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This document was prepared by the NHS Midlands and East Strategic Projects Team on behalf of the Department of Health.

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Part One: Introduction

# Using the Toolkit Introduction

This Toolkit for commissioning community (i.e. direct access) pathology services has been developed specifically to support commissioners who:

- Have undertaken a strategic review of their existing community pathology services;
- Wish to improve the quality, effectiveness, affordability and value for money of these services, in line with locally determined objectives and priorities.

The Toolkit is primarily intended to be a reference document and "how to" manual for commissioners. However existing providers of pathology services who are considering redesigning their services may also find some of the tools helpful. The choice of approach taken at local level will depend on the degree of improvement that is thought to be necessary.

The Toolkit recognises that commissioners will need to decide an approach whether to pursue improvements through:

- i. Local negotiations with existing providers; or
- ii. Competitive tender (either locally or in collaboration with other commissioners across a wider system).

Whichever approach is taken the Toolkit provides the practical and interactive tools, including guidance and templates where appropriate, to support delivery. Each approach consists of a series of Steps intended to help commissioners to produce a local plan which takes into consideration the experiences and views of clinicians, providers and others who have previously been involved in commissioning community pathology services. These Steps are freestanding: they can be combined with others or used on their own to support a single element within the overall process.

The objective of the Toolkit is not to advocate a particular approach, nor to replace local decision-making. Nor does it negate the need to obtain professional advice where appropriate. The Toolkit needs to be used within the context of the locally established project governance and accountability framework e.g. PCT Cluster Executive for local negotiations and Project Board when running a competitive tender.

### Structure of the Toolkit

The Toolkit is divided into three parts: Introduction and overview, Steps and Tools. It is presented in diagram form on the next page (Figure 1).

**Part One** provides an overview of the provision of pathology services and approaches to commissioning them.

**Part Two** describes each of the 11 Steps. Although the Steps are presented sequentially many tools presented later in the document will be useful at earlier stages e.g. Stakeholder engagement.

- Step 1. Outline business case
- Step 2. Project governance
- Step 3. Project management
- Step 4. Stakeholder engagement
- Step 5. Service specification
- Step 6. Market sounding
- Step 7. Procurement strategy
- Step 8. Memorandum of Information and Pre Qualification Questionnaire
- Step 9. Tender
- Step 10. Commissioning Contract
- Step 11. Approvals and contract management

Commissioners intending to use the local negotiation approach should follow (sequentially) Steps 1-5 and Steps 10 -11.

Commissioners intending to use a competitive tender approach follow Steps 1-11.

**Part Three** includes each of the Tools referred to in the Steps (e.g. template for outline business case; pre-qualification questionaire; sample service specification).

It should be noted that:

- There are interdependencies between the Steps, for example the tools in Step 10 (Commissioning Contract) assume that the tools in Step 9 (Tender) have been completed; and
- When Steps and/or Tools are used in isolation (e.g. service specification)
   commissioners should be aware of and take account of these interdependencies.

Figure 1: Drivers in determining the commissioning approach to pathology services

Drivers in determining the commissioning approach to pathology services

Increasing need for step changes in quality Increasing need for affordability Increasing need for value for money Increasing complexity of stakeholders and change Approaches to commissioning pathology services 1. Local negotiation 2. Competitive tender For example, one commissioner Example I. Competitive tendening of a few services using a competition across a large Example 2 Restructuring pethology arranging their opin pathology bervice CCGs pathology services. in isolation. region Supporting tools and templates Relevant steps: Relevant steps: Steps 1-5 and steps 10-11 Steps 1-11

Drivers relevant to determining the appropriate commissioning approach to community pathology services

- Need to ensure a high quality, safe and compliant service
- Need to improve effectiveness
- Need to improve affordability
- Need to improve value for money
- Need to minimise complexity of operation (for stakeholders)
- Need to minimise complexity of process of change

Approaches to commissioning community pathology services

- Local negotiation: one commissioning body commissions freestanding community pathology services from a single local provider: Follow Steps 1-5 and Steps 10-11
- ii. Competitive tender: commissioners issue a tender for providing community pathology services either across a group of local providers or (in conjunction with other commissioners) a tender for the restructuring of service provision on a system-wide or regional basis: Follow Steps 1-11

These approaches form a spectrum where the complexity increases from left to right, as more commissioners and service providers are involved within a single commissioning process.

# Overview of the provision of pathology services

This section describes

- current arrangements for the provision of pathology services and
- how they have been affected by the establishment and merger of hospital Trusts

Current arrangements for the provision of pathology services

In broad terms, commissioners currently commission pathology services in one of two ways: either **directly**, where one or more tests are required within a primary care setting to assist in a patient's diagnosis and treatment ("direct access" pathology services); or **indirectly**, where pathology testing is included as an element in a broader healthcare episode. In either case pathology services are usually provided by departments within NHS acute and foundation trusts, although some may now provide testing facilities in the community. The independent sector also supplies pathology services to the NHS, although its penetration of the market is still relatively limited.

Cost and price of pathology services

In general, it is difficult to determine the cost of providing pathology services across England. Costs are usually built up from the following elements:

- direct costs, for example staffing, equipment, consumables
- infrastructure costs, chiefly transport and IT
- overheads, where a proportion of a trust's total expenditure on management, utilities, and accommodation are allocated to pathology services.

These costs vary between providers; costs also vary depending on the range and number of tests which are undertaken. Establishing a cost per test is complicated, not only because of these variations but also by reference to the size of the service provider, because of economies of scale.

Where pathology tests are included within a particular healthcare episode, the cost (calculated centrally) is included within the tariff chargeable for that episode.

For direct access services, commissioners negotiate directly with providers; the price paid is usually calculated on the basis of an agreed range and volume of tests and is reflected in a block contract.

There is increasing evidence that the price of community pathology services varies considerably across the country and within regions; and that a single provider may charge different commissioners different amounts for the same types and volumes of tests.

### **Historical context**

Historically, each acute hospital maintained its own laboratory. These local laboratories were capable of carrying out all commonly requested tests and in addition might offer a number of more specialist tests. An informal network of relationships between laboratories built up which enabled laboratories to refer samples for tests which they were not locally able to carry out and, in return, to receive requests for tests for which they had capability or expertise.

The establishment of NHS trusts, and subsequently mergers between trusts, created duplication between laboratories which had previously been managed separately but which were now under the same senior management. This duplication of services created the opportunity for rationalisation and consolidation, with scope for concentrating expertise on a reduced number of sites.

In some cases pathology departments within different trusts formed their own consolidated networks in order to benefit from the same economies of scale. Pathology networks vary considerably in size and maturity across the country.

In order to realise the benefits of consolidation extra investment was needed, particularly in transport and IT. Where such investment was not forthcoming, the benefits of consolidation and economies of scale, even within individual trusts, may not yet have been fully realised.

A few commissioners have entered into contracts with the independent sector. Under some contracts the independent sector provides an agreed range and volume of tests; under other contracts the independent sector provides the overall management of the services.

In its report<sup>1</sup>, the Healthcare Commission noted that consolidated pathology networks were tending to invest in additional capacity in order to widen the range of tests carried out internally, with the number of referrals falling commensurately. It questioned whether this was the most cost-effective approach.

<sup>&</sup>lt;sup>1</sup> Healthcare Commission: Getting Results: pathology services in acute and specialist trusts 2006 (<a href="http://archive.cqc.org.uk/">http://archive.cqc.org.uk/</a> db/ documents/Pathology final tagged.pdf)

### Approaches to commissioning community pathology services

This section sets the context for commissioning pathology services and explains how this Toolkit can help.

The context for commissioning pathology services

Commissioners seeking to improve quality and productivity in pathology services will want to ensure that their efforts are aligned with developments elsewhere in the system. These include:

- SHA-led pathology modernisation and rationalisation programmes
- relevant national quality and productivity programmes
- the impact on pathology services of national initiatives such as cancer.

The Independent Review<sup>2</sup> identified potential savings of £500 million annually through service reconfiguration in pathology. The Department of Health is working with the NHS to support local programmes aimed at delivering improvements in quality and productivity in line with the Review's recommendations. The precise scale and phasing of the savings achievable will be determined by the outcome of work being carried forward by the SHA Clusters in each region.

In order to maximise the impact and effectiveness of their own strategy for commissioning pathology services, and in order to reduce duplication of effort, commissioners are urged to make links, through their own SHA Cluster, with:

- the local pathology or diagnostics modernisation programme
- provider performance challenges

Through such links commissioners will be able to play a critical role in:

- the design of the end-to-end process in pathology (from initial collection of the sample to the delivery of the test result) which, because it involves stakeholders beyond the direct control of the pathology service provider, is important in creating fluent pathways of care
- reducing redundant capacity and optimising the utilisation of resources so as to meet current and future projections of demand.

<sup>&</sup>lt;sup>2</sup> http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH 091985

When commissioning pathology services commissioners will expect to:

- Raise the quality of pathology services;
- Improve the experience of pathology services for patients and users;
- Ensure providers adhere to minimum laboratory standards and provide consistency of service:
- Ensure providers deliver an affordable pathology service;
- Ensure providers deliver value for money;
- Have regard to regional pathology programmes.

Usually these objectives arise because of:

- Inadequate service quality:
  - Service outcomes are not being met for users;
  - Laboratory standards are not being met;
  - Patient experience/user satisfaction is poor.
- Unaffordable increases in demand year-on-year
- Significant changes in activity as a result of increasing demand or changes in the commissioning environment
- Diminishing value for money
- Rationalisation aimed at reducing the number of separate contracts and delivering uniformity of service
- Shortage of relevant skills and expertise among local providers, thus reducing their capacity to deliver the required service outcomes.

#### **Toolkit**

This Toolkit contains a set of tools for commissioners to use to drive improvements in pathology services through:

- i. Local negotiations with existing providers; or
- ii. Competitive tender, either locally or across a wider system.

Commissioners may want to use a different approach from the two presented in the Toolkit. The appropriate approach, which must reflect the local context, will be influenced by:

- The primary driver for the change for example quality improvements, better service outcomes, greater value for money
- The timeline and level of urgency for the potential change

- The number of commissioning organisations involved in the process
- The scale of the challenge and the size of the affected health economy.

### **Local negotiation**

This approach is most suitable for a single commissioner intending to improve local pathology service provision by negotiating directly with a single existing pathology services provider. It may also be used where a small number of commissioners wish to act together; or where services are provided by only a few small-scale providers.

When using the local negotiation approach commissioners will need to ensure, as a minimum, improvements in:

- Quality through the incorporation of specific service outcomes in the contract between the relevant parties;
- Value for money
- Affordability.

Local negotiation has the advantage of sustaining working relationships in the local health economy.

However it is more likely to produce incremental change in workforce profile, IM&T, logistics and infrastructure solutions and less likely to achieve transformational change in services. It is also less likely to meet the significant QIPP challenges within the system, deliver significant quality improvements (such as harmonisation of services), encourage significant investment and achieve greater consolidation of services.

### **Competitive tender**

The competitive tender approach is more suited to situations where change is sought over a larger health economy, where there is a requirement for restructuring the provision of pathology services involving several commissioners and providers.

Where only one, or a few, commissioners intend to run a competitive tender across a smaller health economy involving a single, or only a few, pathology service providers, the benefits and challenges will not be as great. Table 1 on page 13 summarises the benefits and challenges of each approach.

Table 1. Benefits and challenges of the approaches

Local Negotiations		Competitive Tender			
		Tender		System wide tender	
Benefits	Challenges	Benefits	Challenges	Benefits	Challenges
<ul> <li>Improve quality</li> <li>Improve effectiveness</li> <li>Improve value for money</li> <li>Maintain affordability</li> <li>Sustain working relationships in the local health economy</li> </ul>	<ul> <li>Unlikely to meet:</li> <li>QIPP targets</li> <li>Carter recommendations</li> <li>Difficult to achieve significant quality improvements</li> <li>Unlikely to encourage significant investment</li> <li>limited (incremental) change in e.g. workforce, IT, logistics and infrastructure</li> </ul>	<ul> <li>Improve quality</li> <li>Improve effectiveness</li> <li>Improve value for money</li> <li>Increase capacity and future-proofing</li> <li>Improve service resilience</li> <li>Maintain affordability</li> <li>Achieve rationalisation of providers</li> <li>Meet policy objectives e.g. Any Qualified Provider (AQP)</li> </ul>	<ul> <li>Can disrupt the local health economy</li> <li>Tender costs can be high</li> <li>Requires commercial / tender expertise</li> <li>Usually takes several months to complete</li> <li>May involve a complex implementation phase</li> <li>Requires a robust stakeholder management process</li> </ul>	<ul> <li>significantly improve quality, effectiveness &amp; VfM</li> <li>Achieve systemwide restructuring in e.g. infrastructure and workforce</li> <li>Support greater investment in e.g. R&amp;D and technology</li> <li>Achieve significant rationalisation of providers</li> <li>Meet policy objectives e.g. AQP, QIPP, Carter</li> </ul>	<ul> <li>All weaknesses of Tender approach plus:</li> <li>Can significantly disrupt the local health economy</li> <li>access required to investment funds for capital &amp; operational changes</li> <li>Increased risk to delivery arising from scale of change</li> <li>Increased complexity of stakeholder management</li> </ul>

Part Two: Steps

# Step 1. Outline Business Case

### Introduction

By completing an Outline Business Case (OBC) commissioners establish a framework for meeting the financial challenges and service improvements set out in the Independent Review. The OBC sets out, for the benefit of all stakeholders, the strategic direction for pathology services.

#### What is it?

"The purpose of the OBC is to revisit the Strategic Case in more detail and to identify a preferred option which demonstrably optimises Value for Money. It also sets out the likely Deal; demonstrates its affordability; sets out how Value for Money will be achieved; and details the supporting Procurement Strategy, together with management arrangements and the timetable for the successful rollout of the Scheme".

It is good practice to draw up an OBC in all instances, because in doing so commissioners will help to identify additional opportunities and potential risks in advance of a competitive tender process. The scale and complexity of the OBC will reflect the scale and complexity of the envisaged change in pathology services. For example, the local negotiation approach will require a much simpler OBC than the competitive tender approach. However,

# Why is it important?

By completing an OBC, commissioners will need to:

- identify which of the two approaches (local negotiation or competitive tender) is most suited to their circumstances.
- undertake a detailed review of current pathology service provision, so as to develop, outline and assess options for future service delivery. This process will enable them to identify a preferred option based on a combination of financial and non-financial criteria, and involving multiple stakeholders, both clinical and managerial, in the decision process.
- acquire the necessary understanding of current service provision, both clinical and non-clinical (including, for example, costs, test volumes, laboratory provision, transport). This will enable them to model and assess the impact on pathology services of broader elements of service operation such as HR, legal, tax.
- be able to work collaboratively, quickly and effectively with clinical and other stakeholders in establishing support for the preferred service delivery option.

<sup>&</sup>lt;sup>3</sup> ASSESSING BUSINESS CASES 'A SHORT PLAIN ENGLISH GUIDE' <a href="http://www.hm-treasury.gov.uk/d/greenbook">http://www.hm-treasury.gov.uk/d/greenbook</a> businesscase shortguide.pdf

In deciding on the preferred service delivery option, commissioners will have to decide whether the scale of intervention required is deliverable and if so whether it can be delivered over an acceptable period of time. Commissioners will also need to decide on the extent of any independent sector involvement in the future provision of pathology services.

### Skills/knowledge needed and external support

In order to produce the OBC, commissioners will need to have – or to obtain - skills in or knowledge of the following:

- Clinical services to understand the strengths and weaknesses of the existing service and identify the potential for change (for example, in terms of performance improvement, cost reduction)
- **Workforce** to understand the opportunities and constraints in terms of workforce mobility, pay and restructuring.
- Commercial to understand the implications of change on functions such as IT, equipment, procurement, facilities and logistics; to design high-level payment mechanisms and assess the commercial benefits of different service options.
- Financial to model costs as a guide to options appraisal
- Legal to understand the legal implications of the contract, employment and procurement processes
- **Tax** to understand the tax implications of the different options.

A more detailed list of skills can be found in the Resourcing Planner in Step 1.

### The tools provided:

There are two tools accompanying this Step:

- Step 1 Tool 1: OBC template, and guidance
- Step 1 Tool 2: Questions and perspectives for commissioners

### 'How to' guidance

In producing the OBC commissioners must carefully examine and balance the commercial, financial, political and clinical aspects of each option. As part of this examination, commissioners should use Step 1 Tool 2: Questions and perspectives for commissioners.

#### Commissioners will need to:

- Have an accountable officer and project manager for the OBC process to take control of time lines and process and manage the re-commissioning budget;
- Identify the lead commissioner and set in place the necessary governance arrangements to empower them;
- Gain a detailed understanding of the current pathology service, such as the standard taxonomy and profile of tests across all participating service providers;
- Understand the current activity levels by pathology discipline and the way they split between primary care and acute Trusts;
- Be aware of imminent service or clinical changes that could affect future requirements, for example the move to an increase in molecular based testing.

### Further guidance

Treasury Green Book (http://www.hm-treasury.gov.uk/data\_greenbook\_index.htm)

Report of the Review of NHS Pathology Services in England (<a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_4137606">http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_4137606</a>)

Report of the Second Phase of the Review of NHS Pathology Services in England (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH 091985)

Quality Innovation Productivity and Prevention (QIPP) (<a href="http://www.dh.gov.uk/en/Healthcare/Qualityandproductivity/QIPP/index.htm">http://www.dh.gov.uk/en/Healthcare/Qualityandproductivity/QIPP/index.htm</a>)

Modernising Pathology Services

(http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH 4073106)

# Step 2. Project Governance

### Introduction

Project Governance refers to the rules and regulations under which a project functions. It is frequently used to describe the processes which need to exist in order for a project to be successful.

It is likely that large projects will have various levels of governance. There may be a project management office, which provides oversight; the role of the office may in turn be overseen by an executive committee or other organisation. Project managers may report to business managers who may in turn report to executive managers. The project's size, costs and level of risk will all play a part in determining the amount and level of governance required for a successful outcome. Many organisations have charters which define the model of project governance which is to be followed. Project Portfolio Management software is used by some organisations to automate budget control, project governance and compliance.

### What is it?

Project governance outlines the relationships between all stakeholders involved in the project. It describes the flow of project information to all stakeholders and ensures reviews and approvals at appropriate stages of the project.

Project governance not only provides a framework for the organisation of responsibilities and decision-making capabilities, it also ensures that the project implementation and execution operate smoothly.

# Why is it important

Before the project starts, it is essential to know who will make project-related decisions and how the decisions will be made. Setting up project governance decreases the probability of making poor decisions during the life of the project.

The appropriate project governance arrangements will need to be determined by the project's scope, the level of risk and the number of organisations involved. All projects require the responsibilities of each individual and entity to be defined. Within a single project there may be many different levels of responsibility, spanning a number of organisations. The project's governance structures must bring all those levels and organisations together within a single accountability structure.

These governance arrangements define the responsibilities which the project board delegates to those individuals and organisations who are involved in delivering the project.

The key aims of project governance are to:

- Set out the lines of responsibility and accountability for the delivery of the project;
- Give stakeholders responsibility for managing their interest in the project;
- Support the project team in delivering the required outcomes by providing resources, giving direction, and enabling trade-offs and timely decision-making;
- Provide a forum for issue resolution;
- Ensure Equality Impact Assessments are completed at the relevant stages
- Provide access to best practice and independent expert advice;
- Disseminate information through regular reporting to stakeholders, so that they can fulfil their roles effectively;
- Plan for exiting the project;
- Manage risk

### Skills needed and external support

This Step assumes that the OBC has been approved (see Step 1) and, as a result, it is necessary to ensure the appropriate budget is allocated and approved. As part of this process appropriate resources to be allocated (see Step 3).

# The tools provided

There is one tool accompanying this Step:

Step 2 Tool 1: Example of a risk framework

### 'How to' guidance

Good project governance provides the project board and key stakeholders with assurances that there is a process for identifying risks and then mitigating them. A single structure for identifying, assessing, categorising and mitigating risks is required in the project. This risk management process needs to be incorporated into the Project Initiation Document (PID) which all organisations involved are advised to approve.

The main activities of project governance are:

- programme direction;
- project ownership and sponsorship;
- ensuring the effectiveness of project management functions;
- reporting and disclosure (including consulting with stakeholders); and
- risk identification and management

# Further guidance

Department of Health, OGC Successful Delivery Toolkit: Risk Management Framework (http://www.dh.gov.uk/en/Managingyourorganisation/NHSprocurement/Publicprivatepartnership/Privatefinanceiniti ative/InvestmentGuidanceRouteMap/DH 4132806)

### Commissioners will need to:

- Ensure that each organisation has provided their lead individual with the appropriate delegated authority to make decisions on behalf of the organisation
- Ensure that within their individual organisations approval processes are in place which are aligned to the project requirements

# Step 3. Project Management

### Introduction

In order to deliver the objectives of any project it is important to ensure all actions are managed through one central, co-ordinated process. When delivering a project that spans numerous commissioners and/or provider services as well as multiple stakeholders it is necessary to provide a robust structure to ensure that accountability and responsibilities are appropriately mandated and delegated.

### What is it?

Project management is defined as the co-ordinated organisation, direction and implementation of projects and activities that achieve outcomes and realise benefits that are of strategic importance.

### Why is it important?

Where a number of commissioners are involved in the project, for example where the competitive tender approach is adopted, the project must ensure that clear accountability, governance and delegated mandates are in place.

Key activities for the project team include setting up the project, agreeing the memorandum of understanding (MOU), developing the project initiation documentation (PID), appointing the team, making appropriate project board arrangements (including developing the terms of reference and identifying appropriate membership) and establishing the governance processes necessary to ensure the project delivers efficiently and effectively and incorporates a clear procurement strategy (Step 7). A PID tool is provided: the content is not exhaustive and should reflect each organisation's requirements.

A vital component of the project will be the development of a communications and engagement plan including clear 'lines to take' and publication protocols. The plan should include the establishment of a customer/stakeholder reference group; this is usually included within the overall governance structure.

For the Local Negotiation approach commissioners should use the existing commissioner and provider arrangements already in place to negotiate a separate pathology contract which, based on their local drivers for change, incorporates quality and service standards and other relevant outcomes for community pathology services.

### Skills needed and external support

This Step assumes that the OBC has been approved and, as a result, it is necessary to ensure the appropriate budget is allocated and approved. As part of this process the resource allocation will need to be confirmed. The resources should include, as a minimum, the following:

- Named executive Lead for the project (also known as the Senior Responsible Officer)
- Project manager
- Project support including administration
- Commercial expert
- Clinical pathology expert(s)
- Information management & technology expert
- Estates & logistics expert
- Legal advisors
- Financial advisors
- Mobilisation lead

The local drivers for change will determine whether there is a need to bring in external experts. Although it will be cheaper to provide the resources internally, the decision should not be made on grounds of cost alone. An example of a resource planner (Step 3 Tool 1) has been provided. When using this tool the level of input must be assessed for each role within each step in the process. There will always be differing levels of input ranging from full-time to attendance at a Project Board meeting. It is imperative that this tool is used in conjunction with the project's key milestones.

# The tools provided:

There are two tools accompanying this Step:

- Step 3 Tool 1: Example resource planner
- Step 3 Tool 2: PID Template

### 'How to' Guidance

Where the approach involves a competitive tender, including a system-wide tender, the project team will be responsible for several key activities within this process. These are listed below and some are described in further detail in the relevant Steps, as shown:

- Engagement with key stakeholders (Step 4);
- Undertaking market soundings, publicity events and marketing to encourage interest from potential partners (Step 6);
- Developing a procurement strategy (Step 7);
- Establishing a data room, if required;
- Sourcing the services of an e-procurement portal where appropriate;
- Tendering for and appointing legal and financial advisors for the project;
- Drafting, issuing, receiving, evaluating and reporting on pre-qualification questionnaire (Step 8);
- Developing a dialogue/tender prospectus and evaluating documents (Step 9);
- Drafting and issuing above documents;
- Training evaluators to use a bid evaluation system to provide an extensive and auditable trail, and to report outcomes to the Project Board; and
- Completing the Full Business Case in accordance with HM Treasury's "five case" model (strategic, commercial, management, financial and economic).

#### Commissioners will need to:

Ensure the project has a full delegated mandate to deliver the objectives and key activities for each organisation including their internal Board approvals.

### Further Guidance

Department of Health, OGC Successful Delivery Toolkit: Project Management
 (http://www.dh.gov.uk/en/Managingyourorganisation/NHSprocurement/Publicprivatepartnership/Privatefinanceinitiative/InvestmentGuidanceRouteMap/DH 4132806)

# Step 4. Stakeholder Engagement

### Introduction

When GPs request a pathology test they want to know that the pathology service they choose will help them to make an accurate diagnosis and to formulate an appropriate patient treatment plan. Patients want to be confident that the service will be easy to access when taking or dropping off samples, that results will be prompt and accurate, and relayed in a way which furthers their understanding of their illness or condition.

GPs and patients are just two of the many 'stakeholders' whose expectations and preferences need to be considered when a pathology service is commissioned. Other stakeholders might include pathologists, nurses, carers, delivery co-ordinators and reception staff. So it is important that they are given opportunities to be appropriately and meaningfully involved.

Stakeholder engagement needs to be an underpinning activity threaded through the commissioning process regardless of the approach chosen, and integrated into the planning process as the business objectives are set.

# What is it? **Definitions**

**Stakeholder**: anyone who has a vested interest in the outcome of the commissioning project. Stakeholders can include, for example, individuals, groups, organisations, networks and departments.

**Key stakeholder**: a person with significant influence on or who would be significantly impacted by the project and whose interests must be incorporated if the commissioning is to be successful.

Often, stakeholder engagement is largely reactive, ad hoc or last-minute, and where this happens it can alienate rather than engage those most affected by the commissioning outcome. This Step suggests how commissioners might actively inform and involve stakeholders as part of the commissioning process. It includes a step by step guide to creating a stakeholder engagement plan, including broader communication and marketing activities, which need to dovetail into the strategy.

# Why is it important?

It is important to develop a stakeholder engagement plan because it:

- ensures all stakeholders are informed of and can engage with the commissioning process
- gives them the opportunity to voice their preferences and expectations for the future and input their own ideas
- increases morale and reduces complaints
- gives 'hard to reach' people the opportunity to be involved
- promotes joint working, developing commitment and involvement in the process
- ensures stakeholders have clear roles and responsibilities
- fosters shared learning and the sharing of knowledge and experience
- ensures the commissioning process is transparent, and therefore mitigates the risk of challenge
- can help in the development of service specifications and key performance indicators

### Skills needed and external support

- Stakeholder engagement, communications and marketing leads
- Senior support within the commissioning project team
- Representatives (as appropriate) such as surgery patient participation groups, LINks/Healthwatch, trade unions, The Royal College of Pathologists and local authority scrutiny officials.

# The tools provided

There is one tool (containing six elements) accompanying this Step:

- Step 4 Tool 1: Engaging Stakeholders (Includes five-stage engagement plan, stakeholder analysis template, sample stakeholder map, sample individual stakeholder activity summary, engagement checklist)
- Step 4 Tool 2: Different Types of Public Engagement

### 'How to' guidance

This guidance has been developed to support commissioners in three common approaches to implementation. The approach to stakeholder engagement will vary with each.

Engaging with the public may not seem like a priority when commissioning a pathology service, which is often perceived as being a 'behind the scenes' service. However, as NHS Lancashire describes in its guidance on public engagement, the law recognises three types of issue and requires appropriate public engagement in each case.

Even where negotiations are with an existing provider there are definite benefits in an engagement process, as patient and practice expectations and needs change, and there is currently a renewed focus on stakeholder involvement in local healthcare decisions.

#### Commissioners will need to:

- Build meaningful, relevant engagement activities into the whole commissioning process
- Ensure that there are adequate resources such as the right people, time and money
- Review engagement outcomes as part of the routine project update process
- Keep stakeholders regularly informed

# Further guidance

- NHS Central Lancashire's Public Engagement Toolkit (www.centrallancashire.nhs.uk/Engagement/default.aspx?ltem\_ID=221)
- NHS Midlands and East's Good engagement practice for the NHS (www.eoe.nhs.uk/page.php?page\_id=56)

# Step 5. Service Specification

### Introduction

The service specification is a key document. It collates the comprehensive set of requirements that commissioners will expect from providers of pathology services. It is important to ensure that the specification is based on outcomes wherever possible or, failing that, outputs so that providers are clear about the services and the standards they are expected to deliver.

### What is it?

The service specification is produced by commissioners on behalf of those users and their patients. It sets out the clear and concise set of service requirements that providers will be expected to meet to deliver the required service outcomes.

The service specification should, as a minimum:

- Define the aims of the service
- Identify service users
- Specify service requirements including phlebotomy (see Step 5 Tool 1)
- Indicative test activity by GP practice (use Step 5 Tool 3)
- Set out minimum standards and requirements for accreditation to be met within a limited timeframe
- Set out reporting requirements
- Define key performance indicators

The service specification should include service, clinical, workforce and technical (IM&T and estates & logistics) requirements (see Step 5 Tool 2). Financial and legal support will also be required. These elements will form the key service components to be included within the pathology services contract (see Step 10).

It is important that commissioners refrain from setting input-based requirements, e.g. staff ratios, unless they are essential or required for best practice as they will limit the scope that providers have to develop innovative service delivery models.

# Why is it important

The service specification is important because it:

- Sets out what commissioners, acting on behalf of users and patients, require from providers
- Forms the basis of the service contract
- Provides the basis for defining the key performance indicators to be used.

Where pathology services are commissioned as a part of other clinical services, for example care pathways for long term conditions, commissioners may find it useful to include the quality standards and outcomes set out in the Example Service Specification (Step 5 Tool 1).

### Skills needed and external support

The development of the service specification will require expert input n the following areas:

- Clinical
  - To define the required outcomes for users (this should include the views of GPs); and
  - To set the clinical standards to be met by the provider (including the views of pathologists and laboratory managers).
- Workforce, IM&T, Estates & Logistics and Mobilisation

Commissioners using the competitive tender approach will require access to higher level expertise in respect of workforce, IM&T, estates and logistics and mobilisation than commissioners undertaking a local negotiation.

# The tools provided

There are three tools accompanying this Step:

- Step 5 Tool 1: Example service specification
- Step 5 Tool 2: Example workforce, IM&T estates and logistics requirements
- Step 5 Tool 3: Activity data gathering template

# 'How to' guidance

To complete the development of the service specification, commissioners will need to adapt the Example Service Specification to meet their objectives, as determined by their locally identified drivers for change. The service specification will also require them to:

- Appoint a clinical lead responsible for the development of the service specification;
- Determine the key outcomes required from the service:
- By users such as GPs and other community-based clinicians; and
- in terms of appropriate minimum standards;

- Establish clinical working groups to develop the specification and advise on technical standards;
- Assess impact of specification on other services e.g. screening programmes, cancer networks;
- Engage with wider pathology stakeholders to ensure the specification is appropriate and realistic;
- Ensure there is access to appropriate subject matter expertise to support the development of the specification;
- Determine the clinical governance requirements of any future pathology service provider; and
- Develop key performance indicators (KPIs) relating to the service (the Royal College of Pathologists has developed a useful set of KPIs for pathology) to include in the contract (see Step 10).

### References

Kent & Medway Pathology Network specification

(www.pathology.plus.com/docs/PathServiceSpecKM.pdf)

Bristol pathology specification

(http://www.avon.nhs.uk/pathologyreview/Uploaded%20Docs/Commissioning%20Framework%20v1.2%2005-03-12.pdf)

EoE Patient and GP Surveys of pathology services

(www.strategicprojectseoe.co.uk/index.php?id\_sec=108)

Key Performance Indicators in Pathology. Recommendations from the Royal College of Pathologists

(http://www.rcpath.org/NR/rdonlyres/A9568A98-80B8-4A28-B06E-

AB9A8D769953/0/key performance indicators in pathology 3 2.pdf)

# Step 6. Market Sounding

### Introduction

Market sounding can be used to test interest from potential providers in the procurement. It can also help commissioners to understand the strengths and weaknesses of the procurement. It can be undertaken either formally or informally.

### What is it?

Market sounding enables commissioners to test interest in procuring the services they specify; it can also test potential providers' concerns about service delivery, both in general and in relation to specific areas such as workforce, IM&T and the proposed legal and financial criteria. Through discussion with potential providers, commissioners can ascertain the level of interest and concern - and hear how any concerns may be overcome. The information gained in this way can help develop procurement solutions for inclusion in the OBC.

To discover the level of interest from both the NHS and the independent sector, commissioners may either pursue an informal approach by way of a notice (for example on the Supply to Health website) or a more formal one by way of an OJEU notice.

Once informal soundings of potential providers have been taken, an OJEU or formal tender notice can be issued, and consideration given to holding a bidder day.

# Why is it important

Market sounding helps commissioners to:

- Ascertain the level of interest on their desired approach
- Test their preferred outcomes
- Test their proposed solution
- Ascertain any concerns which potential bidders have
- Develop, in consultation with potential bidders, possible solutions to any such concerns.

# Skills needed and external support

In any market sounding it is important to include in the preliminary documentation all of the information which potential bidders will need. Commissioners should therefore use subject matter experts as necessary, both for the preparation of documents and when sounding the market.

External financial and legal support are also important, particularly if the independent sector is involved, in order to ensure that expert advice is obtained on the current balance sheet and Foundation Trust status of each potential bidder.

### The tools provided

There are five tools accompanying this Step:

- Step 6 Tool 1: Market Sounding Event Invitation Template
- Step 6 Tool 2: Market Sounding Example Guidance Note
- Step 6 Tool 3: Potential Interested Parties Log
- Step 6 Tool 4: Market Sounding Event Agenda Example
- Step 6 Tool 5: Market Sounding Event Cover Letter

### 'How to' guidance

For the informal sounding commissioners will need:

- an agreed proforma that collects information in a consistent manner in respect of each bidder, preferably undertaken by a single team. Examples of the information to be gathered are:
  - Is the potential bidder interested in submitting a bid
  - Does it have the resources to do so and can it meet the timescales
  - What is its previous experience
  - How does it expect to meet the commissioners' anticipated outcomes
  - What risks to these outcomes does it see
  - Does it propose to sub-contract or form partnerships
  - Does it see the suggested procurement route as the optimum
- For the more formal bidder day, most often held after the issue of the Pre
  Qualification Questionnaire / Memorandum of Information, commissioners might
  include on a suggested agenda:
  - The service delivery proposals
  - The anticipated solutions to workforce, IM&T and estates
  - A resume of the projected procurement route
  - The financial model
  - The legal requirements
  - The approach to sub-contracting or partnerships
  - The project's timeline
- As part of the day an open exchange of options/views with potential bidders should be encouraged.

The choice of route – formal or informal - is at the discretion of commissioners; indeed both can be used. The informal route is more informative at an early stage. A bidder day at Pre Qualification Questionnaire /Memorandum of Information stage (see Step 8) will provide potential bidders with more certainty and commissioners with a much more thorough understanding of the market and its concerns.

# Step 7. Procurement Strategy

### Introduction

Commissioners are required to follow EU public procurement law when they seek offers for works, services or goods over certain specified thresholds. In England, Wales and Northern Ireland, it is the Public Contracts Regulations 2006, as amended (the "Regulations") which make EU public procurement law part of our own legal system.

Before embarking on a procurement route for pathology services, commissioners need to be clear on the objectives of the procurement. For example, is the overriding objective to improve clinical service delivery, or to open up the market to competition from non-NHS providers, in order to bring about cost savings and efficiencies? For any procurement of pathology services to be effective, commissioners need to be clear right at the outset about their overarching objectives and strategy, so that a process can be developed around those objectives.

This Step summarises the issues that commissioners need to consider when developing a procurement strategy and route.

### What is it?

Pathology services (as well as health and social services more generally) are currently classified as "Part B" services under the Regulations (this may change in future) and are subject to a "lighter touch" regime than if they were fully-regulated ("Part A") services. Only limited provisions in the Regulations apply to the procurement of Part B services.

Part B services include Regulation 4, which provides that commissioners must treat economic operators (i.e. providers) equally and in a non-discriminatory way and that they must act transparently. Commissioners carrying out a Part B service procurement should ensure that they comply with this Regulation right through the process.

Under Part B services commissioners have greater flexibility about the procurement route for pathology services, and do not need to follow a particular type of procedure (such as the restricted, competitive dialogue, open or negotiated procedures that are specifically prescribed for use when procuring Part A services). This leaves them free to use a simpler, more cost-effective, procedure. In some circumstances, commissioners may still need to advertise – although not necessarily through the Official Journal of the European Union (OJEU) – for example, an advertisement could be placed in the Health Service Journal.

As the European Commission has made clear, if a contract is likely to have sufficient "connection with the internal market" (i.e. to generate sufficient cross-border interest), then commissioners are subject to general EU principles. These principles include transparency, non-discrimination, proportionality, and equal treatment. Commissioners will need to decide on a case by case basis whether a contract will be of cross border interest, but it should be

remembered that this could include interest from providers based in the Republic of Ireland and not just continental Europe.

Commissioners will therefore need to consider factors such as the size and value of the contract and the geographic location (place of performance of the contract). It may well be that pathology service contracts would not be of interest to providers in other member states, but this should never be discounted without prior consideration.

If the contract is deemed to be of cross-border interest then some form of fair, advertised tender procedure may be required to satisfy the transparency principle. However, this would still be more flexible than a Part A service procurement. The extent of advertising required will depend upon the procurement in question, but the more interest which the contract is likely to attract from bidders from other member states, the wider the advertising required (and commissioners could still choose to advertise via OJEU – which removes any question whether the level of advertising actually chosen has been sufficiently wide).

In addition to the Regulations, Commissioners will need to consider Department of Health and Cooperation and Competition Panel policy on procurement. Further information on these is provided in Tool 1 (Key Considerations for Commissioners).

# Why is it important?

The procurement rules provide that compliance with public procurement law is a duty owed by procuring authorities to "economic operators" (in this case, providers of pathology services are likely to be economic operators). A flawed process which does not ensure compliance with procurement law can expose commissioners to a risk of challenge which could result in a damages claim. Where an economic operator can demonstrate that it has suffered, or risks suffering, loss as a result of a breach of the procurement rules it may bring a challenge against the procuring authority in the High Court. However, there are hurdles to overcome in order for any challenge to be successful.

Commissioners will wish to consider undertaking an analysis of the risk – and potential cost - of a damages challenge against them for entering into a direct contract award (i.e. not undertaking a procurement for the services in question), compared to the cost savings that might be achieved by entering into a direct contract with a pathology provider.

There may well be good justifications for not using a full public procurement, given the savings that could be made by commissioners.

# Skills needed and external support

Commissioners who are inexperienced in running procurements are advised to seek independent legal advice on the nature and extent of their proposed procurement process.

# The tools provided:

Two tools accompany this Step:

- Step 7 Tool 1: Key Considerations for Commissioners; and
- Step 7 Tool 2: Which procurement route to use.

# Further Guidance:

PCT Procurement Guide for Health Services
 (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_113745)

# Step 8. Memorandum of Information and Pre Qualification Questionnaire

#### Introduction

The Memorandum of Information ("MOI") and the Pre-Qualification Questionnaire ("PQQ") are documents to be issued by commissioners to prospective providers of pathology services.

On receipt of completed PQQs commissioners will evaluate bidders' responses by reference to their pre-qualification criteria in order to select those bidders who will be invited to submit tenders (or participate in competitive dialogue).

#### What is it?

The MOI sets out in detailed the objectives of the project, the proposed route for securing those objectives, the scope of the services being procured and the project framework.

Prospective bidders must complete the PQQ, which is then used by commissioners to shortlist those bidders who are suitable to proceed to the next stage of the procurement. This stage of the procurement is the commissioners' opportunity to generate interest in the project and to find out more about the potential bidders.

# Why is it important?

The MOI/PQQ are important because:

- i. the MOI provides prospective bidders with the information they need in order to decide whether or not to participate in the procurement; and
- ii. the PQQ enables the economic and financial standing, capacity and capability and technical and professional ability of prospective pathology service providers to be evaluated. Bidders may be eliminated if they do not meet the specified standards.

It is therefore worth producing a detailed and informative MOI and PQQ to ensure sufficient potential bidders respond and to enable commissioners to make a preliminary assessment of the capability, capacity and eligibility of potential bidders to undertake the services.

The PQQ process enables commissioners to select a a manageable number of bidders who meet the selection criteria, and can therefore progress to the next stage of the procurement.

### Skills needed and external support

The MOI/PQQ and the associated evaluation criteria must be tailored to the project. Commissioners will need a clear understanding of:

- i. The service being tendered and how it is currently being provided;
- ii. why it is being tendered;
- iii. what difference the project is designed to make to the local or region-wide health economy.

It is usual for commissioners to seek appropriate expertise to develop this documentation. A typical project team includes clinical, workforce, IM&T, estates and logistics and financial subject matter experts.

## The tools provided

There are three tools accompanying this Step:

- Step 8 Tool 1: MOI/PQQ Template (including example pre-qualification questions);
- Step 8 Tool 2: Example PQQ evaluation criteria;
- Step 8 Tool 3: 'How to' Guidance.

# Step 9. Tender

#### Introduction

Before commencing any tender process for commissioning pathology services, commissioners must have clearly defined objectives and have explained what it is they are trying to achieve. In running a competitive tender process commissioners have an opportunity to reach informed decisions on price, funding models and length of contract, the level of risk acceptable to providers and incentives for providers. All of those elements can be driven forward through a process in which there is competitive tension, to the benefit of commissioners and ultimately patients and the tax payer. As part of this process, commissioners should develop a detailed financial business model to:

- i. collate financial information in a structured and consistent way during the procurement;
- ii. provide the basis on which the financial submissions can be fairly assessed and scored.

#### What is it?

The Tender Document: 'tender' is a generic term often used to describe an invitation from a contracting authority to potential bidders to submit bids to provide works or services. Colloquially it is used to cover a variety of specific documents including an Invitation to Negotiate (ITN), Invitation to Participate in Dialogue (ITPD) and Invitation to Tender (ITT).

The nature of the tender document itself will depend on the procurement route used.

One of the Tools attached to this Step is a template ITT which follows a PQQ where no competitive dialogue process has taken place (one of the options available to commissioners as discussed in Step 7 (Procurement Strategy)).

The substantial part of the ITT will be the draft Pathology Services Contract. Commissioners need to be clear which elements of the contract will be used to asses bidders' responses, for example in relation to quality and value for money. These elements could include, by way of example, risk transfer (financial robustness of bidder and liability cap in contract), service levels and price per test.

The ITT would usually contain:

**Clinical requirements.** This section should (i) provide an overview of the existing level of pathology services (by way of a supplement to the information in the MOI) (ii) outline the objectives of commissioners and the pathology service requirements and (iii) describe the clinical standards that potential providers must meet (e.g. as detailed in the specification/ set out in the KPIs). The questions should be designed to test the ability of potential providers to meet these criteria.

**Workforce requirements.** This section should test the potential provider's ability to provide a suitably qualified and properly trained workforce to deliver the pathology services and to draw out any impact (e.g. redundancies) on the workforce providing the services currently.

**Estates and logistics.** This section should test whether the proposed provider's property solution meets commissioners' requirements, for example to ensure that all sites are appropriate and equipped to support the provision of pathology services

**IM&T.** This section should test the potential provider's ability to deliver effective and integrated IM&T systems and infrastructure in each provider location

**Mobilisation.** This section should deal with the steps that need to occur to move from existing provision of services to the provider's new model .A detailed mobilisation plan should be requested.

**Financial**. This section should require potential providers to demonstrate that they have developed a robust financial proposal to support the development, operation and provision of pathology services.

**Legal**. This section should establish the legal status of the proposed provider and the availability of the requisite powers/vires to enter into a commissioning contract. The form of commissioning contract should also be issued with the ITT.

### Why is it important?

A competitive tender process enables commissioners to obtain the best bid and select the provider who best meets their pathology services commissioning needs.

# Skills needed and external support

It is usual for commissioners to seek expertise from throughout their organisation to develop this documentation. For example, a typical project team contains clinical, workforce, IM&T, estates and logistics as well as financial subject matter experts.

# The tools provided

There are five tools accompanying this Step:

- Step 9 Tool 1: Template ITT document;
- Step 9 Tool 2: Guidance on developing the specification for the financial model;
- Step 9 Tool 3: Example ITT evaluation criteria;
- Step 9 Tool 4: Guide to developing a financial evaluation model; and
- Step 9 Tool 5: 'How to' Guidance

# Step 10. Contract

#### Introduction

The commissioning contract will document what the parties have agreed to do in relation to the provision of pathology services. In the case of a local negotiation, it is likely that a commissioning contract is already in place and the parties are updating and varying its terms. In a tender, agreeing the commissioning contract will be the final stage in the tender and award process.

Whilst developing and negotiating the commissioning contract, commissioners must consider what approvals will be required before the contract can be signed. This is dealt with in the last step in this Toolkit, Step 11 (Approvals and contract management).

#### What is it?

The commissioning contract documents the terms on which the parties have agreed to provide and receive pathology services. It will therefore cover: (i) what services are being provided; (ii) how long the services will be provided for; (iii) the price to be paid by the Commissioner to the Provider for the services; (iv) the standards to which the services are to be performed; and (v) how the parties terminate the arrangement.

The commissioning contract is usually produced by the Commissioner and sent to the Provider for comment and review. In the tender scenario, it is envisaged that the commissioning contract is issued to the bidders with the Invitation to Tender documentation.

Prior to issuing the commissioning contract, commissioners must give consideration to the strategy they wish to take with regard to the negotiation of the contract. The options are:

- "take it or leave it": the Commissioner issues a contract which must be accepted by the Provider. This may be appropriate where: (i) there is a degree of competitive tension and the Commissioner is in the stronger bargaining position; and (ii) all information is known by the Commissioner and therefore a complete contract can be issued to the Provider without the need for further discussion.
- partial negotiation: the Commissioner issues a contract with defined areas for comment and review by the Provider. This may be appropriate where: (i) the Commissioner is reliant on the knowledge and experience of the Provider; or (ii) the Commissioner requires the Provider to complete or agree certain sections of the contract, such as Schedule 2, Part 3 (Prices).
- **full negotiation:** the Commissioner issues a draft contract for review, comment and mark-up by the Provider. This may be appropriate where: (i) the Provider has the stronger bargaining position; or (ii) the Provider has greater skill or expertise; or

(iii) the procurement is 'unique' and the terms of the contract require a greater level of discussion.

Commissioners should make clear to potential providers which strategy they are pursuing when the contract is issued. In the case of a tender, it should be made clear in the ITT by, for example, including a question asking the bidder to confirm acceptance of the terms of the contract.

## Why is it important?

The commissioning contract is fundamental to the procurement whether the approach taken is local negotiation or competitive tender. The commissioning contract sets out what has been agreed by the parties and it is therefore important to ensure it reflects commercial reality.

This Step includes a model commissioning contract which has been developed on the basis of the NHS standard commissioning contract. The front end of the contract is largely standard "boiler plate" clauses which should be familiar to both commissioners and providers. The main areas for consideration are:

- services specification (Step 5);
- prices and pricing mechanism;
- managing activity and requests and, in particular, the quality requirements, such as key performance indicators; and
- transformation.

Commissioners should note that the commissioning contract tool is no more than a starting point and is not (and is not intended to be) definitive. Accordingly, commissioners:

- must not follow the tool blindly: amendments will be required;
- must tailor the tool to meet their needs; the commissioning contract tool has sections which must be completed (such as completing the specification at Schedule 2 and the prices at Schedule 2, Part 3) must check that it is up-to-date at the time it is being used;
- read and understand the contract; and
- take specialist legal and financial advice if required.

# The tools provided

There are two tools accompanying this Step:

- Step 10 Tool 1 Commissioning Contract front end; and
- Step 10 Tool 2 Commissioning Contract schedules.

# Step 11. Approvals and Contract Management

#### Introduction

This Step, the final stage of this Toolkit, follows the appointment of the preferred bidder and agreement of the terms of the commissioning contract. It looks at the approvals that may be required and the on-going contract management following contract signature.

#### What is it?

Once the commissioning contract has been agreed with the preferred provider, commissioners may need to obtain the following approvals:

- Local approvals: commissioners will need to approve the Full Business Case prior
  to appointment of the Preferred Bidder and issuing the Preferred Bidder
  appointment letter. Additional internal approval (for example by the project board)
  may be required depending upon the governance and project management
  structure and processes established.
- Full Business Case (FBC) approval: Approval from the project board will be
  required on all commissioning contracts whether they are as a result of a local
  negotiation or a competitive tender. Approval of the contract, and the parties
  entering into the contract, should at the very least be recorded by the project board.
- Co-operation and Competition Panel (CCP) approval: In certain cases (large-scale reorganisations between providers which fall within CCP's remit) approval from the CCP may be required. The CCP reviews proposed "mergers" (which covers mergers, acquisitions, joint ventures and vertical integration arrangements) between NHS-funded healthcare providers. It advises the Department of Health and Monitor whether the merger should be allowed to proceed, or to proceed subject to certain conditions, or prohibited. Commissioners and the preferred provider will therefore need to consider whether they need to submit the procurement to CCP for review.
- Monitor approval: Monitor's role is to evaluate the impact of a proposed transaction on a Foundation Trust's governance and finances and to issue indicative risk ratings. FTs are required to report proposed transactions which exceed the thresholds set out in the Compliance Framework. Commissioners and the preferred provider will therefore need to consider whether they will need to report the procurement to Monitor (i.e. if the procurement is of substantial value and falls within the set thresholds).

#### Why is it important?

#### **Approvals Process**

The approvals process is important. If the necessary consents are not obtained, the procurement may be subject to investigation at a later date. If challenged successfully it can be set aside.

#### **Contract Management**

Providers are required to provide substantial amounts of information and to comply with the reporting requirements set out in the commissioning contract. Commissioners need to be in a position to receive, assimilate, review and disseminate such information and where appropriate act on any issues or concerns arising from the content of the reports they receive. Financial and quality benefits that are envisaged within the contract need to be closely tracked and monitored with providers in order to ensure that they are delivered on time and at the level expected.

#### Skills needed and external support

#### **Approvals Process**

Commissioners need to assess whether the contract requires CCP and Monitor approval, and to do so should contact CCP and Monitor. This should be done at an early stage in the procurement to establish a good working relationship and obtain helpful guidance.

#### **Contract Management**

Commissioners should assign responsibility for management of the pathology services commissioning contract to an individual or a team. As a minimum the individual or one of the team must have an understanding of the range of tests and disciplines in pathology to ensure that a knowledgeable review of monthly information and reporting is able to take place. Financial and quality benefits that are envisaged within the contract need to be closely tracked and monitored with providers in order to ensure that they are delivered on time and at the level expected.

The provider should be given a single designated point of contact for receipt of all reports and information requests which are required to be delivered by the provider to commissioners.

Five key areas for contract management:

- **Information and reporting:** Knowing what information and reporting obligations you and the Provider are under;
- **Payment mechanism:** Understanding how the payment mechanisms works, including how and when any reconciliations are made;
- Review, records and contract management: Knowing when review meetings will
  take place, what they will achieve, what documents need to be maintained to
  document each review and the procedure for dealing with any performance issues
  which arise during the term of the contract; and

- **Benefits delivery:** Identifying the mechanisms and information needed to ensure benefits are tracked and achieved, the appropriate changes are made to achieve them and make them sustainable.
- Mobilisation: Oversee the implementation plans of the contracted providers to ensure benefits delivered.

For each of these elements, the Commissioner must review the terms of the commissioning contract carefully so that the relevant people are aware of their responsibilities under the contract.

# Tools provided

There is one tool accompanying this Step:

Step 11 Tool 1: Guidance on key areas of contract management

Part Three: Tools

# List of tools

Step	Tool Provided			
Outline Business Case	Step 1 Tool 1: Sample OBC			
	Step 1 Tool 2: Questions and perspectives for commissioners			
Project Governance	Step 2 Tool 1: Example risk framework			
Project Management	Step 3 Tool 1: Example resource planner			
	Step 3 Tool 2: PID template			
Stakeholder Engagement	Step 4 Tool 1: Engaging stakeholders			
	Step 4 Tool 2: Different Types of Public Engagement			
Service Specification	Step 5 Tool 1: Example service specification			
	Step 5 Tool 2: Example workforce, IM&T, estates and logistics requirements			
	Step 5 Tool 3: Activity data gathering template			
Market Sounding	Step 6 Tool 1: Market Sounding Event Invitation Template			
	Step 6 Tool 2: Market Sounding Example Guidance Note			
	Step 6 Tool 3: Potential Interested Parties Log			
	Step 6 Tool 4: Market Sounding Event Agenda Example			
	Step 6 Tool 5: Market Sounding Event Cover Letter			
Procurement Strategy	Step 7 Tool 1: Key Considerations for Commissioners			
	Step 7 Tool 2: Which procurement route to use.			
MOI and PQQ	Step 8 Tool 1: MOI/PQQ Template (including example prequalification questions)			
	Step 8 Tool 2: Example PQQ evaluation criteria			
	Step 8 Tool 3: 'How to' Guidance.			
Tender	Step 9 Tool 1: Template ITT document			
	Step 9 Tool 2: Guidance on developing the specification for the financial model			
	Step 9 Tool 3: Example ITT evaluation criteria			
	Step 9 Tool 4: Guide to developing a financial evaluation model			
	Step 9 Tool 5: 'How to' Guidance			
Contract	Step 10 Tool 1 Commissioning Contract front end			
	Step 10 Tool 2 Commissioning Contract schedules.			
Approvals and Contract Management	Step 11 Tool 1: Guidance on key areas of contract management			