

Consolidated pathology network

Structural, commercial and regulatory issues to address in business cases

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We support providers to give patients safe, high quality, compassionate care within local health systems that are financially sustainable.

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1. Introduction

About 130 NHS trusts and foundation trusts provide their own pathology services, often using outdated operating models that need investment in premises, IT and equipment. This also exacerbates competition for increasingly scarce staff. The Carter reports¹ into pathology optimisation recommended the consolidation of pathology laboratories to maximise existing capacity and savings from economies of scale. This recommendation is endorsed by international and NHS evidence that the sustainable pathology services resulting from consolidation and modernisation increase both quality of service for patients and efficiency.

We are looking for an increase in ambition behind and speed of consolidation of pathology services across the NHS. The Carter reports propose consolidation by introducing a 'hub and spoke' model whereby high volume, non-urgent work is transferred to a central laboratory to maximise benefits through economies of scale. Spoke laboratories, referred to as essential service laboratories (ESL), then provide low volume urgent testing close to the patient.

The consolidation model has inherent challenges for trusts, including the formation of a desired operating model and the governance to control it. Also, these changes need to be delivered at a time of constraints on capital and internal resources.

1.1. Purpose

This document provides trusts consolidating their pathology services with guidance on the key structural, commercial and regulatory requirements – the watchpoints – that should be addressed when designing and implementing the commercial structure and agreements between member trusts.

The watchpoints cover different available commercial structures for this process.

¹ [Report of the Review of NHS Pathology Services in England](#) (DH 2006)
[Report of the Second Phase of the Review of NHS Pathology Services in England](#) (DH 2008)
[Operational productivity and performance in English NHS acute hospitals: Unwarranted variations](#) (DH 2016)

1.2. Methodology

We have compiled this guidance using laboratory management experience and expertise, review of several case studies of pathology consolidation and input from trust executives who have been through the consolidation process, both successfully and unsuccessfully. It has been reviewed and approved by the National Pathology Optimisation Delivery Group which has broad representation from the pathology industry, including the Royal College of Pathologists and the Institute of Biomedical Sciences.

We will update this guide regularly to reflect new information regarding legal and other issues in the context of consolidating pathology services.

1.3. Disclaimer

We provide guidance only and you should seek independent legal advice in relation to addressing the watchpoints identified. Organisations should seek specific advice about tax implications.

NHS Improvement can support trusts as they explore their particular model of working.

Also note that when consolidating pathology services, the issues requiring legal advice and attention are not limited to the watchpoints identified in this document.

1.4. Useful resources

This document does not provide a comprehensive list of all necessary legal considerations for the consolidation of pathology services. For further legal considerations outside the scope of this guide, the following documents may be useful:

- [NHS foundation trusts code of governance](#)
- Mergers guidance:
<https://improvement.nhs.uk/resources/supporting-nhs-providers-considering-transactions-and-mergers/>
<https://improvement.nhs.uk/resources/how-make-nhs-mergers-work-better-patients/>

<https://www.gov.uk/topic/competition/mergers>

<https://www.gov.uk/government/publications/review-of-nhs-mergers-cma29>

- Merger rules: How they affect pathology service reconfigurations:
<https://www.gov.uk/government/publications/merger-rules-how-they-affect-pathology-service-reconfigurations>
- NHS healthcare providers: working with choice and competition:
<https://www.gov.uk/government/publications/nhs-healthcare-providers-working-with-choice-and-competition>
Competition Act 1998
- NHS Constitution:
<https://www.gov.uk/government/publications/the-nhs-constitution-for-england>
- NHS procurement policies:
<https://www.gov.uk/government/collections/nhs-procurement>
- NHS England and CCG standing rules:
<https://www.nhs.uk/choiceintheNHS/Rightsandpledges/Waitingtimes/Documents/nhs-england-and-ccg-regulations.pdf>
- Procurement, patient choice and competition regulations: guidance:
<https://improvement.nhs.uk/resources/procurement-patient-choice-and-competition-regulations/>

2. Guidance framework structure

The framework identifies the key legal watchpoints in establishing a consolidated pathology service in the NHS. These relate to:

- organisational form
- governance
- finance
- competition
- workforce
- relationship with customers
- procurement
- outsourcing.

The framework also provides guidance on when these considerations should be addressed in the process of establishing the consolidated service. The stages are:

- before a strategic outline case (SOC) is drafted
- in the SOC process
- in the outline business case (OBC) process
- in the full business case (FBC) process.

2.1. Legal watchpoints framework

	Pre SOC	SOC	OBC	FBC
Organisational form	<p>Initial considerations on the features of the model that best fits the collaborative principles agreed by the trust partners</p> <p>Member rights (foundation trust versus non-foundation trust)</p>	<p>Methodology for selecting organisational form</p> <p>If required, selection criteria for host/lead organisation if a unit organisation or partnership is being proposed</p>	<p>Obligations of members defined</p> <p>Methodology for valuing ownership 'shares' or interests</p> <p>Approach to termination, including an understanding of the implications in the following scenarios:</p> <ul style="list-style-type: none"> • service provider voluntary termination • customer voluntary termination • service provider default • customer default • single partner voluntary or default termination in multi-partner agreements 	<p>Appointment process for board members and future board members</p> <p>Appointment process for chair and independent members</p> <p>Exit arrangements (including notification period and penalties)</p> <p>Exclusivity and non-competition clause considerations</p> <p>Approach to new members and customers of the entity, including transition costs and, if applicable, transfers under Transfer of Undertakings (Protection of Employment) regulations (TUPE)</p> <p>Approach to corporate services, including which services will be performed by the new entity and which will be procured from the owner trusts or third parties</p>

Governance	Approach to values and principles in association with the NHS Constitution*		Representation on operating/governance board from member trusts Mechanism for effectively and transparently reporting performance Dispute resolution Mechanism used by owner trusts to decide reserved matters Scheme of delegation Clinical governance considerations Indemnities and legal liability arrangements for medical/clinical negligence, damage to property resulting from negligence, breaches of confidentiality, patient confidentiality and third-party intellectual property rights	Principles for the management and monitoring of service-level agreements (SLAs)
Finance		Approach to transfer of currently owned assets Initial considerations on the treatment of assets, including equipment and information management and technology (IM&T). Trusts should discuss: <ul style="list-style-type: none"> assets each trust should commit for use by the entity 	Annual recharges and the commitment to operating expenses Agreement on dealing with profit and losses Agreement on transition cost delegation between member trusts Capital funding obligations Arrangements for member trusts	Approach to approval of investments Limits above which owner trust board approval will be required (if applicable) Ownership of new assets (if hosted arm's length organisation) Accounting principles, including the responsibility for

		<ul style="list-style-type: none"> • value and remaining life of those assets • party to be responsible for the replacement of obsolete assets • use of managed equipment service (MES) contracts • current situation at each trust in terms of MES • other contracts, leases and rentals • approach to determining IM&T requirements • investment principles for IM&T • management of IM&T external contracts and maintenance <p>Investigation of tax implications**</p> <p>Investigation of VAT implications**</p>	<p>that cannot afford required investment</p> <p>Approach to dealing with intellectual property from member trusts and intellectual property created by the reconfigured service</p>	<p>producing trading accounts and their regularity</p>
Competition**	Competition regulations on existing customer contracts (see	Competition regulations on customer contracts as the new entity Procurement, patient choice	Commitment from owner partnership and partnership term. What is the commitment length from each member trust?	

	<p>Section 1.4) Procurement, patient choice and competition regulations apply to commissioners but trusts should be aware of implications</p>	<p>and competition regulations apply to commissioners but trusts should be aware of implications</p> <p>Approach to competitive behaviour post exit from a member trust. Implications for competitive behaviour following exit from joint venture</p> <p>Consideration of whether review of the network arrangements by the Competition and Markets Authority (CMA) will be required – NHS Improvement can help trusts that are consolidating pathology to understand whether any competition issues are likely to arise and facilitate any conversations with the CMA (if necessary)</p>		
Workforce		<p>Approach to staff transfer and recruitment (employed by own trust or transferred to new entity if created)</p>	<p>Staff TUPE transfer consultation period (if applicable)</p> <p>Agreement on how redundancy cost arrangements will be delegated among member trusts (if applicable)</p> <p>Approach for consultant workforce (employed staff or purchased activity)</p>	<p>Approach for new recruits</p> <p>Approach to solicitation of provider staff</p>

Relationship with customers			<p>Methodology to agree key performance indicators (KPIs) in relation to internal (trusts) and external customers (GPs and other organisations)</p> <p>Charging on commercial basis of services which could be in-sourced</p> <p>Level of acceptable risk and rewards to customers</p>	<p>Terms of commitment of contract with the entity</p> <p>Longer commitment or sharing of risk will lead to better pricing</p>
Procurement	<p>Considerations on potential penalties for exiting any existing contractual arrangements with equipment suppliers</p> <p>Novation or new procurement process. Existing penalties for termination</p>	<p>Approach to existing managed service contracts</p> <p>Novation or new procurement process. Existing penalties for termination</p>	<p>Approach to new managed service contracts</p>	
Outsourcing of entire service	<p>Procurement regulations</p> <p>Workforce considerations (as above)</p>	<p>Agree scope of outsourcing</p>	<p>Tender output specifications</p> <p>Approach to payment mechanism</p> <p>Selection criteria and approach to challenges</p> <p>Performance monitoring of supplier</p> <p>Approach to medical negligence from supplier</p>	

			Exclusivity clause considerations	
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*The NHS Constitution establishes the principles and values of the NHS in England. It sets out the rights to which patients, public and staff are entitled, and pledges which the NHS is committed to achieve, together with responsibilities, which the public, patients and staff owe to one another to ensure that the NHS operates fairly and effectively. The seven key principles which guide the NHS in all it does are:

- (i) The NHS provides a comprehensive service, available to all irrespective of gender, race, disability, age, sexual orientation, religion, belief, gender reassignment, pregnancy and maternity or marital or civil partnership status.
- (ii) Access to NHS services is based on clinical need, not an individual's ability to pay.
- (iii) The NHS aspires to the highest standards of excellence and professionalism.
- (iv) The patient will be at the heart of everything the NHS does.
- (v) The NHS works across organisational boundaries and in partnership with other organisations in the interest of patients, local communities and the wider population.
- (vi) The NHS is committed to providing best value for taxpayers' money and the most effective, fair and sustainable use of finite resources.
- (vii) The NHS is accountable to the public, communities and patients that it serves.

** Organisations should seek specific advice about tax implications. NHS Improvement can support trusts as they explore their particular model of working

3. Governance – key commercial terms

The following framework identifies the key commercial terms for operational governance of a consolidated pathology service. For a more comprehensive guide to governance and commercial structures for consolidated pathology operations, please refer to the NHS Improvement’s [Operational governance guide and associated tool kits](#).

Key term	Description and issues	Outsourced option	Joint venture and partnership options
Ownership shares or interests	A methodology based on the ‘value’ of each trust’s contributions to the new entity will be defined and agreed	As the trust will outsource the management and delivery of pathology, it will no longer retain ownership of the pathology service. This will be fully owned by the licensed provider	Contribution method, cost base method and volume/revenue method. All of these can be tailored to accommodate local needs and changes
Profit and loss	A methodology for the distribution of profit and loss generated by the pathology service	Annualised profits and losses are the responsibility of the provider of the pathology service	Annualised profits will be shared and losses underwritten by the membership organisations in proportion to their interest or negotiated risk
Exit arrangements	A methodology for the potential exit of an organisation	Break clauses will be determined in the contract with the outsourced provider and will be subject to negotiation It is critical that the trust retains an ability to exit the contract if the provider repeatedly does not meet the KPIs in the contract	If any member organisation wishes to terminate its customer contract (that is, cease to use the consolidated service for the provision of clinical service), it should give the joint venture at least 12 months’ notice If the termination is before the first break period, then the terminating organisation will be

Key term	Description and issues	Outsourced option	Joint venture and partnership options
			responsible for any additional costs incurred by the joint venture for the 12 months following their termination
Intellectual property (IP)	A methodology for use of the organisations' IP for the delivery of pathology	IP will be retained by the provider of services	The IP will be owned by the joint venture/ partnership and be exploited by it on behalf of its member organisations
Capital investment	A methodology for the approval and financing of capital investments	All capital investments will be the provider's responsibility	<p>Any capital investment approved by the new Joint Venture will be 'called up' from the member trusts per their interests.</p> <p>All capital calls will require a business case approved by the pathology management board. Capital calls above an agreed threshold will require approval by the owner trusts per the scheme of delegation</p> <p>Any capital investments (from which the new joint venture will benefit) committed by potential membership trusts within three months of the creation of the new entity will be included in the valuation of ownership shares</p>
Clinical governance	Ensuring input from clinicians and oversight of laboratory operations	Clinicians from the outsourced supplier are responsible for clinical quality and accreditation. Service to be delivered in accordance with the contract	Input into governance through the establishment of a joint clinical governance group where all shareholders have representatives. This group is independent from the operational management board and can make recommendations on laboratory performance. In addition, consultant

Key term	Description and issues	Outsourced option	Joint venture and partnership options
			<p>programmed activities are bought from owner trusts to ensure consultant input into laboratory operations</p>
<p>Pathology management board</p>	<p>A methodology for the day-to-day management of the pathology service</p>	<p>Management of the pathology service will be the responsibility of the pathology provider</p>	<p>The day-to-day operations of the new joint venture will be governed by a pathology management board. This board will comprise non-executive and executive positions. Membership trusts can nominate representatives to take up non-executive positions</p> <p>An independent chair will be appointed by the owner trusts</p> <p>The executive team will be selected, through an agreed interview process, from the appropriately qualified staff from the owner trusts</p> <p>If matters require the pathology management board to vote, decisions will be made using a simple majority</p>

3.1. Key commercial terms not relevant when outsourcing

Key term	Description and issues	Joint venture and partnership options
Trust contracts	A methodology for each trust to contract with the pathology service	Each trust will agree an exclusive contract with the new entity for a period of [10] years with an optional break at [7] years A [7]-year initial contract period is considered the minimum required to allow for the required integration, new operating practices and economies of skill and scale to be realised, and the benefits shared between the customers and owners
Performance management	The contracts with customers will include key performance metrics. If these are not met, revenue will be deducted from the new entity	As above
Pathology pricing	A methodology for pricing pathology testing to parties	The new entity executive team will prepare a three-year operating plan that sets a price list for its customer owner trusts All prices will be consistently applied to the owner trusts and should decrease in real terms over the three years to reflect the expected operating efficiencies to be achieved by the new entity
Marketing	A methodology for the marketing of the pathology service to partners outside the current service provision	Marketing of the pathology services to trusts and organisations outside the current owner organisations will be the responsibility of each individual organisation. Each organisation will have the option, but not the obligation, to seek delivery of future additional pathology service from the joint venture under terms to be agreed at that point
Accounting principles	A methodology for accounting for the pathology service	The new entity will have its own trading account that will determine the bottom-line contribution. The trading account should include all recharges for staff and services received from trusts The trading account will be presented quarterly to the pathology management board, then to each respective owner organisation board

Key term	Description and issues	Joint venture and partnership options
Corporate support	A methodology for provision of corporate support to the pathology service	Corporate support services will be provided by the [joint venture/host trust] and recharged based on actual costs as agreed with the new entity (The new entity may give 12 months' notice to the host trust of its intention to acquire its corporate support services by another means)
TUPE transfers	A methodology for the transfer of staff to the new provider of the service	All pathology staff from the owner trusts will be able to apply for jobs in the new entity or partnership (per its agreed operating model) Once the interview process is complete the appointed staff will transfer under TUPE from their current trust to the host trust (This option could be used for all staff or just for defined key posts to ensure the sustainability of the new entity) This will apply to clinical staff with the exception of those who have clinical (patient-facing) sessions. If their clinical (patient-facing) time exceeds diagnostic pathology time, the latter service will be recharged (and vice versa)
Redundancy costs	A methodology for the coverage of potential redundancy costs	Any redundancy costs will be met by the joint venture, and shared between owner organisations based on their ownership share of the joint venture Redundancy only considered after all redeployment routes are exhausted

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