



BRIEFING PAPER

Number 7970, 9 June 2017

NHS Commissioning of Specialised Services

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Summary

NHS specialised services, those providing treatment for rare conditions or requiring specialised teams, are commissioned differently in England to most NHS care. Due to the highly specialised nature of services, the relatively small number of hospitals providing some treatments, and the small number of patients accessing these services, they are coordinated and commissioned nationally by NHS England.

This briefing looks at how decisions are made on which treatments are routinely commissioned for rare or specialised conditions, and what evidence and expertise is used to assess the clinical and cost effectiveness of specialised services.

It also examines some recent controversial specialised commissioning decisions, such as those on HIV Pre-Exposure Prophylaxis (PrEP) and on second stem cell transplants for conditions including a number of rare blood cancers.

In 2016 the National Audit Office and the Public Accounts Committee highlighted a number of criticisms of the specialised commissioning process, including its lack of transparency in decision-making and its financial management. These are examined further in this briefing, as well as recent NHS England reforms to improve, such as closer alignment with the National Institute for Health and Care Excellence (NICE).

Another area of specialised commissioning that has undergone substantial reforms is the Cancer Drugs Fund, which is Government funding to access cancer treatments that have potential for routine commissioning, but where there remains uncertainty about their clinical effectiveness. This briefing looks at the reform of the Cancer Drugs Fund and criticisms of the old system, including its ability to stay within its budget and its lack of effective data collection.

Health is a devolved policy area. Although this briefing largely focuses on specialised services in the NHS in England, it also briefly explores the situation in the NHS in Scotland, Wales and Northern Ireland, as well as some UK-wide links in the provision of specialised services.

1. Commissioning NHS services (England)

Commissioning is the securing of NHS services to meet patients' health needs. NHS England defines commissioning as:

At its simplest, commissioning is the process of planning, agreeing and monitoring services. However, securing services is much more complicated than securing goods and the diversity and intricacy of the services delivered by the NHS is unparalleled.

Commissioning is not one action but many, ranging from the health-needs assessment for a population, through the clinically based design of patient pathways, to service specification and contract negotiation or procurement, with continuous quality assessment.

There is no single geography across which all services should be commissioned: some local services can be designed and secured for a population of a few thousand, while for rare disorders, services need to be considered and secured nationally.¹

Since 1 April 2013, under the *Health and Social Care Act 2012*, responsibility for commissioning has largely been divided between three organisations:

- The majority of healthcare commissioning is the statutory responsibility of 209 local Clinical Commissioning Groups (CCGs). Their commissioning responsibilities include urgent and emergency care, such as A&E, elective hospital care, and community health services:
- NHS England is responsible for commissioning some services centrally, including primary care and **specialised services**
- In addition to CCGs' and NHS England's commissioning roles, local authorities also have statutory commissioning responsibilities for public health services.

More information can be found in the Commons Library briefing paper, [The structure of the NHS in England](#)

In planning how best to allocate resources, CCGs and NHS England can set policies on whether or not to routinely commission certain treatments, based on clinical and cost effectiveness. However, in setting these policies, they are not able to impose a blanket ban on providing a particular treatment. Where clinicians feel it is appropriate for patients, they can submit an Individual Funding Request (IFR) asking that that CCGs or NHS England consider funding the treatment in individual cases, based on individual circumstances. More detail on IFRs is available in a 2015 NHS England guide, [Individual funding requests - A guide for patients and service users](#).

In addition, where the National Institute for Health and Care Excellence (NICE) recommends that a treatment should be routinely commissioned, commissioners are legally obliged to provide funding for it.

¹ NHS England, [NHS Commissioning](#), last accessed 18 May 2017

2. Commissioning specialised services (England)

2.1 Specialised services

Specialised services are those provided in relatively few hospitals, accessed by comparatively small numbers of patients. These patients usually have rare conditions or need specialised teams providing coordinated care.

A 2016 National Audit Office (NAO) report into specialised services found that in 2015/16 NHS England provided 146 specialised services, including organ transplants, radiotherapy, secure mental health services, genetic services, renal dialysis and gender identity disorder services.

Some specialised services are provided in specialised hospitals, such as the Royal National Hospital for Rheumatic Diseases and the Walton Centre (neurology), whilst other services, such as chemotherapy, are provided in most acute hospital trusts.

Specialised services are commissioned centrally by NHS England through ten regional commissioning hubs (North West, South West, Wessex, Yorkshire and the Humber, West Midlands, North East, London, South East, East of England and East Midlands).

The specialised commissioning budget for 2017/18 is £16.4 billion, 14.9% of the total NHS budget.

Although health is a devolved policy area, there is some UK-wide cooperation on specialised commissioning, largely through the Rare Diseases Advisory Group (RDAG). RDAG makes recommendations to the NHS in all four nations on their implementation of the 2013 [UK Strategy for Rare Diseases](#), as well as making recommendations to the Clinical Priorities Advisory Group in England (see section 2.3) on how specialised services should be commissioned.

2.2 NICE highly specialised technology evaluations

NICE produces recommendations, known as technology appraisals, on whether or not treatments should be routinely commissioned on the NHS. It describes the appraisal process as follows:

NICE is asked to look at particular drugs and devices when the availability of the drug or device varies across the country. This may be because of different local prescribing or funding policies, or because there is confusion or uncertainty over its value. Our advice ends the uncertainty and helps to standardise access to healthcare across the country.²

It also undertakes separate appraisals for specialised services, known as highly specialised technology (HST) evaluations. These have a higher cost effectiveness threshold than technology appraisals.

² NICE, [NICE technology appraisal guidance](#), last accessed 18 May 2017

An appraisal or evaluation can classify a treatment, drug or device as 'recommended' (to be routinely commissioned), 'optimised' (to be commissioned in certain circumstances), 'only in research' or 'not recommended'.

Under the NHS Constitution, the relevant commissioning body (NHS England in the case of specialised treatments) is legally obliged to fund treatments recommended by NICE within three months of the publication of the technology appraisal or HST evaluation (or longer, if a different time period is specified).³

As well as looking at the clinical effectiveness of a treatment, technology appraisals and HST evaluations also assess its cost effectiveness. This is usually measured in terms of the cost per additional Quality-Adjusted Life Year (QALY) that the treatment provides. QALYs are a measure of the years of life remaining for a patient, weighted on a quality of life scale. One QALY is equal to one year of life in perfect health.⁴

Following changes introduced in April 2017, NICE set a maximum additional QALY threshold of £300,000 for highly specialised treatments, under which they will automatically be approved for routine commissioning. This is ten times higher than the standard NICE threshold of £30,000 for non-specialised treatments.⁵

The threshold was originally proposed at £100,000 in the consultation, but was increased following concerns raised by stakeholders including the Cystic Fibrosis Trust and the Cancer 52 group.⁶

Treatments that cost more than £300,000 per additional QALY can still be assessed through NHS England's Annual Prioritisation Process (see section 2.3).

Although NICE technology appraisals and HST evaluations assess cost effectiveness, they do not assess affordability in terms of overall cost to the NHS of routinely commissioning a treatment. The NAO argued that as commissioners have no choice whether or not to commission a NICE-approved treatment, this makes it difficult for them to negotiate a good price with manufacturers.⁷

In its 2016 report, the Public Accounts Committee recommended that NICE and NHS England should collaborate to ensure that affordability is considered when making decisions on specialised services.⁸ The Government agreed with this recommendation, and noted that NICE had published proposals for reform of the process in October 2016.⁹

³ Department of Health, *NHS Constitution for England*, July 2015, p7

⁴ NICE, *Glossary: Quality-adjusted life year*

⁵ NICE, *NICE gets go-ahead to fast track more drug approvals*, 15 March 2017

⁶ NICE, *Consultation on changes to technology appraisals and highly specialised technologies: Analysis of responses to the consultation*, March 2017, pp30-2

⁷ NAO, *The commissioning of specialised services in the NHS*, 27 April 2016, HC 950 2015-16, para 2.12

⁸ Committee of Public Accounts, *NHS specialised services*, 15 July 2016, HC 387 2016-17, recommendation 5

⁹ HM Treasury, *Treasury Minutes: Government responses to the Committee of Public Accounts on the Thirty Seventh and the Thirty Ninth reports from Session 2015-16*:

Following changes introduced in April 2017, NICE can now allow for a phased introduction of any new treatment that may have a substantial impact on the NHS budget, for a period of usually no more than three years (as opposed to the three month standard set out in the NHS Constitution).¹⁰

2.3 Annual Prioritisation Process

For treatments that are not being considered under a NICE technology appraisal or HST evaluation, NHS England can assess whether these should be commissioned under its own commissioning process. The decisions for all treatments considered this way are announced on an annual basis, depending on their clinical effectiveness and expected cost to the NHS.

For treatments assessed as cost-neutral or cost-saving for the NHS, these are processed as In Year Service Developments (IYSD), and assessed for routine commissioning based on their clinical effectiveness.

For treatments with an associated cost to the NHS, these are assessed under NHS England's Annual Prioritisation Process (APP), assuming that the total cost of introducing all the treatments exceeds the remaining specialised services budget for the year.¹¹

As part of this, the Clinical Priorities Advisory Group (CPAG) submits recommendations to NHS England on the clinical effectiveness and cost effectiveness of these treatments.

CPAG's recommendations are then considered by NHS England's Specialised Commissioning Oversight Group (SCOG) to assess the financial resources available for the APP and to determine the impact of any decisions to commission the treatments.

SCOG's analysis is used by the Specialised Services Commissioning Committee (SSCC) to rank the treatments in terms of cost-benefit and decide which treatments will be routinely commissioned. Treatments that will not be routinely commissioned can still be commissioned on an individual patient basis. In addition, these treatments will be assessed again as part of the following year's APP.¹²

As part of moves to bring together NICE's appraisal and evaluation processes and the APP (see also section 2.2), NICE will provide a summary of available clinical evidence as part of the process. According to a May 2017 report in the *Health Service Journal*, NICE will also start to provide information on the financial impact of new treatments. This evidence will be used by CPAG, SCOG and SSCC to help inform their decisions.¹³

[and the First to the Thirteenth reports from Session 2016-17](#), Cm 9351, November 2016, pp54-5

¹⁰ NICE, [NICE gets go-ahead to fast track more drug approvals](#), 15 March 2017

¹¹ [PO 62401](#), 8 February 2017

¹² NHS England, [Clinical Priorities Advisory Group \(CPAG\)](#), last accessed 18 May 2017

¹³ ['Exclusive: NICE to routinely review drugs' budget impact for NHS England](#), *Health Service Journal*, 11 May 2017

2016/17 APP and Pre-Exposure Prophylaxis (PrEP) court case

£25 million was allocated to the 2016/17 APP, for which 22 treatments were considered for routine commissioning.¹⁴ CPAG grouped each treatment into three categories of patient benefit and three categories of cost. These were then used to group the treatments into five levels of cost-benefit.

It was announced in July 2016 that the 18 treatments placed in the first four levels would be routinely commissioned, but that this decision was subject to the ongoing judicial review over the commissioning of the Pre-Exposure Prophylaxis (PrEP) for HIV.¹⁵

NHS England had excluded PrEP from the 2016/17 APP on that basis that commissioning of HIV prevention services was the responsibility of local authorities, as this fell under their role as commissioners of public health services.¹⁶

The National Aids Trust (NAT) challenged the legality of this exclusion. It argued that NHS England already commissioned Post-Exposure Prophylaxis (PEP) for patients who were not yet infected, but at risk of infection, and that this was not substantially different from the commissioning of PrEP.¹⁷ In addition, NAT highlighted that in September 2014, NHS England had decided it was responsible for funding PrEP treatment, with local authorities responsible for funding the services that provided it to patients, before subsequently revising this interpretation of its commissioning responsibilities.¹⁸

The High Court found in favour of NAT on 2 August 2016, and stated that NHS England were responsible for commissioning PrEP.¹⁹ NHS England subsequently appealed the decision, which it lost in November 2016. The Court of Appeal confirmed that NHS England had the ability, but not the obligation, to commission PrEP.²⁰

As a result of the Court of Appeal's decision, NHS England announced that it would have to re-run the 2016/17 APP, so that it would also consider PrEP. Given the estimated annual cost of £10-20 million to routinely commissioning PrEP, it also stated that it was no longer able to guarantee funding for level 3 or 4 treatments until the APP had been re-run. As part of the new APP, the manufacturers of the drugs and treatments for level 3, 4 and 5 treatments would be invited to submit their "best and final" prices.²¹

¹⁴ [PO 44063 \[on Health Services: Finance\], 12 September 2016](#)

¹⁵ NHS England, [NHS England announces provisional investment decisions for specialised services](#), 11 July 2016

¹⁶ NHS England, [Update on commissioning and provision of Pre Exposure Prophylaxis \(PrEP\) for HIV prevention](#), 21 March 2016

¹⁷ [2016] EWHC 2005 (Admin), [CO/2979/2016](#), para 21

¹⁸ [2016] EWHC 2005 (Admin), [CO/2979/2016](#), para 26

¹⁹ ['NHS can fund 'game-changing' PrEP HIV drug, court says'](#), *The Guardian*, 2 August 2016

²⁰ NHS England, [Update on PrEP](#), 10 November 2016

²¹ NHS England, [August update on the commissioning and provision of Pre Exposure Prophylaxis \(PrEP\) for HIV prevention](#), 2 August 2016

Although NHS England did not specifically mention any treatments in levels 3 or 4, press coverage of the announcement did highlight particular conditions which could be affected, such as *The Guardian* in its report on the High Court case:

As well as a cystic fibrosis drug for children, eight other treatments would be under threat of having funding cut, according to the NHS, including stem cell transplants for a rare blood cancer and prosthetic knees for amputees.

In response to NHS England's announcement, the *Daily Mail* reported comments on prioritisation from the Conservative MP Philip Davies:

There isn't a bottomless pit to spend on the NHS. We've got to prioritise and decide where we should rank this in the list of NHS spending priorities.

The fact that we're depriving cancer patients of crucial drugs at the expense of other treatments is something we've got to look at. You can't fund everything on the NHS.²²

As a result, NAT subsequently released a statement that was highly critical of the way NHS England had presented the implications of the High Court's decision:

In their press statements, NHS England has also said that were they to fund PrEP they would not be able to fund other interventions, for example for children with cystic fibrosis.

No assessment has as yet been made of the cost benefit of PrEP and what level of prioritisation it will be afforded. Every policy funded involves money being spent on that policy and not on a policy which in the end is not funded. To single just PrEP out as a policy which would be funded at the expense of others is invidious, prejudices NHS England's position in relation to PrEP and raises serious questions as to the integrity and impartiality of NHS England's approach.²³

Several health organisations also wrote an open letter to *The Times*, criticising what they called NHS England's "'divide and rule' tactics." Signatories included the Terrence Higgins Trust, the Specialist Healthcare Alliance and Waldenström's Macroglobulinemia (WM) UK.²⁴ A treatment for WM was included at level 4 in the AAP, and could potentially have been affected by commissioning decisions following the High Court's ruling.

When the results of the re-run APP were announced in December 2016, all 18 treatments previously approved remained approved for routine commissioning, as well as a three year clinical trial for PrEP, and one treatment previously in level 5 (Everolimus for subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex).²⁵

²² ['What a Skewed Sense of Values – NHS told to give out £5,000-a-year lifestyle drug to prevent HIV – as vital cataract surgery is rationed'](#), *Daily Mail*, 2 August 2016

²³ ['NAT urges NHS England to respect the court's ruling and give PrEP a fair hearing'](#), NAT press release, 3 August 2016

²⁴ Specialist Healthcare Alliance, [SHCA signs #PatientsTogether letter to The Times](#), September 2016

²⁵ ['NHS England and PHE extend HIV prevention programme'](#), *NHS England press release*, 4 December 2016

Three treatments remained in level 5 and were therefore set not to be routinely commissioned in 2016/17. Treatments that are not successful in the APP process are able to be considered again as part of the next year's APP.

The decision on one of these three level 5 treatments, second allogeneic haematopoietic stem cell transplant for relapsed disease, had been particularly controversial. In response, a campaign to reconsider the decision was launched by the blood cancer charity Anthony Nolan. They delivered an open letter, written by health professionals and signed by 18,000 people, to the Secretary of State for Health.²⁶ The letter criticised that fact that the treatment would not be reassessed until 2017/18, arguing that "another year without a resolution is unacceptable and will only mean that even more lives are lost."²⁷

In February 2017 it was announced that new funding meant that the three level 5 treatments, including second stem cell transplants, were now able to be routinely commissioned from April 2017.²⁸

2.4 Commissioning through Evaluation

Where there is insufficient clinical evidence to refer a treatment through NICE's HST evaluation process or NHS England's commissioning processes, limited numbers of patients can sometimes access treatments under the Commissioning through Evaluation programme. The then Health Minister David Mowat, in response to a July 2016 PQ, gave the following information on the programme:

Commissioning through Evaluation (CtE) is an innovative £25 million programme introduced by NHS England in 2013. It specifically aims to generate valuable new evaluation data in promising areas of specialised care where the current evidence base of cost and clinical effectiveness is insufficient to support routine National Health Service commissioning, and where further formal research trials are thought to be less likely.

Each scheme - put forward by senior clinicians and other stakeholders - is funded on a time limited basis in a small number of selected centres, and then evaluated by the National Institute for Health and Care Excellence.

Once the planned number of patients has been recruited across the participating centres, each scheme closes to new patients and analysis begins. This means that the funding identified for each scheme can then be reinvested into the evaluation of additional potentially life changing specialised treatments to maximise the value and impact of the overall evaluation fund for patients. As an example, routinely funding Selective Dorsal Rhizotomy contrary to the currently published clinical commissioning policy and in advance of a formal review of any new evidence would mean that between £2 million and £4 million per year (covering the surgical

²⁶ Anthony Nolan, [Ask your MP to support funding for second stem cell transplants](#), last accessed 18 May 2017

²⁷ Anthony Nolan, [Our letter following NHS England announcement on funding for second transplants](#), 14 July 2016

²⁸ NHS England, [Patients with rare conditions to benefit from new treatments](#), 24 February 2017

costs and immediate follow up only) would then be unavailable to support the evaluation of other promising treatments.

The analysis phase for each CtE scheme will typically take between one and two years depending on how long we need to follow up patients after their treatment to identify its effectiveness. The three cardiology based CtE schemes are currently scheduled for a 15 month analysis and reporting phase, after which the data can be used by NHS England to support policy review.²⁹

There has been some criticism of the time-limited nature of the process. The British Society of Interventional Radiology (BSIR), in relation to a Selective Internal Radiation Therapy available through CtE, argued that closing the process whilst the data was analysed was unfair to new patients who could have benefitted. BSIR also argued that the hiatus might result in the de-skilling of multidisciplinary teams and that referral networks for the treatment could be lost during this period.³⁰

²⁹ [PQ 43395, 27 July 2016](#)

³⁰ [‘SIRT access “under threat” from commissioning through evaluation process’](#), *Interventional News*, 24 November 2016

3. Comment on commissioning of specialised services (England)

NHS England is allocating an increasing proportion of the NHS budget to specialised commissioning up to 2020/21, and the commissioning process is therefore of increasing importance. The complexity, transparency and financial management are all issues that have been raised in debates surrounding the commissioning of specialised services.

A number of these debates have been looked at in detail in the NAO's 2016 report, [The commissioning of specialised services in the NHS](#), and the Public Accounts Committee's (PAC) follow-up report, [NHS specialised services](#). Some of the main issues are explored below.

3.1 Financial management

In its 2016 report, the NAO highlighted the increasing proportion of the NHS budget to be allocated to specialised commissioning, rising from 14.4% in 2015/16 to 15.8% by 2020/21 and argued that "NHS England has found it challenging to live within its (specialised commissioning) budget."³¹ In recent years however the overspend has been decreasing, and a significant proportion of the total overspend can be attributed to the Cancer Drugs Fund (CDF, see section 4), which is managed separately to other specialised commissioning but is included in the specialised services budget.

Specialised services annual overspend (£ million)				
	Total	% of annual	Overspend	% of annual
	overspend	budget	excluding	budget
			CDF	
2013/14	377	2.9%	346	2.7%
2014/15	214	1.5%	78	0.6%
2015/16*	142	-	32	0.1%

Source: National Audit Office, 2016

*first ten months

Some of the reasons behind this, highlighted by the NAO, included an underestimation of the budget required to effectively commission specialised services when NHS England took over responsibility for commissioning in 2013/14, and a lack of effective data on how services are being commissioned by NHS England regional teams. It argued that this led to variations in the costs of services that could be better managed, and gave the example of kidney transplantation:

These data limitations mean that NHS England does not have a good understanding of what is causing the changes in cost across

³¹ NAO, [The commissioning of specialised services in the NHS](#), 27 April 2016, HC 950 2015-16, para 8

each specialised service area. In addition, these differences mean that price variations still exist. For example, in 2014-15 although the price paid for a kidney transplant with a live donor varied from £13,000 to £42,000 across the eight centres providing this service, it is not clear how much of the variation is justified because what is included in the price for each centre varies depending on the contract arrangements.³²

In its response to similar points from the Public Accounts Committee, the Government noted that from April 2017 it would introduce better data sharing on specialised services:

NHS England is taking steps to provide a clear method for providers to report meaningful data regarding quality, patient outcomes and patient experience. This data will provide a cohesive overview of specialised services by April 2017 and is intended to support effective commissioning, service change and improve assurance of NHS England's specialised commissioning.

This overview will be delivered in part through stepped improvements in the quality of commissioning data and by the national adoption of identification rules in April 2017. Both improvements will enable more consistent specialised services activity reporting, with meaningful benchmarking across providers and across locations – and in a way that is integrated with NHS England's wider strategy for improving data and information.

To support this improvement, NHS England has commissioned a new data portal for the storage and presentation of specialised services and its associated spend at a local level. This data will be linked to the clinical quality and patient reported outcomes metrics, to support clearer assessment of value-for money.³³

One of the major drivers of the increasing specialised services budget is the increasing use of new treatments for previously untreatable conditions. The NAO raised concerns that the mandatory requirement on NHS England to commission any service or treatment with a NICE technology appraisal or HST evaluation makes it difficult to effectively negotiate on price with suppliers. However, recent changes to the highly specialised technology evaluation process, and closer working between NICE and NHS England in their respective commissioning processes, are in part attempts to address this issues (see sections 2.2 and 2.3).

The NAO identified changes in the NHS tariff as a factor behind the decreasing overspend from 2013/14 to 2015/16, although this was argued to be having a negative impact on the financial sustainability of NHS trusts.

3.2 Transparency

One of the main criticisms of the commissioning process by the Public Accounts Committee was that there was a lack of transparency as to

³² NAO, [The commissioning of specialised services in the NHS](#), 27 April 2016, HC 950 2015-16, para 2.14

³³ HM Treasury, [Treasury Minutes: Government responses to the Committee of Public Accounts on the Thirty Seventh and the Thirty Ninth reports from Session 2015-16; and the First to the Thirteenth reports from Session 2016-17](#), Cm 9351, November 2016, para 4.2-4.4

why some treatments were approved for routine commissioning and some were not, as well as a lack of transparency around how the process operates.³⁴

This issue is often raised by stakeholders following the decision not to commission specific treatments. For example, in a January 2017 Westminster Hall debate on stem cell transplants, Mark Tami MP made the following statement after the decision not to routinely commission second stem cell transplants (this decision was changed in February 2017, see section 2.3 for more information):

NHS England has not been remotely transparent in its decision making. All it has said is that second stem cell transplants are “not currently affordable and will not be routinely commissioned at this time”.

That tells us nothing about how NHS England reached its decision. Neither the minutes of the Clinical Priorities Advisory Group nor those of the Specialised Services Commissioning Committee are publicly available. The Government agreed with the Public Accounts Committee when it said that NHS England’s decision making in relation to specialised services should be far more transparent. Will the Minister please ensure that the minutes of those two groups are published on NHS England’s website in future?

...The way in which NHS England’s decision has been communicated to patients has been shocking. It consists of a single bullet point retrospectively added to the bottom of a press release under the heading “Further information”. Does the Minister agree that that is unacceptable, and that far more needs to be done to ensure that decisions that could cost patients their lives are shared in a sensitive and caring manner, rather than merely being added as some sort of footnote?³⁵

According to the *Health Service Journal*, plans to allow NICE to assist with NHS England’s annual commissioning process, are in part to counter accusations of a lack of transparency:

The National Institute for Health and Care Excellence has been asked to routinely assess the financial impact of specialised commissioning treatments for NHS England, a document seen by HSJ reveals.

[...]

The documents said the aim of the commissioning support programme is to ensure “transparency in decision making” and “fairness in assessment” – two areas of criticism around NHS England’s specialised commissioning process.³⁶

In response to PAC’s recommendations on improving transparency, the Government noted steps it had taken, along with NHS England, to improve the transparency of the decision-making process and to better explain how the process operates:

³⁴ Committee of Public Accounts, [NHS specialised services](#), 15 July 2016, HC 387 2016-17, para 9-11

³⁵ [HC Deb 24 January 2017, c265WH](#)

³⁶ [‘Exclusive: NICE to routinely review drugs’ budget impact for NHS England’](#), *Health Service Journal*, 11 May 2017

NHS England's Specialised Services Commissioning Committee (SSCC) is the sub-committee of the NHS England Board responsible for oversight of specialised service. Details of considerations and decisions made by the SSCC are reported to NHS England and published through regular updates to the Board and NHS England's website. To improve clarity of its decision making processes, NHS England has also published on its website the details of the key roles and functions of the advisory committees and decision-making bodies for specialised services.

In terms of decisions on new treatments, NHS England published *Developing a method to assist investment decisions in specialised commissioning: NHS England's response to consultation* in June 2016 to support investment decisions in specialised commissioning. This describes how new clinical commissioning policy is initiated, developed, evaluated and determined. NHS England is working on similar documents which will describe the process for developing service specifications – *Commissioning through Evaluation and Managed Access* schemes. Each document will be published Autumn 2016 and describe how the decisions of NHS England will be communicated.

However, the Government response did not address PAC's concern that NHS England does not make publicly available any of the minutes or meeting notes, including those on the funding decisions for new treatments, of its key decision-making groups, such as the Specialised Commissioning Oversight Group.³⁷

In a PQ response in April 2017, the then Health Minister David Mowat noted that although minutes were not published, the information used as the basis of commissioning policy was made public when decisions were made.³⁸

3.3 Strategic vision

Although the broad strategic vision for the NHS was set out in its [Five Year Forward View](#) (5YFV) publication in 2014, PAC criticised NHS England for not making clear how specialised services fit within this framework. It also noted that in 2013/14, following the reorganisation of the NHS introduced by the *Health and Social Care Act 2012*, NHS England's focus had been more on the establishment of CCGs, rather than the effective development of specialised commissioning.³⁹

In its 2016 report, the NAO found that 65% of NHS trusts and 73% of CCGs did not think there had been clear communication of the long-term plans for specialised services.⁴⁰ Although CCGs and NHS England have different commissioning responsibilities, provision of effective specialised services depends on collaborative work between both. For example, patients whose cancer care is the responsibility of

³⁷ HM Treasury, [Treasury Minutes: Government responses to the Committee of Public Accounts on the Thirty Seventh and the Thirty Ninth reports from Session 2015-16; and the First to the Thirteenth reports from Session 2016-17](#), Cm 9351, November 2016, para 2.2-2.3

³⁸ [PO 69493, 4 April 2017](#)

³⁹ Committee of Public Accounts, [NHS specialised services](#), 15 July 2016, HC 387 2016-17, para 6-8

⁴⁰ NAO, [The commissioning of specialised services in the NHS](#), 27 April 2016, HC 950 2015-16, para 2.5

their local CCG, but whose chemotherapy or radiotherapy is the responsibility of NHS England. One of the PAC report's recommendations to NHS England was to overcome the barriers to collaborative commissioning.

In response to the NAO and PAC reports, the Government pointed to NHS England's September 2016 publication, [Commissioning Intentions 2017/2018 and 2018/2019 For Prescribed Specialised Services](#), which set specialised services within the framework of the 5YFV in more detail.

As part of the broader aim to find £22 billion of efficiency savings over the 5YFV period, the commissioning intentions set out a range of measures to improve efficiency in specialised services, including:

- Centralising the supply chain for high cost devices. NHS Supply Chain will be the single point of ordering for all contracted hospitals;
- New specialised tariffs to more accurately reimburse NHS trusts that provide complex care.
- Improved data on high cost drugs, to improve benchmarking and identify unwanted variations.⁴¹

NHS England also set out its ambition for specialised services to fit into a broader strategic aim of place and population based services, delivered through 44 Sustainability and Transformation Plan (STP) areas.

As noted by the King's Fund in 2015, by the nature of covering rarer conditions and treatments, specialised services cover a large catchment area, often across multiple health systems.⁴² This means that specialised services, in working collaboratively with local areas, will have to adapt to and work flexibly with local NHS governance arrangements. Health Minister Lord O'Shaughnessy expanded upon this in response to a 2017 PQ:

To support CCGs to move to place-based commissioning arrangements for relevant specialised services, NHS England is in the process of developing a framework of options for CCGs, ranging from less formal 'seat at the table' type arrangements, to more formal joint arrangements, delegated commissioning, or devolution.

Depending on the type of arrangement that is pursued in a given geographical area, there will be different implications for governance arrangements and how reporting and assurance arrangements would operate.

NHS England is working through these various implications – including reviewing the existing reporting and assurance arrangements for specialised commissioning and determining whether these may need to change in light of moving to place-based arrangements. This will include exploring the issues set out here around ensuring adherence to national standards and data transparency.

⁴¹ NHS England, [Commissioning Intentions 2017/18 and 2018/10 for Prescribed Specialised Services](#), September 2016,

⁴² The King's Fund, [Place-based systems of care](#), November 2015, p14

NHS England is keen to test and engage with key stakeholders as it develops its framework of options.⁴³

In March 2017, in its [Next Steps on the NHS Five Year Forward View](#) publication, NHS England confirmed that the most integrated STP areas (known as Accountable Care Systems), could be delegated decision rights on specialised commissioning, moving responsibility from a national to a local level.⁴⁴

NHS Providers, which represents NHS trusts, welcomed the PAC report and NHS England's strategic framework's focus on collaborative commissioning:

We welcome the PAC's recommendations for greater transparency on costs and more consistency of information from all providers. Engaging providers in this process will be crucial to designing and delivering more effective services. It is only through genuine partnership working between NHS England, local commissioners and providers that we can reduce variation, increase efficiency and most importantly improve the health outcomes for patients living with the most complex and rare conditions.

Finally, as the recent report from the commission on specialised services recommended, we need a national strategy that takes better account of which services should be designed and commissioned nationally, regionally in networks, and locally in communities. The strategic framework recently developed by NHS England is an important first step in building this strategy.⁴⁵

⁴³ [PO HL6096, 27 March 2017](#)

⁴⁴ NHS England, [Next Steps on the NHS Five Year Forward View](#), March 2017, p37

⁴⁵ ['Public Accounts Committee Delivers Tough but Right Message on Specialised Services Budget'](#), *NHS Providers press release*, July 2016

4. Cancer Drugs Fund (England)

The Cancer Drugs Fund (CDF) is Government funding to pay for cancer treatments that have plausible potential for routine commissioning, but where there is some uncertainty about their clinical effectiveness.

The fund was set up in 2010 to allow people to access cancer drugs not otherwise routinely available on the NHS, but underwent significant reform in 2016 following criticism about its effectiveness and financial management.

A national list of drugs that can be funded by the CDF is maintained by NHS England, and the fund for 2017/18 is worth £340 million.

NHS England includes the CDF when reporting its overall spend for specialised services. However, the fund is managed separately from other specialised services.⁴⁶

4.1 How the CDF works

All new systemic⁴⁷ cancer treatments expected to receive market authorisation are assessed by NICE, with a final appraisal published within 90 days of authorisation. This appraisal can provide one of three outcomes:

- Recommended for routine commissioning ('yes')
- Not recommended for routine commissioning ('no')
- Recommended for use within the CDF

Where NICE recommends 'yes', CDF funding can be used to make the drug immediately available (interim funding), rather than the usual 90 day wait to implement NICE appraisals. After 90 days, the drug is funded from NHS England commissioning budgets rather than from the CDF.

Where NICE recommends 'no', treatment can still be accessed through Individual Funding Requests (IFRs), where treatments are provided in exceptional circumstances, assessed on a case-by-case basis.

NICE recommendations 'for use within the CDF' are where there is plausible potential for routine commissioning, but there is still clinical uncertainty. In these circumstances, a period of managed access is implemented, where patients can access the drug, funded by the CDF, to collect more data on its clinical effectiveness. The length of this managed access period is set out at the start, but usually will not last more than two years.

At the end of the managed access period, NICE re-appraises the treatment, following which an outcome of 'yes' or 'no' can be made.

⁴⁶ National Audit Office, *The Commissioning of specialised services in the NHS*, 27 April 2016, HC 950 2015-16, para 2.10

⁴⁷ Systemic treatments treat the whole body, as opposed to localised cancer treatments, such as surgery or radiotherapy.

Following this final recommendation, CDF funding can still be used for interim funding, in the case of a 'yes' recommendation.

The CDF can also be used to fund off-label cancer treatments – that is, treatments used in a different way or for a different condition than that for which they were licensed. However, as NICE is only allowed to appraise a drug within its marketing authorisation, access for off-label treatments to the CDF is determined by NHS England, as part of its annual specialised commissioning process.⁴⁸

4.2 Financial control

Although the CDF stayed within budget between 2010/11 and 2012/13, in the following years it significantly overspent. In 2014/15, it overspent its budget by 48% (£136 million).⁴⁹

As a result, when the reformed operating model was introduced in July 2016, it included new financial control mechanisms.

Under the new system, if the fund has overcommitted its budget at the end of a financial year, pharmaceutical companies which have received CDF funding will be required to pay a rebate to NHS England.

Estimated of potential rebates are provided to affected pharmaceutical companies on a quarterly basis.

Although the CDF budget for 2017/18 is £340 million, NHS England agreed with the Association of the British Pharmaceutical Industry that only CDF expenditure up to £300 million for that year would be covered under the rebate scheme.⁵⁰

As well as some transitional costs from the old CDF, the annual budget covers:

- Approved drugs in receipt of interim funding
- Managed access agreements
- Off-label drugs approved for funding from the CDF
- The administrative costs of the CDF

In February 2016, Lord Clement-Jones asked in a PQ why the pharmaceutical industry was expected to share the financial risks of CDF cost over-runs. In response the then Health Minister, Lord Prior of Brampton, stated that:

This earlier access to cancer drugs will benefit both patients and the pharmaceutical industry and NHS England believes it is only fair that the pharmaceutical industry makes a contribution if any overspend occurs.⁵¹

⁴⁸ NHS England, [Appraisal and Funding of Cancer Drugs from July 2016 \(including the new Cancer Drugs Fund\): A new deal for patients, taxpayers and industry](#), July 2016

⁴⁹ NAO, [Investigation into the Cancer Drugs Fund](#), 17 September 2015, HC 442 2015-16, Figure 1

⁵⁰ NHS England, [Appraisal and Funding of Cancer Drugs from July 2016 \(including the new Cancer Drugs Fund\): A new deal for patients, taxpayers and industry](#), July 2016, para 26

⁵¹ [PQ HL6426, 9 March 2016](#)

4.3 Reform of the old CDF

A 2015 NAO report, [Investigation into the Cancer Drugs Fund](#), and a follow-up 2016 PAC report, [Cancer Drugs Fund](#), both concluded that the original design of the CDF was “not sustainable in its current form.”⁵² By the time of publication of the NAO report, NHS England was already planning to consult on a new framework for the CDF.

As set out in the previous section (4.2), much of the criticism centred on the growing costs of the CDF and its growing annual overspend. The NAO noted that although NHS England had had a mechanism to remove drugs from the CDF list since the fund’s inception, no drugs had been taken off the national list on the basis of cost between 2010 and March 2015. PAC argued this had made it difficult to negotiate a better deals with pharmaceutical companies. It noted that once drugs were advocated for removal from 2015, NHS England had been able to secure discounts from some pharmaceutical companies so that they could remain on the CDF list.

The 2016 reforms brought in a clearer ‘exit’ process for drugs, where patients could get managed access to drugs for a defined period, prior to a final NICE appraisal being made. NHS England would also negotiate a cost with the pharmaceutical companies for this managed access period. However, Prostate Cancer UK did raise concerns about the potential effectiveness of this new arrangement:

While we think that these proposed changes could offer a speedier and more flexible NICE appraisal process, we’re concerned that the proposed system depends entirely on the willingness of pharmaceutical companies to make many of their treatments available at a highly discounted rate - or in some cases for free - with no guarantee of full-price approval from NICE at a later date.⁵³

Criticisms were also made that under the old system, before its closer alignment with NICE, the CDF cut-across NICE, rather than complemented it. Whilst the NAO report noted that the fund did improve access to drugs not routinely available on the NHS, a number of these were drugs that NICE had explicitly not recommended:

Around half of the cancer drugs accessed through the Fund have previously been appraised but not recommended by NICE. 51% of the patients supported between April 2013 and March 2015 accessed drugs that were appraised by NICE but not recommended for routine NHS commissioning because they did not meet its clinical and/or cost-effectiveness thresholds.⁵⁴

PAC also strongly criticised the old fund for not collecting data to evaluate the impact of the CDF:

⁵² NAO, [Investigation into the Cancer Drugs Fund](#), 17 September 2015, HC 442 2015-16, para 16; Committee of Public Accounts, [Cancer Drugs Fund](#), 5 February 2016, HC 583 2015-16, para 24

⁵³ Prostate Cancer UK, [Reforming the Cancer Drugs Fund in England](#), last accessed 18 May 2017

⁵⁴ NAO, [Investigation into the Cancer Drugs Fund](#), 17 September 2015, HC 442 2015-16, para 9

When it set up the Fund in 2010, the Department noted the importance of collecting data to provide evidence of how the drugs performed in clinical practice and to gain assurance on how well the Fund had been used. The Department issued guidance encouraging trusts to collect data but did not require them to do so. As a result, no consistent data were collected until NHS England mandated NHS trusts to collect outcomes data from April 2014. The previous Committee highlighted its concerns about the lack of outcomes data in its report on cancer services and outcomes in March 2015, noting that the gaps in data made it difficult to evaluate in a meaningful way the money spent through the Fund. We are disappointed to find that there were still significant gaps in the data that were collected for 2014–15—for example, 93% of records had no outcomes summary.⁵⁵

To get around this data absence, a 2017 study in the *Annals of Oncology* used a proxy assessment method, which found that of the 47 drug indications in the old CDF, only 18 (38%) reported a statistically significant overall survival benefit. The median overall survival benefit was 3.2 months. Given this short survival benefit, and the negative side effects of most cancer drugs, the study argued that the CDF may not have been meeting patient needs:

Patients would find many of the approved indications wanting as regards actual benefit, even before considering the burden of the associated toxicities. Current evidence suggests the majority of cancer patients with a life expectancy ≤ 4 months prefer treatment that relieves pain and discomfort rather than extending life and that they expect a minimum survival benefit of 3 months in this setting and potentially longer if the therapy is associated with more severe side effects.⁵⁶

The design of the new fund, where managed access to treatments would be used to inform NICE about their clinical effectiveness, was welcomed by stakeholders including Cancer Research UK, who argued that it was “shocking that this has been lacking in the system for the last five years.”⁵⁷

However, in a 2016 editorial, the British Medical Journal criticised the used of ‘real world’ observational data in the CDF managed access period, as opposed to the randomised control data used in most clinical trials:

The central role given to “real world” data is a major cause for concern. Accurate estimates of relative effectiveness require that outcomes are compared for patients who do, and do not, take the new drug, but who have similar prognostic characteristics.⁴ However, in observational studies key characteristics are unmeasured and estimates of effectiveness are biased by residual confounding. Also, the conduct of observational studies is more prone to manipulation by those with vested interests than in randomised trials. The presumption that, without addressing these difficulties, “real world” data can provide unbiased evidence,

⁵⁵ Committee of Public Accounts, *Cancer Drugs Fund*, 5 February 2016, HC 583 2015-16, conclusion 3

⁵⁶ A Aggarwal, T Fojo et al, ‘Do patient access schemes for high-cost cancer drugs deliver value to society? – lessons from the NHS Cancer Drugs Fund’, *Annals of Oncology*, 0:1-13, 27 April 2017, p9

⁵⁷ Cancer Research UK, *Changing the Cancer Drugs Fund: a step towards fixing how the NHS provides the best medicines*, 11 February 2016

ignores all we know about good research design for identifying causal effects, and the reasons why well designed randomised trials are the cornerstone of evidence based medicine.

The editorial argued that this encouraged early access to drugs, with high prices but uncertain benefits, and that since once a drug is recommended by NICE it is difficult to stop its use, NICE should have access to trial evidence before making a final decision.⁵⁸

However, the 2017 *Annals of Oncology* study argued that randomised control trials tended to exclude types of patients frequently encountered in clinical cancer settings – for example, under-representing numbers of men and women over 65 – and therefore there were questions about the general applicability of control trials compared to ‘real world’ data.⁵⁹

PAC also raised concerns that NICE may struggle to effectively and quickly evaluate all new cancer drugs under the new system, as this represented an increase in its workload.⁶⁰

⁵⁸ [‘Cancer Drugs Fund requires further reform’](#), *British Medical Journal*, 27 September 2016, BMJ 2016;354:i5090

⁵⁹ A Aggarwal, T Fojo et al, [‘Do patient access schemes for high-cost cancer drugs deliver value to society? – lessons from the NHS Cancer Drugs Fund’](#), *Annals of Oncology*, 0:1-13, 27 April 2017, p3

⁶⁰ Committee of Public Accounts, [Cancer Drugs Fund](#), 5 February 2016, HC 583 2015-16, conclusion 5

5. Devolved administrations

As health is a devolved competence, England, Wales, Scotland and Northern Ireland all have different structures for commissioning specialised services.

Some UK-wide cooperation does exist for specialised commissioning, particularly through the Rare Diseases Advisory Group (RDAG), which makes recommendations to the NHS in each nation on how specialised services should be commissioned. Each national NHS also reports to RDAG on its implementation of the 2013 [UK Strategy for Rare Diseases](#).

Due to the highly specialised nature of the care provided for a number of specialised services, there are often only a few locations which can provide this. As a result, Scotland, Wales and Northern Ireland all commission significant number of specialised services in England.

5.1 Scotland

Specialised services are commissioned nationally in Scotland by the National Services Division (NSD) of NHS Scotland.

A large number of specialised services are commissioned from hospitals in England, for which NSD makes a contribution to NHS England. Services that can be provided in Scotland are funded by a pooled fund from local NHS boards, managed by NSD.⁶¹

Decisions on what is commissioned at a national level are made by the National Specialist Services Committee (NSSC), which comprises representatives of each territorial NHS board in Scotland.⁶²

Unlike the rest of the UK, commissioning decisions are not based on NICE recommendations. Decisions by the NSSC are based on input from a range of stakeholders including the Scottish Academy of Royal Colleges and Faculties, the Scottish Medicines Consortium (SMC, a Scottish body largely equivalent to NICE), patient groups and GP groups.⁶³

Local NHS boards can also access specialist funding through the New Medicines Fund (NMF), which covers the acquisition and support costs to allow SMC-recommended medicines to be made available for medicines for rare conditions and end-of-life medicines. The NMF was introduced in 2014, replacing the Rare Conditions Medicine Fund, and was worth up to £90 million in 2016/17.⁶⁴

A 2016 review of access to new medicines found that the NMF had largely served its purpose of improving access to treatments for rare

⁶¹ National Services Division, [Specialist Services \(UK and EU\)](#), last accessed 17 May 2017

⁶² [SP WA 2 June 2014, S4W-21180](#)

⁶³ National Services Division, [The national designation process](#), last accessed 17 May 2017

⁶⁴ Scottish Government, [Scotland's Spending Plans and Draft Budget 2016-17](#), December 2015, table 4.03

conditions, but noted that there remained concerns over future funding levels:

So far the monies available have covered the calls made on the Fund but it is anticipated that demands will grow and that maintaining the current level of access to new medicines will only be achievable if the current funding arrangements are maintained and availability of funds keeps pace with demand. Comparisons were regularly made with the Cancer Drugs Fund in England and while the operation of the fund differs from Scotland the trend there has been one of significant growth in demand that has outstripped the available budget year on year.⁶⁵

5.2 Wales

The Welsh Health Specialised Services Committee (WHSSC), a joint committee of the seven Health Boards in Wales, is responsible for the commissioning of specialised services in Wales.

Many specialised services for Welsh patients are commissioned by WHSSC from English providers, as set out by the former Minister for Health and Social Services Mark Drakeford, in response to a 2014 Written Assembly Question on gender identity services:

There is not a sufficient critical mass to support the safe and sustainable provision of the full range of gender confirmation surgical services within Wales. Whilst a small number of procedures, such as a hysterectomy, can be undertaken locally, WHSSC will continue to commission the more highly specialised surgical procedures from recognised English centres.⁶⁶

Decisions on what should be routinely commissioned by the NHS in Wales are made by the All Wales Medicines Strategy Group (AWMSG). However, NICE technology appraisals also apply in Wales, and recommendations by either body to routinely commission a treatment must be adhered to. In order to avoid duplication, AWMSG would not normally consider a treatment that NICE intend to publish a final technology appraisal on within the next 12 months.⁶⁷

Although the recommendations of technology appraisals are automatically adopted within NHS Wales, this is **not** the case for NICE highly specialised technology (HST) evaluations. For HSTs, AWMSG will liaise with WHSSC to consider the applicability of the advice within NHS Wales. AWMSG then advise the Welsh Government on whether the highly specialised technology should be adopted within NHS Wales.

The policy not to automatically adopt NICE HST evaluations followed concerns from WHSSCs about differences in accountability between England and Wales.⁶⁸

WHSSC also has a formalised 'horizon scanning' process, which identifies new treatments for it to consider. Those with relevant

⁶⁵ Scottish Government, [Review of Access to New Medicines: Independent review by Dr Brian Montgomery](#), December 2016, para 6.6.6

⁶⁶ [WAO67379-81, 14 July 2014](#)

⁶⁷ AWMSG, [Frequently Asked Questions](#), October 2016

⁶⁸ AWMSG, [Process for considering the applicability of National Institute for Health and Care Excellence \(NICE\) commissioning advice in relation to highly specialised technologies \(HSTs\) within NHS Wales](#), September 2015

recommendations from NICE or AWMSG require mandatory commissioning, whilst non-mandatory treatments are considered on the basis of their clinical and cost effectiveness by WHSCC's 'prioritisation panel', to determine which will be routinely commissioned.⁶⁹

5.3 Northern Ireland

Commissioning decisions in Northern Ireland are made by the Health and Social Care Board (HSCB). The Northern Ireland Department of Health has formal links with NICE, and considers any recommendations made in its technology appraisals and HST evaluations, although it is not mandated to implement them.⁷⁰

In the 2015 [Rare Disease Implementation Plan for Northern Ireland](#), it is noted that many specialised services are required to be commissioned from providers in Great Britain:

With a population of only 1.8m Northern Ireland is however unlikely to ever be in a position to independently support highly specialist elements of care for rare diseases locally and will need to continue to link with tertiary and quaternary centres in Great Britain (GB) and elsewhere to secure access to the full range of care needed.⁷¹

As a result, the plan emphasises its membership of the RDAG as a way to develop care pathways with the rest of the UK, for those requiring specialised services.

⁶⁹ WHSCC, [An Integrated Commissioning Plan for Specialised Services for Wales 2016-19](#), March 2016, Chapter 6

⁷⁰ Department of Health, Social Services and Public Safety, [Circular HSC \(SOSD\) 3/13](#), December 2013

⁷¹ Department of Health, Social Services and Public Safety, [Providing High Quality Care for people affected by Rare Diseases – The Northern Ireland Implementation Plan for Rare Diseases](#), October 2015, p31

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