary with eligibility to claim allowances for travel and subsistence costs, at rates set by NICE, for expenses incurred on its behalf.

Effective financial management

7.28 NICE complies with all statutory and administrative requirements on the use of public funds.

Communications

7.29 NICE is open, transparent, accountable and responsive.

7.30 NICE's charter sets out the core principles for how NICE works. All of NICE's products are developed taking into account the opinions and views of the people who will be affected by them, including patients, carers and members of the public, as well as health and social care professionals, NHS organisations, industry, social care businesses and local government. NICE conducts extensive consultations which allow stakeholders to comment on recommendations; guidance is created by independent and unbiased advisory committees which include a diverse range of experts and NICE works with manufacturers in delivering technology assessments.

7.31 In line with NICE's commitment to transparency the relevant information on board members, performance, expenditure and complaints are published online along with minutes of the public board meetings.

Conduct and behaviour

7.32 NICE works to the highest personal and professional standards.

NICE's governance of its expert committees

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

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

Area of concern	Issues
Transparency	• Stakeholder criticised the lack of transparency in recruiting members and chairs of the committees. • Despite NICE's extensive work in engaging patients and the public (for example, through its Public Involvement Programme) stakeholders expressed a lack of clarity on how patients could be included on panels and, when rejected, why patients were not successful in meeting the criteria. • A point repeated more than once was that possible conflicts of interests were not handled transparently – for example, panel members, who may be submitting their research to the group or committee may also have the role of deciding which research is eligible for inclusion. • It was not always clear how decisions were arrived at.
Consistency	• Stakeholders felt a lack of consistency in the governance of groups and committees is leading to variations in quality, for example: differing decisions on similar medicines due to the different processes adopted. • Feedback from workshops and interviews suggested that the approach to NICE's governance of each committee or group was dependent on the NICE member of staff responsible for the group.
Accountability	• Some stakeholders felt that NICE did not hold the committees and groups to account sufficiently, being unwilling to challenge decisions or elements of decisions, of groups and committees robustly enough, leading to appeals.

7.35 NICE should ensure that independent advisory committees and groups are robust and transparent in order to address these concerns.

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

- Arrange an independent assessment of the effectiveness of the Board which gives consideration to whether additional expertise is required and how future thinking becomes an integral part of the Board's activity [by April 2016].
- Ensure that the arrangements for operating and quality controlling the work of the independent advisory committees are robust and transparent, publishing these arrangements where feasible.

8. Efficiency

KEY MESSAGES

- NICE is proactive in driving down costs and recognises the need to identify and implement further efficiencies.

Context

8.1　It is important to consider the performance of NICE in the context of the financial regime in which it operates, its expenditure under various functional categories, the income it generates and who pays this and the potential for future changes.

Income, expenditure and other sources

8.2　NICE receives most of its funding directly from the Department of Health. This funding is known as grant-in-aid and is split into two key components:

- Administration funding (used for non-frontline activities and support activities, such as the provision of policy advice, scientific support), and

- Programme funding (costs incurred in providing frontline activities such as direct patient care).

8.3　The grant-in-aid funding is mostly classified as administration funding although there are some exceptions (such as the British National Formulary (BNF)).

8.4　NICE also receives income from other sources (such as the devolved administrations; Health Education England and NHS England) and operates some services on a cost recovery or charged for basis – for example; NICE International and NICE Evidence Services. These two services generated just over £2m in 2014-15. Both teams have been in operation for just over 5 years and continue to grow in a stable and sustainable way.

8.5   There may be an opportunity for NICE to generate income through charging for health technology assessments. We heard from stakeholders that charging the pharmaceutical industry for health technology assessments could offer opportunities to generate revenue and streamline processes. This will be explored further as part of an assessment of the whole system under the Accelerated Access Review.

8.6   In line with Cabinet Office and HM Treasury guidelines, the Department of Health has required NICE to consider how and where it can make savings. Since 2010-11, NICE has seen its baseline administration funding reduced by an average of £3.2m (5%) each year. In 2015-16 NICE will receive £2.2m or 4% less than in 2014-15.

	2013-14 £m	2014-15 £m	2015-16 £m
Sources of Funding			
Administration (Recurrent Baseline)	54.6	55.4	53.1
Administration (New recurrent funding)	2.8	-	-
Administration (Non-recurrent funding)	0.1	0.2	-
Programme (Recurrent Baseline)	8.9	8.9	8.9
Income from Devolved Admins	2.0	2.0	2.0
Income from Health Education England	1.9	2.1	2.1
Income from NHS England	0.7	1.2	1.2
Other Income	-	-	0.2
Non-Cash Funding - Depreciation (Baseline)	0.7	0.9	1.0
Total Sources of Funding	**71.7**	**70.7**	**68.5**
Application of Funds			
Guidance and Advice	56.8	56.4	54.6
Corporate	12.1	12.4	12.4
Contingency reserve	0.7	0.2	0.5
Depreciation Charges	0.7	0.9	1.0
Revenue to Capital transfer	-	0.8	-
Total Applications of Funding	**70.3**	**70.7**	**68.5**
Net Position (- surplus / + deficit)	-1.4	0.0	0.0

8.7   As well as receiving reduced grant-in-aid funding, NICE has also agreed to absorb the cost of several new programmes (staff-staffing guidance, highly specialised technologies and public health quality standards). This has required NICE to make additional cost savings.

8.8   NICE has adopted a proactive approach to achieve the savings target, working to identify strategic savings initiatives without impacting on the quantity and quality of products. These initiatives include reviewing current contracts and looking at ways of reducing the volume of contracted out work or bringing some activities in house, reviewing pay budgets and team structures, including removing vacant posts and closing the Liverpool office in 2013.

Staffing

8.9   NICE employs around 638 staff, based in London and Manchester. See Annex J for the staff numbers by directorate.

Planned efficiencies

8.10 Identification and implementation of savings measure continue. These include:

- Negotiating a sub-lease at the Manchester office with another government body that will provide a significant new income stream of around £300,000.

- Reviewing further opportunities for bringing work in-house if it can be done at lower cost (for example evidence reviews currently performed by universities and other research institutions).

- An ongoing Guidance Development project aimed at harmonising guidance production methods across the Institute is expected to yield efficiencies in time and resource requirements.

- Identifying income generation opportunities, including the syndication of NICE content overseas and some employees becoming more active participants in academic research that is funded through grants, and expanding existing income generating activity of NICE International and Scientific Advice programme.

Benchmarking

8.11 NICE continues to review the costs and resources applied to its corporate 'back-office' functions with the aim of remaining below all the mean benchmarks identified in the 'Benchmarking the back office: Central Government' report[13] as well as maintaining the quality of the corporate functions provided. The finance and HR teams are now predominantly located in Manchester where costs are lower. NICE currently outsources a variety of back office functions to NHS Shared Business Services to help achieve these efficiencies.

Technology/digitisation

8.12 Since 2011-12 all dissemination of guidance has been 100% digital saving the organisation around £250,000. NICE do not print anything for dissemination purposes with the exception of the BNF. NICE still fund the printing of an annual publication of the BNF, but have been steadily reducing volume based on level of use and returns and are developing electronic routes for users.

Channel shift in the production of guidance

8.13 Document supply (accessing the full text of bibliographic references) is still primarily paper based. NICE receive paper copies of articles from the British Library because this has historically been cheaper. However, due to changes in the pricing NICE is in the process of reviewing document supply providers and processes to identify savings. This will result in an increased electronic supply of bibliographic references over the next 3 years.

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[13] https://www.gov.uk/government/publications/back-office-benchmark-information-2009-10

8.14 Significant numbers of documents are printed and mailed to advisory committees. NICE plans to extend all guidance programmes a recently introduced system to support Technology Appraisal Committees that allows secure electronic access and input to documents and consultations.

Property

8.15 The majority of NICE's staff (68%) is based in City Tower, Manchester – a strategic hub for public sector office accommodation in the North West. The remainder are based in Central London or are home-workers.

8.16 Flexible use of all workstations has enabled NICE to make better use of space and arrangements are in train to sub-let space to another Government body. This will not only bring in additional revenue but will also enable NICE to fall below the mean benchmarks for the space per person in their Manchester office. The London based staff share at a ratio of 80% desks to staff in post and the space per person is 7.4 sq. metres.

Shared services

8.17 NICE currently outsources a variety of back office functions to NHS Shared Business Services and Crown Commercial Services such as occupational health and staff assessment services and facilities management.

8.18 During evaluation of Independent Shared Service Centre 1 (ISSC1) in 2014, the business case for the DH and its ALBs to collectively move to ISSC1 was not found to be viable. Accordingly, the Department wrote to ALBs informing them of this, reminding them that they could consider joining ISSC1 independently and also restating the expectation that all organisations needed to plan to deliver year on year efficiencies in their back office functions, so they should continue to explore all options available.

8.19 The Department is currently reviewing its options with respect to ISSC2, looking at the delivery of its own functions. At present, the scope of the project only includes the Department itself and not its arms-length bodies. However, where it identifies possible

opportunities to align requirements or assess functionality in conjunction with ALBs, it will explore these if appropriate.

Comparisons with other bodies

8.20 NICE aims to meet or exceed the mean benchmarks identified in 'Benchmarking the Back Office: Central Government report' and plans the following for 15-16:

Function	Cabinet Office Benchmark	NICE 2015-16 Plan
HR	50:1 ratio of staff to HR employee.	80:1
Finance	Cost of the finance function equates to 1.9% of total funding	1%
IT	Cost of IT equates to 4% of total funding	1.6%

8.21 As part of the review we attempted to benchmark NICE functions against agencies carrying out one or more similar functions in other countries. Due to the wide range of functions, the differences in health systems and other factors, we were unable to get information that would allow these comparisons. That doesn't mean that this is impossible and more efforts should be made to understand whether NICE is performing efficiently compared to other organisations that conduct similar functions.

Procurement and common goods

8.22 NICE manages its procurement through a single procurement unit and makes use of central government frameworks wherever appropriate. It complies with the target of 18% of procurement spend to be with small and medium enterprises (SMEs) by 2015, uses Government Lean sourcing principles for all significant procurements and undertakes most procurements within 120 days. NICE is aware of the Greening Government agenda and complies with Government buying standards as well as using central contract solutions where appropriate for procurement of common goods and

services. NICE also conforms to the Efficiency Reform Group controls and procedures where applicable.

8.23 NICE currently holds 6 contracts over £5m (see Annex K). There may be opportunities to renegotiate major contracts between 2015 and 2019 which relate to collaborating and guideline centres. NICE will negotiate contracts where possible, for example when extending contracts to ensure it is obtaining good value for money.

Recommendation 14: In order to explore opportunities for further efficiencies:

- The Accelerated Access Review should consider the advantages and disadvantages arising from charging industry for health technology appraisals and medical devices and diagnostics evaluations
- NICE should investigate the possibility of benchmarking functions with international comparators. [By July 2016].