Major service change: An interactive handbook





The change process

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The planning and development of reconfiguration proposals are rarely linear. The most successful proposals ensure continuous discussion and involvement of clinicians, the local population and key system partners consistently throughout the process.

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Introduction

About this handbook

This toolkit provides advice, information, and support to those with responsibilities related to service change and reconfiguration.

In this document you will find information, links to supporting resources, case studies, key documents, and other materials for each section of the service change process.

This handbook has been reviewed and refreshed based on legislative and statutory duties as of June 2023, in line with the Health and Care Act 2022. Further updates will be made to the handbook as needed to align with any secondary legislation (if and when commenced) or new guidance issued, and it will be refreshed iteratively to include the most recent information, advice, and examples. Meanwhile, you are encouraged to seek advice from your NHSE regional team on the potential impact of legislative change on your proposals.

This handbook was produced by the System Partnerships team within System Transformation in NHS England (NHSE).

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Promoting equality, addressing health inequalities and meeting our net zero commitments are at the heart of NHSE's values. Throughout the development of the policies and processes cited in this document, we have:

- had due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- had regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Sign up here

Many of the links in this handbook are to our Service Change and Reconfiguration Future NHS Workspace.

This workspace is free and open to anyone working in NHS service change and we suggest subscribing to alerts when you join.

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Who is this handbook for?

The Health and Care Act 2022 brings opportunities for greater and more effective collaboration. Integrated Care Boards (ICBs), Integrated Care Partnerships (ICPs), provider collaboratives and place-based partnerships can provide joined-up, collective approaches to achieving the vision that systems have for the services they provide.

Part of this vision will be to improve how multiple organisations plan and deliver services collaboratively as well as managing any service change as a system. Most major service change requires all partners in an ICS - from hospitals to primary care, local government to the voluntary sector - to work closely together to agree and deliver the improvements needed.

This document aims to help its readers understand the process for service change within a system and explains how joined up engagement and communication can improve outcomes as well as outlining the role each organisation and individual can play in the service change process.



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About service change and reconfiguration

Service change broadly encompasses any change to the provision of NHS services which involves a shift in the way frontline health services are delivered.

There is no formal definition of 'substantial' service change, but this usually involves a change to the range of services available and/or the geographical location from which services are delivered.

Service reconfiguration and service decommissioning are types of service change. Reconfiguration can be small-scale (for example, changing the location of a routine diagnostic test) or large-scale (for example, merging two hospitals across a city at two sites, to one larger city centre hospital).

Changes may or may not require capital expenditure. The degree of local government scrutiny, requirements for public involvement (including formal consultation) and regional or national assurance will vary depending on the specifics of the change.

'Substantial change'

While there is no legal definition of what constitutes a 'significant' or 'substantial' service change, where changes are deemed 'substantial' they may require public consultation, and formal assurance from NHSE and the Department for Health and Social Care (DHSC). Given that there is no single definition of what constitutes a 'significant' or 'substantial' service change, each case should be examined individually.

Commissioners and providers should also reach agreement with the local authority about whether a change is 'substantial' and requires formal public consultation in addition to consultation with the local authority. While it's good practice for a commissioner to seek the views of the local Health Overview Scrutiny Committee (HOSC) as to whether public consultation is required, it's the commissioner who has the final say about whether formal public consultation is or is not required. Commissioners should continue to involve the public in service changes or service improvements, even where it is decided that formal public consultation is not required.

Regular local authority engagement should continue through the lifecycle of service change.

Q: How do you know if your planned changes are 'substantial'?

A: You should seek advice from your regional team, and then begin conversations with your local authority Health Overview and Scrutiny Committee (HOSC) or, where multiple local authorities are involved, the Joint Health Overview and Scrutiny (JHOSC/JOSC). The HOSC or JHOSC will advise on whether they consider your planned changes to be substantial.

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What makes a successful change programme?

Research from the Independent Reconfiguration Panel identified a range of factors in ensuring the success of a change programme.

- Open community and stakeholder involvement from the first stage of considering change
- A clear vision for the health and care of the community that provides the context for service change proposals
- A credible case for change that clinicians and patients advocate
- Plans for implementation are sufficiently comprehensive to be credible to stakeholders
- Money, transport, and emergency care are addressed explicitly
- The benefits for patients of change are articulated and communicated
- Process is transparent from beginning to end so that consultation is truly meaningful, and responses are given proper consideration before final decisions



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Key resources

• Planning, assuring and delivering service change for patients

To be read with the addendum, this is the key guidance document for anyone planning, assuring and delivering service change within the NHS.

Service change: How to use evidence

A guide to support stakeholders to more effectively gather and analyse evidence to inform service change proposals.

• Talking to the public about service change

An independent research piece that seeks to understand public priorities around proposed service changes in the NHS.

• Effective service change: Toolkit

An overview of the support and guidance available to local organisations as they seek to progress service change.

- Guidance on the preparation of integrated care strategies
- Guidance on developing Joint Forward Plan 2022
- Working in partnership with people and communities: statutory guidance
- Joint strategic needs assessment
- Health and Care Act 2022

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Case studies and examples

For case studies and examples visit the case study section of our Service Change and Reconfiguration Future NHS Workspace

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Drivers & context

What's driving your service change?

The first stage in any major service change is to identify the factors which mean that your current configuration of services require review. Key drivers for reconfiguration often fall into one or more of the following:

- Improving clinical quality
- Promoting equality and tackling inequalities
- Financial sustainability challenges
- Ensuring workforce sustainability

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Top tip

Service Change and Reconfiguration Future NHS Workspace has useful content to help you identify potential drivers for change.

When you start thinking about service change, ensure that any proposals are incorporated as part of your system-wide long-term planning.

You'll need to start speaking to others within the system, as well as the relevant national and regional NHSE teams.

Consider a range of possible interventions, and look for examples in other systems that might be relevant – are there any successful pilots that demonstrate implementation of the intervention?

Finally, think about the nature of the system. Service change is often contentious and requires close working with a variety of stakeholders. It's helpful to identify areas of consensus before determining the preferred way forward.

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Tests for service change

The four key tests used by NHSE to assure a service change programme are:

- **1.** Strong public and patient engagement
- 2. Consistency with current and prospective need for patient choice
- 3. Clear, clinical evidence base*
- 4. Support for proposals from clinical commissioners**

*In applying test 3 to new models of care, NHSE recognises that the evidence base may be emerging.

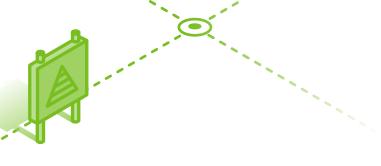
** In applying test 4 to system-led change, NHSE will seek to understand the level of clinical support beyond clinical senior leaders within the system. For example, NHSE may ask to see 'Letters of Support' from neighbouring commissioners or providers that will be affected by the proposed service change.

NHSE's fifth test

For any proposal that includes plans to significantly reduce hospital bed numbers, NHSE will expect systems to be able to evidence that they can meet NHSE's fifth test otherwise known as 'NHSE's Patient Care Test' or the 'NHS Beds Test'. To provide assurance against this test, systems must be able to demonstrate their proposals meet at least one of the following three conditions.

- 1. Demonstrate that sufficient alternative provision, such as increased GP or community services, is being put in place alongside or ahead of bed closures, and that the new workforce will be there to deliver it
- 2. Show that specific new treatments or therapies, such as new anti-coagulation drugs used to treat stroke, will reduce specific categories of admission
- **3.** Where a hospital has been using beds less efficiently than the national average, that it has a credible plan to improve performance without affecting patient care (for example, the <u>Getting It Right First Time</u> programme)





Health inequalities

Commissioners should comply with their duties under the Equality Act 2010 (in particular the Public Sector Equality Duty and the duty to reduce health inequalities, and duties under the NHS Act 2006 (as amended). Service design and communications should be appropriate and accessible to meet the needs of diverse communities. The Public Sector Equality Duty is an ongoing duty and therefore should be at the forefront of NHS bodies' minds during the entirety of the service change process. More information about these duties can be found <u>here</u>.

NHSE, Integrated Care Boards, NHS trusts and NHS foundation trusts are subject to the new 'triple aim' duty in the NHS Act 2006 (as amended by the Health and Care Act 2022) (sections 13NA, 14Z43, 26A and 63A respectively). This requires these bodies to have regard to 'all likely effects' of their decisions in relation to three areas:

- **1.** Health and wellbeing for people, including its effects in relation to inequalities
- **2.** Quality of health services for all individuals, including the effects of inequalities in relation to the benefits that people can obtain from those services
- **3.** The sustainable use of NHS resources



Net zero

The Health and Care Act 2022 introduced new duties in relation to climate change. In accordance with the NHS Act 2006 (as amended by the Health and Care Act 2022 sections 13NC, 14Z44, 26B and 63B respectively) NHSE, ICBs, NHS trusts, and NHS foundation trusts must have regard to the need to:

- contribute towards compliance with section 1 of the Climate Change Act 2008 (UK net zero emissions target) and section 5 of the Environment Act 2021 (environmental targets)
- adapt to any current or predicted impacts of climate change identified in the most recent report under section 56 of the Climate Change Act 2008

The NHS has committed to two net zero targets:

- Net zero for emissions it controls directly (NHS Carbon Footprint) by 2040, with an ambition to reach an 80 per cent reduction by 2028 to 2032
- Net zero for emissions it can influence (NHS Carbon Footprint plus) by 2045, with an ambition to reach an 80 per cent reduction by 2036 to 2039

Find the updated 2022 report *Delivering a net zero health service* and more resources <u>here</u>



Drivers & context

Key documents

- Getting it Right First Time
- Reducing health inequalities
- NHS RightCare
- Effective approaches to major service change and reconfiguration (Executive summary)
- Core20PLUS5 (adults) an approach to reducing healthcare inequalities

- Health Equity Assessment Tool (HEAT)
- Delivering a 'Net Zero' **National Health Service**
- Greener NHS Knowledge Hub
- Core20PLUS5 e-learning modules

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Case studies and examples

• Learning from North Cumbria's large-scale service reconfiguration

This case study describes a service change driven by an urgent need to improve quality that found success in building on the shared ambition to improve health, improve access to services and reduce health inequalities.

• Sunderland and South Tyneside's path to excellence scheme

This communications and engagement strategy provides insight into considerations relating to inequalities.

• Improving Healthcare Together, 2019

This PCBC is a useful example, see pages 204-210 for Integrated Impact Assessment including sustainability.



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Engagement and public consultation

Before developing your proposal, it is vital that you engage all the partners in your system that will be affected by this change.

By including the voices of those affected by service change, such as patients, service users, friends and family, the public, clinicians, staff, healthcare providers and local government, programmes can better understand and respond to stakeholder concerns. This reduces the potential for delay within the process and ensuring proposals are the best fit for commissioners and stakeholders.

This process of engagement differs from a formal public consultation, although the two are often referred to together.

Within this document, engagement describes the continuing and on-going process of developing relationships and partnerships so that the local voices are heard, and includes the activity that happens early on in the development of service change proposals, such as discussions with a wide range of stakeholders to develop a robust case for change.

On the other hand, public consultation specifically refers to the duty for NHS bodies to 'involve and consult' the public when considering a proposal (based on the NHS Act 2006 as amended)). NHS bodies also have a legal duty to consult with local authorities when considering a proposal for a substantial development of the health service, or for a substantial variation in the provision of a service (based on the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013). In practice therefore, public consultation where there is a substantial service change involves compliance with both duties.

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Legal duties

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There are a number of key legal requirements regarding engagement when planning service change.

The NHS Act 2006 (as amended by the Health and Social Care Act 2012 and the Health and care Act 2022)	Equality Act 2010 (Public S	uality Act 2010 (Public Sector Equality Duty)	
S.13Q requires the NHS to make arrangements to involve patients and the public in planning services, developing, and considering proposals for changes in the way services are provided and decisions to be made that affect how those services operate. S.14Z45 requires ICBs to meet the same standards as S.13Q	Requires the NHS to demonstrate how it takes account of the nine protected characteristics of:		
	 Age Disability	 Race Religion or belief	
	Gender reassignmentMarriage and civil partnershipPregnancy and maternity	SexSexual orientation	
S.244 Regulation 23 of the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013 (made under s244 of the NHS Act 2006) requires NHS bodies to consult relevant local authorities on any proposals for substantial variations or substantial developments of health services.	The Public Sector Equality Duty r employees to 'have due regard'		-
	• Eliminate discrimination, harassment, victimisation and any other conduct prohibited under Act		
	 Advance equality of opportunity relevant protected characteristic Foster good relations between p protected characteristic and per 	and those who do not persons who share a relevant	
S.13G and S.14Z35 also includes a statutory duty for NHSE and ICBs to have regard to the need to reduce health inequalities between persons in access t	0		-
health services and the outcomes achieved.			
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An integrated impact assessment includes evaluation of the potential impact of proposed changes on people in relation to equalities and health inequalities and often brings all relevant assessments together, so for example might include impact data related to quality and outcomes, travel, access and choice, sustainability, finance and local economy, other services or providers. Speak to your regional reconfiguration lead if you would like to see an example.

What does this mean for my programme's engagement plans?

The NHS Act 2006 (as amended) means that all service change programmes must involve patients and the public, where necessary, in service change.

- You'll need to demonstrate this involvement throughout the project.
- Depending on the advice of your local HOSC or JHOSC, you may decide to have a formal public consultation as well.

The Equality Act 2010 means that programme leads must take steps to include people with protected characteristics, especially when conducting a public consultation.

- You should also assess how service change might affect people with protected characteristics, and how people with protected characteristics will be able to access information as part of your planned engagement activities.
- As the NHS has a statutory duty to consider reducing inequalities, this must form part of your planning for service change. You will need to complete an Integrated Impact Assessment.

You should also consider accessibility of a formal public consultation if required.

The Health and Care Act 2022 places a duty on NHS organisations to consider climate change in their operations.

• You should engage and consult with your local ICB and trust sustainability leads to ensure alignment with their Green plans.



Stakeholder partnerships – who are my stakeholders?

A proactive approach to stakeholder partnerships is critical to success. This section gives you an overview of some of the key groups for engagement – but you will need to complete your own stakeholder map to ensure that all relevant stakeholders are identified and included in conversations about service change.

You should also consider how to include stakeholders in governance, particularly in reference groups or on decision-making bodies. Inviting stakeholders to participate in formal structures helps to incorporate diverse perspectives into your programme.

People and communities

It's key to engage patients and the public as early as possible in your service change programme. We recommend that programmes talk to residents, people who access care and support, and unpaid carers, about the drivers for change. They should be involved in developing (ideally, co-producing) proposals and options that will then be consulted on.

- Patient and carer support groups
- VCSE and community groups
- Healthwatch
- The seldom heard and/or marginalised groups
- Protected characteristics groups
- Additional groups identified as being disproportionately impacted in your impact assessment

- Campaigners (groups and individuals)
- Trust membership networks
- GP patient participation groups
- Local authority citizen and residents' groups
- Local employers and business groups/forums
- Faith groups

There is, however, a significant difference between engagement with the public, and formal public consultation. A formal public consultation should never take place until regional colleagues and – depending on capital requirements – national colleagues have assured and approved proposals. You may also find it helpful to discuss the public consultation approach with local government partners prior to launch.

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Clinicians

Service change must be evidence-based, and evidence should be publicly available during the consultation and decision-making stages.

It is important that front-line clinicians affected by the proposed changes are involved. Clinicians are powerful advocates and play an important role in communicating the benefits of change to a wider community.

Clinicians should determine and drive the case for change, based on the best available evidence. Medical directors and heads of clinical services of any providers involved can help build the clinical evidence base. Where possible, the clinical lead should also involve senior clinicians not directly connected with the services under review, to ensure outside perspectives are included.

For complex service change, commissioners should always seek the advice and support of their Regional Clinical Senate. Not only can these senates provide independent reviews of your proposals, they are a fundamental part of the assurance process. You should engage your Clinical Senate as early as possible in the process.

Local government

Local government is a key stakeholder in all service reconfiguration, providing an important oversight and scrutiny function.

Commissioners must consult the local authority when considering any proposal for a substantial development or variation of the health service in the area. Once the local authority is aware of a change programme, a Health Overview and Scrutiny committee will discuss the proposal (HOSC), with a Joint Health Overview and Scrutiny committee (JHOSC) formed if a programme lies over multiple local authorities.

The HOSC or JHOSC will scrutinise the options presented to them and advise whether they think a formal public consultation is required. The HOSC and JHOSC may make recommendations to the NHS commissioning body (ICBs or NHSE) or referrals to the Secretary of State for Health for further review.

Individual local councillors and MPs are also included in the range of stakeholders. These two roles are influential as public representatives, and councillors are members of scrutiny bodies. Local government leads on public health, environment, transport, and social care and needs to be fully engaged right from the outset so that these perspectives can be fully integrated into the programme.

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Staff

It's crucial to let staff from across your system know about your plans for service reconfiguration as soon as it's possible to share these. This is especially true before holding a public consultation. Staff can be key advocates in communicating service change to friends, family, and the wider networks that they meet. Their engagement, collaboration, and support are fundamental to the successful delivery of any reconfiguration of services.

The Voluntary, Community and Social Enterprise Sector

VCSE organisations – from large national charities to small local ones – are involved in care pathways covering a wide variety of services, including diseasespecific care, and in coordinating care for those with multi-morbidity across different parts of a pathway.

Those working in the sector, including volunteers, make up a significant proportion of the health and care workforce. The VCSE sector will also often have trusted relationships with residents across local systems. It has a long track record in finding creative solutions to improving outcomes for groups with the poorest health – making it an essential partner in understanding the potential inequalities impact of proposed changes.

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What does engagement mean?

There are many ways in which people might engage in service change, depending on their personal circumstances and interest.

You should plan what you'd like to get out of engagement. For example, you might aim to:

- Inform key stakeholders about a particular phase of work to ensure they are aware of the plans
- Listen to stakeholder requirements and feedback when considering your options appraisal
- Collaborate with a VCSE organisation to reach specific groups with protected characteristics and seldom heard communities during your public consultation

The benefits of engagement

- It offers those who will affect or be affected by the outcomes a chance to voice their opinions
- It ensures that the programme has greater clarity and a shared vision amongst its key influencers
- It brings people together to pool knowledge, experience, and expertise to co-create solutions
- It helps to reduce the level of risk and improves governance
- It enables you to better understand critics and respond to concerns

Key takeaways

- Differentiate your engagement activity according to your stakeholder map – one size doesn't fit all
- Good engagement takes time, resource, and energy it can't be rushed
- Show you have heard as well as listened and informed. Where you've made changes based on feedback, be sure to evidence these using the 'you said, we did' format
- Allocate enough resource time, people, programme budget – to do your engagement properly
- Change programmes can be challenged on process at a judicial review – take time to make your engagement process robust

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Key documents

- Working in partnership with people and communities: statutory guidance
- Engagement and communications for health and care systems
- Toolkit for Communications and Engagement Teams in Service Change Programmes
- Equality Act 2010 Guidance
- Local Authority health scrutiny
- Clinical Senate review process: Guidance notes

- Population Health Management Academy FutureNHS workspace
- Strategic Health Asset Planning and Evaluation (SHAPE)

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Case studies and examples

- Britain Thinks: how to communicate change in the health and social care systems effectively
- Co-production in a cold climate the North Cumbria experience
- Traverse using public evidence in service change
- Holsworthy video
- Shropshire, Telford & Wrekin public consultation
- Joined Up Care Derbyshire Engagement Model (2022)

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Planning and case for change



What is a case for change?

A case for change is a formal document which introduces the reasons that you are seeking to make a service change.

The case for change comprehensively describes the current and future needs of the local population, the provision of local services and the key challenges facing the health and care system. It provides the platform for change and needs to present a compelling picture of what needs to change and why. It should also link to the benefits that the proposed service change will aim to deliver.

You'll need to include:

- A vision statement
- An understanding of the local population and their current outcomes
- Detailed analysis of the performance of local services
- Identification of key challenges
- A review of financial considerations

Top tip: the case for change doesn't include any proposals for future service change. It makes an argument for why change is needed in your area, without suggesting which specific changes are required. <u>See our video</u> outlining how to develop a case for change.

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Top tip

It's helpful to have completed your stakeholder mapping before beginning engagement on your case for change, to help you identify who should review it.

Developing a case for change

Your case for change is a detailed, focused document which gives readers insights into the existing services in your area, and the challenges for the future.

When planning your case for change, it might be helpful to start with a case for change workshop, including regional team members, system colleagues, key health and care professionals, and experts by experience. A workshop is a compelling way of identifying the reasoning underpinning the case for change and reaching consensus on the key challenges.

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What should be included in a case for change?

A vision statement

To introduce your programme, you should develop a statement of why you exist, what you do, and the future you're trying to create. This should be unique, memorable, ambitious, and motivating, including the principles of how you intend to deliver change, and the strategic objectives behind your programme.

An understanding of the local population and their current outcomes

You'll need to demonstrate that you have a solid understanding of the needs of the local population, and current health and wellbeing-related outcomes.

This might include information about demographics, such as the breakdown by age, ethnicity, gender, socio-economic status, or other relevant factors in the local population.

Health and wellbeing outcomes might include life expectancy, qualityadjusted life years (QALYs), insight and feedback on experience of services, and information about the prevalence of different illness.

It's also useful to think about how your population is changing, and the impact that this might have on services. Evidence is key and including data and statistics supports the reader to better understand your case for change.

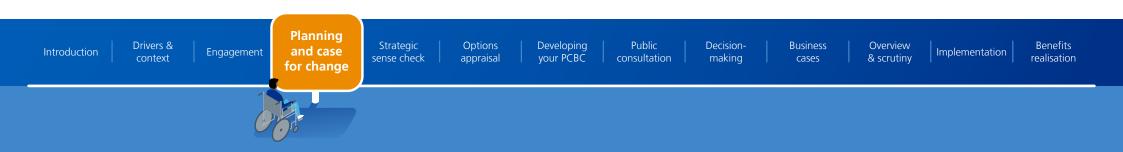
If you're not sure where to start, some key questions to start include:

- Is the average age of your population increasing or decreasing over time? How are other demographic factors changing?
- Are there local non-health factors (such as housing challenges, unemployment) that might lead to increased demand for certain services?
- Are there any trends in the number of patients seen at different types of services? What does this tell you about likely areas of pressure for the future?
- Have you identified the whole population affected by a change to this service, including those who might live outside the local area?
- What are the environmental factors affecting the health of your local population now and in the future?

You'll need some analytical support to bring this together. Talk to your regional team, the <u>Population Health Management team</u>, and your local Commissioning Support Unit for support.

Top tip

Your services might be accessed by people travelling from outside local authority boundaries. Aim to describe all service users, no matter their location.



Detailed analysis of the performance of local services

In this section, you'll need to identify all local services – including those delivered by the NHS, VCSE and the private sector – and how these intersect. Not sure where to start? Look at:

- Who commissions services? 0
- How much do services cost? 0
- Who are your providers? 0
 - GPs and primary care networks
 - Dentists
 - Opticians
 - Mental health trusts, providers, and facilities
 - Community providers
 - Hospital trusts and urgent treatment centres

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Social care

Describe the spread of services and their usage by the community. What trends are easily identifiable?

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Demonstrating that you know your local providers is a real strength in your case for change - this will help to evidence any gaps in current provision.

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Identification of key challenges

The key challenges section will bring together information about the local population (including their needs and health outcomes) and the existing provision and highlight areas of challenge for your system.

Consider the current available service provision, what your local population will need moving forward, and what you see as the future challenges for your area. This is the crux of your case for change – what needs to change to promote positive health outcomes among your local population? Are there non-health outcomes you need to include?



Top tip

This should focus on key challenges for local people, not the challenges in enacting service change.

A review of financial considerations

Finally, it's helpful to give an indication of financial considerations. Where are your areas of high spend? Are the financial considerations likely to develop into future challenges?

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If it's clear at this stage that capital expenditure will be required in order to address the drivers for your service change, it's important to engage your regional colleagues and the relevant NHSE teams as soon as possible, to know how this will impact your change programme.

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Key documents

- The change model guide
- Leading large-scale change: a practical guide
- Library of tools to support modelling and analytics for service change
- Service change guide how to use evidence
- Population health management flatpack
- Making Data Count
- How to produce a Green Plan

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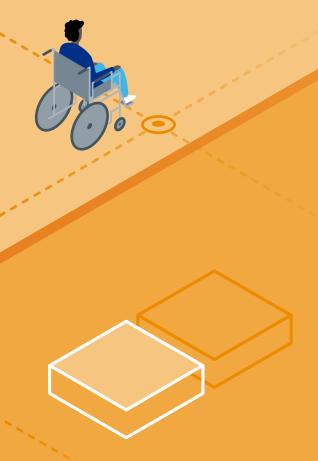
appraisal

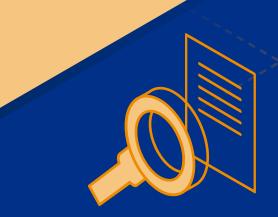
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Case studies and examples

- Fit for my Future (Somerset) case for change
- Transforming Health and Social Care in Kent and Medway – Case for change
- Your Care, Your Future (West Hertfordshire) vision, strategy and case for change
- Path to Excellence Case for Change (2021)
- North Central London Case for Change (2020)

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The aim of NHSE's assurance process is to help commissioners apply a best practice approach when planning complex programmes of service change and to mitigate the risk of successful legal challenge which might otherwise significantly delay or derail service change proposals.

Legal challenge could be in the form of a referral to the Secretary of State for Health and Social Care, or via Judicial Review. An effective assurance process also gives patients, staff, and the public confidence that service change proposals are well thought through, have taken on board their views and will deliver real benefits. For NHSE to assure a set of service change proposals, there must be confidence that a proposal satisfies the government's four tests, NHSE's test for proposed bed closures (where appropriate), best practice checks, and legal duties and is affordable in capital and revenue terms. Assurance checks, both formal and informal, will look at service change with regard to the above, as well as its impact on other organisations in the wider health and social care system.

NHSE has a role to both support and assure the development of proposals by commissioners. You should contact your regional team at an early stage in the development of your service change proposals, as a source of informal advice, check and challenge, and links to best practice.

Assurance is always applied proportionately to the scale of the change being proposed, with the level of assurance tailored to the service change.

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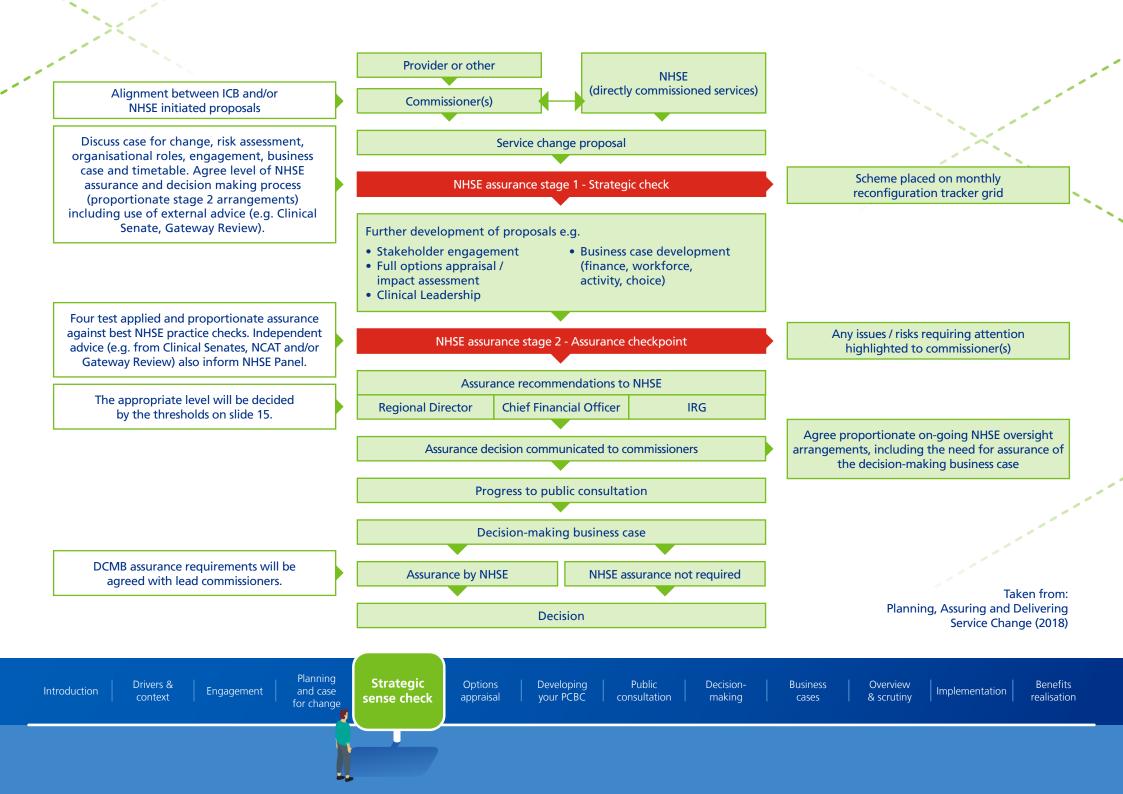
Overview of the assurance process

Whether or not your scheme will need national assurance is determined by the criteria below:

- The reconfiguration scheme requires transition or transaction support of more than £20m from NHSE funds (not including ICB funds); or
- The total turnover of the affected services (for all sites impacted by the transition, at current prices) is above £500m in any one year; or
- The likely capital value of the scheme is above £100m (gross capital value of the scheme, even if the actual value is lower because it is funded through capital receipts); or
- The proposed service change impacts on any provider in special measures.

All proposed service changes undergo regional assurance in the first instance. This helps decide whether national assurance is also required. Before national assurance is sought, however, there are two stages to regional assurance. Your regional teams can help you to understand the requirements of each of these stages, as well as what you will need to do to secure assurance.

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Reducing risk through assurance

NHSE works with commissioners to support a best practice approach and reduce the risk of successful legal challenge by applying a proportionate service change assurance process which helps to support the development of service change proposals in three ways:

- 1. Robustness, openness and transparency An effective external assurance process gives confidence to patients, staff and the public that proposals are well thought through, have taken on board their views and will deliver real benefits. Assurance checks alignment with the four tests for service change, NHSE's test for bed closures, as well as other best practice checks developed from experience of other programmes, and the impact of proposed change upon other organisations in the wider health system.
- 2. Risk mitigation The support and assurance process mitigates the risk of successful legal challenge which might otherwise significantly delay or derail service change proposals. Schemes can be challenged via a referral to the Secretary of State (who may ask for advice from the Independent Reconfiguration Panel), or via a request for judicial review. The risk of successful challenge is greatly reduced by following the appropriate advice and applying a best practice approach.
- **3.** The high costs of getting it wrong A high profile programme that has been subject to both Judicial Review and referral to the Secretary of State is estimated to have cost >£6m.



Stage one - Strategic sense check

Following your case for change, and as proposals are developed, you should approach your NHSE regional team for a strategic sense check of your developing proposals. A strategic sense check is a formal discussion between commissioners and providers leading the change and NHSE at the appropriate level (usually the regional team). The strategic sense check will determine the level for the next stages of assurance and decision-making.

The strategic sense check helps NHSE regional teams to:

- Understand the nature of the service change being proposed
- Determine the level of risk associated with those proposals and agree the proportionate level of assurance required
- Determine what support a commissioner might require in taking these proposals forwards

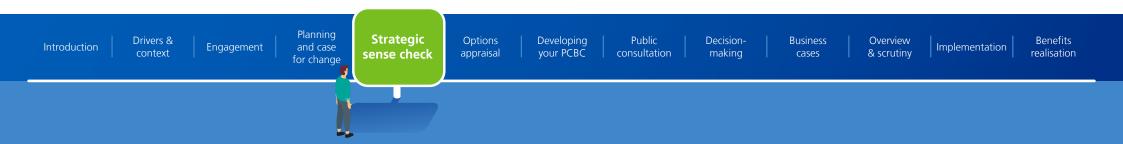
The stage one strategic sense check is a semi-formal discussion between commissioners and providers leading the change and NHSE regional teams. The conversation will explore your case for change, how your proposal aligns to the long-term strategy of your local ICS and relevant national policy, the local context you are operating in, and the level of risk associated with your service change proposals. This conversation will determine the level for the next stages of assurance and decisionmaking. If capital is likely to be required, discussions with the relevant NHSE finance teams should have begun. The earlier a strategic sense check meeting takes place, the more support and advice NHSE can offer a commissioner in relation to the development of their proposals, and the more likely a successful assurance outcome.

NHSE will want to explore the case for change and the level of consensus for change. The strategic sense check will ensure a full range of options are being considered and that potential risks are identified and mitigated. Alignment between the proposed changes and system priorities, other key partners and neighbouring organisations will also be explored.

Your NHSE regional team will help you to identify independent clinical advice at this early point in the process, as most appropriate for each given proposal/programme (e.g. Regional Clinical Senates, clinical networks, royal colleges etc.) on a case-by-case basis. Your Clinical Senates may at this stage be asked to review a service change proposal against the appropriate key tests (clinical evidence base).

Often, Regional Clinical Senates are best placed to provide independent review and advice on service change programmes. Senates provide independent advice on the clinical aspects of service change proposals that commissioners, providers and transformation programmes can draw on to both improve the quality of the proposed service models and help demonstrate that they are built on a strong clinical evidence base.

The next stage of approvals is the stage two assurance checkpoint. This will happen after you have finalised your case for change, appraised all the options you may consult on, and compiled your pre-consultation business case. More information about this checkpoint features later in this handbook.



Options appraisal

The options appraisal process is to help people decide between different options to identify a preferred way forward that will address the issues identified in the case for change.

A strong options appraisal process:

- Gives due consideration to all options
- Reduces the options to a manageable number as quickly as possible
- Supports the weighing up of different options
- Can be completed as simply as possible

Before you can appraise the options, you'll need to develop initial proposals. This should be done with as much wider engagement as possible.

A clinically led group should oversee the design and development of proposals, but it is essential that wider stakeholders such as the people who use care and support, social care and VCSE partners are involved at this stage. Commissioners should ensure that clinical ownership of plans informs any governance and co-design arrangements.

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Any discussions with people who use care and support are considered as part of your engagement, and should be included in your PCBC to demonstrate your engagement under the legal duties of service reconfiguration.

What to consider in your proposal development

Developing proposals can be an opportunity to think outside the box and consider a wide range of options to improve health services in your area. It's important to include multiple perspectives, including:

People who use care and support

Have you considered the experience and expectations of people who use care and support, and unpaid carers, in developing proposals? Colleagues working in commissioning and provider organisations with insight and experience, as well as VCSE partners, will be able to support you to draw on existing insight on services, such as feedback from survey data. Proposal development stage gives the opportunity to engage with local people so they can bring their perspectives as 'experts by experience' to the table and contribute ideas for improvement. They will also help you understand potential impacts of proposed changes.

Involving people who use care and support in proposal development can be done through a range of methodologies, for example:

- Existing or new surveys and other research
- Co-production workshops involving service users, carers and staff
- Outreach meetings with patient groups
- Community outreach sessions to test and seek comments on early proposals
- Having experts by experience, unpaid carers and VCSE colleagues on clinical reference groups.



Legal

Has legal advice been sought to inform governance and decisionmaking processes? A legal view on the approach to consultation may also be helpful at this stage.

Have you taken account of your legal duties under the NHS Act 2006 (as amended), Equality Act 2010 and any other relevant legislation?

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Are proposals developed in the context of a broader vision of integration of services and aligned with other key programmes (e.g. urgent and emergency care, seven-day services, digital strategy)?

Have the interdependencies with other services, organisations or areas (e.g. neighbouring locations; ambulance; social care; community; mental health and specialised services) been thoroughly mapped?

Is there a clear analysis of the travel and transport implications of the proposals including any proposed mitigating actions? Implications could include the impact on carbon emissions.

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How can proposals be framed in terms of potential gains rather than losses/closures? Consider the narrative and language to describe what's being proposed and why.



Top tip

The Independent Reconfiguration Panel has commented that the NHS focuses too much on potentially negative consequences, stating that they 'emphasize what cannot be done and underplay the benefits of change and plans for additional services.' Ensure that you focus on the positives, while acknowledging the negatives as required.

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If any of your proposals include a requirement of capital, the way you conduct your options appraisal – and subsequently discuss it in your preconsultation business case, and strategic outline case – will be impacted. More information is available as we go through this document.

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You should follow the approach set out in the Treasury Green Book. The five case model requires a minimum of four shortlisted options to be included in every Business Case: (1) a 'BAU' option, (2) a 'Do Minimum' option, (3) a 'Preferred Way Forwards' option, and (4) a 'More ambitious / Less ambitious' option. It's helpful to evaluate these four models as part of the appraisal process, so that you can evidence that you have considered these in your future business case.

Developing and appraising your options

The options development and appraisal process must be designed so that the preferred way forward addresses the issues in the case for change. It must also allow you to differentiate between options.

To develop your options, you can hold engagement and stakeholder workshops to involve commissioners and local people in identifying a long list of options and the evaluation criteria. This can help with transparency and perceived robustness of the process, as well as providing an external sense check. For example, a programme may involve members of a public reference group in this way.

Once a long list of options is drawn up, you can apply criteria to evaluate these. Your long list should be comprehensive – your options will be reduced following the appraisal.



Criteria	Long list of options	Shortlist of options
Fixed points	 At this stage, you should identify 'fixed' points that cannot be altered Services must remain at these points and are not in the score to adjust This might include national designation of services, the outcome of previous consultations, road networks and housing developments, location of academic institutions and expensive equipment Fixed points are also referred to as 'Constraints and Dependencies' in the Treasury Green Book 	• The fixed points identified at the long list stage should be considered at the short list stage to ensure these have not been missed
Hurdle criteria	 Hurdle criteria are used to filter the number of existing criteria – reducing the long list to the shortlist These should set out requirements that each option must pass to be considered Criteria could include: will the option deliver quality standards, will there be sufficient workforce, can the population access services within national guideline times, will carbon emissions be reduced Hurdle criteria are also referred to as 'Critical Success Factors' in the Treasury Green Book 	 Only options that have passed hurdle criteria should be included on the shortlist of options
Evaluation criteria	• Only proposals on the shortlist should be subject to evaluation criteria	 Used when options have been reduced to a manageable number (i.e. 7-15 options) Must be differentiating (i.e. enable different assessment of each option) Must be measurable (i.e. must have available data to make a comparison) Criteria could include: accessibility of care for all, workforce affordability and value for money, carbon impact/savings Aim is to reduce to 1-3 options for consultation Used when options have been reduced to a manageable number (i.e. 7-15 options) Further examples of evaluation criteria are found in the 'Shortlist appraisal' section of the Treasury Green Book You should also consider unintended consequences of any new service reconfiguration You must also consider equalities, as defined by the Equality Act 2010, and the reduction of inequalities as defined by the NHS Act 2006 (as amended)
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Options appraisal

Key documents

- Reconfiguration of NHS services (House of Commons Library)
- Treasury Green Book: Appraisal and evaluation in central government



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Case studies and examples

- Towards integrated care in Trafford
- Options appraisal for the Coventry and Warwickshire mental health system redesign for 0-25 year olds
- FutureFit (Shropshire, Telford and Wrekin, and mid-Wales) appraisal of options
- Gloucestershire Fit for Future Evaluation Criteria

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How to develop an effective pre-consultation business case

The pre-consultation business case (PCBC) is the legal document on which the commissioner decides to consult. Therefore, it must contain all the information they need to make this decision. The PCBC is also used to inform assessment of proposals against the government's four tests of service change, NHSE's fifth test, and other best practice checks.

The PCBC should be aligned with:

- The Integrated care strategy produced by the Integrated Care Partnership and the Joint Forward Plan produced by the ICB and partner Trusts / Foundation Trusts
- The NHS Long Term Plan
- NHS net zero targets 0
- Joint strategic needs assessments (JSNAs) and Joint health and wellbeing strategies (JHWSs)
- Your case for change documents
- Your options appraisal

Top tip

Think of the PCBC as an extension of your existing work, not a brand-new piece of work. It should develop and grow on the strategy and research that you've already completed.

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What the PCBC is

What the PCBC is not

The document in which systems show that they have properly considered the options, undertaken pre-consultation engagement, submitted to the required scrutiny and met the four (or five) tests The final business case. Instead, following consultation, a decisionmaking business case (DMBC) will be produced which will be the basis for the final decision to proceed with changes

The legal document that will be closely scrutinised so it must be complete and correct

A report of the project. Instead, it may include a description of the process followed to develop the PCBC at a very high level

A formal Board document which presents the business case for any changes on which the decision-making organisation agrees to consult

The basis upon which you will build further relevant business cases, such as your decisionmaking business case, and any additional capital business cases

What should I include in my PCBC?

Much like service changes themselves, no PCBC is the same as another. Each one is addressing a specific context, a specific set of drivers, and addressing a different, specific requirement for change. Even PCBCs that are proposing changes to the same kind of services will not be identical. As such, there is no template to follow or formal list of items that you must meet in your PCBC. Rather, you should focus on the narrative of your change – the who, what, when, where and why of what you are proposing.

To support you and your colleagues when writing a PCBC, look for as many past examples as you can and speak to colleagues in systems where reconfigurations have taken place. You might find it useful to look at the following examples as you develop your own structure that best supports the narrative for your service change.

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Every PCBC will be different as it has its own unique context. These are intended as examples.

PCBC structure example 1 (with thanks to CF, and as amended by NHSE)

Executive summary

- Foreword
- Executive summary

Introduction

- Purpose and scope of PCBC
- Structure of PCBC
- Geography (including map)
- Strategies (local and national)
- Current provision of services (and high level summary of activity)
- Programme information & governance

Case for change

- Population need
- Key challenges: poor patient experience (not one stop); poor quality estates; difficulty attracting workforce; cost of maintaining current estate

Vision and models of care (all option neutral)

- Vision
- Models of care: primary care; well-being; frailty; supported discharge; outpatients; diagnostics
- Co-dependencies (e.g. for outpatients, if any)
- Capacity requirements (by service)

Development of options

- Approach
- How stakeholders have been involved and feedback incorporated
- Fixed points (e.g. funding conditions)

Options appraisal

- Evaluation criteria: criteria development
- Longlist: minimum thresholds/hurdles for e.g. financial viability, capacity, capital, access; shortlist after hurdle criteria applied
- Shortlist: description of evaluation; options for consultation and preferred option, sensitivity analysis
- Detailed financial modelling

Enablers

- Workforce
- Digital
- Estates and sustainability
- Innovation

Stakeholder engagement

- Stakeholders
- Approach
- Engagement: staff; local authorities; providers; patients and public
- Key themes
- "You said, we did" table



PCBC structure example 1 (continued)

Integrated impact assessment

Impact of integrated model of care (same for all options)For each option for consultation (or for single option if only one)

- Clinical impact
- Access impact
- Equalities impact and mitigations
- Estates and sustainability impact
- Financial impact and timeliness for implementation

Benefits

- Approach
- Benefits framework
- Clinical benefits tables
- Non-clinical benefits tables
- How benefits will be realised and measured

Quality assurance

- Clinical Senate
 - Findings
 - How findings fed into proposals
- NHSE assurance process
 - Process
 - Five tests
 - National programme
- Health overview and scrutiny committee
 - Process
 - Feedback
 - How feedback fed into proposals

Plans for consultation

- Purpose of undertaking consultation
- Consultation approach
- Stakeholders
- Consultation document and questions
- Consultation activities and materials
- Collection and analysis of responses
- Resourcing plan

Implementation planning

- Initial implementation plans
- Transition planning
- Governance
- Resourcing
- Risks

Approvals and next steps

- Process
- Approvals granted / documented
- **Appendices**



PCBC structure example 2

Foreword

Executive summary

Introduction

Vision statement

Case for change

• Outline the case for change

• Be explicit about the number of people affected and the benefits to them

Models of care

• Describe the models of care that your service change programme will use

Benefits framework

- Demonstrate affordability and value for money (including projections on income and expenditure and capital costs/receipts for affected bodies) and satisfaction of any applicable benefit cost ratio (BCR) criteria
- Demonstrate proposals are affordable in revenue and capital terms, proposals are deliverable on site, and transitional and recurrent revenue impact have been robustly identified

Stakeholder engagement

• Outline how stakeholders, patients and the public have been involved, proposed further approaches and how their views have informed options

Identify governance and decision-making arrangements

- Consider completing a privacy impact assessment and summarise any information governance issues identified
- Outline how the proposed service changes will promote equality, tackle health inequalities, and demonstrate how the commissioners have met Public Sector Equality Duty
- Show that options are affordable, clinically viable and deliverable

Development of options and options appraisal

- Description of proposals including preferred way forward
- Demonstrate evaluation of options against a clear set of criteria
- Demonstrate how the proposals meet the governments four tests and NHSE's test for proposed bed closures (where appropriate)

Implementation planning

- Explain how the proposed changes impact on local government services and the response of local government
- Identify any clinical co-dependency issues, including any potential impact on the current or future commissioning or provision of specialised or other services
- Include an analysis of travelling times and distances
- Identify indicative implementation timelines

Plans for consultation

• Your plans for future public consultation, including details of engagement with HOSC/JHOSC

Approvals

• Describe the governance process for the PCBC and who has approved the final draft

Next steps

Appendices

- Integrated Impact Assessment
- Letters of Support

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How to integrate financial detail into your PCBC

Your PCBC needs to include an appropriate level of financial information – including any anticipated capital requirements. Remember: if your change requires capital, the source must be secured before you can go out to consultation.

- One key decision is whether you have a stand-alone finance chapter or integrate within the overall narrative
- Ensure that the clinical case for change stands alone with the finance case for change sitting alongside
- Think carefully who will write the finance sections they need to understand the numbers and be able to explain them in plain English
- Use graphs, tables, and visuals to communicate the key points to the audience
- Avoid overly complicated detail in the main body of the PCBC a detailed technical appendix can cover the detail
- Finance numbers are usually finalised at the last minute so write the narrative thread with estimates, and add before submission

Top tip

Remember that capital requirements will impact how your options appraisal needs to be described at the capital business case stage; if capital is required, consider amending how you conduct and describe your options appraisal. You should align it more closely to the requirements of the strategic outline case, this will become easier to complete later. See <u>Business Cases</u> later in this document for more information.



How to evidence engagement

- The PCBC should demonstrate that you have engaged with a range of people and have developed/amended proposals using feedback from engagement
- One key decision is whether you have a stand-alone engagement chapter or integrate within the overall narrative. Options include:
 - A stand-alone chapter on engagement undertaken, key themes from feedback and resultant changes to proposals
 - A section at the beginning of each chapter highlighting what engagement was used to develop the proposal in the chapter
 - A description of engagement and impact within chapters
- Consider adding 'you said, we did' section this shows how feedback from engagement has been used

How to describe the options appraisal process

- The description of the options development and evaluation in the PCBC should describe the process used to get to the options. It should not just describe the options you have arrived at.
- A useful format to writing the options section is:
 - 1. Describe an options appraisal process (the approach).
 - 2. Go step-by-step through what was done to longlist, shortlist and identify the preferred way forward, presenting the evidence at each point that options are removed from consideration (remember to align your language to the process outlined in the Treasury Green Book).
 - **3.** Present a list of all your shortlisted options, with an explanation of why all the other options that were appraised ultimately weren't shortlisted.
 - **4.** Describe the preferred way(s) forward in detail, including the impact on activity, access, workforce, finance, carbon emissions, etc., in addition to explaining why this is the preferred way(s) forward based on the existing evidence.
- While it might feel quite repetitive, it is crucial that the logical steps taken to evaluate the options and the evidence used are laid out. This assures the people making the decision that the process has been robust.

Top tip

Writing the options sections thoroughly is very helpful to make sure there are no gaps in the decision-making process and to pinpoint areas where questions might be asked during consultation. If you can't answer these questions as part of writing the PCBC, you won't be able to answer them during consultation!

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Writing a compelling PCBC

- **1.** Start with the executive summary. A two-pager narrative is a crucial introduction to the issues and your plans to address them.
- 2. Be clear about your reader at a minimum, this will be the decisionmaking body and other bodies included in the sign-off process (regional team, NHSE, Clinical Senate). The document will also be shared with the public during the formal consultation stage.
- **3.** Be clear about your voice and keep the same voice throughout. Approach your internal comms team for examples of your 'organisational' voice.
- 4. Stick to one sentence, one idea and one paragraph for one point.
- 5. Use subheadings to structure the report and summarise the content - taken together, the subheadings should give the executive summary of the section.
- 6. Leave plenty of time for editing and proof-reading. Give the PCBC to someone who hasn't been closely involved in developing it to make sure it makes sense

Who should review the PCBC?

- The Regional Clinical Senate: they may be asked to review the clinical evidence and produce a report in response.
- The NHSE regional director: this forms part of NHSE assurance. They will also confirm who else from NHSE is required to assess and assure the document
- The J/HOSC: as the PCBC is one of the documents that they will refer to the IRP and/or judicial review, it needs to meet the requirements of these processes.
- Providers: it is crucial to get letters of support for the proposals from providers. This usually requires the PCBC to go through their Boards.

Top tip

Only a few people are likely to read the entire PCBC before sign-off: these should include the lawyer, the Programme Director, the Communications Lead, and the Regional lead.

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Key considerations for streamlining sign-off of the PCBC

- Spend time early on mapping out the meetings that the PCBC will need to go through for discussion or sign-off
- Each section of the PCBC should be read and signed off by a relevant section – for example, the finance section should be signed off by the Chair of the Finance Group
- As the process of writing, iterating, and agreeing the PCBC can take
 5-6 weeks, try to write and signoff sections as you go along
- Be certain about the evidence for everything in the PCBC, especially if external agencies have been involved in developing material

Stage two assurance checkpoint

Before you go out to consultation, you will be required to pass the stage two assurance checkpoint. Much like stage one, it is good practice to once again get your Clinical Senate to review your proposals, especially if proposals are substantial or contentious. By this point you will have created a case for change, reviewed your options, engaged your stakeholders (but not formally consulted them) and created a PCBC. Your proposals should also demonstrate that you have a high degree of confidence that, for all the options being consulted on, they would be capable of being delivered as proposed.

NHSE will put together a stage two assurance panel consisting of NHSE staff suitably qualified to consider evidence submitted against the government's four tests, NHSE's fifth test for proposed bed closures (where appropriate), as well as other checks, including financial deliverability, affordability and value for money.

At this point it may be helpful to receive support for these proposals from the providers that are involved in and impacted by these proposals.

Top tip

For any service change schemes which require capital financing, you must ensure that you receive the support in principle of NHSE, in writing, before public consultation on options requiring capital commences. Your regional teams can support you in obtaining this.

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At the assurance checkpoint, regions, partners, and national teams (depending on the level of assurance required) assure the proposals you have put forward, drawing on the evidence in the PCBC. Support for the development of this business case comes from the strategic sense check, as well as ongoing engagement with regions, NHSE, and stakeholders.

PCBC assurance process

• JHOSC scrutinise proposals and agree the consultation length

• **Decision-making body/bodies sign-off at the end,** directly before consultation (they have to decide to consult based on the PCBC)

High-level assurance process

Regional Clinical Senate	Regional Director	ноѕс/јноѕс	National Assurance	Decision-maker's governing body
The Clinical Senate review the clinical evidence and produce a report in response	Review by Regional Director	The HOSC/ JHOSC agree the consultation length. This can be undertaken at the same time as OGSRC and IC review	NHSE will assess and assure the PCBC and provide final approval	It is possible for commissioners to begin their governance processes in advance of national assurance

Approval of the PCBC by these organisations will allow you to move to the public consultation stage. More information about <u>public consultation</u> can be found in the next section of this document.



Developing your pre-consultation business case



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Key documents

- Planning, assuring and delivering service change for patients & addendum
- Guidance on the preparation of integrated care strategies
- Guidance on developing Joint Forward Plan 2022
- Joint strategic needs assessments (JSNAs) and Joint health and wellbeing strategies (JHWSs)

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• NHS Long Term Plan

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• Delivering a Net Zero National Health Service

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• Core 20PLUS5 (adults) - an approach to reducing health inequalities

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Case studies and examples

- Dorset's clinical services review Pre-consultation business case
- Mid and South Essex success regime Pre-consultation business case
- Sunderland's path to excellence Phase 1 pre-consultation business case
- Wirral's urgent emergency care transformation business case
- Gloucestershire Fit for Future PCBC (2021)
- Better Care Together PCBC
- Epsom and St Helier PCBC (2019)



Public consultation and analysis of feedback

Public consultation, by commissioners and providers, is usually triggered when the proposal under consideration would involve a substantial change to NHS services.

Warning

You must speak to your local authority before going to public consultation. Revisit our guidance on engagement here.

It's recommended to engage an independent body to run the consultation analysis ahead of finalising any consultation documents, and to include a suitable budget for this piece of work in plans including the pre-consultation business case.

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Before starting a public consultation

Use the checklist below to confirm whether you're ready to begin consulting.

- Are you content that your proposals meet the four tests for service change, and have you formally discussed the proposals with NHSE, receiving NHSE support to progress to consultation?
- Are all of your proposals affordable from a capital and revenue perspective?
- Have you formalised your engagement with local authority HOSC/JHOSC, to agree their roles in the process and the regularity of ongoing discussions?
- Have you completed your stakeholder mapping (to include stakeholders, staff, patients, and the public) and used this to inform a communications and engagement strategy?
- Have you implemented your engagement strategy?
- Have you had the appropriate discussions with health and social care organisations to establish the interfaces of your proposals with the wider health and care system, for example with neighbouring areas, specialised services, community, mental health, or ambulance providers?
- Are arrangements in place to correct any inaccuracy or misrepresentation of the programme quickly and consistently?
- Are the implementation plans comprehensive and credible to the public?

Once you can tick off all the statements above, it's time to plan your public consultation.



The Gunning Principles

Public consultations must follow a set of guidelines referred to as the Gunning Principles, based on the legal case R v London Borough of Brent ex parte Gunning, 1985. These should guide the consultation process.

1. Proposals must still be at a formative stage

Public bodies need to have an open mind during a consultation and decisions cannot already have been made.

2. Sufficient information around proposals to permit 'intelligent consideration' People involved in the consultation need to have enough information to make an intelligent input into the process.

3. Adequate time for consideration and response

Timing is crucial – is it an appropriate time, was enough time given for people to undertake informed consideration and then provide that feedback, and is there enough time to analyse those results and make the final decision?

4. Consultation feedback must be conscientiously taken into account

Think about how to prove decision-makers have taken consultation responses into account.

Please note

These guidelines ensure that public consultations are fair and proportionate.



Fair

The Gunning Principles require consultations to be fair, including allowing adequate time to respond to the consultation and requiring commissioners to consider the issues raised by respondents. In addition, it is important to be aware of recent guidance provided by the Supreme Court in a case (ex p. Moseley) which supported the Gunning Principles. The Court suggested that, for a consultation to be 'fair', those responding should be consulted on both the preferred option and all other viable and realistic options.

In addition, Covid-19 has increased the spotlight on health inequalities. Systems need to understand how proposed changes could affect groups that experience poorer health outcomes, with particular focus on the groups that have been most affected by Covid-19, including those from BAME backgrounds and those living in areas with higher levels of deprivation.

It is good practice to design a public consultation with local partners such as local government, your public reference group for the programme, Healthwatch, and experts by experience who can advise on how best to reach specific groups such as young people or people with learning disabilities.

By ensuring accessible and inclusive consultations, you will help ensure that health inequalities do not widen because of service changes.

Practically, it's good practice for all consultation materials to be available in a range of formats:

- Easy Read
- Braille or large print 0
- In other languages 0
- In a non-electronic (i.e. paper) format, available at an easily accessible location for those without a computer or internet

You should also consider how the consultation is publicised – online methods may help to spread information guickly, while traditional advertising methods, such as through newspapers, leaflets, posters and information at public centres such as libraries, may help to reach those who are digitally excluded.

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Proportionate

Programmes usually draw on a combination of internal resource and externally commissioned support for a formal public consultation, depending on the individual circumstances. Examples of external support that can be commissioned include:

- a phone survey with a reflective sample of the local population
- outreach support from voluntary, community and social enterprise sector (VCSE) partners to hear from 'seldom heard' groups and communities
- online events and engagement exercises (made more popular during the Covid-19 pandemic)
- independent analysis and reporting of consultation feedback from both structured surveys and other engagement activity, to inform decision-making on completion of the consultation

A service change programme will need to consider the impact of proposals on people who may be affected. Generally, the greater the extent of changes and number of people affected, the greater the level of activity that is likely to be necessary.

Location, access, and demographic issues need to be considered. This might differ across your consultations – for example, adults in a rural area will have different needs to urban children and young people in terms of accessing a consultation. These issues also need to be considered when planning participation itself. For example, in a small market town it may be best to carry out surveys on a market day when there are more people around than on other days.

You should monitor the extent to which people are responding to the public consultation throughout the process and take steps to identify any challenges to participation. Some examples of issues that might arise include:

- Poor attendance at public events or low response rates to a survey
- Lack of engagement by a particular group that staff feel would be significantly affected
- Multiple questions from consultees on the same topic, suggesting that further information might be required

If such issues arise, the programme should try to understand why this is the case and how the issues could be addressed. This could include attempting different engagement methods or approaching partners for advice on how to reach certain groups.



Consultation methods

Using your existing stakeholder map, you can group your stakeholders and work with communications and engagement professionals to identify the best methods for developing and sustaining their interest during your public consultation.



Interest

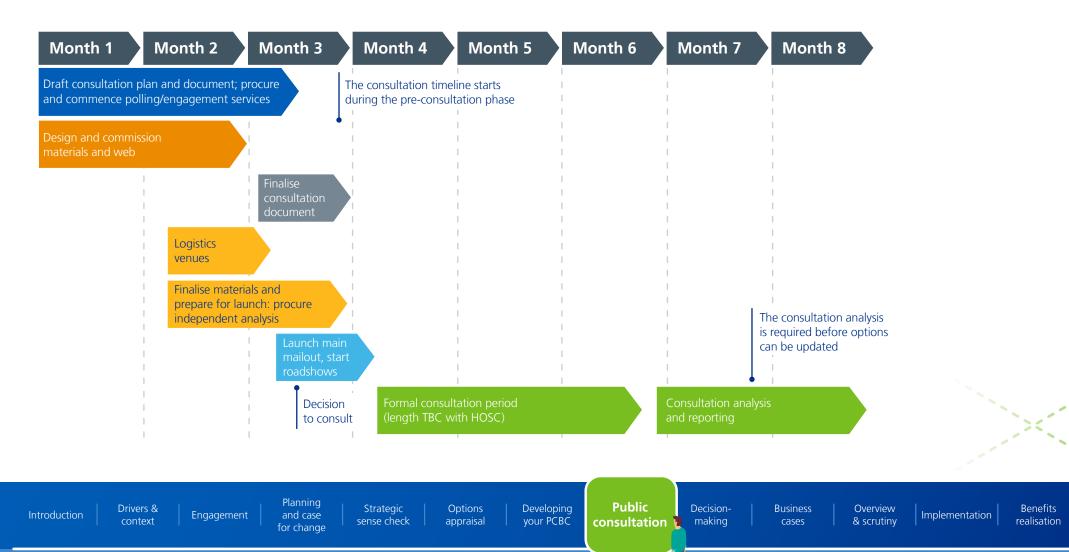
Top tip

As well as having a clear consultation plan, it is important to audit the consultation that takes place, so you have a record of who you have spoken to, when, and what feedback was received. This will be needed if the scheme is challenged in court or elsewhere.



The consultation timeline

This example timeline indicates the possible timeframe for consultation – but in consultation with the HOSC/JHOSC, you might find that the formal consultation period can be longer or shorter. While many consultations last for 12 weeks, Cabinet Office guidelines suggest that consultations should be a proportionate amount of time, taking into account the context of the individual proposal for change. There is no formal legal requirement for consultations to last 12 weeks.





What next?

Consultation responses need to be collated, analysed and a report produced, ideally by an independent provider. Data may include online, phone and written survey responses, notes from meetings, petitions, submissions, and letters. A final report of the findings from the public consultation needs to be written, reviewed, and published. You should continue to engage with the public so that the next steps are clear to all respondents. Once the consultation is closed, responses have been analysed, and considered, you'll need to begin writing the decision-making business case.

Good practice in public consultation

- It's good practice not to run a public consultation during the school holidays (Jul - Aug) or Christmas (Dec - Jan) when people may not be able or available to respond to the public consultation. Alternatively, you could consider adapting or extending the length of the public consultation to take this into account.
- It's good practice not to start a (new) public consultation in the run-up to government elections, during the preelection period of sensitivity. However, an existing public consultation can continue to run during this period. You may want to consider adapting or extending the length of the public consultation to take this into account. NHSE will often produce guidance for the NHS during this time, which will be based on the guidance issued by the Cabinet Office. All NHS bodies should take that into account for decisions on how to proceed with any service reconfiguration programme.
- It's good practice to include a group of clinical leaders to communicate with staff and local residents about the consultation ensuring they are trained, briefed, and supported to deliver your message locally.



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Key documents

- Working in partnership with people and communities: statutory guidance
- Engagement and communications for health and care systems
- Consultation principles
- Toolkit for communications and engagement teams in service change programmes

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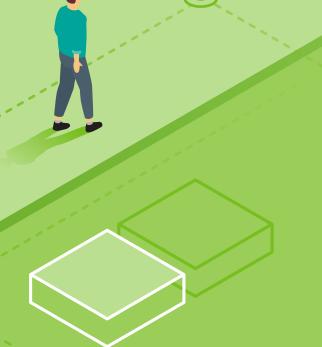
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Case studies and examples

- Preparing for and conducting a public consultation (with the Consultation Institute)
- Best practice online-consultation

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• Gloucestershire Fit for The Future Consultation report

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• Dorset CCG - Dementia Consultation analysis

Decision-making



The DMBC should demonstrate how the proposed change is sustainable in service, economic, environmental and financial terms and can be delivered within the planned capital total.

You should think about everything that's come before this point and build your DMBC from your case for change narrative and your PCBC. Make sure to also include subsequent stakeholder engagement, as well as your consultation analysis and discussions. Where capital is required, the DMBC will inform the development of the strategic outline case (SOC).

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Final decision-making should be made in public.

Following consultation and analysis of all responses, a DMBC should show how views captured by consultation have informed the final proposal.

The decision on whether the DMBC needs to be formally assured by NHSE will be discussed at the pre-consultation assurance checkpoint. This is to ensure that any major deviation from the original proposals is given proper consideration and to assure that the proposals remain clinically sound and financially viable.

Top tip

You should be prepared to communicate this decision to a variety of audiences, such as:

- Patients and the public
- Staff
- The media
- The local authority, or authorities
- Your local voluntary, community, and social enterprise sector stakeholders

How you do this is important. You should be able to clearly articulate how your proposal reflects the extensive engagement you've already undertaken with all of these audiences, and why you have come to the decision that you've arrived at, and what that means for the service. You should be realistic about when you will be able to implement this change, too.



Business cases

Some service changes will require further business cases to progress implementation of new models once the outcome of a consultation is decided. There are several different types of business cases.

The process for capital business cases

Once you've completed your consultation and made amendments to your proposal on the back of the engagement you've done, you should now begin the capital business case process.

Not all service changes require capital expenditure, but you should know quite early on in your change programme whether yours does. And, if it does require capital, the amount of capital needed – and where that secured capital is coming from – will affect what business cases you need to prepare.

You should always consult with your regional colleagues, and national colleagues if necessary, to understand what requirements regarding business cases your specific service change will need to meet.

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Assurance processes require service change programmes to complete a number of business cases. The main ones are set out below.

This list is not exhaustive. Trusts may need to complete their own organisation-specific business cases, and capital requirements sought outside NHSE will require other business cases. Not every business case in this list may be needed (for instance, if capital is not required).

Name of business case	Description				
Pre-Consultation Business Case (PCBC)	This is the business case on which the commissioner decides to consult. Contains information about case for change, clinical model and review, options appraisal, evidence of pre-consultation engagement, evidence of how proposals meet the five tests. Forms the basis of further business cases and will be the document that local government scrutinises.				
Decision-Making Business Case (DMBC)	Developed after public consultation. Analyses consultation responses and sets out agreed way forward for proposed changes. Demonstrates how preferred option meets the challenges identified in the case for change, and how it is sustainable in service, economic, environmental and financial terms. If capital is required, the DMBC informs development of the SOC.				
Capital business cases					
All capital business cases must comply with the requirements of the Treasury Green Book. This means they must describe the five 'cases', or dimensions, which constitute the proposed service change: strategic, economic, commercial, financial, management.					
Strategic Outline Case (SOC)	Establishes the case for change and a preferred way forward before the more detailed planning stage at OBC				
Outline Business Case (OBC)	Identifies the investment option which optimises Value for Money (VfM), prepares the scheme for procurement and the funding and management arrangements for successful delivery of the scheme.				
Full Business Case (FBC)	Submitted before formal signing of contract. Records result of negotiations with potential suppliers and identifies tender which is best public value. Records contractual arrangements, confirms affordability and finalises management arrangements				



Generally, if capital is required, you should follow at least some of the below steps for completing these business cases accordingly.

It's really important to make sure that your business cases adhere to the requirements of the <u>Treasury Green Book</u>, as well as the NHSE five case model. The Green Book sets out five different cases for your proposal:

- The strategic case (not to be confused with the strategic outline case)
- The economic case
- The commercial case
- The financial case
- The management case

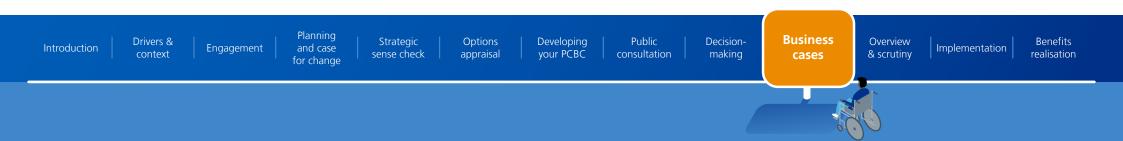
Box 5. The Five Case Model

Strategic dimension	What is the case for change, including the rationale for intervention? What is the current situation? What is to be done? What outcomes are expected? How do these fit with wider government policies and objectives?
Economic dimension	What is the net value to society (the social value) of the intervention compared to continuing with business as usual? What are the risks and their costs, and how are they best managed? Which option reflects the optimal net value to society?
Commercial dimension	Can a realistic and credible commercial deal be struck? Who will manage which risks?
Financial dimension	What is the impact of the proposal on the public sector budget in terms of the total cost of both capital and revenue?
Management dimension	Are there realistic and robust delivery plans? How can the proposal be delivered?

Treasury Green Book

There are several requirements for this process. You can read all about them in the guidance on **Capital regime, investment and property business case approval.**

It's important that all the partners in your service change are fully aware of the scale, level of complexity and the risk involved in both proposing capital investment and having a confirmed funding source, and that all are agreed with the appropriate level of capital requirement.



The strategic dimension

The strategic section covers the relationship between the content of your business case with the overall service change journey. In this part of the process you should be able to demonstrate the golden thread of information, from as early as your case for change document. In this section, you should highlight the key drivers for this change, and how it aligns to the current strategic policy of the organisation. You should be able to demonstrate how the proposals align with regional and national contexts, and you should be able to clearly articulate the SMART objectives related to the delivery of the change. SMART: specific, measurable, achievable, relevant, time-bound.

The economic dimension

This part of your business case should look at the economic issues surrounding your proposed service change. Its critical success factors should be well articulated. You should demonstrate that all relevant options have been considered. Including a scenario of 'business as usual' and 'do-minimum', you should be able to present the benefits of each possible option clearly. After this, you should demonstrate how your preferred option has been arrived at.

The commercial dimension

This aspect of the business case considers the commercial viability of your proposals. Do you have a strategy for procuring the service, and is that strategy deliverable within your context? And, given the timeframe of your proposals, are the key milestones and delivery dates realistic?

The financial dimension

Although like the economic and commercial cases in some respects, the financial case of the capital business case should look at the financial affordability of the service change proposal. An affordability analysis should have been undertaken, and you should demonstrate the results here. It is helpful to clearly identify the funding arrangements that are driving your change proposal, and assure the reader that contingencies are in place for things such as cost overruns.

The management dimension

The management case covers the feasibility of delivering the proposal. You should explain your delivery plans in detail, identify clear delivery dates and milestones, expand on any contract management plans you have in place for the programme, and include how you have successfully embedded regional and national review and assurance.

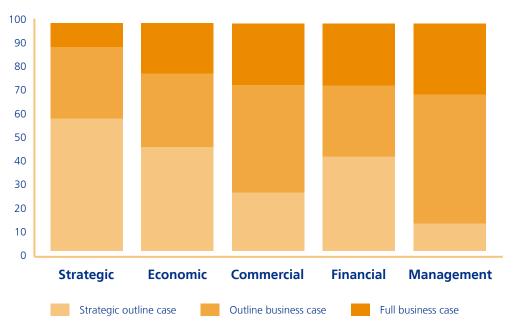
As well as meeting these five cases as part of the Green Book requirements, you should remember <u>NHSE's five tests for service change</u>.

Each stage of the capital business case process – the SOC, OBC, and FBC – should include each of these five aspects in its narrative. More information about each business case is on the next page.



For service change, there are three main parts to this process: the strategic outline case (SOC), the outline business case (OBC), and the full business case (FBC). Each case builds on the one before and adds more detail against each of the five cases in the green book. On the next few pages, we'll investigate these business cases in detail, as well as the green book requirements.

Development of the business case



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The strategic outline case

If your service change requires capital of at least £15 million, then you'll need to complete the strategic outline case (SOC). This documents the strategic case for investment, supported by an <u>options appraisal</u> that includes robust economic and financial analysis of longlisted and shortlisted options. Approval of the SOC enables the project to move to outline business case (OBC) stage to further test the shortlisted options – if there are multiple – and agree on a preferred option.



Top tip

As far as possible, you should design your <u>PCBC</u> with your SOC in mind. But you should never write your SOC before going out to public consultation. The SOC requires you to think about no change as a baseline for your options – think about including this analysis in your options appraisal and PCBC stages.

Because the SOC documents the strategic case for investment, you should build it on the <u>case</u> for change. It should also build on the PCBC, and further detail your preferred way forward. The SOC provides the information necessary for NHSE, DHSC and where appropriate, the Treasury, to approve the project to move to Outline Business Case (OBC) stage.



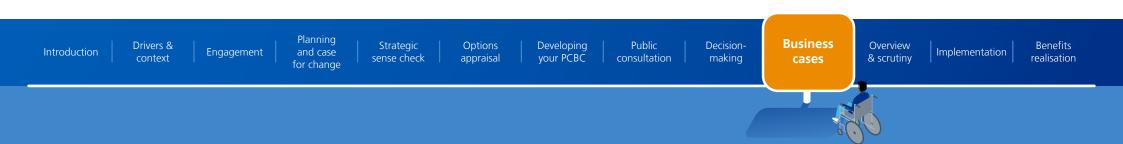
Top tip

Remember to refer to the <u>assurance</u> process to understand who will be approving your SOC, and why.

The outline business case

The Outline Business Case (OBC) sets out a more detailed economic and financial appraisal of the shortlist of options and is aimed at determining a preferred option. Approval of the OBC enables the project to start its procurement process and secure a preferred bidder to deliver the capital project.

The OBC should fully explain how your proposal solves the requirement for the change you are proposing. Building on the Green Book five case methodology, at this point in the change process you should be able to gather data on health outcomes, point to extensive consultation with patients and the public, explain how your proposal is robustly planned and prepared for, and line your information up for completion of the Full Business Case.





A full business case (FBC) is created setting out the outcome of the procurement process. The final, preferred option to implement your change should be described in its fullest level of detail. This will most likely set out the commercial and contractual arrangements for a negotiated deal (confirming the deal is affordable) to deliver the change, as well as the detailed management arrangements for delivery, monitoring and evaluation.

Questions to ask during the business case process:

- Does each case include all the elements of the Green Book five case model?
- Is the information in each element of the business case sufficient for the level that it's at?
- Is the case compliant with all other aspects of the Green Book?
- Are your cases aligned with your case for change narrative, and Pre-Consultation Business Case?
- Is everyone involved in your programme in agreement with the contents of the capital business case at each of its stages?



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Key documents

- Planning, assuring and delivering service change for patients with Addendum
- Capital regime, investment and property business case approval guidance

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Commissioners have a legal duty to consult with their local authorities when they have under consideration any proposal for a substantial development or variation of the health service in the relevant local authority.

Generally, you should engage and involve your local authority as early as possible in the process. This will normally be through consulting with the local <u>Health Overview and Scrutiny</u> <u>Committees (HOSC)</u>. If the change covers more than one local authority area, you will need to consult the Joint Health Overview and Scrutiny Committees that the local authorities must create to undertake their overview and scrutiny function. It is also good practice to ensure you engage with the relevant local Health and Wellbeing Boards (HWBs), and other interested local organisations, such as Healthwatch.

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The context of your proposals will affect how and who to engage with in terms of your local authority.

A local authority can refer a proposal to the Secretary of State for Health and Social Care under the 2013 Regulations, if they have reason to believe that:

- The consultation has been inadequate in relation to the content or the amount of time allowed,
- The NHS body has given inadequate reasons where it has not consulted for reasons of urgency related to the safety or welfare of patients or staff, or
- A proposal would not be in the interests of the health service in its area.

Referral to the Secretary of State for Health and Social Care should only happen if all organisations involved in the proposals cannot come to a meaningful resolution together. If a referral takes place, the Secretary of State will ask the Independent Reconfiguration Panel (IRP) to carry out an initial assessment as to whether the referral should be investigated. After an initial assessment or following a full investigation, the IRP will report back to the Secretary of State and they will then make a decision on the issues referred to them.

A local authority that disagrees with the decision of the Secretary of State may challenge that decision by issuing Judicial Review proceedings. Separately, a local authority or member of the public with sufficient standing and interest – can also challenge a decision by bringing judicial review proceedings.

Regulation following legislation in 2022 may significantly change the processes referred to here - NHSE regional colleagues will be able to advise.

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- Effective service change: A toolkit
- List of regional reconfiguration leads
- Local Authority health scrutiny
- How the IRP advises the Secretary of State for Health and Social Care
- Learning from the independent reconfiguration panel

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The penultimate, and often longest, stage of service change is implementing the proposal that has been approved. Following the decision on which option to take forward, there should be an implementation plan which sets out how the changes will be taken forward, when, and by whom.

The implementation plan includes the prioritisation and phasing of tasks, identification of resources to deliver implementation and a robust governance structure. It is also important to evaluate the changes as they are implemented to ensure benefits are being realised.

Transitioning to implementation (6 months+)	 Implementation needs to be done in the context of on-going legal challenges and any referral to the Independent Reconfiguration Panel (IRP) Before implementation capital will need to be agreed through provider outline business cases - this can take a long time!
Planning for implementation	 Agree principles and implementation framework Understand requirements and capacity Identify resources to implement changes and agree/appoint senior leadership Agree delivery methodology Identify first priorities for implementation Identify first prerequisites for implementation Agree timing, phasing and governance Establish information platform including access to integrated dataset Identify metrics to measure progress

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The implementation plan should identify a clear benefits realisation timetable with key milestones against which progress can be monitored. Ongoing support, guidance and assurance through the implementation phase will be provided by NHSE regional and national teams.

It can take several years for a proposal to move into full implementation if the stages beforehand have not been fully completed. You might also still be facing legal challenges, or a referral. This can be disheartening, but you should focus on planning in as much detail as possible how you will implement the approved proposal.

Top tip

It serves to keep your stakeholders informed and involved, even at this stage. Don't forget to make sure your local population know that these plans, which they should have been extensively engaged on for a significant period, are still underway.



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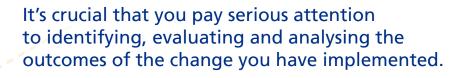
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Not only will this support you to demonstrate the successes of the programme, but doing so will help support the wider, contextual issues which you addressed at the very start of your change programme.

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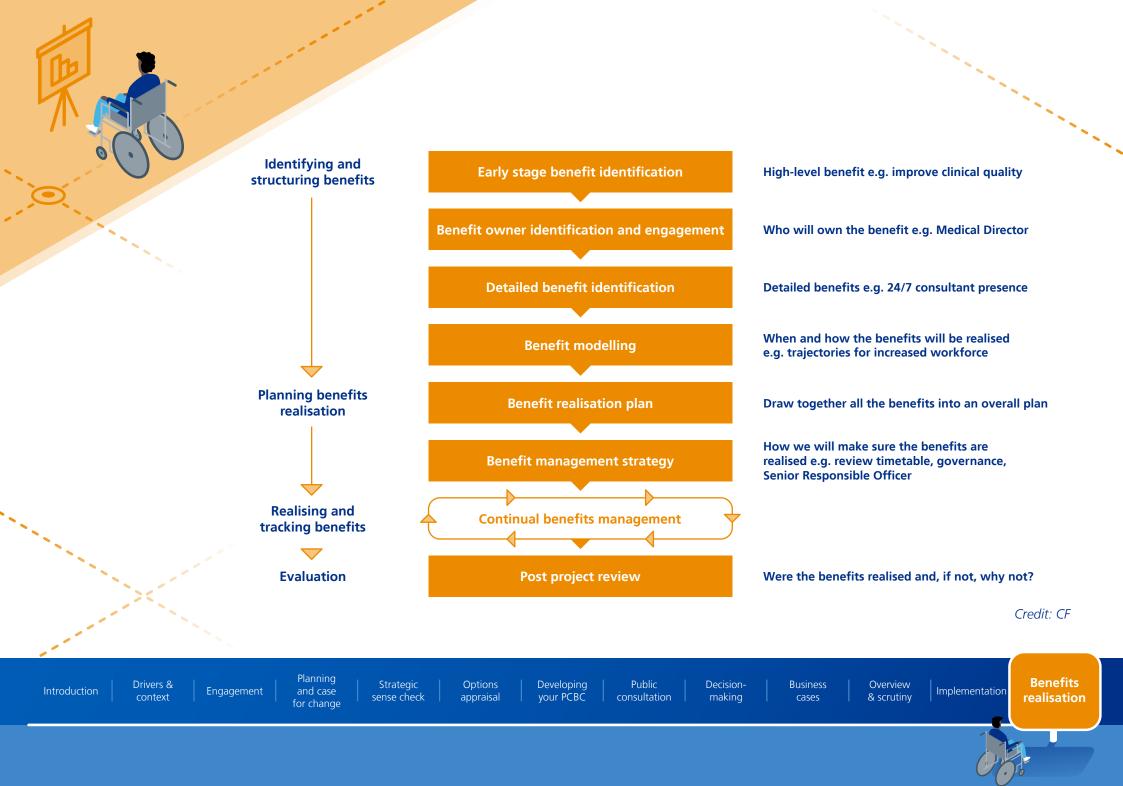
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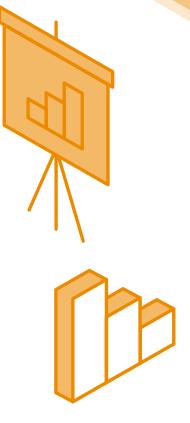


As your change proposals have been developed and evaluated, you will have already identified criteria with which to evaluate the benefits of the change you have implemented. These could focus on such things as:

- Clinical outcomes and quality
- Financial issues
- Patient experience
- Access to services
- Workforce issues
- Research and education
- Reducing health inequalities
- Reducing carbon emissions

As with the rest of the programme, this final stage of service change should incorporate a wide range of stakeholders.

- Involve residents and people who use care and support in your evaluation - how have they been impacted by this change?
- Are VCSE partners, local government colleagues and fellow providers and commissioners conscious of the benefits of this implementation, and in support of its outcomes?
- Can the data and modelling used at the start of your programme demonstrate improvements as a result of implementation?





Conclusion

The goal of any service change should be to transform health and care services to provide better care, tailored to the needs of local people and fit for the future.

The service change process is not linear. While it can be a long and challenging process, it brings opportunities to look at how needs can be met differently and better, and to develop new ways of working between different partners across health and care.

National and regional teams in NHSE are on hand to support health and care systems with their service change and reconfiguration journeys. For more information and support, please visit our FutureNHS Service Change and Reconfiguration workspace, or contact the relevant NHSE regional team.

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