

# **Strengthening National Commissioning Consultation**

*Summary of Responses to the Consultatio*

## Strengthening National Commissioning Consultation – Summary of Responses

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# Strengthening National Commissioning Consultation

## *Summary of Responses to the Consultation*

Prepared by: The Department of Health

# Contents

Contents.....	4
Executive summary.....	5
Introduction .....	7
Responses to the Consultation .....	9
Next steps .....	15
Glossary .....	18

# Executive summary

1. This document is a report following the consultation undertaken by the Department of Health on proposals for strengthening national commissioning. The purpose of the consultation was to seek views on the Government's proposals for an incremental development of some of the arrangements put in place following Sir David Carter's review of specialised commissioning in 2006.

2. In particular, the consultation sought views and comments on the proposal 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 the 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;
- dissolve the current National Commissioning Group and establish a new, single, advisory group to make recommendations to Ministers on services and technologies for national commissioning.

3. The consultation ran from the 11<sup>th</sup> December 2009 to the 19<sup>th</sup> February 2010, and the views and comments received as part of the consultation have been analysed and summarised in this document. The proposals for strengthening national commissioning, particularly around membership of the new advisory group, have been refined in light of those views and comments.

4. The consultation suggested that the proposed membership of the new advisory group would need to be wide-ranging to include both clinical and commissioning expertise, as well as public health, financial, health economics, health technology assessment, patients and lay members. Consultation responses were broadly in favour of this membership, but suggested widening it further to include a pharmacist and an ethicist. These are helpful suggestions and the new group will include representatives from these areas.

5. We are now working with the National Specialised Commissioning Team to develop the detail of these proposals including confirming the process for making appointments to the new advisory group.



# Introduction

## Background on the consultation

6. On 11<sup>th</sup> December 2009, the Department of Health published a consultation document “Strengthening National Commissioning”. The purpose of the consultation was to seek views on the Government’s 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 the 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;
- dissolve the current National Commissioning Group and establish a new, single, advisory group to make recommendations to Ministers on services and technologies for national commissioning.

7. The overall aim of the changes proposed is to make sure that patients with extremely rare conditions or who need high cost technologies are not left behind, while also securing best use of NHS resources. This is in line with the outcome of the work carried out NICE Citizens’ Council in 2004, on very rare and severe conditions, and survey activity to support the NHS Constitution, revealing strong public support for the NHS “not leaving anyone behind.”

8. The proposals aim to address several issues of the current system for national specialised commissioning for costly new services, developed in 2007 following the Carter review in 2006. In particular:

- 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.

### Changes proposed

9. In the consultation document we outlined a number of specific proposals to achieve the stated objectives. These can be summarised as follow:

**Single advisory group** – Provide a single source of robust and transparent advice to Ministers on which services should be designated for national commissioning by dissolving the NCG and establishing a new advisory group (referred to as “NCAG” in the consultation document) which would make recommendations directly to Ministers.

**Expertise and appointment of the group** – Ensure that this group has a wide range of expertise to take account of both clinical and commissioning issues. In particular, it was suggested that membership would include the following expertise:

- Clinical
- Public health
- Financial and investment
- Health economics
- Commissioning
- Health technology assessment
- Patients
- Lay members

We suggested that the group would be appointed for their expertise and would be drawn from SHAs and the current membership of the NSCG and NCG. It was suggested that both members and the Chair would be appointed by the Secretary of State after an appropriate nomination process.

**Decision making criteria** – The advisory group would consider the needs of patients with rare diseases, or those that need highly specialised services, alongside clinical effectiveness and best use of NHS resources.

**Scope** – Broaden the function of the national commissioning process to include the assessment of a very small number of additional services that are not appropriate for appraisal by NICE but may be suitable for national specialised commissioning.

### Timing

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



# Responses to the Consultation

## Number of responses received

11. The Department of Health received 61 responses from various groups of stakeholders, including both individuals and organisations. The vast majority of the responses were sent in the format of the response proforma as laid out in the consultation document. A minority of responses were drafted in the format of other written communication. A breakdown of the responses by stakeholder group is shown below.

Stakeholder group		Number of responses
<b>NHS Organisations</b>	National bodies	6
	Primary Care Trusts	2
	Specialised Commissioning Groups	9
	NHS Trusts	6
	<i>Total NHS Organisations</i>	<u>23</u>
<b>Professional bodies</b>	Royal Colleges	7
	Other	3
	<i>Total professional bodies</i>	<u>10</u>
<b>Patient groups and Associations</b>		<u>9</u>
<b>Industry</b>	Trade Associations	2
	Manufacturers	6
	<i>Total Industry</i>	<u>8</u>
<b>Healthcare Professionals</b>		<u>5</u>
<b>Members of the public</b>		<u>4</u>
<b>Other</b>		<u>2</u>
<b>Total</b>		<b><u>61</u></b>

We have included further detail on how we intend to develop our proposals further in light of the comments received in this consultation in the Next Steps chapter.

## Consultation responses

12. **Question 1. In the proposed changes, we are recommending a single group to advise Ministers on nationally commissioned specialised services. Do you agree to combining this advice into one group? If not, why not?**

### Appropriateness of a single advisory group

- Almost all respondents (53) answered the first question. The majority of them (48) across different groups of stakeholders agreed with the need to strengthen the national specialised

## Strengthening National Commissioning Consultation – Summary of Responses

commissioning system and with the proposal that advice to Ministers should come from one combined group.

- Generally the respondents thought that merging the two existing sources of advice on national commissioning to Ministers would have a number of advantages, such as:
  - Combining commissioning and clinical expertise to ensure consistent and joined up recommendations;
  - Streamlining current arrangements and making national dialogue more clear and focused; and
  - Reducing duplication and the potential for differing views.
  
- Some of the respondents in agreement had conditions and concerns:
  - The terms of reference, remit and membership of the new advisory group need to be clearly defined and transparent.
  - The new group needs to fully engage with the clinical opinion from major stakeholders in each medical field.
  - The revised arrangements should not delay any designation or review of services for national commissioning due to a longer national decision-making process.
  - The specific arrangements could leave some stakeholders out of the process whereby recommendations are made. In particular, this refers to the role of SHAs and of Specialised Commissioning Groups (SCGs) through the NSCG.
  - Establishing a direct link between the new advisory group and Ministers could weaken the Carter review arrangements by undermining the role of the NSCG and centralising the decision making process. They felt that the new advisory body should instead be accountable to the NHS.
  - NSCG should be the single source of advice to Ministers.
  - Greater clarity is needed on how NSCG will provide oversight on the effectiveness of national commissioning.
  
- Respondents who did not agree with the proposal of combining the two existing sources of advice raised a number of concerns:
  - Ministers receiving recommendations from different sources was not necessarily a bad thing.
  - A centralised approach might lead to reduced responsiveness to requests from local providers and limited understanding of the local contexts.

**13. Question 2. We have proposed the expertise the new advisory group will need and have suggested that the Secretary of State appoints the Chair and members of the group. Do you think this is right? Is there other expertise we should include?**

- Almost all respondents (52) answered the second question. Whilst the majority of them broadly agreed with the suggested appointments arrangements (37), some other respondents (15) – including SCGs, national NHS bodies and members of the public – did not.

### **Expertise and representation**

- All respondents agreed that the proposed expertise for the new advisory group is appropriate. In addition, some respondents suggested that the new advisory group could include representatives or expertise from the following areas: field of ethics; industry; providers; carers; third sector; pharmacy, genetics, paediatrics, clinical psychologists, physiotherapy; occupational therapy, Duchenne Muscular Dystrophy; research; independent international experts for specific considerations; horizon scanning; an equal balance between clinical and commissioning and a fair geographical representation.
- There is a broad consensus that the proposed national advisory group should:
  - Draw members from SHAs and the wider NHS;
  - Draw on current membership of NSCG and NCG;
  - Seek an appropriate breadth of the areas of expertise as mentioned in the consultation.

### **Appointments**

- Respondents suggested that the members and Chair could be selected and appointed in a number of different ways:
  - Drawn from, and chosen by, NHS commissioners;
  - Appointed by the NSCG, but with ministerial sign off;
  - Selected and appointed by the Appointments Commission;
  - Members should be appointed by the Chair;
  - Members should be selected in a way that better reflects the responsibilities of the NHS;
  - The Chair should be selected from a list of nominees by the members of the committee;
  - The current Chair of NCG should remain to ensure continuity.

14. **Question 3. Do you have any other suggestions for strengthening national commissioning?**

- The majority of respondents (37) answered the third question, providing a wide array of proposals to strengthen the arrangements for national specialised commissioning, including suggestions on how to develop a robust decision-making process. These included:
  - the new advisory group could also assume a performance management role of the nationally commissioned services;
  - NHS commissioners from PCTs and SCGs could be involved as appropriate in the applications evaluation process;
  - the revised commissioning processes should operate in a manner consistent with mainstream NHS commissioning and World Class Commissioning;
  - the funds available for national commissioning should increase annually in line with NHS spending growth;
  - the budget for national commissioning should be capable of upward or downward adjustment;
  - funds for national specialised commissioning should be allocated directly to SHAs;
  - there needs to be more honesty and consistency about what the NHS can afford in driving recommendations on investments for national specialised commissioning;
  - the decision-making process should include open and transparent dialogue with manufacturers and sponsors from the early stages of the evaluation;
  - decisions could be benchmarked against other European countries;
  - there should be a guaranteed time limit as well as a review process to ensure there are no delays;
  - there should be a right of appeal to recommendations from the advisory group;
  - the consultation should apply to a wider group of medicines and technologies than those identified as ‘ultra-orphan’. These processes would require reliable decision-making criteria specific for “ultra orphan” therapies and should be subject to further consultation;
  - the process to make proposals for national commissioning could be led by the NHS, instead of being generated by service providers. As part of this, proposals could have a local or regional commissioning sponsor.
- There was general consensus that the revised decision-making process should be consistent and transparent, as well as based on a full and independent review of the evidence. However, one industry representative was concerned that the criteria may not adequately account for the fact that any evidence-based decision making process can be unreliable when the supporting evidence base is small and the ability to generate robust health economic assessments is extremely limited.

- A few industry representatives suggested that limiting treatment centres to four or fewer may impose an additional and unnecessary burden on the patients and their families.
- One respondent suggested that a group of therapies seem to fall between NICE and the new process, namely those where patient numbers are between 500 and 1,000.

### Coordination with NICE

- Various groups of stakeholders asked for clarifications or made comments on the process to coordinate the scope of the work of the advisory group for national specialised commissioning with that of the NICE appraisal committee. It was felt that NICE and the new advisory group should work together to determine which products may be suitable for consideration for national commissioning. The following additional comments were made:
  - There needs to be greater clarity as to how the entry criteria for the advisory group on national commissioning differ from the entry criteria for the NICE process;
  - There should be a system in place that ensures products are only evaluated once by either the advisory group or NICE;
  - Effective horizon-scanning would be important in avoiding a potentially lengthy process of referral from NICE to the advisory group and provide advanced notice to Commissioners of any emerging products.

Some SCGs suggested that the NICE role should be extended to carry out national commissioning appraisal instead of the proposed group<sup>1</sup>.

### 15. **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.**

- There were 36 responses to this question. The majority of the respondents (25) agreed that some savings would be achieved through the implementation of the proposals, however a number of them found the figures too optimistic.
- The respondents expecting some financial benefit under the proposed arrangements mentioned a number of potential savings sources:
  - Savings at PCT level from costs remitted nationally and at national level from a reduced number of successful litigation;

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<sup>1</sup> See the consultation document (page 11) for further details on why the Department of Health prefers the proposed arrangements to other options, including using an existing body such as NICE or the creation of a completely new system.

- Local savings from spreading of the risk of the cost of very specialised drugs and treatments nationally rather than regionally.
- The respondents who did not expect significant savings mainly disagreed with the assumptions around the efficiency gains from the centralisation of the appraisal work at national level. This is in view of their statement that most SCGs are actually not undertaking this type of appraisal work. Furthermore, it is believed that PCTs could still wish SCGs to contribute to the recommendations of the national advisory group, with costs attached.
- Finally, a member of the public suggested that any savings made should be reinvested into emerging technologies.

**16. 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?**

- Nearly half of the respondents provided comments to the fifth question (29). Most of these envisage a positive or neutral impact of the proposed arrangements. However a minority of respondents highlighted risks in terms of equality, for example:
  - Having a different process in place for nationally commissioned services in comparison to other services or other specialised services may discriminate in favour of patients with selected rare conditions, at the expense of the great majority of patients who have less rare conditions.

**17. Question 6. Do you have any other comments you would like to make in relation to this consultation?**

- Some responses emphasised the need for the new advisory group and decision-making framework to be implemented as soon as possible, to secure the benefits to the patients of the revised arrangements earlier on.
- A few respondents proposed that Devolved Administrations should have the right level of exposure to and involvement with the work of the advisory group.
- It was also suggested that there is a strong case for connecting the new arrangements to some process in the Research & Development directorate so that a view can be given by the advisory group as to where the deficiencies in knowledge are most problematic.

# Next steps

## Introduction

18. The Department of Health welcomes the high level of interest shown by the various stakeholders from across the spectrum of the NHS, specialised commissioners and providers, as well as patient organisations and the pharmaceutical industry. The comments received are important for the refinement of robust detailed governance arrangements for national specialised commissioning, as well as for the redefinition of the scope and criteria of the evaluation process.

19. The consultation exercise yielded some valuable suggestions for amendments and additions to both the process and membership of the new advisory group and we are now considering these as we work up the detail of the proposals.

20. After consideration of all the consultation responses, our intention for the further development of these proposals is set out below:

## The new advisory group

21. In light of the broad consensus expressed by the responses received, we propose to replace the National Commissioning Group with a differently constituted group on national specialised commissioning. The group will:

- Advise Ministers on which services should be designated for national specialised commissioning, which centres should provide those services and whether to renew or withdraw the designation at the appropriate time, and will
- Have oversight of and provide advice on the whole of national specialised services and their associated funding to Ministers and the NHS.

## Membership

22. The membership of the new advisory group will include the range of expertise outlined in the consultation document as well as additional skills and representation suggested by some respondents. As a result, the committee will include the following expertise: clinical, public health, commissioning, financial, patients, carers, lay members, health economics, health technology assessment, pharmacy, genetics, and ethics. This will allow the committee to achieve a balanced view and to be able to take into account a wide range of factors in making recommendations to Ministers.



23. A fair representation of members from SHAs and SCGs in the new advisory group will help make sure that a joined-up approach across different NHS levels is adopted, as recommended by a number of respondents. As part of this, the advisory group will work with other NHS commissioners and stakeholders, such as SCGs, to ensure that their input is obtained and considered during the analysis and evaluation of applications.

24. As per the suggestion of some respondents, the membership mix will reflect a fair geographical representation from across the country, to ensure that different local needs are adequately accounted for.

25. Officers from the Devolved Administrations may also attend meetings of the advisory group as observers. This is in line with comments received that it could be beneficial to give the Devolved Administrations adequate exposure to the work of the group.

26. Finally, experts, mostly with clinical or academic backgrounds, may be invited to advisory group meetings or sessions of meetings on an ad-hoc basis to provide opinions, information and evidence on specific matters.

27. We are now working with the National Specialised Commissioning Team to develop the process for making appointments to the new advisory group. Following further evaluation of the responses and discussions, we are changing the way in which the members of the new advisory group will be appointed from the process described in the consultation process. We are now proposing that the Chair will be appointed by the NHS Chief Executive and the members will be appointed by the NHS Medical Director. Some will also be appointed via a public appointments process.

### Decision-making process

28. A number of respondents provided comments and suggestions on the decision-making process. Whilst the detail of this was not covered in the consultation document, the National Specialised Commissioning Team are developing the details of the decision making framework and will consider the comments received in this consultation as they further develop these proposals.

29. Some Specialised Commissioning Groups (SCGs) responsible for regional specialised commissioning and current members of the National Specialised Commissioning Group (NSCG) where the Chairs of SCGs meet, have voiced concerns that this is a way of cutting PCTs out of the decision-making process and taking more money out of their baseline allocations. Some argue for devolving responsibility for national specialised commissioning entirely to PCTs. This would fundamentally alter the current arrangements in place. A key policy aim of the proposal is to build on the current arrangements, rather than radically revised



them, ensuring balanced membership of all views within one single group credible with a wide range of stakeholders and not just commissioning. To address the SCG concerns DH will:

- i. ensure that NHS commissioners are well represented on the new group;
- ii. work with the NSCT and NSCG to support them in delivering effective specialised commissioning at a regional and supra-regional level.

30. The decision making framework being developed outlines a two-step decision-making process. The first step – for the review of outline applications – is based on a list of eligibility requirements related to rarity of the condition and complexity of the proposed services. The second step – for the review of full applications – includes a comprehensive assessment centred around patients' needs. This will be based on four groups of criteria including: health gain, societal value, reasonable cost for the public and best clinical practice in service delivery.

31. In evaluating the providers' applications, the advisory group will consider information submitted by applicants as well as sources of sound evidence from outside the NHS, as well as opinions from NICE, professional bodies, and other relevant organisations as appropriate.

32. The advisory group, NICE and the Department of Health will work closely in order to determine the most appropriate route for evaluation, commissioning and funding of new products and technologies.

33. A number of respondents questioned the role of NICE. New products or technologies, which are deemed appropriate for a NICE technology appraisal are outside the scope of the new process. The decision whether a NICE appraisal is the most appropriate route of evaluation, is based on published criteria which have themselves been the subject of public consultation. Details on these criteria and the process by which they are applied can be found on the NICE website. Products selected for funding through the new Innovation Pass process should be suitable for review by NICE in future and therefore would not normally be considered for national commissioning.

### Timescale

34. During 2010/11 we will be working with the National Specialised Commissioning Team to develop the appointments process, set up the new advisory group and publish the application process. Commissioning any new services and technologies approved by Ministers will then start from April 2011.

### Glossary

**Decision-making framework** – It is the framework to be used by the proposed new national advisory group in evaluating the submissions from providers to make recommendations to Ministers on national specialised commissioning.

The framework has been developed with input from a wide range of stakeholders to drive a fair, transparent and structured process to produce high quality and consistent recommendations. The framework outlines a two-step decision-making process. The first step - used for the review of outline applications - is based on a list of eligibility requirements related to rarity of the condition and complexity of the proposed services. The second step of the process – for the review of full applications – includes a comprehensive assessment centred around patients’ need. This will be based on four cornerstones: health gain, societal value, reasonable cost for the public and best clinical practice in service delivery.

**NCG** – The National Commissioning Group (NCG) is a Standing Committee of the National Specialised Services Commissioning Group (NSCG), established as a result of the Carter Review of Commissioning Arrangements for Specialised Services. NCG is currently mainly responsible for:

- Providing recommendations to Ministers through the NSCG on the portfolio of services to be nationally commissioned, designation of national centres, and budget for national specialised commissioning;
- Overseeing the national commissioning of national specialised services by the National Specialised Commissioning Team;

**NCAG** – National Commissioning Advisory Group (NCAG) is the name used in the consultation document published on December 11<sup>th</sup> to indicate the proposed new advisory group, responsible for providing recommendations to Ministers on national specialised commissioning as a single source of advice. In this Summary of Responses we have referred to the same group simply as “advisory group” or “national advisory group”, as the final name has yet to be defined.

**NSCG** – The National Specialised Commissioning Group (NSCG) is currently responsible for supporting supra-SCG decision-making, facilitating collaborative working across SCGs and between SCGs and NCG, as well as providing oversight of specialised commissioning undertaken by SCGs, where the service has a catchment/planning population bigger than that of a single SCG.

NSCG’s current responsibilities for commissioning at national level (relevant to this consultation) are:

## Strengthening National Commissioning Consultation – Summary of Responses

- Agreeing NCG's recommendations on the portfolio of services to be nationally commissioned, designation of national centres, and budget for national specialised commissioning;
- Communicating the final recommendations to the NHS Operations Board and Ministers as appropriate.

**NICE** – National Institute for Health & Clinical Excellence

**PCT** – Primary Care Trust

**SCGs** – Specialised Commissioning Groups

**SHA** – Strategic Health Authority

**Specialised services** – Those services provided in relatively few specialist centres to catchment populations of more than a million people for the care of rare conditions<sup>2</sup>. Specialised services are not provided by every hospital and will tend to be found in larger hospitals based in big towns and cities. They include services such as kidney transplantation, services for haemophilia, specialised mental health services and services for very rare cancers. The term “services” encompasses also treatments, products and technologies used and provided for the care of the relevant conditions.

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<sup>2</sup> Statutory Instrument No. 2375, The National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002 defines specialised services as those services with planning populations of more than one million people.