



Strengthening National Commissioning

A Consultation document

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Strengthening National Commissioning – A consultation

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Strengthening National Commissioning

A consultation document

Prepared by Department of Health

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Executive summary

This document sets out proposals to:

- **improve the process by which decisions are made on funding very specialised new technologies (drugs and treatments) which are candidates for national specialised commissioning, by adapting and strengthening the existing arrangements for national commissioning;**
- **adapt the scope of this system to allow it to consider a small number of additional technologies that are not appropriate for assessment by the National Institute for Health and Clinical Excellence (NICE), and which may be suitable for nationally specialised commissioning services;**

National specialised commissioning arrangements need to be fit for purpose to take forward the principles set out in the NHS Constitution. The NHS Constitution states “Everyone counts. We use our resources for the benefit of the whole community, and make sure nobody is excluded or left behind”¹. Work carried out by the NICE Citizens’ Council in 2004², on treatments of very rare and severe conditions, and research activity to support the NHS Constitution, revealed strong public support for “not leaving people behind”. This underlines the case for investing in treatments that can bring significant benefits to people with very rare conditions, even though doing so may not be a cost effective use of resources using conventional decision criteria.

It is proposed to have a single expert advisory group making recommendations to Ministers on services and technologies to be considered for national commissioning and to extend the scope of this group slightly to include a small number of additional very specialised, new technologies which fall outside NICE’s remit, but which may be suitable for nationally commissioned specialised services.

The aims of these proposals are to:

- improve the governance and transparency of the decision making process;
- ensure that recommendations are robust where new, sometimes costly, technologies are part of a proposed service;

Our aim is to introduce the new arrangements during the financial year 2010/11, so they can be used to make commissioning decisions in the summer and autumn of 2010.

¹ The NHS Constitution January 2009

² NICE Citizens’ Council Report on Ultra Orphan Drugs, London, November 2004

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Commissioning any new services and technologies approved by Ministers will start from April 2011.

Consultation process

- Purpose

This consultation seeks views on the Government's proposals for an incremental development of some of the arrangements implemented following the Carter Review of NHS specialised commissioning arrangements³. It is proposed to have a single expert advisory group making recommendations to Ministers on services and technologies to be considered for national commissioning. This group would have a wide range of expertise to take account of both clinical and commissioning issues and an expanded scope to include responsibility for assessing a small number of additional very specialised new technologies for very rare conditions that may be suitable for nationally commissioned specialised services.

- Timetable

The consultation will start on 11th December 2009 and run until 19th February 2010. Any views submitted after this date may not be considered or reflected in our analysis.

- Responses

Following this consultation we shall continue to refine the proposals in light of the responses to this consultation and other emerging information from our discussions both within and outside Government.

If you would like to respond please use the response proforma published alongside this document. Please send responses to

By email strengtheningnationalcommissioning@dh.gsi.gov.uk

By Post Sarah Bramley-Harker
Room 5W55
Quarry House
Quarry Hill
Leeds
LS2 7UE

We will consider requests for accessible formats that may be required. Please send your requests to the above.

³ Professor Sir David Carter, the Review of Commissioning Arrangements for Specialised Services May 2006

Information handling

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's [Information Charter](#).

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Summary of the consultation

A summary of the response to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the Consultations website at

<http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm>

Code of Practice on Consultation

This consultation follows the 'Government Code of Practice on Consultations'. In particular we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for at least 12 weeks with consideration given to longer timescales where feasible and sensible. Minister has agreed to a shortened consultation of 10 weeks. This will enable any new arrangements to become operational in 2010/11 for implementation at the start of 2011/12.
- be clear about the consultations process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;
- analyse responses carefully and give clear feedback to participants following the consultation;
- ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

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The full text of the code of practice is on the Better Regulation website at:

<http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html>

- **Comments on the consultation process itself**

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please

Contact: Consultations Co-ordinator
 Department of Health
 3E48, Quarry House
 Leeds
 LS2 7UE

e-mail: consultations@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Introduction

1.1 It is widely acknowledged that there are particular challenges in making decisions on whether the NHS should fund certain very high cost technologies that can offer significant benefits to individuals with extremely rare conditions.

1.2 Work carried out by the NICE Citizens' Council in 2004, on very rare and severe conditions, and survey activity to support the NHS Constitution, revealed strong public support for the NHS "not leaving anyone behind." We need to ensure that patients with extremely rare conditions who need high cost technologies are not left behind, but we also need to ensure best use of NHS resources.

1.3 The current arrangements for national commissioning were developed in 2007 following the Carter review in 2006. These are described in Annex A. The benefits of national commissioning are:

- patients have equitable access to services regardless of the rarity of their condition;
- a consistent approach is taken to service development and delivery;
- assessment and commissioning work is undertaken once nationally, and therefore is more cost effective;
- it ensures a concentration of clinical expertise in a few centres providing these services to improve patient safety and outcomes.

1.4 National commissioning arrangements have already been used to assess some new technologies, as part of their existing function of assessing new treatments and services. However, there are several issues with the process for decisions on services which contain costly new technologies:

- in the current national specialised commissioning system, there is a potential for the National Commissioning Group (NCG) and National Specialised Commissioning Group (NSCG) to reach different conclusions on advice for Ministers, and the responsibilities and processes of each group are not always fully understood;
- the current decision-making process and eligibility criteria could be made more robust;
- there is a case for enabling the national commissioning system to consider a very small number of drugs and technologies that may not fit within the current eligibility criteria because of the way relevant services are organised.

1.5 Ministers have asked officials to review how decisions are made on nationally commissioned specialised services which incorporate new technologies for very rare conditions.

1.6 An improved system should:

- protect the rights of the small number of people with rare conditions so they can access effective interventions through the NHS;
- incorporate a robust analytical framework with a strong national perspective and clear criteria for deciding which services should be recommended to Ministers for national commissioning;

- support controlled implementation of innovation, while enabling the development of continued clinical and commissioning expertise about rare treatments, including learning from ongoing systematic data collection and evaluation.

1.7 We propose to adapt the existing national commissioning process to ensure that the issues listed above are addressed. Other options have been considered, including using an existing body such as NICE or the creation of a completely new system. The Government's preferred option is to adapt the existing process because:

- it builds on and strengthens the implementation of the recommendations of the review led by Professor Sir David Carter;
- it is administratively efficient;
- it has the capacity to take on the small amount of additional business;
- it connects the decision to commission with the subsequent commissioning activity.

1.8 NICE is able to appraise the great majority of significant new technologies (in particular medicines) that come onto the market. However, difficulties can arise for a very small number of effective interventions used only in very small groups of patients. The cost of these interventions can be so high that they could not be regarded as a cost-effective use of NHS resources if the current NICE decision criteria are used.

1.9 As part of these changes, we propose to broaden the function of the national commissioning process to include the assessment of a very small number of additional technologies that are not appropriate for appraisal by NICE, but which may not fit existing criteria for nationally specialised commissioning services because of the way relevant NHS services are organised.

1.10 The Department of Health is consulting separately on the operation of the Innovation Pass, where selected innovative medicines will be made available on the NHS for a time-limited period prior to being appraised through NICE's processes. The Innovation Pass consultation is different to this proposal and the proposed criteria for the Innovation Pass are designed to avoid duplication. The two proposals will clearly complement one another in ensuring access for patients to innovative medicines.

Proposed changes to the current system

2.1 We propose adapting existing national commissioning arrangements by:

- dissolving the National Commissioning Group (NCG) and establishing a National Commissioning Advisory Group (NCAG) which will make recommendations directly to Ministers;

- giving NCAG a new responsibility of considering a small number of additional drugs and technologies that may meet the criteria for nationally commissioned specialised services;

2.2 We propose that NCAG will:

- consider clinical, cost effectiveness and affordability issues at the same time, alongside best practice in service delivery; and
- provide a single source of robust and transparent advice direct to Ministers on which services should be designated for national commissioning.

Consultation question 1: Do you agree to combining this advice into one group? If not, why not?

The process

3.1 We propose that NCAG will develop recommendations for all national commissioning decisions using a robust, transparent, two step process:

Step 1. The application will be considered against explicit entry criteria set out in Annex B. The application will be initially assessed to ensure that:

- a topic has either been considered by NICE or is clearly not suitable for consideration by NICE (or another body) and
- candidate treatments or services for national commissioning sufficiently meet the NCAG entry criteria for full work up.

Step 2. A detailed evaluation of the application's suitability for national commissioning for full consideration by NCAG. The National Specialised Commissioning Team (NSCT) is currently developing an ethical framework to support these decisions and testing this with a wide range of stakeholders. It will be available early next year.

3.2 The new arrangements will not be an alternative to NICE. NICE will continue to assess the great majority of new drugs including many for a relatively small number of patients. For NCAG to consider a technology, it must first be determined that it is unsuitable for assessment by NICE. The topic selection process and criteria for NICE Technology Appraisals have recently been reviewed following a consultation earlier in 2009 and are unchanged by these proposals.

Potential decisions

3.3 We propose NCAG will consider the findings of the evaluation and will recommend whether a service is or is not suitable for national commissioning.

3.4 As now:

- there will be no right of appeal but it will be possible for NCAG to consider resubmitted proposals in future rounds, for example if new evidence subsequently emerges.

- Ministers will take the final decision on the designation of services for national commissioning.
- nationally commissioned services will continue to be paid for from a national commissioning budget within the NHS budget. The size of the budget will be adjusted to accommodate services designated by Secretary of State.

Proposed membership and Chair of National Commissioning Advisory Group

4.1 NCAG will consider the needs of patients with rare diseases, or those that need highly specialised treatments, alongside clinical effectiveness and best use of NHS resources. The group will be appointed for their expertise, rather than to represent any particular constituency. We expect to draw from Strategic Health Authorities and the current membership of NSCG and NCG.

4.2 Our view is that the group will need a balance of the following expertise:

- clinical
- public health
- financial and investment
- health economics
- commissioning
- health technology assessment
- patients
- lay representation

4.3 We propose that the Secretary of State appoints the Chair and members of NCAG.

Consultation question 2: Do you think this is right? Is there other expertise we should include?

Timing

5.1 Our aim is to introduce the new arrangements during the financial year 2010/11, so they can be used to make commissioning decisions in the summer and autumn 2010. Commissioning any new services and technologies approved by Ministers will start from April 2011.

Roles and responsibilities

6.1 We consider these changes provide a good opportunity to consolidate the roles and responsibilities of SHAs and NSCG. Both will have representation on NCAG.

- **SHAs** – continue their statutory responsibility for specialised commissioning delegated to NHS London and will receive an Annual Report on NCAG recommendations to Ministers through NHS London.
- **NSCG** – continue general oversight and co-ordination for regionally specialised commissioning where specialised services have a planning population bigger than that of a single specialised commissioning group. They will also facilitate collaborative working across SCGs and between SCG and NCAG. They will be a stakeholder in advising NCAG on its assessments and members from NSCG will be appointed to NCAG for their expertise in commissioning. They will continue to provide oversight on the effectiveness of national commissioning, including advising on value for money. The role of the NSCG therefore remains largely unchanged.

Conclusion

7.1 We believe that the proposed arrangements will have the following advantages. They

- will build on and strengthen the implementation of Professor Sir David Carter’s review of specialised services commissioning arrangements, rather than fundamentally re-engineering it and will be administratively efficient;
- will have particular advantages for existing and new services and technologies for rare diseases, as the commissioning and funding decision and the commissioning itself are part of the same process. If approved, most of the relevant technologies will be part of nationally commissioned services, avoiding duplication of assessment;
- will provide a “risk-share” which protects PCTs from the financial risks of encountering clusters of high-cost patients, and helps to protect patients from a “postcode lottery” of care;
- will be robust.

Consultation question 3: Do you have any other suggestions for strengthening national commissioning?

Consultation questions

List of Questions

In the proposed changes, we are recommending a single group to advise Ministers on nationally commissioned specialised services.

Question 1: Do you agree to combining this advice into one group? If not, why not?

We have proposed the expertise NCAG will need and have suggested that the Secretary of State appoints the Chair and members of NCAG

Question 2: Do you think this is right? Is there other expertise we should include?

We believe that the proposed changes will build on and strengthen the implementation of Professor Sir David Carter's review of specialised services commissioning arrangements and will provide a stronger and more robust process for national commissioning.

Question 3: Do you have any other suggestions for strengthening national commissioning?

In the accompanying Impact Assessment we have attempted to estimate the likely costs and benefits of the new proposals.

Question 4: Do you agree with our estimate of the likely costs and benefits? If not please indicate and provide evidence, where possible, of any areas of disagreement.

Equality Impact Assessment

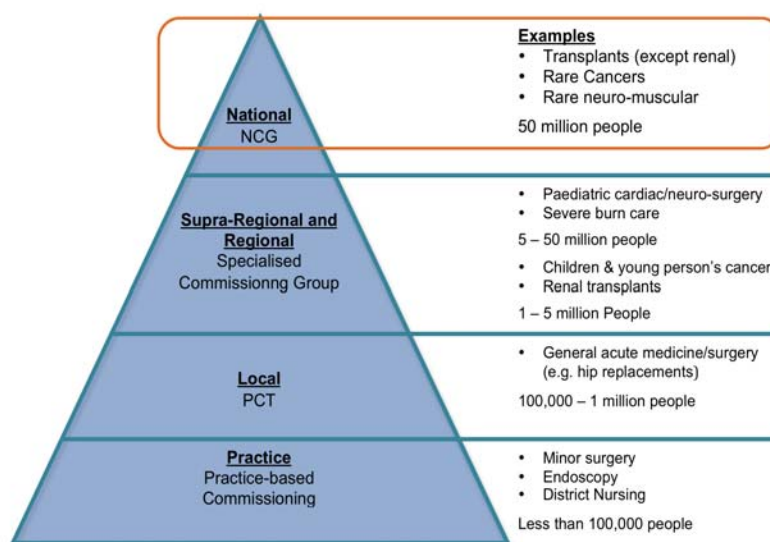
Question 5: Please identify the impact the proposals in this document might have from the perspective of ethnicity, age, gender, gender reassignment, sexual orientation, religion or belief or socio economic considerations? If there is a negative impact, what proportionate measures could address those issues?

SPECIALISED SERVICES COMMISSIONING

1. Specialised services are provided in relatively few specialist centres to catchment populations of more than 1 million people (as defined in SI 2002 No.2375), and are often high-cost, low-volume interventions and treatments. PCTs group together in ten Specialised Commissioning Groups (SCGs) to commission some of these services collectively to ensure high quality care and share financial risk from expensive, unpredictable activity. Some services, for very rare and sometimes high cost conditions, where the national caseload is usually fewer than 400, are commissioned at national level. Whilst PCTs commission the majority of NHS services – either directly or through SCGs – the national commissioning function is hosted by NHS London and undertaken on behalf of the 10 SHAs as set out in SI 2007 No.559.

2. The most common conditions and the majority of work across the NHS are effectively catered for by local commissioning arrangements led by PCTs. Figure 1 shows the split between the types of services commissioned at a national level and those commissioned regionally by Specialised Commissioning Groups (SCGs) and PCTs.

Figure 1



3. If there was no system of national commissioning it would be for each PCT to decide whether to fund treatment at a national centre for each patient with a very rare disease. Not only would there be uneven decisions (post code lottery) but PCTs would need to undertake costly assessment if these decisions were to withstand Judicial Review and there would be an unequal distribution of these costs between PCTs.

4. Sir David Carter led an independent *review of commissioning arrangements for specialised services* in 2006. Implementation of the review's recommendations strengthened arrangements from April 2007, as follows:

SCGs (Specialised Commissioning Groups)

5. There are 10 SCGs, coterminous with the 10 Strategic Health Authorities (SHAs), through which PCTs act collectively on behalf of a population of about five million. Most of them are chaired by a PCT chief executive and they are supported by a commissioning team. All constituent PCTs are members of the SCG Board. There is a national definitions set of 34 specialised services to assist SCGs in identifying and planning activity.

The NSCG (National Specialised Commissioning Group)

6. This was established to facilitate collaborative working between the 10 SCGs in addition to its national oversight to agreeing the annual commissioning and management budget for the NCG and providing concerted advice to Ministers on which services should move into, or leave, the portfolio of services to be nationally commissioned, and on proposed designation of centres to provide these services. Examples of collaborative working across SCGs include the development of a national policy on pulmonary hypertension. Its membership includes the 10 SCG chairs, plus representation from the Royal Colleges, SHAs, and others.

The NCG (National Commissioning Group)

7. The NCG is a standing committee of the NSCG and maintains functions previously led by National Specialised Commissioning Advisory Group. It oversees the national commissioning of highly specialised services by the National Specialised Commissioning Team (NSCT) and works to ensure nationally commissioned services are safe, accessible and sustainable; have high quality patient outcomes; and have robust clinical governance systems.

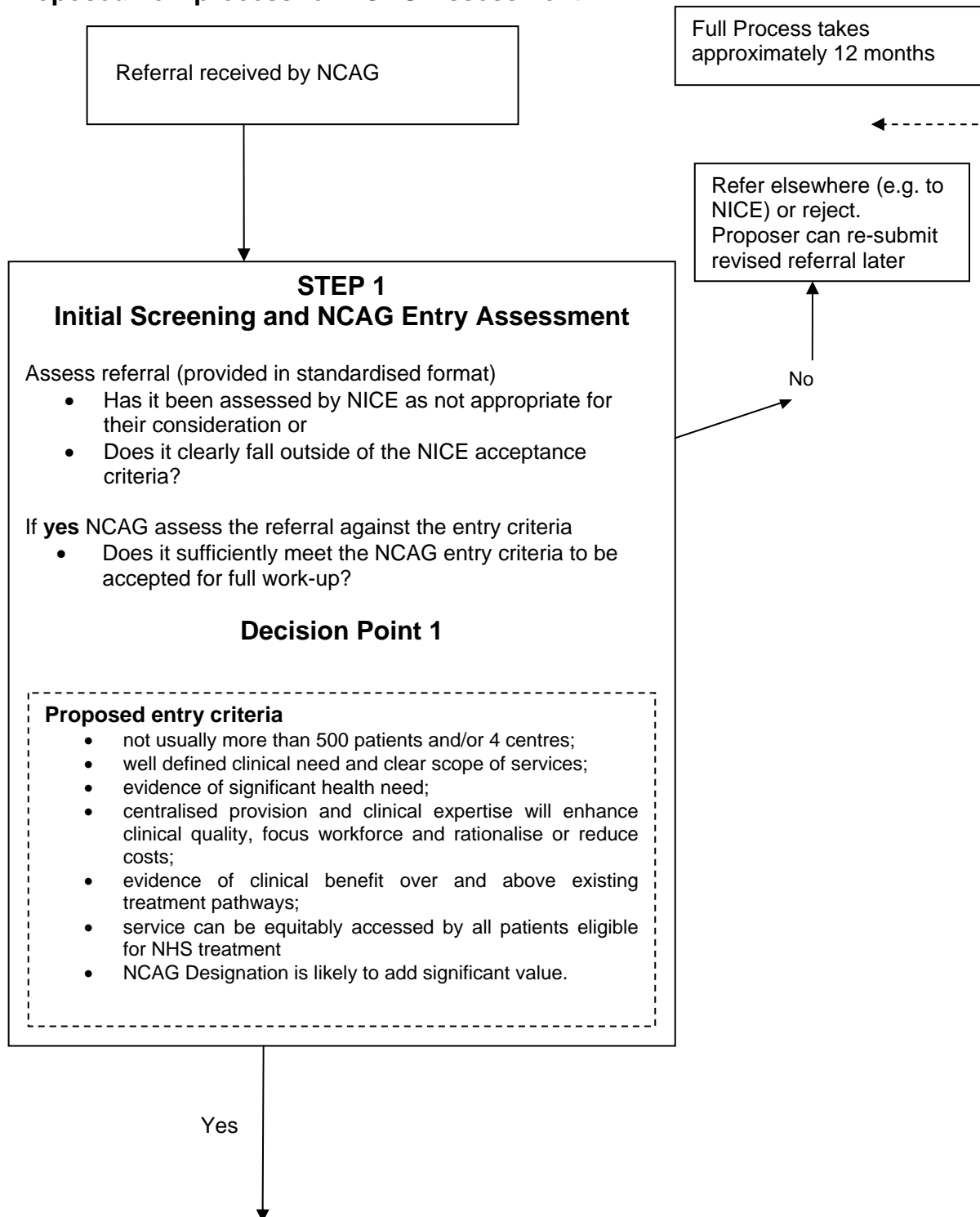
8. The NCG advises Ministers through the NSCG on which NHS services are best commissioned nationally to ensure a high quality of clinical care and equity of access for patients as well as securing value for money.

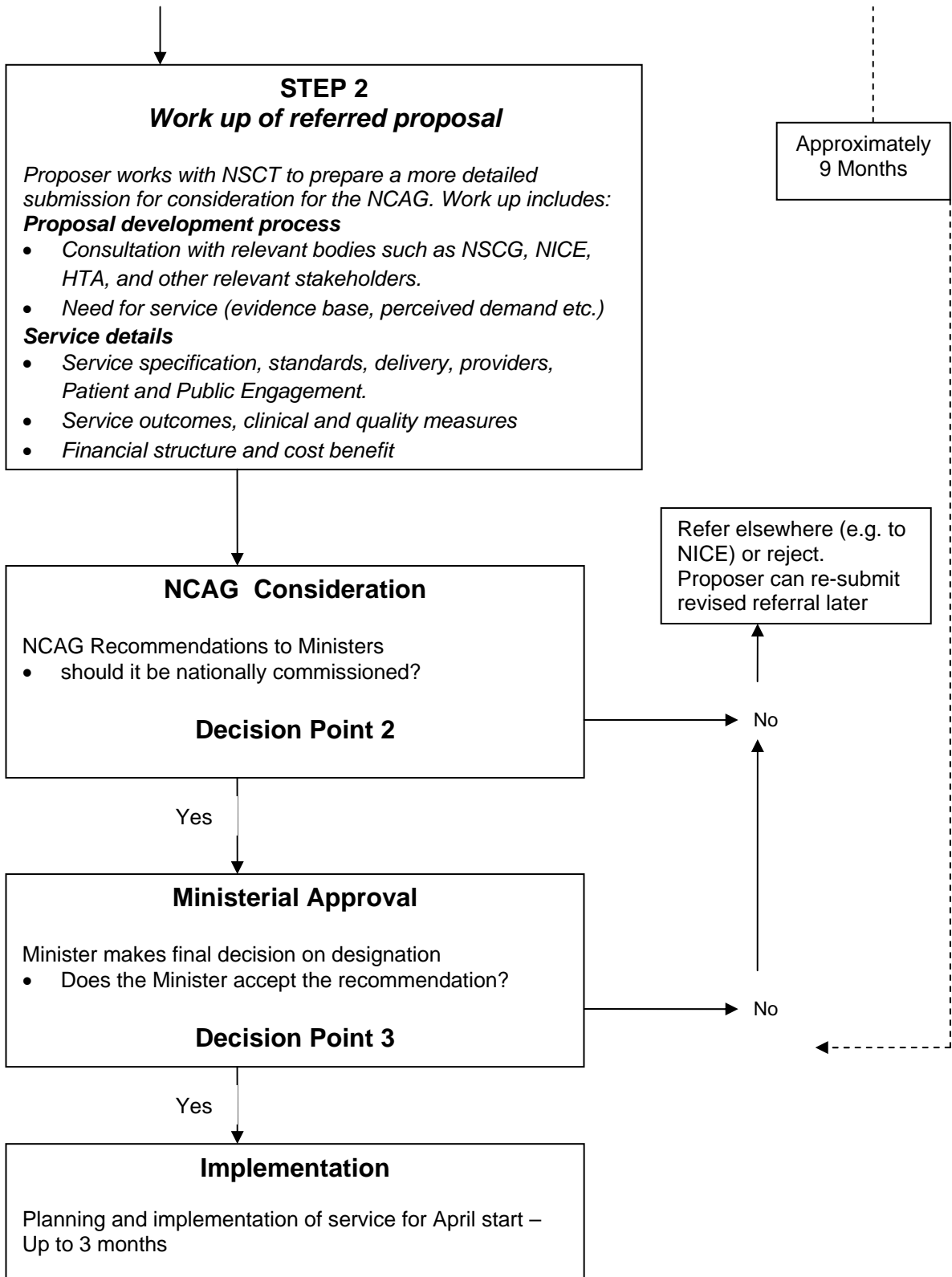
9. The NCG operates a cycle of annual applications from local services to consider new applicants for national commissioning against common criteria. Ministers continue to have the final decision on the designation (and de-designation) of nationally commissioned specialised services, based on recommendations from the NCG and NSCG.

The National Specialised Commissioning Team (NSCT)

10. The NSCT supports the work of the NCG and the NSCG. The Team commissions national services and supports the SCGs in pan-regional work such as the national programmes for paediatric cardiac surgery and paediatric neurosurgery. It also facilitates collaboration between the 10 SCGs, in particular through an SCG Directors' Network, an SCG Finance Network and an SCG Public Health Network. The NSCT also proactively identifies areas where a joint approach is needed between regionally and nationally commissioned services, for example, severe intestinal failure.

Proposed new process for NCAG Assessment





Summary: Intervention & Options

Department /Agency: Department of Health	Title: Impact Assessment for strengthening national commissioning for specialised services	
Stage: Consultation	Version: 6	Date: 7th December 2009
Related Publications: N/A		

Available to view or download at: <http://www.dh.gov.uk>

Contact for enquiries:
strengtheningnationalcommissioning@dh.gsi.gov.uk

Telephone:

What is the problem under consideration? Why is government intervention necessary?

There are some issues with the decision making process within National Commissioning:

- In the current specialised commissioning system, clinical effectiveness and issues of cost are broadly considered separately by National Commissioning Group (NCG) and National Specialised Commissioning Group (NSCG) respectively, rather than in the round. Given that NSCG largely comprises commissioning experts and NCG largely comprises clinical experts, there is a potential for differing advice to be put forward to go to Ministers.
- The current decision-making process could made more robust and transparent.
- There is a case for enabling the national commissioning system to consider a very small number of technologies that may not fit within the current eligibility criteria.

Ministers asked officials to review how decisions were made on nationally commissioned specialised services which could incorporate new technologies for very rare conditions.

What are the policy objectives and the intended effects?

The main objective of the policy is to strengthen the arrangements for national commissioning in order to make it more robust and transparent, and ensure it meets the issues above. A further objective is to extend the potential scope of national commissioning to assess a small number of additional high cost technologies for patients with very rare conditions.

What policy options have been considered? Please justify any preferred option.

The options considered were: 1. strengthen current national commissioning arrangements by dissolving the current NCG and create a new group - the National Commissioning Advisory Group and whose scope will include the high cost specialised technologies for very rare conditions currently commissioned by PCTs. 2. Do nothing. The preferred option builds on the implementation of the recommendations of the review led by Professor Sir David Carter; it is administratively efficient; it has the capacity to take on the small amount of additional business; it will consolidate and rationalise management of national specialised commissioning; connects the decision to commission with the subsequent commissioning activity.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The new arrangements will be introduced during 2010/11, with a view to commission April 2011. Any review of costs and benefits is likely to be considered after at least two full years of the new arrangements being operational, in order to have some meaningful data.

Ministerial Sign-off For Consultation Stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

.....Date:

Summary: Analysis & Evidence					
Policy Option: 1		Description: Strengthening and extension of specialised commissioning in the National Commissioning Advisory Group			
COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups'		
	One-off (Transition)	Yrs			
	£		The proposals are expected to be cost-saving (with the qualification described in the Key Assumptions / Sensitivities section)		
	Average Annual Cost (excluding one-off)				
	£ 0		Total Cost (PV) £ 0		
Other key non-monetised costs by 'main affected groups'					
BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups'		
	One-off	Yrs			
	£		Cost savings – administration cost savings (one national process versus ten SCG processes for highly specialised treatments)		
	Average Annual Benefit (excluding one-off)				
	£ 2,200,000	10	Total Benefit (PV) £ 18,400,000		
Other key non-monetised benefits by 'main affected groups'					
As a consequence of strengthening national commissioning there may be benefits for patients within existing scope of national commissioning.					
Public confidence from robust and transparent decision-making.					
Key Assumptions/Sensitivities/Risks					
It is assumed that the total spending on high cost treatments for rare conditions will be constant. In fact it is possible that this value could increase or decrease – depending on the decisions of the NCAG. This will result in a commensurate increase or decrease in NHS costs					
Price Base Year 2009	Time Period Years	Net Benefit Range (NPV) £	NET BENEFIT (NPV Best estimate) £ 28,776,000		
What is the geographic coverage of the policy/option?			England		
On what date will the policy be implemented?			Financial year 2010/2011		
Which organisation(s) will enforce the policy?			DH and NSCT.		
What is the total annual cost of enforcement for these organisations?			£ n/a		
Does enforcement comply with Hampton principles?			n/a		
Will implementation go beyond minimum EU requirements?			n/a		
What is the value of the proposed offsetting measure per year?			£ n/a		
What is the value of changes in greenhouse gas emissions?			£ n/a		
Will the proposal have a significant impact on competition?			No		
Annual cost (£-£) per organisation (excluding one-off)		Micro	Small	Medium	Large
Are any of these organisations exempt?		n/a	n/a	N/A	N/A

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Impact on Admin Burdens Baseline (2005 Prices)		(Increase - Decrease)	
Increase of £	Decrease of £	Net Impact	£
		Key:	Annual costs and benefits: Constant Prices
			(Net) Present Value

Evidence Base

Aim

There is a need to improve the process through which decisions are made on whether to designate services which are candidates for national commissioning, particularly where they include a small number of services or drugs for very rare conditions that do not fit well within NICE's remit.

The Case for Change

The current arrangements for national commissioning were developed following the Carter review⁴ and in general have been working effectively. However, there are several issues with the process for decisions on the national funding of new technologies and a need has been identified for further incremental development of some of the arrangements proposed in the Carter Review.

- In the current specialised commissioning system, clinical effectiveness and issues of cost are broadly considered separately by National Commissioning Group (NCG) and National Specialised Commissioning Group (NSCG) respectively, rather than in the round. Given that NSCG largely comprises commissioning experts and NCG largely comprises clinical experts, there is a potential for differing advice to be put forward to go to Ministers. The responsibilities of the NCG and NSCG are not fully clear or well-understood
- The current decision-making process and eligibility criteria could be made more robust.
- There is a case for enabling the national commissioning system to assess a very small number of technologies that do not fit within the current eligibility criteria for considering services, principally by virtue of the way in which the relevant services are organised across the NHS.

NICE

It is acknowledged that there are particular challenges in making decisions on whether the NHS should fund certain very high-cost technologies that can offer significant benefits to individuals with extremely rare conditions. Such interventions are sometimes referred to informally as “ultra orphan” technologies, though unlike the “orphan” drugs supported by specific EU regulatory provisions there is no formal or binding definition of these technologies.

NICE is able to appraise the great majority of significant new drugs that come onto the market, including some for small patient groups (only a few hundred patients a year), using the flexibilities that it has to take account of particular factors such as priority for “end of life” treatments in developing its guidance. Difficulties centre on a small number of interventions, the cost of which is so high (potentially hundreds of thousands of pounds per patient per year), that they could not conceivably be regarded as a cost-effective use of NHS resources using conventional decision paradigms of the kind employed by NICE. The significant fixed costs associated with bringing a new technology to market, combined with a highly specialised indication (perhaps only a few dozen patients in the UK) means that manufacturers may need to charge high prices to make a return on investment.

⁴ Professor Sir David Carter, the Review of Commissioning Arrangements for Specialised Services May 2006

Work carried out by the NICE Citizens' Council in 2004, on very rare and very severe conditions, and survey activity to support the NHS Constitution revealed strong public support for the NHS "not leaving anyone behind". This supports the case for investing in technologies that can bring significant benefits to people with very rare conditions, even though doing so may not be a "cost effective" use of resources using conventional decision criteria.

In the absence of NICE guidance, expensive treatments for such very rare conditions may be within services proposed for national commissioning as a way of achieving equitable access. In some cases this is the appropriate route for evaluation, and some interventions have been considered in this way. However difficulties have arisen because in the uncommon case that a new service proposed for national commissioning has included a very high cost new drug, the process for making recommendations about national commissioning has not always provided consistent or robust advice. This can make it difficult for Ministers to make a decision on a recommendation for national designation. This is in part because the current system broadly requires clinical effectiveness and issues of cost to be considered separately by the National Commissioning Group (NCG) and National Specialised Commissioning Group (NSCG) respectively.

There are a few drugs which will clearly be regarded as cost-ineffective if considered by NICE, but which do not quite fit within the existing criteria for assessing if a service should be nationally commissioned. Without an alternative method for considering the economic case the NICE method and threshold range may be applied by commissioners - with the inevitable result that these drugs are seen not to be a cost-effective use of resource. Some PCTs may decide to provide funding, while others may not, leading to perceptions of a treatment lottery.

The Proposed Changes

We propose adapting existing national commissioning arrangements by:

- dissolving the National Commissioning Group (NCG) and establishing a National Commissioning Advisory Group (NCAG) which will make recommendations directly to Ministers;
- giving NCAG a new responsibility of considering a small number of additional drugs and technologies that may meet the criteria for nationally commissioned specialised services;

2.2 We propose that NCAG will:

- consider clinical, cost effectiveness and affordability issues at the same time, alongside best practice in service delivery; and
- provide a single source of robust and transparent advice direct to Ministers on which services should be designated for national commissioning.

These changes are being proposed to enhance the process for national commissioning. They do not seek to re-engineer current specialised commissioning arrangements on a fundamental level, rather they seek to deliver incremental improvement within the framework established following the Carter review. The suggested approach changes only what needs to be changed.

The objective of these proposed changes is to enhance the structure of specialised commissioning which has been in place since Ministers accepted the recommendation of 2006

Strengthening National Commissioning – A consultation

Sir David Carter's independent review of commissioning arrangements for specialised services in 2006.

A number of options were considered before reaching the preferred option which is being developed further as part of this consultation. The option to adapt the existing national commissioning arrangements by dissolving the current body advising on national commissioning and by creating a group to take forward the benefits as listed previously was considered to be the best workable solution.

Economic evaluation

Option 2 – Doing nothing

Costs of doing nothing

There are no additional costs of doing nothing

Benefits of doing nothing

There are no additional benefits of doing nothing.

Option 1

Overview of economic impacts

The proposals described will consolidate decisions on national specialised commissioning into a single national body – the National Commissioning Advisory Group. This will result in two major changes to current practice:

- The NCAG – rather than multiple bodies - will determine which specialised services and treatments are provided nationally, using a more robust and transparent process than the current arrangements. This change in practice will be applied to existing services and treatments, and does not imply an increased scope for national specialised commissioning.
- The NCAG will also extend the scope of national specialised commissioning, by centralising commissioning of a small number of high cost treatments for very rare conditions, which are currently commissioned by individual PCTs or their SCGs.

The effects of these two changes in practice are now considered separately.

Consolidation national commissioning decisions in respect of patients with rare conditions in the NCAG

The most important objective of the proposals is to consolidated decision-making about existing national commissioning of highly specialised services in a single new body - the NCAG.

This reform is expected to improve the transparency and robustness of the national specialised commissioning process, to increase public and patient confidence in the system.

These benefits are difficult to quantify, and no attempt has been made to monetise them in this analysis. As the net benefit of the policy is expected to be positive *without* monetisation of this beneficial effect, the true impact is likely to be even more positive.

As well as improved public confidence and robustness there may be some additional benefit to patients arising from the improved efficiency of delivering highly specialised services, as the NCAG makes better use of the national resources and facilities available. This will result in an increase in the patient benefits provided from the funds allotted to these services. The magnitude of this benefit is highly uncertain, and it has also been left unmonetised.

There is expected to be no net change in costs as a result of this part of the policy proposal.

Extending the scope of national specialised commissioning to consider a small number of additional technologies and which may be suitable for nationally commissioned specialised services

The potential agreement to strengthening and extending the scope of national commissioning to include assessment of these high cost treatments for patients with rare conditions, which are currently commissioned by individual PCTs or their SCGs, is assumed to result in no net change in the spending on such treatments. However, as explained below, this assumption is the subject of significant uncertainty, and the actual impact of the policy could be to increase or decrease spending on these treatments, with commensurate implications for NHS costs.

The extension of the current scope could deliver greater patient benefits from this, as there is expected to be a net cost saving through efficiencies of scale, as administration activities that were previously duplicated across the NHS are consolidated in the NCAG.

These impacts are described in more detail in the following sections.

Impact of extending scope of national commissioning for NHS spending on treatments

This section evaluates the expected effect on NHS spending of the proposal to extend the scope of national commissioning as described, to include the assessment of high cost technologies for patients with very rare conditions. Note that administration costs of the NCAG are considered elsewhere.

The extension of scope of national specialised commissioning to include some services with some high cost treatments for rare conditions could result in a net change in spending on these treatments. Under the current arrangements, individual PCTs or SCGs may decide to fund a drug with agreement with a particular provider thus leading to variation in practice, such that, for example, 30% of PCTs might commission the service, while 70% may not. In this situation, 30% of patients nationally will receive the treatment, while 70% will not. If these treatments are commissioned by NCAG, they will either be available for all patients nationally (i.e.~100% of eligible patients), or they will be deemed inappropriate for national funding (i.e.~0%). The decisions of NCAG could therefore result in a net increase in spending on services, if, overall, nationwide commissioning resulted in treatment of more patients. Alternatively, if the NCAG overall made more decisions to reject treatments nationwide, there could be a reduction in spending.

The actual outcome of widening the scope of national commissioning in respect of these treatments is subject to considerable uncertainty, as the outcome of decisions made by the NCAG is not known.

As well as effects on the volume of patients treated, there may be an additional impact of the proposals on the price of treatments. If companies believe that NCAG will employ a more robust process in commissioning highly specialised services – which would imply prioritisation of those services that gave the greatest benefit from the funding available – then they may be expected to reduce the prices of their products in order to increase the chances of commissioning by the NCAG. This would have the effect, all else being equal, of reducing the spending on these treatments.

In summary, the net impact of these proposals on NHS spending on treatments is estimated to be zero. However confidence in this estimate is very low, and it is subject to great uncertainty.

Benefits to patients of extending scope of national commissioning

Extending the scope of national commissioning to include assessment of high cost treatments that may currently be commissioned by individual PCTs is likely to improve the quality of

decision-making, so that the benefits gained from the funds spent on these treatments are increased.

Under the current system, individual PCTs or SCGs decide whether to fund certain high-cost drugs for the patients with rare conditions that they represent.

Under the new system, high cost technologies are put forward for assessment to the NCAG, and if they fulfil the entry and assessment criteria, and if approved by Ministers, decisions will be more consistent. Patients will benefit as a consequence as it will be accessed by all patients and not just those in PCTs that fund the technology.

Administration costs

Widening the scope of national commissioning to include these high cost technologies is expected to result in a net reduction in administration costs. The cost of conducting Health Technology Assessments for new treatments is not expected to change – as it is assumed that a single such assessment would ordinarily be carried out under both existing and new systems. However the costs sustained by each of the 10 regional SCGs in administering the commissioning process, and reaching a decision, will be reduced as the activity is consolidated into a single body.

It is estimated that the annual costs to the NCAG of administering the scheme are **£230,000**, comprising **£175,000** in staff costs, **£50,000** in legal expenses, and **£5,000** in general administrative expenses.

In order to generate a conservative estimate of the cost savings, it is assumed that each of the 10 SCGs would incur **50%** of these costs in carrying out the equivalent activities. This implies a gross cost annual saving of **£1,150,000**, and a net annual cost saving of **£920,000**.

Additional spending in the NHS is estimated to provide benefits to society worth 2.4 times its direct cost (see Annex). The social value of these cost savings is therefore **£2.2m** annually. The present value of these benefits over 10 years is **£18.4m**.

Reduction in regional variation of patient access

Widening the scope of National Commissioning will potentially decrease the regional variability resulting from the current system, by which patients in one area may be denied treatments available to those elsewhere in the country. This increase in consistency is clearly desired by the public's notion of "fairness", and must therefore result in a social benefit. Evaluation of such benefits is difficult, and it has therefore been left unmonetised.

Risks and Assumptions

The above evaluation is largely based on scenarios as it is impossible to pre-empt the decisions made of the new group NCAG. This change is about strengthening and widening the scope of national commissioning, and the aim is to address the current risks and issues already in the system.

Specific Impact Tests

Competition Assessment

The OFT has published screening questions to help determine whether a policy is likely to have an impact on competition⁵. These are:

Would the proposal directly limit the number or range of suppliers? These proposals would have no impact on the number or range of suppliers that can provide medicines to the UK pharmaceuticals market.

Would the proposal indirectly limit the number or range of suppliers? As above, there is no reason to expect any indirect impact on the number or range of suppliers that can provide medicines to the UK pharmaceuticals market.

Would the proposal limit the ability of suppliers to compete? Any provider is free to offer products for purchase by the NHS. These proposals impose no additional restrictions on companies, and they cannot limit in any way the ability of suppliers to compete.

Would the proposal reduce the incentives of suppliers to compete vigorously? It is possible that the introduction of a more robust commissioning process for high-cost treatments for rare conditions will increase the incentives for companies supplying such products to set competitive prices, in order to improve their prospects of approval by the NCAG.

Small Firms Impact Test

These proposals will most likely be cost neutral as providers will continue to purchase the treatments from firms.

Health Impact Assessment

The health impacts of the policy have been considered in the main Analysis and Evidence section of this document.

Are the potential positive and/or negative health and well-being impacts likely to affect specific sub groups disproportionately compared with the whole population?

Because the NCAG is expected to improve the decision-making in respect of treatments for patients with very rare conditions, it is expected that these sub-groups of patients will benefit from these proposals.

Are the potential positive and/or negative health and well-being effects likely to cause changes in contacts with health and/or care services, quality of life, disability or death rates?

The net health impacts have been evaluated in the main body of the Impact Assessment.

⁵ http://www.of.gov.uk/advice_and_resources/resource_base/guidelines/#named3

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Are there likely to be public or community concerns about potential health impacts of this policy change?

There is no reason to expect any such concern. To the extent that the proposals ameliorate the perceived “post-code lottery” for treatments of rare conditions, it is likely that public concerns will be favourably affected.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annexes

Measuring the Opportunity Cost of NHS Spending

The total NHS budget is fixed, in a given period. Any funds committed to new policies must therefore be reallocated away from some other use, elsewhere in the NHS. To fully reflect the impact of a particular policy, it is important to consider the effect of reallocating funds away from this alternative use. The impact of reallocation is the policy's true cost – or "opportunity cost" – that must be measured in Impact Assessments.

This 2.4:1 ratio of benefits to costs implies that the alternative use of a given quantity of NHS funds will generate benefits valued 2.4 times as highly. This means that any policy which involves spending from the NHS budget will deprive society of benefits worth 2.4 times as much (before the policy's own benefits are taken into account). Similarly, any cost saving measure that releases NHS budget to be spent elsewhere is expected to provide benefits valued at 2.4 times the cost saving.

To correctly reflect the cost impacts of policies and programmes, all effects on the NHS budget should therefore be multiplied by 2.4 in order to calculate their true cost to society. This adjustment reflects the amount of benefits lost by diverting spending to the policy in question – and it follows that the policy should itself generate greater benefits, in order to provide an overall positive impact.

Equality Impact Assessment Screening

A consultation on strengthening national commissioning of specialised services

This consultation aims to:

- improve the process by which decisions are made on funding very specialised new technologies (drugs and treatments) which are candidates for national specialised commissioning, by adapting and strengthening the existing arrangements for national commissioning; and

- adapt the scope of this system to allow it to consider a small number of additional technologies that are not appropriate for assessment by the National Institute for Health and Clinical Excellence (NICE), and which may be suitable for national commissioning.

Negative impact

Could your policy have a significant negative impact on equality in relation to:

- disability
- ethnicity
- gender
- sexual orientation
- age
- religion or belief

The policy is not expected to have a negative impact on any of these groups.

- Will the policy present any **problems or barriers** to any community or group? Potentially there may be groups that do not support this change in policy but we will consider this further following the consultation.
- Will any group of people be **excluded** as a result of your policy? No.
- Does the policy have the potential to **worsen** existing discrimination and inequality? No
- Will the policy have a negative effect on **community relations**? No

Positive impact

- Could the policy have a significant positive impact on equality by reducing inequalities that already exist? How will it meet our duty to:

1. Promote **equality of opportunity**? Yes

The main aim of strengthening national commissioning of specialised services is to create a more robust decision making process, and bring together two separate sources of advice to Ministers by forming the proposed National Commissioning Advisory Group. The new system should lead to better decision making and increased public confidence in the way decisions are made.

2. Eliminate **discrimination**? Yes

This development may help to limit discrimination as to the geographical location where a patient resides in that some PCTs fund these treatments and others do not.

3. Eliminate **harassment**? No

4. Promote **good community relations**? No

5. Promote **positive attitudes** towards disabled people? Yes, some of the interventions that will be considered will be patients with chronic conditions.

6. Encourage the **participation** of disabled people? No

7. Consider **more favourable treatment** of disabled people? No

8. Promote and protect **human rights**? No.

Evidence

The consultation “strengthening national commissioning” is about modifying some of the arrangements, which are already in place following the Carter Review in 2006. In particular, it focuses on reshaping the National Commissioning Group (NCG), revising its membership to bring together a wider range of expertise, and expanding its scope to include responsibility for assessing a very small number of high cost drugs and technologies for treating very rare conditions.

The current arrangement for national commissioning were developed following the Carter review and in general have been working effectively. However, there are several issues with the process for decisions on the national funding of new technologies and a need has been identified for further incremental development of some of the arrangements proposed in the Carter review:

- in the current specialised commissioning system, clinical effectiveness and issues of cost are broadly considered separately by the National Commissioning Group and National Specialised Commissioning Group. The responsibilities of each group are not widely understood.

- The current decision making process and eligibility criteria could be made more robust.
- There is a case for enabling the national commissioning system to assess a very small number of technologies that do not fit within the current eligibility criteria, principally by virtue of the way in which the relevant services are organised across the NHS

There is no evidence that the proposed new system will have a significant positive or negative impact on any particular group of society, as the new arrangements are purely about clarifying and strengthening an existing process. Access to services which are nationally commissioned is open equally to all those who fit the clinical criteria. The national commissioning team monitor equality of access to nationally commissioned services.

If the strengthened arrangements are adopted, for services which are nationally commissioned, we should expect a reduction in inequalities in prescribing that sometimes exist across PCTs, where some commission treatment using certain drugs and technologies for very rare conditions, and others do not. This can be monitored for individual services after implementation if the proposals go ahead after the consultation.

There was an extensive consultation at the time of the Carter review, which broadly supported the way in which national commissioning of specialised services worked to patients' benefit. The present proposals strengthen the arrangements recommended by the Carter review, giving a clearer locus for making the decision on new proposals for national commissioning of services with costly drugs for rare conditions within them. The proposals do not alter the way in which nationally commissioned services are accessed by patients; the changes are within the framework set out by Carter⁶.

The rarity of this situation, and nature of the changes proposed in the process of assessing these drugs and technologies mean that there is no relevant research evidence from other sources.

Screening Assessment

If implemented, the new arrangements may help to reduce inequalities as a consequence of strengthening national commissioning arrangements.

An adverse impact is unlikely.

A full EqIA is not required.

⁶ Professor Sir David Carter's review of commissioning 2006

Next steps

If, following consultation, the suggested proposals are implemented, the impact of new processes will be monitored by the national policy team. The new arrangements could help reduce the potential for inequalities of prescribing of high cost drugs for very rare conditions that sometimes occurs across PCTs.

Strengthening National Commissioning

Reply Form

Closing date for responses: 19th February 2010

Please fill in and/or tick the appropriate response.

Response form

Name
Contact address
Organisation representing (if appropriate)
Postcode
Contact telephone
Email

Before submitting your response to the Department, please make sure that it has been saved in a name (i.e. Strengthening national commissioning) that will make it easier for us to track. Many thanks.

Freedom of Information

We manage the information you provide in response to this consultation in accordance with the Department of Health's [Information Charter](#).

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. The relevant legislation in this context is the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 1998 (DPA).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

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The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties. However, the information you send us may need to be passed on to colleagues within the UK Health Departments and/or published in a summary of responses to this consultation.

I do not wish my response to be passed to other UK Health Departments

I do not wish my response to be published in a summary of responses

Please indicate the country the consultation and your comments relate:

UK-wide *and/or:*
England *Northern Ireland*
Scotland *Wales*

Are you responding:

- *as a member of the public*
- *as a health or social care professional*
- *on behalf of an organisation*

Area of work:

NHS	
Social Care	
Private Health	
Third Sector	
Regulatory Body	
Professional Body	
Education	
Trade Union	
Local Authority	
Trade Body	
Other (Please give details)	
Independent Contractor to NHS	
Manufacturer	
Supplier	
Other (where relevant)	

In which of the following areas do you live: (please tick <u>one</u> box only)	
North East	
North West	
West Midlands	
South East	
London	
Humberside/Yorkshire	
East Midlands	
East of England	
South West	
No answer	

If you are responding on behalf of an organisation, please indicate which type of organisation you represent:

NHS	
Social Care	
Private Health/Independent Sector	
Third Sector	
Regulatory Body	
Professional Body	
Education	
Trade Union	
Local Authority	
Trade Body	
Other (Please give details)	

1 What is your sex? *
Tick one box only.

Male	<input type="checkbox"/>
Female	<input type="checkbox"/>
Prefer not to say	<input type="checkbox"/>

2 What is your Age?*

Age	
Prefer not to say	

3 Are your day to day activities limited because of any health problem or disability which has lasted, or is expected to last at least 12 months?

Tick one box only.

- Yes, limited
- Yes, limited, a little
- No
- Prefer not to say

4 Do you look after, or give any help or support to family members, friends, neighbours or others because of either long term physical or mental ill-health/disability or problems related to old age?

Tick one box only.

- Yes
- No
- Prefer not to say

5 What is your ethnic group?
Tick one box only.

A White

- British
- Irish
- Any other White background, write

B Mixed

- White and Black
- White and Black African
- White and Asian
- Any other Mixed background, write

C Asian, or Asian British

- Indian
- Pakistani
- Bangladeshi
- Any other Asian background, write

D Black, or Black British

- Caribbean
- African
- Any other Black background, write

E Chinese, or other ethnic group

- Chinese
- Any other, write below

F Prefer not to say

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6 What is your religion or belief?
Tick one box only.

Christian includes Church of
Wales, Catholic, Protestant and all
other Christian denominations.

None	<input type="checkbox"/>
Christian	<input type="checkbox"/>
Buddhist	<input type="checkbox"/>
Hindu	<input type="checkbox"/>
Jewish	<input type="checkbox"/>
Muslim	<input type="checkbox"/>
Sikh	<input type="checkbox"/>
Prefer not to say	<input type="checkbox"/>
Other, write below	
<input type="text"/>	

7 Which of the following best
describes your sexual orientation?
Tick one box only.

Only answer this question if you
are aged **16** years or over.

Heterosexual Straight	<input type="checkbox"/>
Lesbian / Gay Woman	<input type="checkbox"/>
Gay Man	<input type="checkbox"/>
Bisexual	<input type="checkbox"/>
Prefer not to say	<input type="checkbox"/>
Other, write below	
<input type="text"/>	

Strengthening National Commissioning

Consultation Questions

In the proposed changes, we are recommending a single group to advise Ministers on nationally commissioned specialised services.

Question 1: Do you agree to combining this advice into one group? If not, why not?

We have proposed the expertise NCAG will need and have suggested that the Secretary of State appoints the Chair and members of NCAG

Question 2: Do you think this is right? Is there other expertise we should include?

We believe that the proposed changes will build on and strengthen the implementation of Professor Sir David Carter’s review of specialised services commissioning arrangements and will provide a stronger and more robust process for national commissioning.

Question 3: Do you have any other suggestions for strengthening national commissioning?

In the accompanying Impact Assessment we have attempted to estimate the likely costs and benefits of the new proposals.

Question 4: Do you agree with our estimate of the likely costs and benefits? If not please indicate and provide evidence, where possible, of any areas of disagreement.

Equality Impact Assessment

Question 5: Please identify the impact the proposals in this document might have from the perspective of ethnicity, age, gender, gender reassignment, sexual orientation, religion or belief or socio economic considerations? If there is a negative impact, what proportionate measures could address those issues?

General comments

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Do you have any other comments you would like to make in relation to this consultation?

Before submitting your response to the Department, please make sure that it has been saved in a name (i.e Strengthening national commissioning) that will make it easier for us to track. Many thanks.