



Framework for patient and public participation in specialised commissioning

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Framework for patient and public participation in specialised commissioning

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Summary of key points and actions for specialised services commissioners

- Patient and public participation is an essential component of commissioning, and should be considered at all stages of the commissioning cycle (planning, buying and monitoring health and care services).
- To help prioritise involvement activity, commissioners should be guided by legal requirements – is there a duty to involve? In addition, they should consider where there may be the greatest impact on service and health outcome improvements, including inequalities.
- Consider the need for – and best approach – to participation depending on the situation, the population in question, and existing sources of information and insight; these sources may be national, regional or local.
- Involve people in ways that are appropriate to their needs and preferences, and provide them with the necessary information, resources and support to enable them to participate.
- Work with partners to involve people, including other commissioners, local authorities, providers, service user and carer networks, Healthwatch, and the voluntary and community sector.
- Plan for participation – including identifying benefits (with measures of impact where appropriate) and costing participation activity; participation plans need to be factored in to overall business planning and programme planning, and evaluation needs to be planned.
- Involve people early on, not as an afterthought.
- Feed back to those you have involved about the impact of their participation. Explain how their participation has influenced commissioning, and if not, why not.
- Keep good records of your approach to participation including how you have assessed the legal duty to involve the public in commissioning. **NHS England commissioners are required to document their assessment of whether Section 13Q (the legal duty to involve the public in commissioning) applies using the [standard form available on the NHS England intranet](#).**
- Document and report on participation activities and evaluate the **impact**, publicising and celebrating success and sharing learning.

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1 Introduction

This framework is a guide for specialised services commissioners - and anyone who is interested, including patients and the public, the voluntary sector, and providers of health and social care services – on how to involve patients and the public in the commissioning of specialised services. Our definition of ‘patients and the public’ includes service users and carers. Participation in specialised commissioning refers to how people are involved in planning (including policy making), buying and monitoring specialised services. Specialised services include:

- Internal medicine – digestion, renal, hepatobiliary and circulatory system
- Cancer
- Mental health
- Trauma – traumatic injury, orthopaedics, head and neck and rehabilitation
- Women and children – women and children, congenital and inherited diseases
- Blood and infection – infection, immunity and haematology.

Whilst participation is an essential consideration in our work, and is not merely a ‘nice to do’ task, we recognise that it can take many different forms. For example, patients and the public may be involved through a consultation, by being sent a newsletter, or through a face to face meeting.

The framework is designed to be read in conjunction with the [NHS England Patient and Public Participation Policy](#) and the [Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning](#).

The Patient and Public Participation Policy sets out our ambition to strengthen patient and public participation in all of our work, and how we intend to achieve this, in line with the vision for the NHS set out in the [Five Year Forward View](#). Our values are rooted in the [NHS Constitution](#), which states that the NHS belongs to us all. Our policy and associated documents are based on the belief that health services and outcomes are better when people who need, use and care about services have meaningful opportunities to be involved in them.

The Statement of Arrangements is for NHS England commissioners working in all areas of direct commissioning (primary care, public health, health and justice, specialised services and services for the armed forces). It identifies where our legal duty to involve the public in commissioning under Section 13Q of the Health and Social Care Act 2006 (as amended) applies. It sets out guidance for commissioners on how to involve the public, including:

- Principles for fair and proportionate involvement
- When public involvement should take place.

This framework has been developed through consultation with a range of Patient and Public Voice partners within specialised commissioning.

2 Context

2.1 What is specialised services commissioning?

Specialised services are generally provided in relatively few hospitals and accessed by small numbers of patients. They are usually for patients who have rare conditions or who need a specialised team working together in one place. There are currently 146 specialised services, covering a diverse range of distinct and complex conditions. These range from services for long-term conditions, such as renal (kidney) and specific mental health problems, to services for uncommon conditions such as rare cancers.

Some specialised services, such as those for cystic fibrosis, deliver the majority of care to patients with specific conditions. However, most specialised services only form part of a patient's care and treatment pathway. Some highly specialised services, including those for very rare diseases, are only provided at a very small number of expert centres across the country. Others, such as chemotherapy services, are provided by most acute hospitals.

NHS England is responsible for commissioning £15.6 billion of specialised services to meet a wide range of health and care needs.

2.2 Patient and public participation in specialised commissioning

NHS England has set out its expectations around patient and public participation for all commissioners, including ourselves as direct commissioners, in its Patient and Public Participation Policy. This has been further enhanced and supported by the development of a bespoke approach to engagement for specialised commissioning as set out in this framework. This approach demonstrates our commitment to participation at each stage of the commissioning process and how patient and public oversight is embedded at each layer of governance for specialised commissioning.

Many patients of specialised commissioning services (and their carers or families) are highly engaged. Their conditions mean they are frequent users of health and social care services, and the quality of service they receive has a huge impact on their quality of life. In addition, there are many patient organisations interested in this area of commissioning, which represent an important resource to support effective and meaningful patient engagement.

2.3 Equality and health inequalities considerations

NHS England has completed an [equality and health inequalities analysis of patient and public participation](#) in its work which can be found on the NHS England website. Several themes in relation to specialised commissioning were highlighted during production of this framework.

- Participation should particularly include those who experience health inequalities (Marmot, 2010); people with protected characteristics and those eligible for services but who do not access them. Participation should be tailored to meet the harder to reach audiences, e.g. refugees and asylum seekers.
- Activities should be planned and adapted to ensure equitable access to public participation opportunities regardless of a person's cultural, linguistic, religious background, communication and accessibility needs. This means that activities should not ideally be planned during key religious dates such as Ramadan; also documents should be available in other languages and in plain English versions. Toilet facilities at event venues should accommodate transgender and non-binary people.
- Participation budgets should support accessible engagement. This means that commissioners should have allocated funds to pay for Disability Discrimination Act accessible venues and offer catering at events that is suitable for special dietary needs. NHS England has a clear [expenses policy](#) that ensures individuals are not out of pocket as a result of participation.
- Commissioners are required to support the [Accessible Information Standard](#). This mandatory standard aims to make sure that disabled people have access to information that they can understand and any communication support they might need. This means that documents should be available at request in other formats such as braille and that hearing induction loops are available at events. Sign language translation should be made available on request.
- Auditing and monitoring participation of equalities protected groups supports commissioners to manage and improve performance, patient experience and outcomes by involving a diverse range of patients and service users. This means that surveys and event invites should include requests for information about the nine protected characteristics groups.

The [Equalities and Health Inequalities hub](#) on the NHS England website is a source of resources on equalities and health inequalities and provides useful links and information for the sharing of best practice.

3 Governance, reporting and assurance of participation in specialised commissioning

3.1.1 The commissioning cycle

NHS England is committed to involving patients and the public at each stage of the commissioning cycle for specialised services. The [commissioning cycle](#) refers to the different activities that make up the process of planning and buying health services

and ensuring that services are being delivered to the right quality standards, within the available financial resource. For specialised commissioning, activities may take place at a national, regional or local level.

Engagement should be carried out at an appropriate time and proportionate to the situation. Commissioners have significant flexibility to use a range of different participation approaches, from simply providing information through to [co-production](#). The [ladder of engagement](#) is a useful tool that outlines different approaches to participation.

3.1.2 Public and patient participation governance structure

Public and patient participation is well embedded in the governance structure of specialised commissioning. Patients and the public are now included at almost every level of governance for specialised commissioning (see Appendix A), with Clinical Reference Groups (CRGs), Programme of Care Boards, Rare Diseases Advisory Group (RDAG) and Clinical Priorities Advisory Group (CPAG) all having lay member/patient and public voice (PPV) partner representation. Table 1 provides more detail of how patient and public participation is embedded in each component of the governance structure for specialised commissioning.

Table 1

Name	Role of PPV Partner	How many PPV Partners?
Specialised Commissioning Oversight Group (SCOG)	Advisory role and to constructively challenge, influence and help SCOG to make decisions that reflect the patient and public perspective.	2
Patient and Public Voice Assurance Group (PPVAG)	Provides assurance on the overall approach to engagement for specialised services.	1 PPV partner from each of the governance groups except CRGs (12 members total) plus an addition 4 external PPV partners
Rare Diseases Advisory Group (RDAG)	Advisory role and constructively challenge, influence and help RDAG develop strategies in respect of complex clinical prioritisations.	4
Clinical Priorities Advisory Group (CPAG)	Advisory role and constructively challenge, influence and help CPAG to make decisions that reflect the patient and public perspective.	5
Individual Funding Request (IFR) Panel	Championing a public, service user, patient and/or carer/family viewpoint, ensuring that patient and public needs are considered when decisions are made.	6
National Programme of Care Boards (NPOC)	Championing a public, service user, patient and/or carer/family viewpoint, ensuring patient and public needs are met through the outcomes of the programme.	12

Clinical Reference Group (CRG)	Provide a crucial advisory role and help to constructively challenge, influence and help the CRG develop strategies in respect of the CRGs work programme.	126
Collaborative Commissioning Oversight Group (CCOG)	Championing a public, service user, patient and/or carer/family viewpoint, ensuring patients' needs are met through the outcomes of the work programme	2
Quality Assurance Implementation Programme Board (QAIPB)	Championing a public, service user, patient and/or carer/family viewpoint, ensuring patient and public needs are met through the outcomes of the programme	2

Specialised Commissioning Oversight Group (SCOG)

The SCOG makes decisions on operational commissioning issues and monitors the performance of specialised services, including delivery of the specialised commissioning business plan. It considers recommendations (made by CPAG) on drugs, devices and treatments in specialised services to determine resource and commissioning implications of any recommended service change. The SCOG has two PPV partners, one of whom is the current PPVAG chair and the other is an independent PPVAG partner. These PPV partners provide an advisory role and constructively challenge, influence and help SCOG to make decisions that reflect the patient and public perspective.

PPV Assurance Group (PPVAG)

The [PPV Assurance Group](#) provides assurance on the overall approach to engagement for specialised services and also provides a valuable channel of communication with a wide range of stakeholders. Its role is to include patients and partners with relevant experience and expertise, to champion patient and public participation throughout the commissioning cycle and at all levels of governance. It acts as a 'critical friend' to NHS England and plays an important role in escalating concerns and issues from PPV partners involved in specialised commissioning.

Rare Diseases Advisory Group (RDAG)

Highly specialised services are provided to a smaller number of patients than other specialised services – usually no more than 500 patients each year. For this reason, they are typically best delivered nationally through a very small number of centres of excellence. Examples of highly specialised services include liver transplant services, enzyme replacement therapy, and proton beam therapy for specific cancers.

The Rare Diseases Advisory Group (RDAG) is responsible for making recommendations to NHS England and the devolved administrations of Scotland, Wales and Northern Ireland, on the development of services for people with rare diseases who require highly specialised services.

The group develops advice based on the recommendations it receives from CRGs and other sources of sound evidence from outside the NHS, such as professional bodies and patient groups.

RDAG makes recommendations to the clinical priorities advisory group about how highly specialised services should be commissioned. This includes recommending which expert centres should be chosen to deliver highly specialised services. This group has four PPV partners who provide an advisory role and constructively challenge, influence and help RDAG develop strategies for complex clinical prioritisations. The PPV partners help RDAG to make decisions that reflect the patient and public perspective.

Clinical Priorities Advisory Group (CPAG)

The Clinical Priorities Advisory Group (CPAG) makes recommendations on NHS England's approach to commissioning services, treatments and technologies, and considers which of these should be prioritised for investment. Its scope includes all specialised services of NHS England. CPAG assesses drugs, medical devices and treatments according to their clinical effectiveness benefit for patients and value for money. It considers recommendations from CRGs and teams covering NHS England's specialised commissioning responsibilities, and takes into account detailed information about the financial impact of investments. This group has a lay chair as well as four PPV partners, who provide a crucial independent advisory role. CPAG is not a decision-making body, but does make recommendations.

Individual Funding Request (IFR) Panel

Where a treatment or service is not routinely offered by the NHS, a healthcare professional may submit an Individual Funding Request (IFR) to NHS England. The aim of the IFR process is to ensure a more timely and consistent approach to managing IFRs for NHS England prescribed services. Decisions on the requests are made by an expert panel (IFR Panel). The panel is made up of clinicians, who are not involved in the patient's treatment, four independent PPV partners and two lay chairs. These independent roles are essential in ensuring patient needs are understood when administering funds. All panel members have received training to enable them to assess IFRs fairly and thoroughly.

National Programmes of Care Boards (NPoCs)

Each NPoC has a Board that oversees the commissioning of specialised services. The role of the NPoC Board is to provide leadership and oversight of the development and delivery of a comprehensive work programme that achieves demonstrable improvements in the quality, equity, value and outcomes of commissioned specialised services. Each NPoC Board has two PPV partners. Their role is essential in championing a public, service user, patient and/or carer/family viewpoint, ensuring patient and public needs are met through the outcomes of the programme.

The six NPoCs are:

- Internal medicine – digestion, renal, hepatobiliary and circulatory system
- Cancer
- Mental health
- Trauma – traumatic injury, orthopaedics, head and neck and rehabilitation

- Women and children – women and children, congenital and inherited diseases
- Blood and infection – infection, immunity and haematology.

Clinical Reference Groups (CRGs)

CRGs provide expert clinical advice and leadership on specialised services for a group of conditions or treatments. Together, clinicians, commissioners, public health experts, patients and carers use their specific knowledge and expertise to advise NHS England on the best ways that specialised services should be provided to meet patients' needs. CRGs with the support of working groups lead on the development of clinical policies, service specifications and many other aspects of the clinical commissioning of services.

There are two places on each CRG for PPV partners and one for a representative from a community or voluntary organisation. These representatives play a crucial advisory role and bring the patients' perspective. They help to constructively challenge and influence the CRG's work programme to improve services for patients.

This direct patient and public voice is complemented by engagement with wider stakeholders for each CRG, planned around the groups' work programmes, and using a [stakeholder registration process](#) (see Appendix C). The work of the CRGs is informed by patient feedback and perspectives received from local commissioners, and targeted work with groups that may be harder to hear, such as children and young people, and service users in the criminal justice system.

Each CRG will also have dedicated working groups that will inform clinical commissioning policy and service specification development. These working groups will have PPV representation to ensure that patient insight and experiences relevant to the clinical policy area are represented. The PPV representation could be either from patients/people with lived experience of the condition/treatment or people (ideally from a patient group) who can bring a wider patient perspective and help identify relevant stakeholder groups for stakeholder testing and consultation.

In 2016, NHS England conducted a consultation to review the structure of CRGs, please see the summary [report](#) for more detailed analysis and information on the outcomes of this consultation.

Collaborative Commissioning Programme Oversight Group (CCOG)

NHS England has listened to patients' experiences of specialised services. Their feedback tells us that current care pathways can be disjointed, particularly where the commissioning responsibility for services changes. This can lead to gaps in provision and poor sharing of data, which cannot produce the best outcomes for patients.

To support [collaborative commissioning](#) NHS England has set up a national Programme Oversight Group. The CCOG has a responsibility for moving towards new collaborative commissioning arrangements. This includes supporting Clinical Commissioning Groups (CCGs) to get involved in decision making and, where appropriate, delegating some specialised commissioning to a sub-national level. There are two PPV partners on this group and they bring important views, perspective and challenge into the CCOG. Their role is essential in championing a

public, service user, patient and/or carer/family viewpoint, ensuring that patients' needs are met through the outcomes of the work programme.

Quality Assurance Implementation Programme Board (QAIPB) - Quality from a patient's perspective

The Quality Assurance and Improvement Framework (QAIF) provides an overarching framework for quality assurance of specialised services. The QAIF is designed to underpin the delivery of NHS England's responsibilities in respect of quality and is integrated with wider NHS England quality assurance responsibilities. Patient experience is a key dimension of the framework. The approach to the development of patient insight will be overseen by the specialised commissioning Quality Assurance Implementation Programme Board (QAIPB) which has patient and public representation as part of its core membership and will complement the contribution of other PPV partners in specialised commissioning.

PPV representation will bring important views, perspective and challenge to the QAIPB. The board has two PPV partners and their roles will be essential in championing a patient and public perspective, seeking to ensure that their needs are met through the programme.

3.1.3 Empowering the patient voice and ensuring accountability in specialised commissioning

It is vital that PPV partners feel empowered and supported in their roles and the specialised commissioning team has therefore put in place the following measures:

- Training for clinicians and managers on the importance of patient voice.
- Training for PPV partners to empower and support them in their roles, such as PPV induction training.
- A virtual forum to connect representatives and create a strong network with peer support.
- [A clear expenses policy](#) so that personal participation expenses can be reimbursed.
- A 'red flag' system through the PPVAG chair, to challenge poor practice and highlight areas of disagreement.
- Opportunities to draw on voluntary and community sector partners to connect to wider networks and resources, including links to user-led organisations.
- Involving PPV partners in interview panels for senior staff appointments and other appointments (such as CRG chairs).

Some of these measures are specific to specialised commissioning and some (such as the expenses policy) are NHS England standard policies.

3.1.4 National and regional specialised commissioning responsibilities

The Specialised Services Commissioning Committee

This group has responsibility for ensuring that patient and public participation is embedded in commissioning arrangements, including assuring the quality of participation arrangements and appropriate feedback loops are in place.

NHS England Regional Directors

Regional Directors are responsible for ensuring appropriate patient and public participation within the work of their own regions.

Regional Directors of specialised commissioning

Regional Directors of specialised commissioning take an overview of patient and public engagement across all specialised services within their region including receiving reports from local commissioners. They also ensure that regional priorities for action are identified and addressed.

3.1.5 What do I need to do in relation to patient and public participation as a commissioning manager of specialised services?

In accordance with NHS England's section 13Q duty (the legal duty to involve the public in commissioning) commissioners are required to undertake patient and public participation in certain circumstances. Reference should be made to the [Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning](#). Commissioning managers of specialised services should also use the processes and resources set out in section 4.

4 Processes and resources

The following section of the framework outlines processes and resources to help commissioners undertake patient and public participation in specialised commissioning. The [Involvement Hub on the NHS England website](#) also includes a range of tools and resources.

4.1 Stakeholder mapping

Stakeholder mapping is also known as audience mapping or stakeholder analysis. It is a process that aims to understand who the engagement activity is likely to impact on and who is interested.

There are four steps within a stakeholder mapping exercise:

- Identifying the relevant stakeholders/stakeholder groups.
- Analysing their perspectives, current vision or arguments.
- Visualising the relationships between the organisation and stakeholders, and the relationships between the different stakeholders.
- Deciding how best to respond to the priorities of different stakeholder groups.

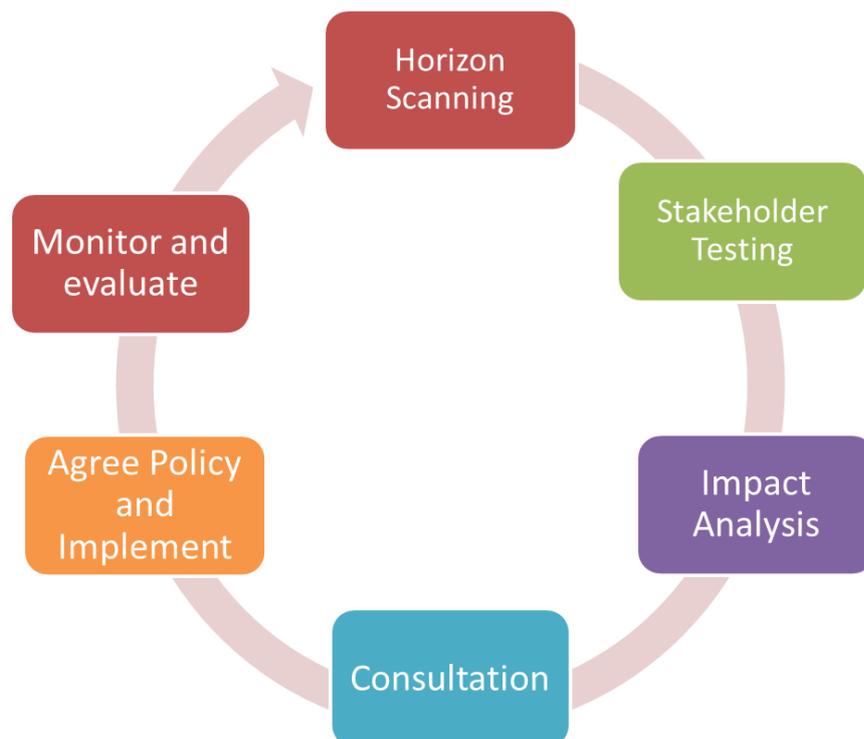
Links to sources of a range of stakeholder mapping tools can be found on the [Involvement Hub](#) on the NHS England website.

4.2 How to engage with PPV partners for the development of a clinical policy

Under section 13Q of the National Health Service Act 2006 (as amended) NHS England has a statutory duty to 'make arrangements' to involve the public in commissioning services for NHS patients.

NHS England must also seek to comply with the [best practice consultation principles published by the Cabinet Office in 2012](#).

Ongoing engagement with patient groups and representatives is key to enabling ongoing dialogue throughout the course of a decision making process. In the course of developing a policy change, if it becomes apparent that there will be a significant impact on the services delivered to patients then more wide scale patient engagement (a formal consultation of up to 12 weeks) should be carried out. There is a defined process of stakeholder engagement in policy development (see Appendix B). The diagram below illustrates how the policy build process works.



The stakeholder engagement process includes:

- Creating working groups with membership reflecting the range of different stakeholders (including people with lived experience of the condition).
- Early stakeholder testing (to ensure key people involved or affected have the chance to shape the policy during development).
- Public consultation (to allow wider scrutiny of and comment on the policy).

4.3 Registered stakeholder process

NHS England has a process for members of the public to [register](#) their interest for one or more CRGs. Essentially this means that members of the public can decide to what extent they would like to be involved in the work of a CRG/NPOC (see Appendix C).

4.4 Key aspects of engagement planning

In accordance with the [Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning](#), formal consultation and other means of public involvement must be fair and proportionate. The following table is used within specialised services commissioning to help consider, describe and decide on an appropriate level of public involvement in light of various relevant factors including the extent and anticipated impact of the changes.

Level	Description
1	Minor changes – no formal consultation required. However, there may be some benefits to carrying out some engagement activity, if appropriate.
2	Intermediate changes that are broadly supported by stakeholders through prior engagement – reduced length consultation, limited engagement activity during the live consultation period.
3	Significant changes that are broadly supported by stakeholders through prior engagement – reduced length consultation, to include some proactive engagement activities during the live consultation period.
4	Significant changes with some contentious aspects - 12 week consultation to include some proactive engagement activities during the live consultation period.
5	Highly contentious/high volume impact on numbers of stakeholders/ high levels of dissent/ high financial implications/ high media or political profile - 12 week consultation period plus an extensive range of engagement activity, before during and after consultation.

It must be borne in mind that the nature and extent of public involvement required will always depend on the specific circumstances of an individual commissioning process or decision. Therefore the levels and descriptions set out in the table above are not binding and NHS England must take into account all relevant circumstances and, where necessary, adopt a flexible approach when determining what level of public involvement is appropriate.

Below are some important tips to consider when planning any engagement activity:

- Participation activity would depend on the level of change proposed but would likely be a mixture of electronic and face to face activity (webinars/surveys/deliberative events).
- NHS England has a bespoke [online questionnaire tool](#) to capture feedback on consultations.

- To support any formal consultation activity a consultation guide will need to be produced – normally by the commissioner - and then the communications and engagement team will review and edit as required.
- You will need to map the relevant stakeholders and identify who the opinion formers are and how you will manage them (see section 4.1 on stakeholder mapping).
- There will be a lead in time for all specialised commissioning related engagement activity – one week to arrange the events and then ideally publicity sent out six weeks in advance for a face to face event involving clinicians and three weeks in advance for webinars.
- Anything requiring publication/posting on the NHS England website (consultation guide and supporting documents) would require [Gateway and Publications Control Committee \(PCC\) approval](#) – this can take a week or more – you will need to complete the relevant forms.
- Consultation plans should be tested with PPVAG to gain assurance of the process proposed.
- You will need to have funds allocated within your budget, to cover any additional costs such as events venues/catering.

Before you undertake any engagement activity it is crucial to develop a communications and engagement plan (see Appendix D).

The communications and engagement team within specialised commissioning can help you with this, but before you ask them for help it is important to go through the checklist in section 4.5.

There are certain (larger, national) pieces of work that the central communications and engagement team will lead on. However, it is the responsibility of the commissioner to lead on service reviews, policy development and NPOC related pieces of work. Please note the communications and engagement team are still able to help and offer advice in the first instance.

4.5 Communications and engagement checklist and section 13Q form

The checklist which follows is designed to help you:

- Plan and implement a patient and public engagement activity.
- Review its effectiveness once you have completed the work.
- Demonstrate how NHS England is meeting the requirements under the 13Q duty to involve.

You should complete this checklist **before** undertaking your engagement work, to help you plan it. **After** you have completed the patient and public engagement work, you should review the checklist and update it as appropriate. This will help you to reflect on the effectiveness of the engagement work and evidence how NHS England is meeting its 13Q legal duty to involve. This includes documenting the decisions made on the [standard 13Q assessment form available on the NHS England Intranet](#).

Engagement planning checklist

What are the objectives and key issues or questions that you are seeking to answer through the engagement process?

What influence will the process and findings have?

Is formal consultation required or do you plan to engage in other ways? Have you recorded the decision on the [13Q assessment form](#), as required (see the [Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning](#)) and sent it to england.scengagement@nhs.net

What relevant evidence or data might NHS England or partner organisations already hold?

What is the timetable for this activity, given the internal decision-making and [sign-off processes](#) that it needs to align with?

Who are the stakeholders that you wish to engage with? (see section 4.3) Have you carried out [Equalities and Health Inequalities screening/assessment](#)?

What activity or activities will you use to engage with stakeholders? [Do you need to tailor the engagement for different stakeholders?](#) See the resources on the [Involvement Hub on the NHS England website](#)

What support or resources (budgets, staff) will you need to undertake these activities?

How will you evaluate whether the engagement has been effective? Including feeding back on the impact of the feedback.

How will you report the findings of the engagement process to those who have been involved and to wider stakeholders?
[Include internal sign off processes into planning timelines](#)

5 Specialised commissioning key engagement contacts

Specialised Commissioning Engagement team (National)

england.scengagement@nhs.net

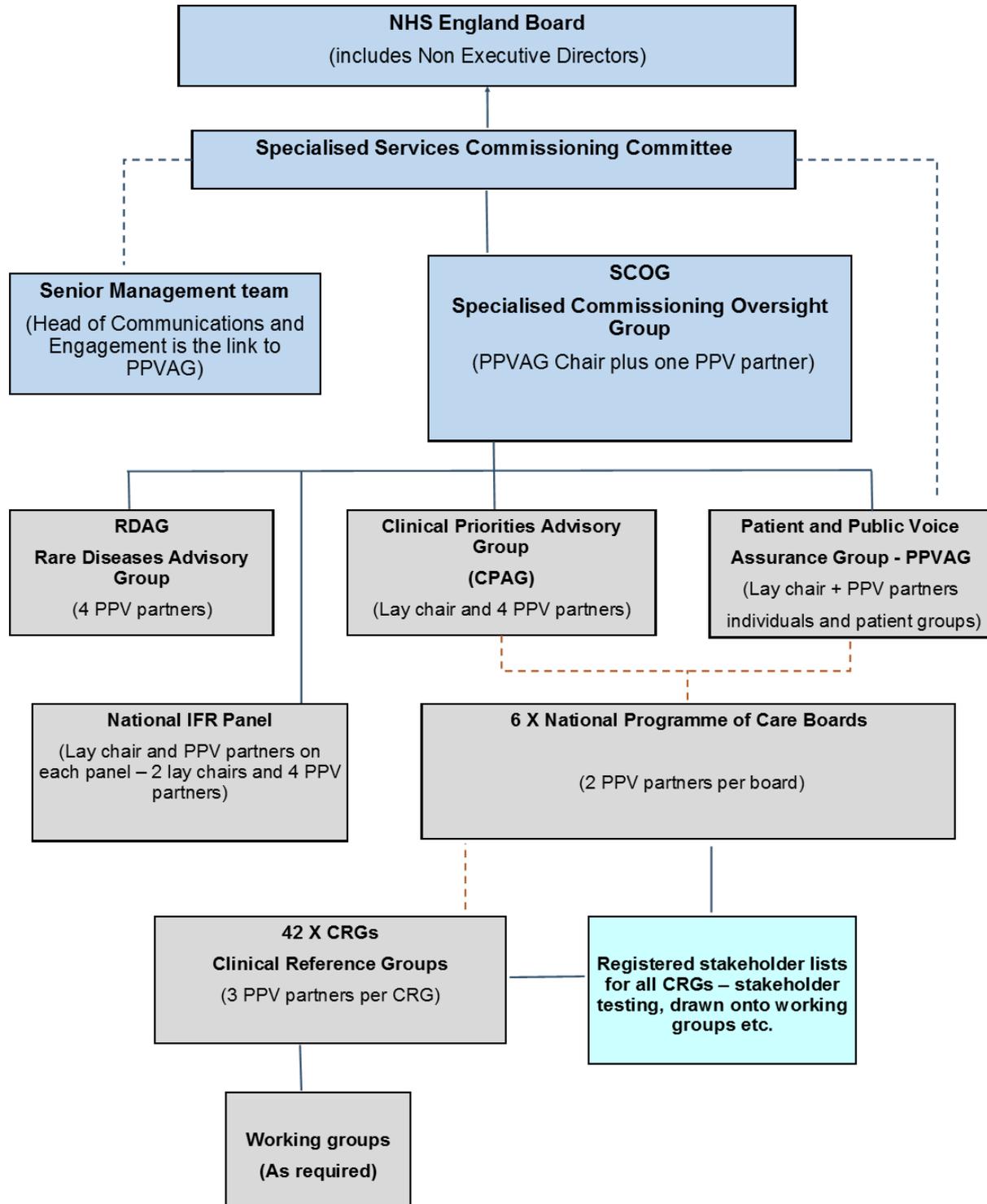
Public participation team

england.engagement@nhs.net

Insight team

england.PPVI-insight@nhs.net

Appendix A - Map of patient and public voice in specialised commissioning governance



Appendix B – Policy Build

Clinical Commissioning Policy Methods

A. Clinical Build

The **clinical build** is one of three phases to form a national clinical commissioning policy. It is coordinated and managed by the Clinical Effectiveness Team and concludes through a Gateway managed by the Clinical Panel. The second phase is the 'Impact Analysis' managed by the National Programme of Care and concludes through a Gateway at the National Programme of Care Board. The third and final stage is the 'Decision' through the Clinical Priorities Advisory Group, Specialised Commissioning Oversight Group, and Specialised Commissioning Committee.

Step 1. Propose Policy Clinical Lead

A clinician who undertakes to take the proposal through each step will lead each clinical commissioning policy development.

1.1 All clinical policy proposals will have a clinical lead. For most proposals this is the Chair or Clinical Member of a Clinical Reference Group. A clinical lead may also be identified outside of the CRG membership. The clinical lead should have detailed clinical understanding of the policy proposal and must not have a conflict of interest associated with the technology.

1.2 Patient organisations, Royal Colleges, the industry and other organisations can initiate the formation of clinical policy proposal but they have to identify a clinical lead to make the proposal.

1.3 Some clinical policies proposals will be initiated by NHS England either to introduce new interventions or to decommission existing interventions. In circumstances where an appropriate clinician cannot be identified who is willing to lead the proposal development a public health consultant or NHS England employed clinician will be identified as the Policy Clinical Lead. In addition the Public Health network may lead policies of a wider public health benefit.

1.4 The proposal is submitted using the Policy Clinical Lead Proposal Form to an on line form the link to which is received by contacting the email england.CET@nhs.net. The Clinical Effectiveness Team confirms receipt of the Policy Clinical Lead Proposal Form.

Step 2. The Clinical Reference Group Endorses the Clinical Lead

The relevant Clinical Reference Group endorses that the nominated Policy Clinical Lead has the support of peers to lead the development of a proposal.

2.1 The Clinical Effectiveness Team contacts the relevant CRG Chair by email with the Policy Clinical Lead Proposal Form.

2.2 The CRG Chair confirms the CRG support for the Policy Clinical Lead having discussed with the CRG members. A confirming email is sent to the Clinical Effectiveness Team.

2.3 Where a lead is nominated by NHS England the CRG membership are informed and are asked to provide assistance in building clinical involvement in the Policy Working Group (see 6.1).

2.4 The Head of Clinical Effectiveness undertakes a check that the proposed intervention and indication are consistent with the formation of a clinical policy. Where the proposed area is not suitable the Head of Clinical Effectiveness writes to the submitting clinician.

2.5 The Clinical Effectiveness Team confirms with the clinician the Policy Clinical Lead supplying the on line Preliminary Policy Proposal form link, a guide for completing the form and a Policy Proposal Reference number.

Step 3. Production of Preliminary Policy Proposal

The Policy Clinical Lead forms the Preliminary Policy Proposal (PPP) and submits to the Clinical Effectiveness Team via the on line submission.

3.1 The Policy Clinical Lead completes the Preliminary Policy Proposal Form. This is likely to take some time depending in the complexity of the issue, the lead may need to secure other assistance to complete all elements of the proposal.

3.2 The Policy Clinical Lead shares and agrees the final Preliminary Policy Proposal Form with the CRG Chair. The CRG Chair can give chair's action to agree but ideally should secure support from the full CRG.

3.3 The Policy Clinical Lead submits the Preliminary Policy Proposal form to the Clinical Effectiveness Team to the on line submission.

3.4 The Clinical Effectiveness Team confirms receipt of the PPP.

Step 4. The NHS England Clinical Panel Reviews the Preliminary Policy Proposal

The clinical panel (with the National Programme of Care Senior Managers) confirms that the policy proceeds into the work plan on the basis of core qualifying criteria and determines the required methodology for a fully independent evidence review proportional to the complexity of the proposal.

4.1 The Head of Clinical Effectiveness submits the PPP to the next available clinical panel having confirmed that:

- 4.1.1 the proposal is for a specialised commissioned service;
- 4.1.2 NICE is not undertaking an appraisal in the TA or HST programme;
- 4.1.3 the intervention is not included in tariff.

4.2 The Clinical Panel confirms that the policy proceeds into the work plan. The Clinical Panel can exclude a preliminary policy proposal in the following circumstances:

4.2.1 The Preliminary Policy Proposal has failed to identify any qualifying evidence of the intervention benefit.

4.2.2 The clinical utility of implementing the intervention through national clinical policy is not well defined.

4.3 The Clinical Panel determines the required methodology for evidence review:

4.3.1 Very small number of publications and top 3 selected publications clearly define efficacy (or lack of efficacy). The clinical panel can state there is no need for a further clinical evidence review.

4.3.2 Small number of relevant publications (circa 30 or less), high complexity, small population. The clinical panel can offer a grant for a postgraduate student (or public health trainee) to undertake the evidence review under the guidance of a representative from the Public Health England network. The individual must have completed a training package in the method of systematic evidence review.

4.3.3 The intervention is a licenced drug. The Clinical Panel can refer the proposal to NICE for consideration in the NICE-CSD programme.

4.3.4 The intervention is a device. The Clinical Panel can refer the proposal to NICE for a Medical Innovation Briefing (MIB).

4.3.5 Clinical urgency. The Clinical Panel can refer the proposal to NICE for a Rapid Evidence Review (RER).

4.3.6 Larger number of relevant publications and/or larger populations. The Clinical Panel recommends an NHS England funded independent evidence review and prioritise subject to available resources.

4.4 The Clinical Panel defines the clinical urgency of the requirement of the policy by reviewing the clinical problem and the degree to which the intervention meets clinical need and the number and outcomes of IFR and CCU applications (The CET will provide information on IFR and CCU activity relevant to the policy proposal):

4.4.1 Inclusion in annual work programme for relative prioritisation for most proposals except those with high clinical urgency.

4.4.2 Inclusion in annual work programme for In Year Service Development for proposals of high clinical urgency.

4.4.3 The need to form an immediate Policy Statement for proposals of Clinically Critical Urgency (and inclusion for an In Year Service Development). The Clinical Panel is likely to have recommended a NICE Rapid Evidence Review as above.

Step 5. Evidence Review Commissioned

The NHS England Clinical Effectiveness team commissions an evidence review guided by the Preliminary Policy Proposal.

5.1 The Clinical Effectiveness Team (CET) identifies a lead public health consultant to form the PICO for the commissioning of the evidence review. This is built from the information in the PPP and is tested with the clinical lead and as many members of the Policy Working Group who are available.

5.2 The CET coordinates the evidence review as defined by Step 4.

5.3 The CET establishes communication between the evidence review team and the Policy Clinical Lead to clarify elements of the evidence review.

5.4 The CET receives the evidence review, assures the quality and prepares the document for future publication.

5.5 While the evidence review is underway the meeting dates for the Policy Working Group are defined to receive the evidence review and build the policy proposition.

Step 6. Policy Proposal Formed

Working with a Policy Working Group the Policy Clinical Lead forms a Policy Proposition built from the evidence base.

6.1 The Policy Clinical Lead establishes the Policy Working Group (PWG) to include a lead from the Public Health Network and a commissioner from the relevant Programme of Care.

6.2 All members of the PWG are asked to complete an on-line learning package providing training on the fundamentals of evidence review, interpretation, and clinical policy formation.

6.3 On receipt of the Evidence Review from the CET the PWG proceeds to form a Policy Proposition.

6.4 The Policy Clinical Lead secures consensus agreement to the Policy Proposition from members of the PWG. The Policy Clinical Lead shares and agrees the final Policy Proposal with the CRG Chair. The CRG Chair can give chair's action to agree but ideally should secure support from the full CRG.

6.5 The Head of Clinical Effectiveness submits the Evidence Summary and the Policy Proposition to the next available clinical panel.

Step 7. Clinical Panel – Clinical Policy Gateway 1

The clinical panel tests whether the Policy Proposition is built on the Clinical Evidence and whether the policy proceeds into the impact analysis phase as either a 'routine' or 'no-routine' commissioning proposal.

7.1 The Clinical Panel receives the original Preliminary Policy Proposal, the Evidence Summary, and the Policy Proposition.

7.2 The Clinical Panel determines:

7.2.1 Whether the population is adequately defined.

7.2.2 Whether any subpopulations are adequately defined.

7.2.3 That the Policy Proposition is built on the evidence base as defined in the evidence summary.

7.2.4 That the evidence presented is supportive of a 'Routine Commissioning' policy.

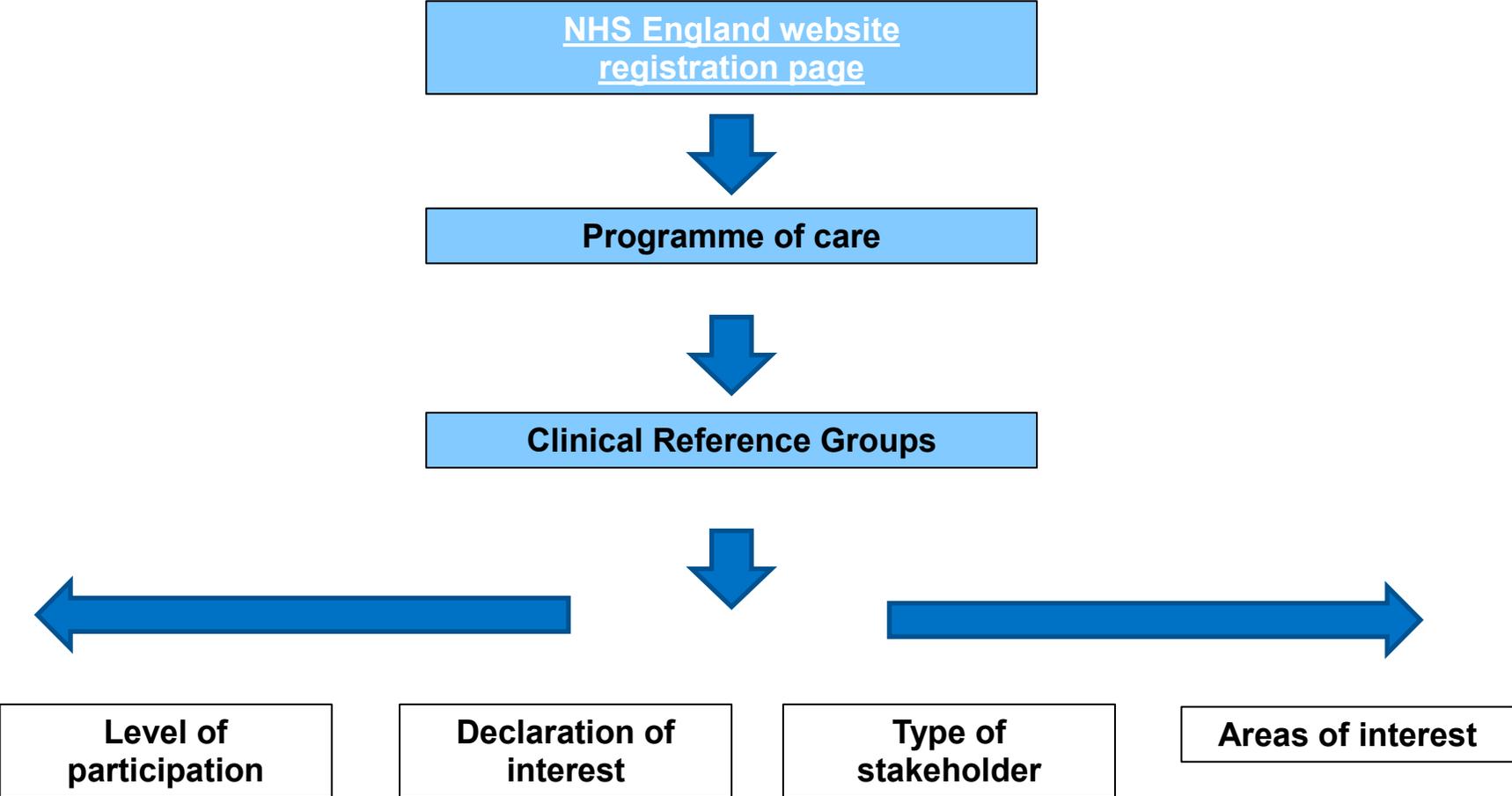
7.3 If the Clinical Panel supports the Policy Proposition the CET passes the Proposition to the relevant Programme of Care to move to the second 'Impact Analysis' phase.

7.4 If the Clinical Panel does not support the Policy Proposition, the Policy Clinical Lead receives written report of the clinical panel; the Clinical Lead reports back to CRG chair with a proposal that either a) the CRG needs to work up the proposal further before re-submission to clinical panel or b) CRG has demonstrably valid grounds for disputing the findings of the clinical panel. CRG Chair to decide on preferred course of action, and may need to discuss with CRG members first. The panel chair or delegate, will be available to informally give feedback / discuss should this be needed, but it must be for CRG chair to formally confirm next steps.

Glossary

CCU Clinically Critically Urgent.
CET Clinical Effectiveness Team (NHS England)
CRG Clinical Reference Group
CSD Commissioning Support Documents
HST Highly Specialised Technology
IFR Individual Funding Request
MIB Medical Innovation Briefing
PPP Preliminary Policy Proposal
PWG Policy Working Group
RER Rapid Evidence Review
TA Technology

Appendix C – Stakeholder registration process



Appendix D - Communications and Engagement plan

This template should be completed after reading the Participation Framework for Specialised Commissioning

Name of Responsible Commissioner/s	
Contact details for the person(s) responsible for development and implementation of this plan	
Background Information	
<p>What are the drivers for this work (e.g. national service specification compliance; NICE guidance)?</p>	
Anticipated Impact & Public Reaction	
<p>Potential benefits and drawbacks of this piece of work (loss/increase in activity)</p> <p>Benefits:</p> <p>Things to be considered:</p>	
<p>Potential benefits and drawbacks of this work on patients/public and carers?</p> <p>Benefits:</p> <p>Things to be considered:</p> <p>Potential Media/stakeholder reactions: High/medium/low and why? (Have you spoken to comms)?</p>	

Expected public and service user reaction of this change: High/medium/low and why?

Target Stakeholders

Have you spoken to the Public Affairs team? Do you have your stakeholder lists ready? Have you completed stakeholder analysis?

What can people influence?

What can't people influence?

Comms and Engagement Methods

(Please list all methods being applied and explain how the method/s applied, are proportional size of the service change (if applicable) and appropriate for the target population)

Have you considered what communications you will need to publish to supplement this piece of work? Have you factored in [Gateway/PCC clearance](#) and internal signoff processes?

What engagement activities are you planning? How will you ensure engagement activities are proportionate to the size of the service change if applicable and appropriate for the target population?

How will you ensure the Equalities Duties are met? How will you ensure engagement activities are accessible to all?

Have you spoken to the Equalities team?

How will you assess the local impact of service changes?

Timeline	
Engagement period	Have you spoken to the engagement team to assess the time period?
Reporting deadline (date 'you said, we did report' will be sent by NHS England)	Have you factored in PCC/Gateway clearance?
Transparency & Accountability	
How will the 'you said, we did' report be made available to the public?	Have you considered a plain English version?
How were patients involved in the development of this plan?	Have you spoken to PPVAG for assurance of your plans? Have you checked if any existing engagement work has been done?

Please send to england.scengagement@nhs.net once completed.

