

Consolidated pathology network

Commercial structure and operational guide

February 2018

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About 130 NHS trusts and foundation trusts provide their own pathology services, often using outdated operating models that need investment in premises, IT and equipment.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 the ambition behind and speed of consolidation of pathology services across the NHS. The Carter reports¹ 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 formation of the 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 explains the options available to trusts consolidating their pathology services for the commercial structure of the consolidated pathology network, and gives guidance on the operational governance structure.

Clinical governance and outsourcing commercial structure, while acknowledged in this guide, are covered in their own guideline documents to be published separately.

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 by a broad representation from the pathology industry.

We will update this guide regularly to reflect new information regarding commercial and governance structures in the context of consolidating pathology services.

1.3. Disclaimer

We provide guidance only and you should seek further specialist advice regarding the formation of commercial structures and governance policies.

1.4. Useful resources

Please also refer to the following:

- [Care Quality Commission new provider registration information](#)
- [UKAS application process](#)
- *Good governance guide.*

2. Commercial structure

The new consolidated pathology network must define its commercial structure to have its own identity and operating flexibility. This will be distinct from how each trust's existing divisional management structure manages pathology services.

To be accredited by the United Kingdom Accreditation Service (UKAS) the organisation must be a defined legal entity. In the context of a network, accreditation could be held by, for example, the host NHS trust or foundation trust, or a new legal entity created to run a network (such as by a joint venture). The legal entity does not need to supply all aspects of the pathology service but it does need a clear contractual relationship.

A new identity and operating model is important because:

- The trusts' pathology operations are being transformed under a seamless management and governance structure.
- Operationally the new consolidated pathology network will serve all the trusts equally in providing first class pathology services and as such needs a distinct identity and arm's length separation from the trusts.
- Staff are more likely to be equally and significantly engaged (in a challenging transformation) if they can identify a common loyalty to a new 'brand' and operational management structure distinct from existing arrangements in their individual trusts.
- The consolidated pathology network will require a degree of operational flexibility to set and execute its own priorities if it is to grow as a sustainable business; it is unlikely to have this as part of the trusts' divisions.
- The consolidated pathology network will be required to operate with a degree of autonomy and governance arrangements in accordance with the standing orders and scheme of delegation of the host trust.
- According to [Care Quality Commission \(CQC\) guidelines](#), CQC must nominate and approve accountable persons and new entities must be registered.
- Customer and owner behaviours, roles and responsibilities need to be clearly separated. There should be a clear customer expectation through a

unified specification to drive a single service offering rather than a bespoke offering.

Below we give some examples of the types of commercial structures that a new consolidated pathology network could adopt to underpin the implementation of a target operating model. These are the options that support autonomous operation. They are:

- collaboration across multiple organisations with a single operational management team (most suitable for the distributed network model)
- alliance contracting
- unit organisation hosted by one trust (suitable where the partners looking to collaborate are all NHS parties)
- joint venture – limited liability partnership (LLP; suitable where the aim is to create a private organisation)
- joint venture – limited company (by shares or guarantee)
- community interest company (CIC)
- outsourcing.

2.1. Collaboration across two organisations with a single operational management team

This structure is only suitable if all parties are NHS bodies and does not involve the creation of a new legal entity. It is likely only suitable for the formation of a distributed network or collaboration for a joint Managed Equipment Service procurement. Under this, the parties enter an agreement to collaborate in, and jointly manage, the delivery of pathology services. Staff remain employed by each trust and the pathology management team reports to all trust boards. Investments or changes in the operations must be approved through the normal mechanisms of each trust. While the operational management of the service may be joint, it is overseen by each of the trusts' boards and these remain accountable for decisions about the service. Under this option all trusts retain full responsibility for their services to pathology (such as provision of finance, HR, back office support). Pathology services at each trust are largely independent of each other although the joint management team will look to standardise operations across sites. Each member trust is responsible for its own quality accreditation but the creation of a joint quality oversight body is highly recommended to ensure good governance.

2.2. Alliance contracting

Alliance contracting is similar to an informal joint venture, and is only suitable when all the trusts are NHS bodies. No new legal entity is created and instead the trusts work together on aspects of the service, with individual trusts taking the lead for certain aspects. Therefore, one trust may take the lead for a particular area of the pathology service (eg IT) and another trust the lead for another area (eg equipment) , and as such the contracting on behalf of all the trusts. Although certain aspects of contracting or control can be transferred informally between parties, most of the delivery and contracting remain with each trust.

Another example is each provider retaining its commissioning contract with the CCG but entering an alliance agreement setting out how the trusts will co-operate with each other. The alliance agreement therefore sits over existing contracts. It sets out shared objectives and principles, and shared governance; there may also be gain/loss share arrangements. Each member trust is responsible for its own quality accreditation.

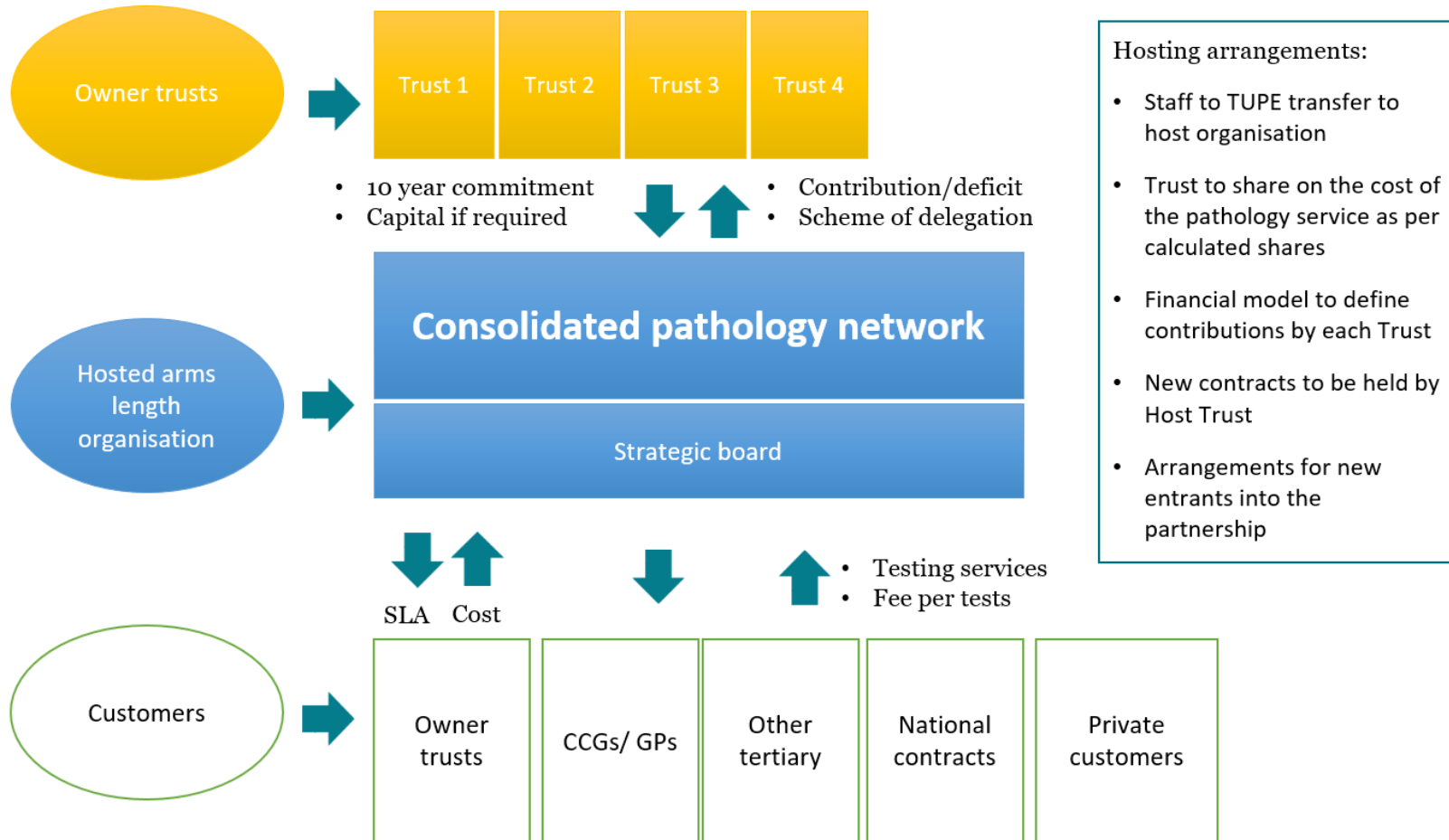
2.3. Unit organisation hosted by one trust

This commercial structure is only suitable where all parties are NHS bodies and does not involve the creation of a new legal entity. It involves the full integration of all pathology services to create a unit organisation hosted by one of the trusts but serving all trusts. This may involve the transfer of some staff from the non-host trusts to the host trust under Transfer of Undertakings (Protection of Employment) regulations (TUPE). All contracts, finance systems, liabilities and responsibilities transfer to the host trust and are shared through the joint venture agreement. It is worth noting that some commissioning contracts can remain with the original trust and be novated into the joint venture at a later point, or when this work is recommissioned, the joint venture could tender for it. The joint venture cannot enter into long-term contracts or raise capital other than through the normal channels at the hosting trust (See figure 1).

This structure allows for a responsive service that is well-defined commercially and where the operational management team has full control of operations at all sites. This means it has greater leverage to optimise the efficiency of the service and implement change. Each trust retains clinical control through the clinical governance structure which is managed by the clinical committee with

representatives from all parties. Equally, a level of operational control is retained by all trusts through the consolidated network management board where all trusts have representatives and voting rights. The operational management teams can only implement changes in accordance with a well-defined scheme of delegation.

Figure 1: Example of a hosted unit organisation



2.4. Joint venture (thick or thin) – limited liability partnership (LLP)

A **thick joint venture** is where the legal entity actually employs all the staff and takes ownership of all liabilities. In a **thin joint venture**, the legal entity provides strategic guidance and holds customer contracts, with all or defined risks passed to a sub-contractor.

An LLP is a corporate body with a separate legal personality similar to that of a company (although it is not a company). It is suitable for the purposes of a joint venture when the parties to the joint venture are NHS foundation trusts.² Unlike in a normal partnership, the members of an LLP enjoy limited liability, as the name suggests – liability is limited to the amount of money each trust invests in the business and to any guarantees the trusts give to raise finance. Each member takes an equal share of the profits, unless the members' agreement specifies otherwise. LLPs are allowed to raise finance. NHS trusts cannot participate in the formation of a joint venture, but can enter into a contractual arrangement with a joint venture formed by a network

2.5. Joint venture (thick or thin) – limited company by shares or guarantee

This is the most common organisational structure for setting up businesses. It is only suitable when the parties to the joint venture are NHS foundation trusts. The incorporated organisation will have a memorandum (describing the members setting up the organisation) and articles of association (describing how the company is to be run and any benefits shared). Liability is limited to the assets of the company and not the individual finances of the shareholders. Under this structure the joint venture can raise capital and enter into long-term contracts.

2.6. Community interest company

A CIC is a form of company (limited either by shares or by guarantee) created for so-called 'social enterprises' that want to use their profits and assets for community benefit. CICs are easy to set up and have all the flexibility and certainty of the

company form, but with the following special features that ensure they serve a community interest:

- the company must submit a community interest statement
- the company must have an 'asset lock' (all assets are for the benefit of the community)
- caps on how profits are distributed and the level of reinvestment required.

As with other company forms, it is only suitable when the parties forming the CIC are NHS foundation trusts.

2.7. Outsourcing

A trust or network of trusts can contract the pathology services and operations through a tender process to a third party and become a customer of a pathology service. This option has advantages including access to economies of scale and disadvantages including the loss of direct control of operations, as covered in the Outsourcing guide to be published separately.

2.8. Summary of commercial structures

Commercial structures	Raise capital	Feasibility	Profits and liabilities	Autonomy of operation	VAT
Collaboration	Each trust is responsible for raising the capital required or contracting with a private organisation to supply capital	Highly feasible (common across the country) – though dependent on organisational form chosen	Each trust to hold own accounts	Poor autonomy as all decisions are subject to approval by all trusts, including clinical governance	As per current NHS rules
Alliance contracting	Each trust is responsible for raising the capital required or contracting with a private organisation to supply capital	Requires common agreement between the trusts, commitment and trust	Each trust to hold own accounts	Poor autonomy as all decisions are subject to approval by all trusts, including clinical governance	As per current NHS rules
Unit organisation within host trust	Host trust is responsible for raising capital or contracting as above	Possible if one trust agrees to host – clear operational and clinical governance structures to be set up	To be shared in accordance with joint venture agreement	Almost full autonomy as pathology operates as a division of the host trust under a delegated authority scheme	As per current NHS rules
Joint venture – LLP	Commercially or through partners as per partnership agreement	Only suitable for NHS foundation trusts	Distributed to partners as per the partnership agreement	Full autonomy	HMRC approval
Joint venture – limited liability company	Commercially or through partners as per articles of association	Only suitable for NHS foundation trusts	Distributed in accordance with shares	Full autonomy	HMRC approval

Commercial structures	Raise capital	Feasibility	Profits and liabilities	Autonomy of operation	VAT
CIC	Commercially or through partners as per articles of association	Possible as there is precedent in the UK, although only suitable for NHS foundation trusts	Profits and liabilities are capped and an asset lock is in place	Full autonomy although activities and reinvestment by the CIC principles are limited	HMRC approval
Outsourcing	Each trust is responsible for raising the capital required or contracting with a private organisation to supply capital	Highly feasible (common across the country)	Each trust to hold own accounts	Autonomy over the contract outsourcing arrangements and key performance indicators (KPIs)	As per current NHS rules

3. Key commercial terms

This section describes the key commercial terms that need to be discussed and agreed during the development of an outline business case (OBC). The joint venture and NHS partnership options are considered together because the commercial terms that apply to them are similar.

3.1. Ownership and calculation of ownership shares

The ownership stake on the liabilities and benefits the partnership might create need to be agreed early, including how they are calculated.

In an LLP the formation agreement should define how liabilities, benefits and capital investments are apportioned by the contracting parties as there are no ownership shares.

The proposed methodology for calculating the respective ownership shares of a partnership between trusts applies to all the commercial models involving the formation of a company.

The underlying rationale for the methodology is to identify and value the contributions of each organisation to a joint venture at the time it is established. Value can be defined as contribution forgone for work transferred to a joint venture or via the exclusive use of key assets, be they staff or equipment.

Consideration should be given to the quality management system to be implemented and accreditation to ISO:15189 through UKAS. This is covered in more detail in the clinical governance toolkit to be published separately.

Value is not intended to be attributed to services used on an arm's length basis – for example, the renting of space from a trust, as this obligation – the payment of rent – will pass to a joint venture at the time of its establishment.

Below we set out the proposed contributions from each trust that form the basis for valuing the ownership shares.

Contribution	Description	Valuation method
Existing activity	<p>Each trust will contribute its existing activity to the new entity, under a contractual agreement.</p> <p>Trusts will retain external contracts (if permitted by the existing contractual agreement), including GP direct access work, and will be charged by the new entity for the delivery of the work.</p>	<p>Existing organisations' activity to be provided by the new entity will be valued against an agreed common test price list for all organisations.</p> <p>This activity will be contributed to the joint venture with potential margin retained by the organisations.</p>
Key pathology delivery staff	Each trust will contribute key clinical and scientific staff to the new entity.	Agree the level of posts/individuals jointly with each trust's clinical lead and value them at their current full-year cost.
Key executive management staff	Value the contribution of existing senior managers (director level) from the organisations to both the creation of the new entity and then as part of the executive team operating the new service.	<p>Two elements to valuing this contribution:</p> <ul style="list-style-type: none"> • agree with the finance leads of the project who the key executive staff have been and their contribution to establishing the new entity • value the appointments to the new entity's executive management team from each trust.
Land or other assets	If any organisation contributes, for no cash consideration, any land or other asset for the exclusive use of the new entity, this will be valued and attributed to the respective trust.	Any land or other asset made available in this way will be valued at its existing book value.
Capital investment	<p>If any organisation agrees to a capital investment as part of the formation of a new entity, this will be attributed to the respective organisation.</p> <p>This also includes any planned capital expenditure within the predicted lifespan of the new entity as agreed by all parties at its formation.</p>	<p>Any initial investment will be valued at the current cost.</p> <p>Future capital investment will be discounted by an agreed rate, taking into account the relevant inflation rate and cost of capital.</p>

Contribution	Description	Valuation method
Pathology equipment	Any pathology equipment that is required by the new entity and to be made exclusively available to the new organisation will be valued.	An initial estimate is based on the entire inventory (asset register) value of pathology equipment held by each organisation. This valuation is then refined once the final equipment requirements of the new pathology entity are agreed.
IT equipment	As above but for IT equipment.	As above.
Working capital	Any agreed initial start-up working capital to fund the new entity provided by the organisation will be valued and attributed to that organisation.	This will be determined when the detailed three-year operating plan is developed by the new entity, and agreed by all organisations.
Stranded costs	An organisation may have a stranded cost as a result of changes to the relocation of any laboratories. This will be considered as part of the valuation exercise given that the organisation will be taking on a liability in establishing the new entity. Stranded costs will be agreed with all organisations before the new entity is formed.	Proposed that stranded costs will be valued at the cost for the 12 months following when they become redundant; this will give the respective organisation the time to re-deploy, re-use or remove them .

4. Governance

Project governance refers to the rules and procedures under which a project functions. It is frequently used to describe the processes necessary for a project to succeed. 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, but also ensures that the project is smoothly implemented and executed.

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
- manage risk.

The following governance structures are generally applicable to all the commercial structures outlined in Section 3, with the exception of outsourcing. Outsourcing is covered in the Outsourcing guide to be published separately.

4.1. Executive governance

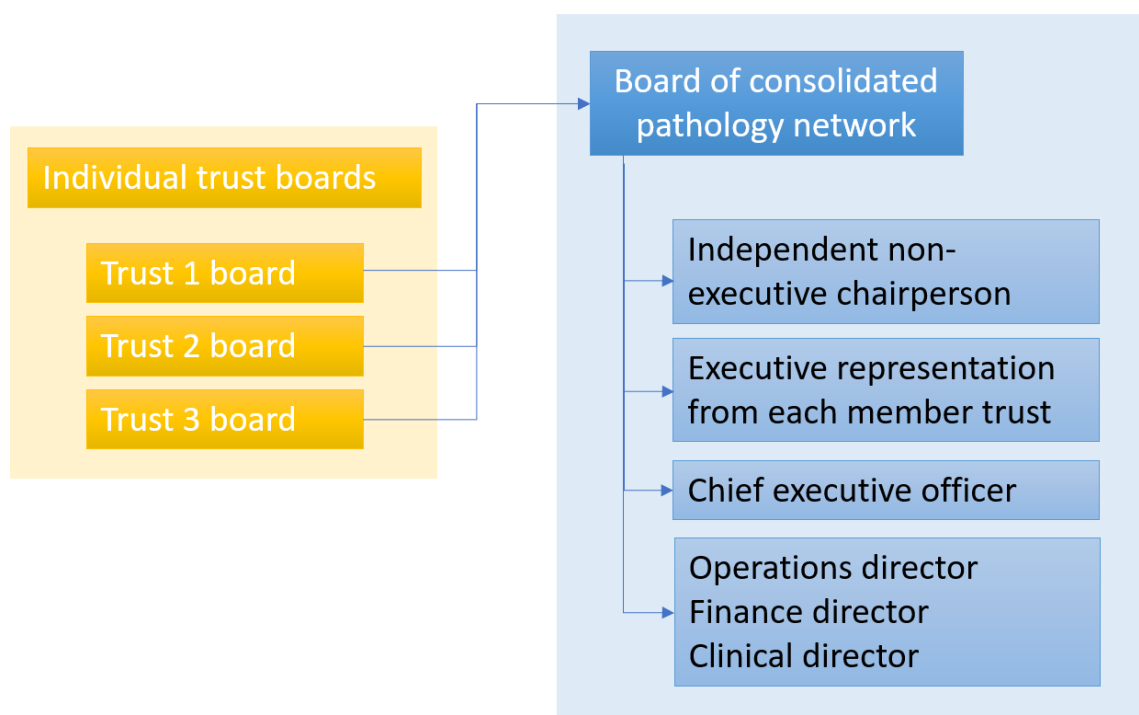
The new pathology operation should establish a partnership board with executive representation from each member trust. Each trust should be represented by a clinical director and either a financial or operational director.

The board should be chaired by an independent non-executive chairperson and meet monthly. The board will hold overall accountability for the performance of the new pathology operation, including governance, strategy, clinical viability, financial viability and quality.

Along with trust executive representation, the board should appoint a chief executive to the new pathology consolidated network to ensure there is a single point of responsibility for delivery. The board should also have clinical, financial and operational representation from the new pathology operation (See figure 2).

Where the board representatives have both an ownership and customer relationship with the joint venture, non-executive board members should be appointed to provide effective challenge to the board. An alternative is a mechanism that focuses the board on its role as directors of the joint venture rather than service users.

Figure 2: Example of an executive governance structure



4.2. Clinical governance

While clinical governance is outside the scope of this guide, we recommend a clinical steering group consisting of the clinical users of the service feeds into the board of the consolidated pathology network. One of the trust representatives from the consolidated pathology network's board should be its chair.

Initial considerations will focus on the board's role and composition, such as:

- representation on board
- creation of an executive and non-executive team
- management of a large business and staff responsible for finance, operational, commercial and clinical initiatives
- a mechanism for transparently and effectively reporting performance (this is required because of the size of the business)
- appointment of immediate and future board members (internal and external)
- appointment of chair
- appointment process for independent members
- organisational form and model that best fits the collaborative principles agreed by the trust partners.

4.3. Other key commercial terms

Other key commercial terms that the executive board may like to consider are listed below with reference to partnership models and outsourcing arrangements.

Key term	Description and issues	Outsourced option	Joint venture and partnership options
Ownership shares	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 an ownership share of the pathology service. This will be fully owned by the 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 should be shared and losses underwritten by the owner organisations in proportion to their ownership shares. In an LLP the formation agreement should define how profits and losses are handled.
Exit arrangements	A methodology for the potential exit of an organisation.	Break clauses will be determined in the contract with the outsource 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 organisation wishes to terminate its customer contract it should give the joint venture a defined period of notice, and this should be set as the minimum in the initial agreement. A 12-month notice period would be appropriate. If the termination happens before the first break period, then the terminating organisation may be responsible for any additional costs incurred by the joint venture for the notice period following its termination. This should be defined in the original agreement.
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.	Normally, the IP will be owned by the new entity and be exploited by it on behalf of its owner organisations. The joint venture agreement may allow individual organisations to retain IP under certain circumstances. The aim should be to facilitate innovation effectively.

Key term	Description and issues	Outsourced option	Joint venture and partnership options
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 entity will be 'called up' from the owner trusts per their ownership shares. In an LLP the formation agreement should define how capital investments are shared.</p> <p>All capital calls require a business case approved by the pathology management board. Capital calls above an agreed threshold require approval by the owner trusts per the scheme of delegation.</p> <p>Any capital investments (from which the new entity will benefit) committed by potential owner 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.	<p>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 programmed activities are bought from owner trusts to ensure consultant input into laboratory operations.</p>
Pathology management board	A methodology for the day-to-day management of the pathology service	Management of the pathology service will be the responsibility of the pathology provider.	<p>The day-to-day operations of the new entity should be governed by a pathology management board. This board should comprise non-executive and executive positions. Owner trusts can nominate representatives to take up non-executive positions.</p> <p>An independent chair ideally will be appointed by the owner trusts. The executive team will be selected, through an agreed interview process, from the appropriately qualified staff from the owner trusts. If matters require the pathology management board to vote, decisions should be made using a simple majority.</p>

These key commercial terms do not extend to outsourcing arrangements:

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 should agree an exclusive contract with the new entity for a defined period. A seven-year initial contract period is considered the minimum required to allow 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 NHS 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 should 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 time 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 should be the responsibility of each individual organisation. Each organisation will have the option, but not the obligation, to seek delivery of future additional pathology services 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 should be presented quarterly to the pathology management board, then to each respective owner organisation board.
Corporate support	A methodology for provision of corporate support to the pathology service.	Corporate support services should be provided by the joint venture/host trust and recharged based on actual costs as agreed with the new entity.

Key term	Description and issues	Joint venture and partnership options
TUPE transfers	A methodology for the transfer of staff to the new provider of the service	All pathology staff from the owner trusts should be eligible for jobs in the new entity or partnership (per its agreed operating model). Once the 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.	The cost of any redundancy costs should be met by the joint venture, and shares between owner organisations based on their ownership share of the joint venture. Redundancy only considered after all redeployment routes are exhausted.

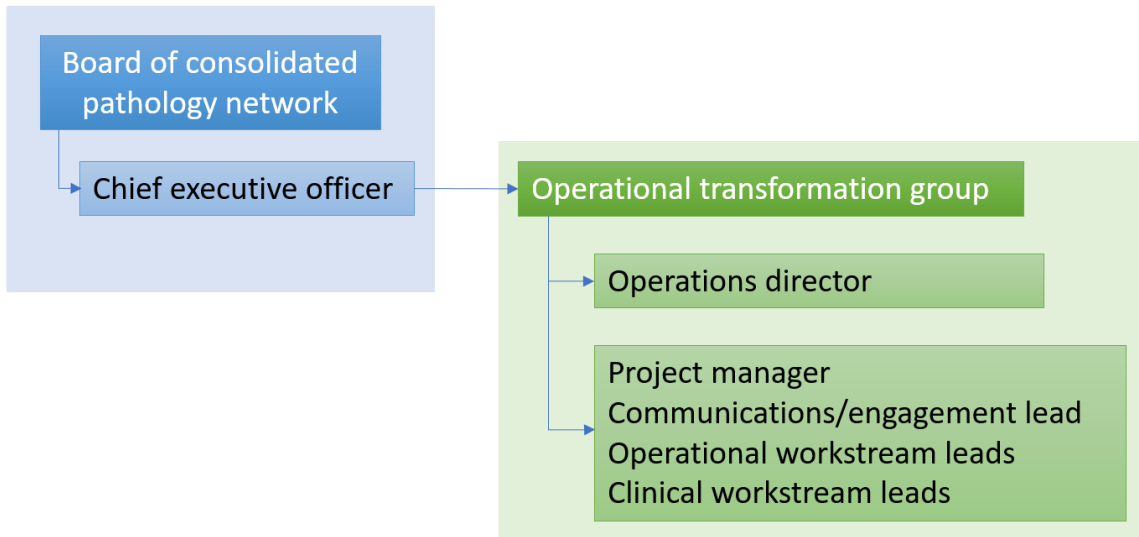
4.4. Operational transformation group

An operational working group should report directly to the pathology board. This group is responsible for delivering the objectives set out by the pathology board and is chaired by the chief executive officer. Representation should include the operations director and leads from all clinical and operational workstreams (See figure 3).

The remit of the operational working group is to drive the objectives of the board, and report progress and barriers as well as risks and opportunities.

Project management should be run from the operational working group with key decisions presented to the board for approval.

Figure 3: Example of an operational group structure



4.5. Workstreams

The pathology operation should have a dedicated workstream group for each clinical discipline and key operational function.

Suggested groups include (but are not limited to):

- automated blood sciences and blood transfusion
- manual blood sciences
- infectious diseases and microbiology
- genetics
- anatomical and cellular pathology
- essential services laboratories and blood transfusion
- central specimen reception including logistics.

Depending on the services offered by the pathology operation, workstream groups may be required for:

- reference haematology
- reference chemistry
- paediatric chemistry

- immunophenotyping.

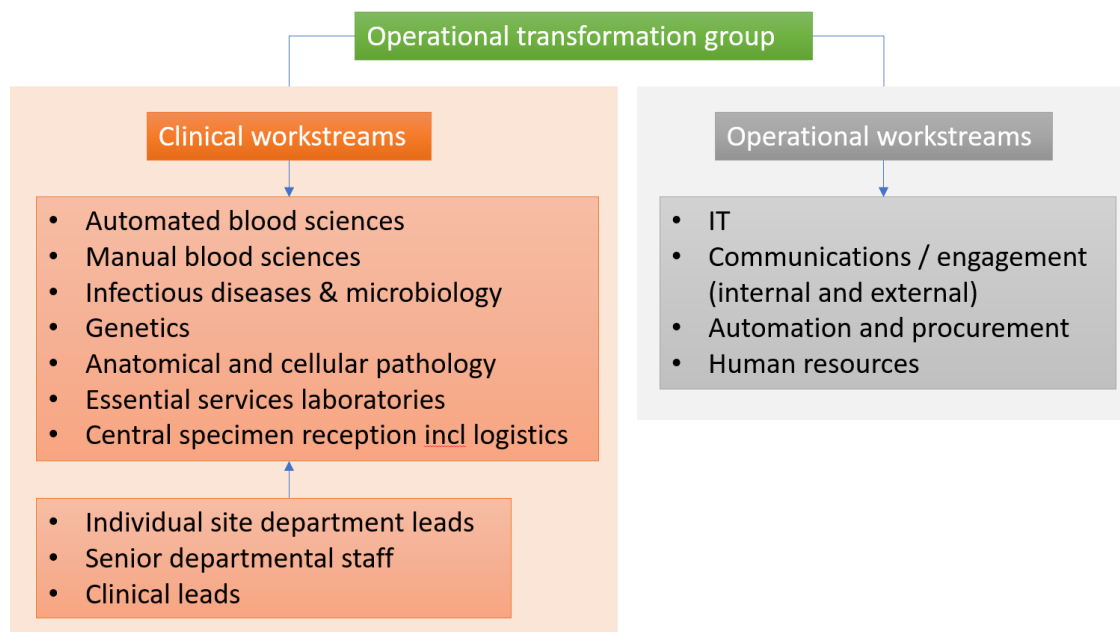
Each of these groups should have laboratory management representation and discipline lead representation from each of the individual trust sites. Clinical lead engagement will be crucial during the design of the future state model for each clinical discipline.

Operational workstream groups should be formed for:

- IT
- communications/engagement (internal and external)
- automation and procurement
- human resources.

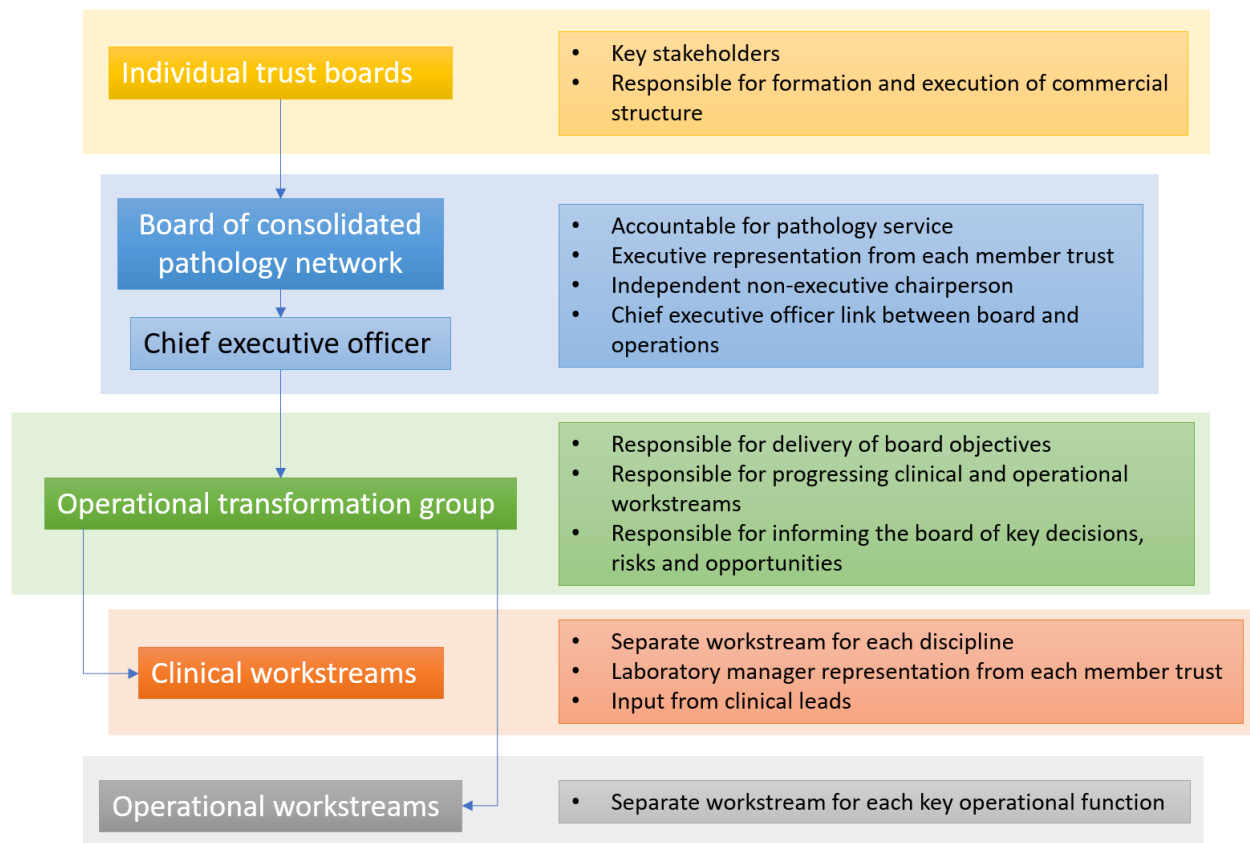
These groups should meet weekly and progress their individual workstreams toward the target operating model. The workstream lead reports into the operational working group (see Figure 4).

Figure 4: Example Clinical and Operational workstreams

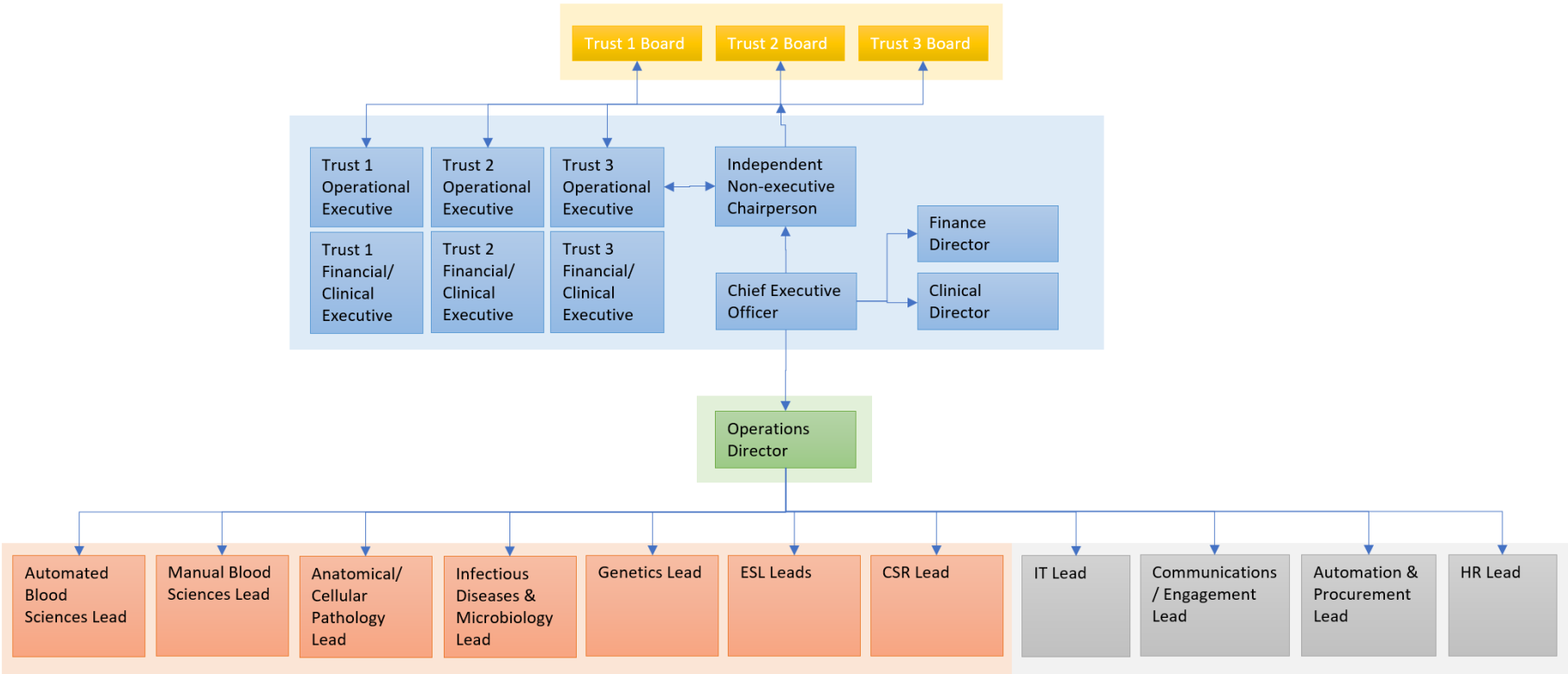


4.6. Summary of operational governance principles and structure

Principles



Structure



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