NHS Improvement

Consolidated pathology network

Clinical governance guide

April 2018

collaboration trust respect innovation courage compassion

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

Contents

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About 130 NHS trusts and foundation trusts provide their own pathology services, often using outdated operating models that need investment in premises, IT and equipment.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 reports[1] 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 reports[1] 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 provides trusts consolidating their pathology services with guidance on the clinical governance structure of the consolidated pathology network. It should be read in conjunction with the *Operational governance guide* and *Outsourcing guide* (latter to be published in June 2018).

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

[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)

trust executives who have been through the consolidation process, both successfully and unsuccessfully.

We will update this guidance regularly to reflect new information.

1.3. Disclaimer

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

1.4. Useful resources

Please refer to the following:

- Care Quality Commission new provider registration information
- UKAS application process
- good governance guide.

2. Clinical governance

Clinical governance has been defined as a system through which healthcare organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. Effective clinical governance ensures that risks are mitigated, adverse events are rapidly detected and investigated openly, and lessons are learned.

Clinical governance in a pathology setting is accountability for delivering the right service to the right patients at the right time and delivering it right the first time.

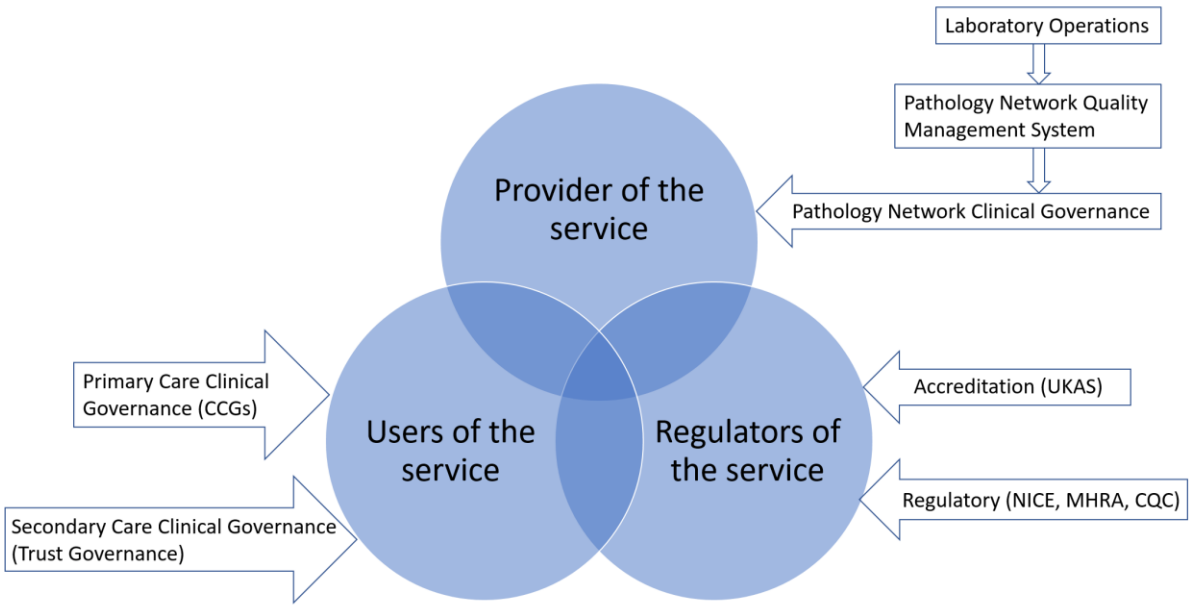
Clinical governance should permeate all facets of a pathology service. In a network setting this will mean it extends to areas previously outside the scope of a traditional laboratory's quality management system (QMS).

2.1. Clinical governance framework

Many bodies have a role in the assurance of pathology quality. These can be divided into three groups:

- providers of the service: their operations should be controlled by a QMS and governed by a clinical governance structure
- regulators that provide guidelines for laboratory operations and quality QMS, and inspect and accredit pathology networks to carry out operations
- service users that need to ensure they are receiving a quality service.

Figure 1: Clinical governance framework



Pathology services should regularly report their performance to their host organisation, commissioners and other interested parties. Reports should include current accreditation status, results of external quality assessment (EQA) scheme participation and quality indicators.

2.2. Accountability

A pathology network's clinical governance structure should be accountable for:

1. clinical audit
2. clinical risk management
3. quality assurance
4. clinical effectiveness
5. staff and organisational development.

Figure 2: Accountability framework

Clinical audit

Clinical audit is an established part of the NHS landscape, forming part of the system for reviewing and improving the standard of clinical practice.

Clinical risk management

A risk management system needs to be developed to minimise and mitigate identified risks, to inform internal and external stakeholders when risks exist, and to provide confidence that risks are being continuously assessed and appropriately managed. The system should encompass all elements of a networked service, including logistics, working practices and IT. Appropriate reporting of identified risks and an escalation process need to be established.

Quality assurance

Executive accountability for clinical governance quality assurance should centre on:

- oversight of the QMS
- ensuring a system of clinical governance reporting to all stakeholders
- monitoring and supporting quality improvement
- ensuring compliance with regulation
- ensuring continued accreditation

- oversight of risk management and reporting.

The wider clinical governance structure should be accountable for the provision of all aspects of ISO 15189, including:

- organisation and management
- personnel
- equipment
- purchasing and inventory
- process control
- document control
- information management
- occurrence management
- assessment
- process improvement
- service satisfaction
- facilities and safety.

For multi-site accreditation through ISO 15189, evidence of the following is required:

- documentation of the level of interaction between the locations – for example, allocation of testing/calibration work, transfer of samples between locations, movement of technical staff and/or equipment, and centralised or otherwise rationalised reporting arrangements
- mechanisms to ensure that enquiries about work in progress are handled efficiently, regardless of any transfer between locations
- requests, tenders and contracts are appropriately reviewed to support service users.

Clinical effectiveness

Clinical effectiveness is the application of knowledge from research, clinical experience and patient preferences to achieve optimum processes and patient outcomes. Processes should inform, change and monitor practice.

The clinical governance structure should be accountable for the consistency of clinical processes across a pathology network. A service user should experience a consistently high quality of service regardless of the origin of the sample and the site of testing. Staff competence, equipment and consistency of results should be comparable across sites.

Staff and organisational development

The governance structure should oversee delivery of a robust and consistent training and professional development programme across sites.

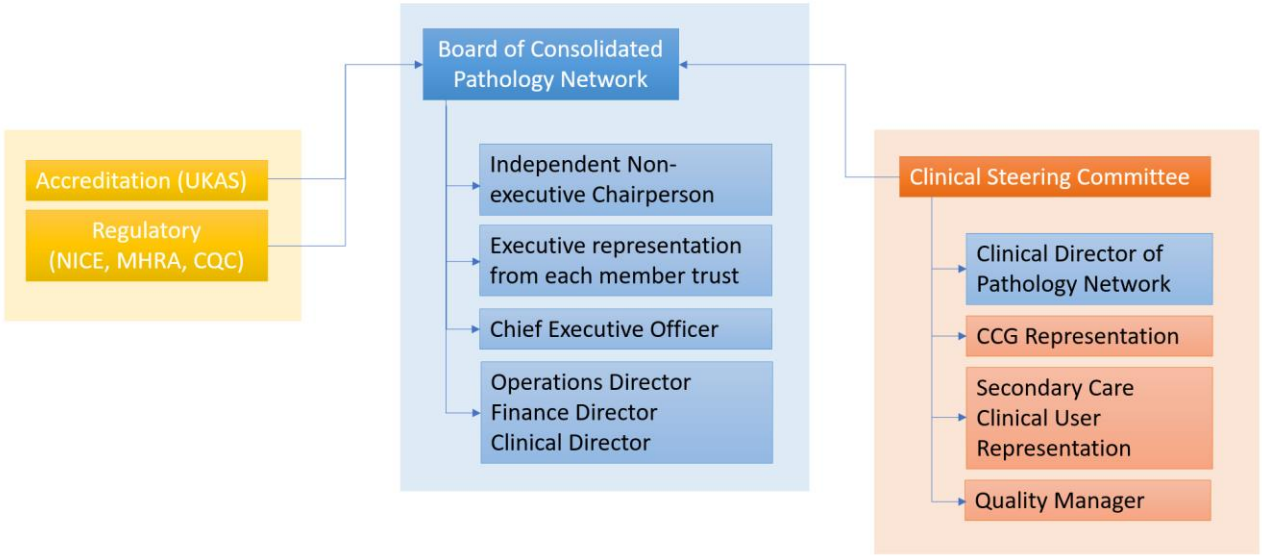
A system should record the inter-site transfers of people and skills and ensure they are covered by all aspects of the QMS.

3. Governance structure

The clinical governance structure should be appropriately equipped to deliver the services accountable to it (see Section 2).

We recommend establishing a board for the consolidated pathology network (see Figure 5). A clinical steering group consisting of the service users should feed into the board (Figure 3). One of the trust representatives from the network board should chair the clinical steering committee – the clinical director of the network board would be the most appropriate person – and the network board's quality manager should also sit on this committee. When selecting leaders for these positions patient and service user interests must be represented.

Figure 3: Clinical steering group structure



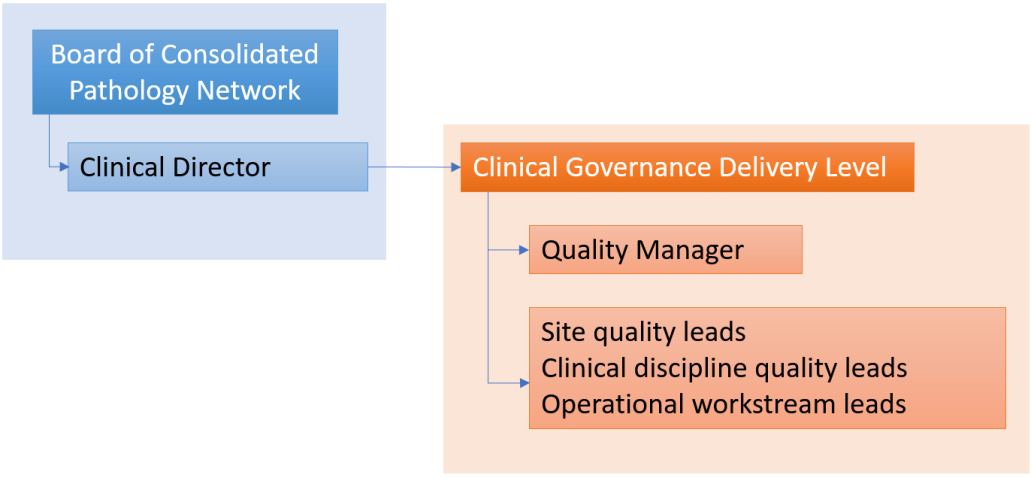
This structure allows for full clinical governance and accountability, with the board of the consolidated pathology network directly linked to all the stakeholders in the clinical governance framework (see Figure 1). The board has overall responsibility and accountability for providing the service, and is the registered party with respect to regulatory and accreditation providers. The clinical steering committee provides the link to the service users.

The inclusion of the quality manager in the clinical steering committee accords with recommendations from the Institute of Biomedical Science.[2]

If an organisation has a single clinical laboratory quality manager, this individual should be a member of the appropriate committee dealing with clinical governance. Operationally the quality manager will be accountable for the delivery of the clinical governance objectives (outlined in Section 2) set by the board and reports to the clinical director. They will be responsible for ensuring adherence to the clinical audit schedule and that reporting on quality performance to the board is appropriate. Each clinical discipline, laboratory site and operational workstream (IT, logistics, etc) should have a quality lead reporting to the quality manager.

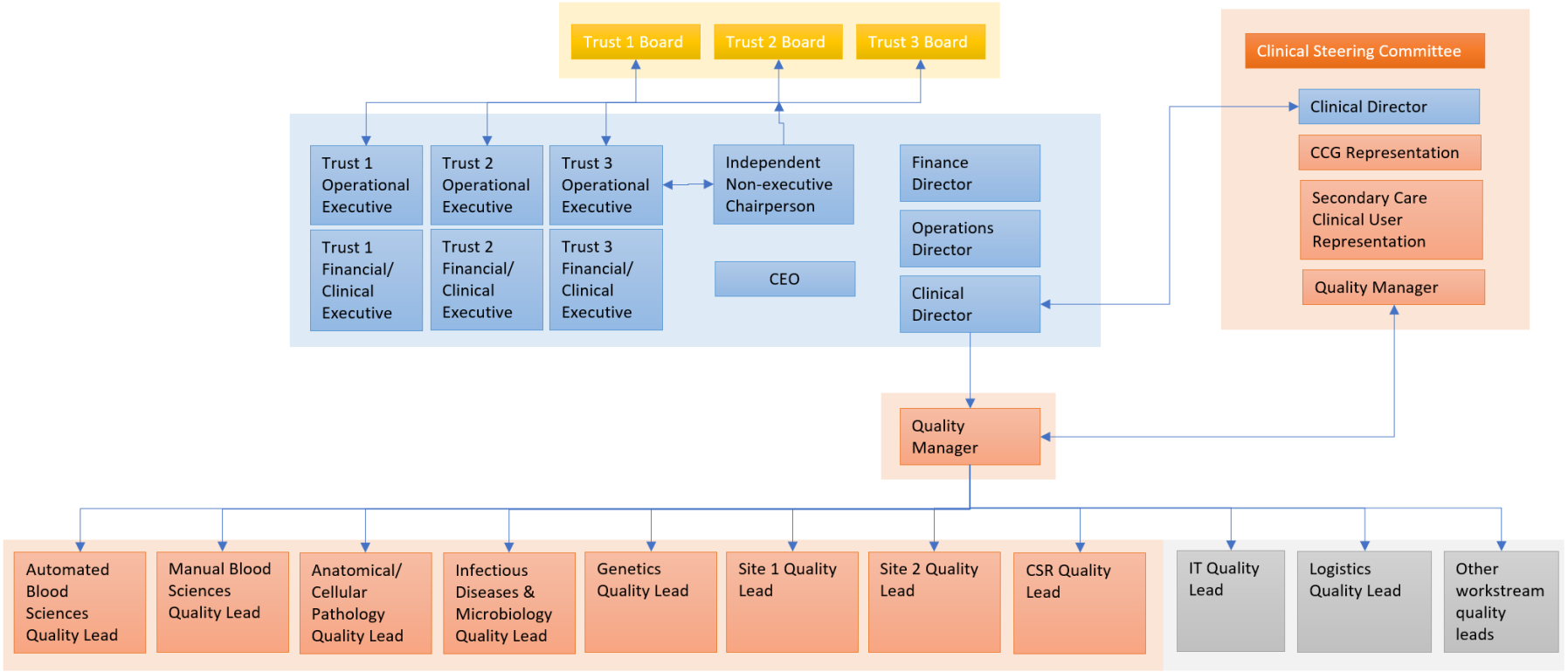
As operational objectives must align with quality and clinical objectives, we recommend that these groups work closely at the delivery level as well as the executive level. The operations director, clinical director and quality manager should meet regularly to discuss operational and delivery objectives, interdependencies and progress (Figure 4).

Figure 4: Clinical governance delivery level



[2] *Guidance on quality management in laboratories* (IBMS 2015).

Figure 5: Full clinical governance structure



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